Started on 28 February 2017 at 7:19pm | Completed on 28 February 2017 at 7:55pm

some research uses people who are not able to say if they want to take part or not.

This is the form to tell the Health and Disability Commissioner what you think.

Questions and Answers

This form has **questions** to find out what you think about doing research with people who are not able to say if they want to take part or not.

Health and Disability Commissioner
Te Toihau Hauora, Hauātanga

Your **answers** will help the **Health and Disability Commissioner** know what needs to be done.

You do not have to **answer** all the questions.

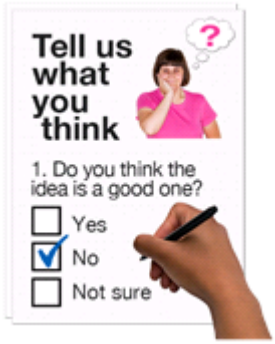
Case studies and questions

Case studies are stories that help us to understand something.

5

Here are 5 case studies that show when research cannot be done without informed consent at the moment in New Zealand.

These may help you decide if the law should change.



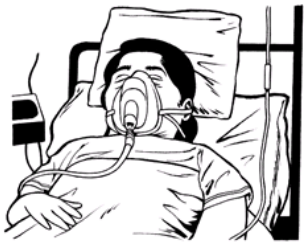
Each case study has questions that we would like you to answer.

Health and Disability Commissioner
Te Toihau Hauora, Hauātanga

Your answers to the questions will help the Health and Disability Commissioner know what is important to you.

Case study 1: Observational research on people with a bad infection

Some people with a bad infection will:



- get very sick
- not be able to tell other people what they think or feel

- have to take medicine to get healthy.

In this case study a doctor wants to do some research on people who:

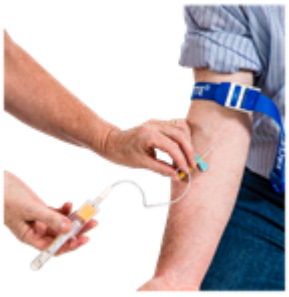
- have a bad infection

- have been given medicine.

The doctor will not change the medicine the people are getting.

The doctor:

- wants to know how much medicine these people need to take to get better



- will take samples from their bodies to find out how much medicine they need to take to get better.

The doctor wants to do this research on people who:

- cannot give informed consent to take part

- will not get better health from being part of the research
- will get the same medicine whether they take part in the research or not.

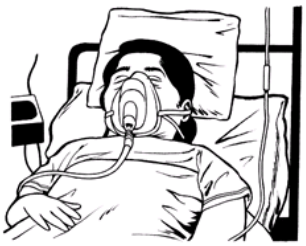
This research may help other people who get bad infections to get the medicine that will help them.

Questions about observational research on people with a bad infection

In these questions we will ask you to think about what you would choose to do if you were sick with a bad infection.

These questions are not about you.

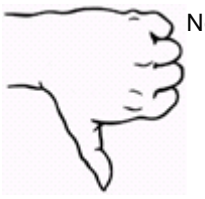
The questions are a made up example.



1. If you had a bad infection and could not give informed consent would you want to take part in research about how much medicine is needed to get better?

Choose the answer that is right for you:

Yes



No

I do not have an answer

If you said yes to question 1:

2. Why would you want to take part in this research?

This research will not cause me harm. It will help other people.

If you said no to question 1:

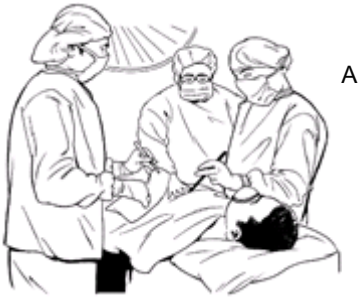
3. Why would you not want to take part in this research?

4. Do you want to say any more about this question?

The ethical question for me, is the blood test. Is the blood test already happening for health reasons, or is it solely for the researcher?

Perhaps the researcher could look to see whether I am an organ donor, as a measurement of whether I am happy for the blood tests to occur without giving explicit permission.

Case study 2: Research on brain operations



A person has to have a brain operation.

There are 2 things doctors use to make sure a person who has a brain operation is OK after their operation has finished.

No one knows which thing works best.

In this case study a doctor wants to do some research to find out which of the 2 things will work best for other people in the future to help them get better.

In the research the doctor will give some people 1 thing and other people a different thing.

The doctor will see which thing works best.

The people cannot say if they want to be part of the research or not.

The doctor wants to get **delayed consent** for the research from some of the people after their brain operation is done.

Delayed consent means asking for consent to do research on you after it has already been done.

Questions about research on brain operations

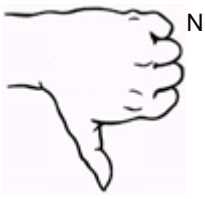
In these questions we will ask you to think about what you would choose to do if you were sick and have to have a brain operation.

These questions are not about you.

The questions are a made up example.

1. If you were not able to say yes or no to taking part in this research before your brain operation would you be OK with the doctor doing the research anyway? Choose the answer that is right for you.

Yes



No

I do not have an answer

If you said yes to question 1

2. Why would you want to take part in this research?

Personally, I would want to help contribute to knowledge about the brain if it were to help others in the future. However, I would not want to see this happen to people who had not considered it or provided permission.

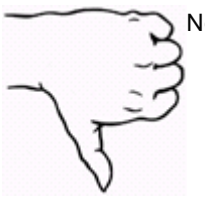
If you said no to question 1

3. Why would you not want to take part in this research?

4. Do you want to say any more about this question?

5. Do you think delayed consent is ok? Choose the answer that is right for you.

Yes



No

I do not have an answer

If you said yes to question 5:

6. Why do you think delayed consent is OK?

If you said no to question 5:

7. Why do you think delayed consent is not OK?

Delayed consent is based on the assumption that I would be ok with it. You can never know what people are ok with, especially if there is so much uncertainty around the treatment.

Case study 3: Research on people who have a brain disease

Sometimes people get a brain disease that makes it hard for them to:

- remember
- say what they think and feel.

In this case study a doctor wants to do some research on the care given to these people.

Some people will get 1 kind of care and others will get different care.

The doctor will see if any of the people get better.

No one knows if taking part in the research will mean the people will get better or worse.

The doctor does not know if the research will mean better care for people in the future or not.

The research is trying to find this out.

Some of the people the doctor wants to do research on cannot give **informed consent** to take part in the research.

Questions about research on people who have a brain disease

In these questions we will ask you to think about what you would want to happen if you had a brain disease.

These questions are not about you.

The questions are a made up example.

1. If you had a brain disease and could not give informed consent would you want to take part in this research?
Choose the answer that is right for you.

Yes

No

I do not have an answer

If you said yes to question 1
2. Why would you want to take part in this research?

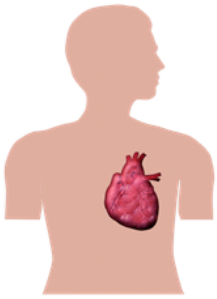
If you said no to question 1

3. Why would you not want to take part in this research?

There is too much uncertainty around the outcome. It could have negative consequences, which is just not worth the risk of bypassing consent.

4. Do you want to say any more about this question?

Case study 4: Research on people who are having a cardiac arrest

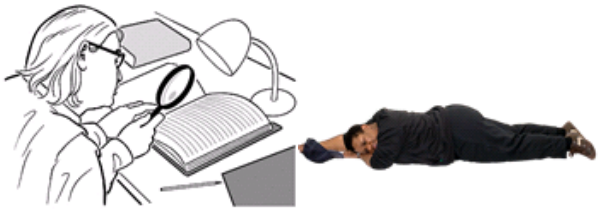


Cardiac arrest is when you have a big problem with your heart and it stops working.

Most of the time when a person's heart stops they are given a medicine.

No one knows if the medicine helps or hurts people.

In this case study a doctor wants to research whether the medicine helps people whose heart has stopped.



If somebody's heart stops working they will not be awake.

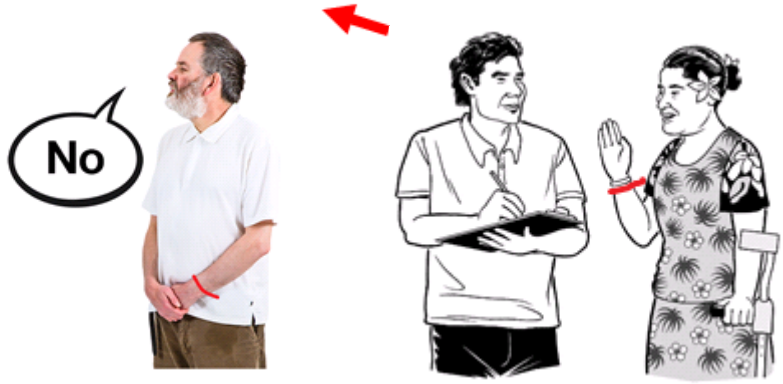
This means the doctor will not be able to ask for **informed consent** to take part in the research.

The doctor wants to give some people the medicine and others no medicine to see which group gets better.

People can choose to **opt out** of this research.

Opt out means you say you do **not** want to take part in the research if your heart stops in the future.

People who want to **opt out** of this research can wear a bracelet that says **no study** on it.



To do this people need to:

- ask for a bracelet in case their heart stops 1 day in the future
- wear the bracelet

Questions about research on people that are having a cardiac arrest

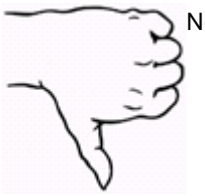
In these questions we will ask you to think about what you would want to happen if your heart stopped working.

These questions are not about you.

The questions are a made up example.

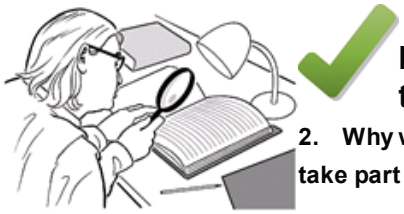
1. If your heart stopped would you want to take part in research to find out if taking this medicine is better than no medicine?
Choose the answer that is right for you.

Yes



No

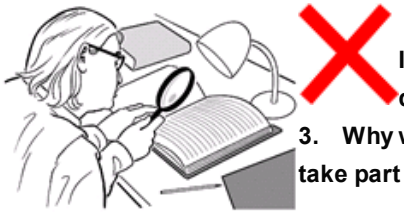
I do not have an answer



If you said yes to question 1

2. Why would you want to take part in this research?

Personally, I would like my experience to contribute to greater knowledge about the heart.

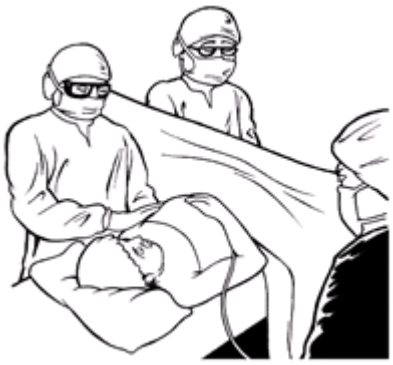


If you said no to question 1

3. Why would you not want to take part in this research?

4. Do you want to say any more about this question?

I would not assume others would want to, and therefore wouldn't follow through without permission.

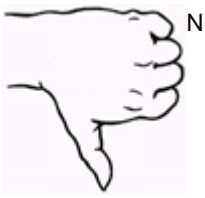


5. People who are wearing the bracelets will not be in the research if their heart stops.

Do you think it is OK for the doctors to do the research on anyone who is not wearing a bracelet when their heart stops?

Choose the answer that is right for you.

Yes



No

I do not have an answer

If you said yes to question 5:

6. Why do you think this?

If you said no to question 5:

7. Why do you think this?

The bracelet should be considered consent. Those who are not wearing a bracelet should not have that consent breached.

Case study 5: Research on people who have Down Syndrome

Down Syndrome is a learning disability.

In this case study a doctor wants to do some research to find out if a medicine can help people with Down Syndrome with their learning.

The medicine may make some people with Down Syndrome think sad things and want to hurt themselves.

Some people with Down Syndrome who take part in the research **will** get the medicine.

Some people with Down Syndrome who take part in the research will **not** get the medicine.

This is so that the doctor can see if the medicine is helping the people with Down Syndrome who get it.

Some people with Down Syndrome will be able to give **informed consent** to take part in the research.

Some people with Down Syndrome will **not** be able to give **informed consent** to take part in the research.

The doctor wants to have people with Down Syndrome in their research who:

- can give **informed consent** to take part
- cannot give **informed consent** to take part.

The doctor wants to be able to get **informed consent** from the family members or support workers of the people with Down Syndrome who cannot give **informed consent**.

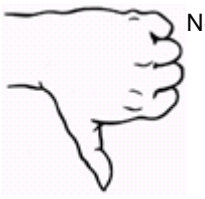
Questions about research on people with Down Syndrome

These questions are not about you.

The questions are a made up example.

1. Do you think people with Down Syndrome who cannot give informed consent should be in this research?
Choose the answer that is right for you.

Yes



No

I do not have an answer

If you said yes to question 1:

2. Why do you think people with Down Syndrome who cannot give informed consent should be in this research?

If you said no to question 1:

3. Why do you think people with Down Syndrome who cannot give informed consent should not be in this research?

4. Do you want to say any more about this question?

I have selected that I do not have an answer as I believe that all people can contribute to the consent process in one way or another. Perhaps it is through the knowledge of those they know and trust. This situation would need to be looked at on a case-by-case basis, and how well the welfare guardians know the individual. I would want to understand the circumstances and individual preferences before committing to an answer. This is not a case of one size fits all.

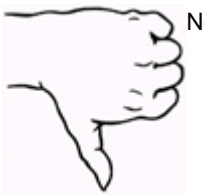
5. Do you think other people should decide if people with Down Syndrome will be in this research?

These other people could be:

- **family / whānau**
- **support workers**

Choose the answer that is right for you.

Yes



No

I do not have an answer

If you said yes to question 5:

6. Why do you think this?

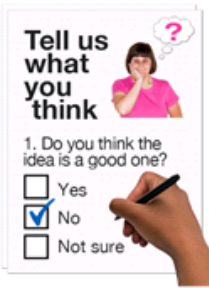
I think that it is possible, but I don't think it should be a blanket rule or assumption. I think there are a variety of factors that need to be taken into consideration including who the welfare guardians/family/supports are, different opinions, how long they've known the individual, their experience in these matters, the character of the individual with Down Syndrome etc.

If you said no to question 5:

7. Why do you think this?

8. Do you want to say any more about this?

Questions about informed consent



Here are some more questions.

These questions will ask you what you think about **informed consent** to take part in research.

Health and Disability Commissioner
Te Toihau Hauora, Hauātanga

Your answers will help the **Health and Disability Commissioner** know what is important to you.

1. Do you think it is OK for adults who cannot give informed consent to take part in research when no one knows if it will help them or hurt them?
Choose the answer that is right for you.

Yes

No

I do not have an answer

2. When do you think it is OK for adults who cannot give informed consent to take part in research?

When their supports are informed, there is consensus among support people who know the individual well and for an extended period of time, there are safety procedures in place and legal advice has been sought.

3. Some people doing research are not health or disability providers so they do not have to follow the Health and Disability Code of Rights.

Do you think everyone doing health and disability research should have to follow the Code?

Choose the answer that is right for you.


Yes

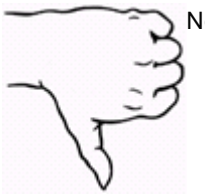
No

I do not have an answer

4. Do you think the law should say that if any person taking part in research looks like they are scared or in pain they should not be part of the research anymore?

Choose the answer that is right for you.


Yes



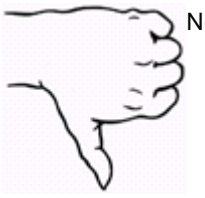
No

I do not have an answer

5. Do you think the law should change to say it is OK for people to give delayed consent to research after they wake up?

Delayed consent means asking for consent to do research on you after it has already been done. Choose the answer that is right for you.

Yes

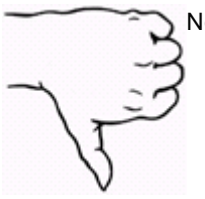


No

I do not have an answer

6. If the research can be done with people who can give informed consent is it OK to do the research with people who cannot give informed consent? Choose the answer that is right for you.

Yes

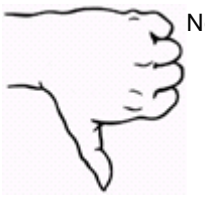


No

I do not have an answer

7. Do you think research should be done on a person that cannot give informed consent if the research may or may not help them but might help other people in the future? Choose the answer that is right for you.

Yes



No

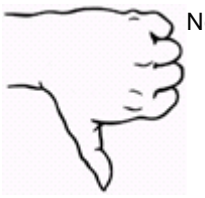
I do not have an answer

8. Why do you think this?

Again, it is not clear cut. I think that doing the research should be a possibility under the right circumstances - considering support networks, legal advice, safety, character etc.

9. Do you think all people that want to do research with adults who cannot give informed consent should have to get the OK from an ethics committee to do it?Choose the answer that is right for you.

Yes



No

I do not have an answer

10. Why do you think this?

You can't assume that all researchers have an individual's best interests at heart. For example, not all researchers understand or respect the ethos of the Convention on the Rights of Persons with Disabilities (CRPD).

11. Who do you think should have a say in whether or not a person who cannot give informed consent will be part of research?

You can choose as many as you want.

- [x] Someone who is Enduring Power of Attorney or Welfare Guardian for the person
- [x] Family / whanau of the person
- [x] The person's doctor (if they are not part of the research)
- [ ] The person who wants to do the research
- [x] Someone else

12. Do you think anyone else should have a say in whether or not a person who cannot give informed consent will be part of research?

Someone who has a long-term and intimate relationship with the individual such as a support worker, service provider etc.

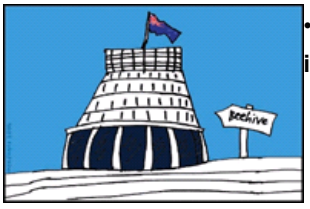
They must be totally informed about the research, risks and benefits and ensure the individual's health and safety remains at the forefront of the decision.

13. Do you want to say any more about question 11?

What happens next?

The **Health and Disability Commissioner** will:

- think about what everyone has said about people who cannot give **informed consent** being part of research



- decide what to tell the Government about whether changes are needed to the law on **informed consent** to be in research

- decide whether the **Code** needs to be changed about **informed consent** to be in research.

If the Health and Disability Commissioner thinks the **Code** needs to be changed he will ask everyone about the changes.

Your name

Organisation (if you represent an organisation)

Thank you.

Thank you for:

- reading this information
- thinking about the hard topics

- telling the **Health and Disability Commissioner** what you think.

This will help the **Health and Disability Commissioner** to know what needs to be done.

Health and Disability Commissioner
Te Toihau Hauora, Hauātanga

PeopleFirst
New Zealand
Ngā Tāngata Tuatahi

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Started on 28 February 2017 at 8:10pm | Completed on 28 February 2017 at 8:24pm

some research uses people who are not able to say if they want to take part or not.

This is the form to tell the Health and Disability Commissioner what you think.

Questions and Answers

This form has **questions** to find out what you think about doing research with people who are not able to say if they want to take part or not.

Health and Disability Commissioner
Te Toihau Hauora, Hauātanga

Your **answers** will help the **Health and Disability Commissioner** know what needs to be done.

You do not have to **answer** all the questions.

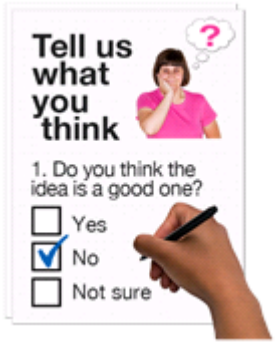
Case studies and questions

Case studies are stories that help us to understand something.

5

Here are 5 case studies that show when research cannot be done without informed consent at the moment in New Zealand.

These may help you decide if the law should change.



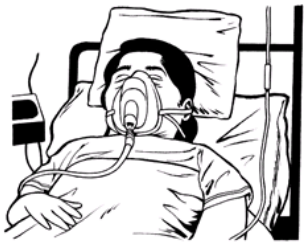
Each case study has questions that we would like you to answer.

Health and Disability Commissioner
Te Toihau Hauora, Hauātanga

Your answers to the questions will help the Health and Disability Commissioner know what is important to you.

Case study 1: Observational research on people with a bad infection

Some people with a bad infection will:



- get very sick
- not be able to tell other people what they think or feel

- have to take medicine to get healthy.

In this case study a doctor wants to do some research on people who:

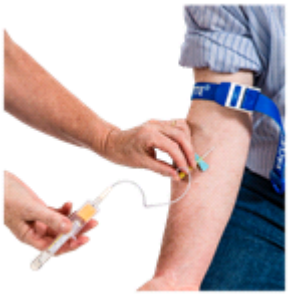
- have a bad infection

- have been given medicine.

The doctor will not change the medicine the people are getting.

The doctor:

- wants to know how much medicine these people need to take to get better



- will take samples from their bodies to find out how much medicine they need to take to get better.

The doctor wants to do this research on people who:

- cannot give informed consent to take part

- will not get better health from being part of the research
- will get the same medicine whether they take part in the research or not.

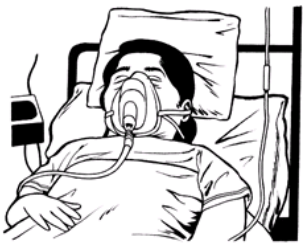
This research may help other people who get bad infections to get the medicine that will help them.

Questions about observational research on people with a bad infection

In these questions we will ask you to think about what you would choose to do if you were sick with a bad infection.

These questions are not about you.

The questions are a made up example.

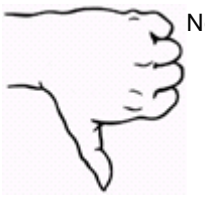


1. If you had a bad infection and could not give informed consent would you want to take part in research about how much medicine is needed to get better?

Choose the answer that is right for you:

Yes

No



I do not have an answer

If you said yes to question 1:

2. Why would you want to take part in this research?

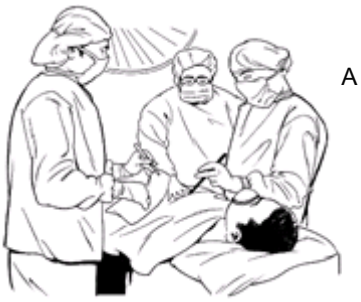
If you said no to question 1:

3. Why would you not want to take part in this research?

I would not know what and why they were doing it

4. Do you want to say any more about this question?

Case study 2: Research on brain operations



A person has to have a brain operation.

There are 2 things doctors use to make sure a person who has a brain operation is OK after their operation has finished.

No one knows which thing works best.

In this case study a doctor wants to do some research to find out which of the 2 things will work best for other people in the future to help them get better.

In the research the doctor will give some people 1 thing and other people a different thing.

The doctor will see which thing works best.

The people cannot say if they want to be part of the research or not.

The doctor wants to get **delayed consent** for the research from some of the people after their brain operation is done.

Delayed consent means asking for consent to do research on you after it has already been done.

Questions about research on brain operations

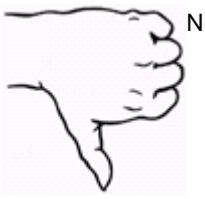
In these questions we will ask you to think about what you would choose to do if you were sick and have to have a brain operation.

These questions are not about you.

The questions are a made up example.

1. If you were not able to say yes or no to taking part in this research before your brain operation would you be OK with the doctor doing the research anyway? Choose the answer that is right for you.

Yes



No

I do not have an answer

If you said yes to question 1

2. Why would you want to take part in this research?

Feel it would really help others

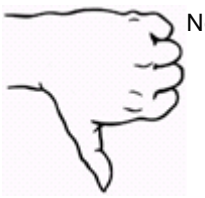
If you said no to question 1

3. Why would you not want to take part in this research?

4. Do you want to say any more about this question?

5. Do you think delayed consent is ok? Choose the answer that is right for you.

Yes



No

I do not have an answer

If you said yes to question 5:

6. Why do you think delayed consent is OK?

If you said no to question 5:

7. Why do you think delayed consent is not OK?

Case study 3: Research on people who have a brain disease

Sometimes people get a brain disease that makes it hard for them to:

- remember
- say what they think and feel.

In this case study a doctor wants to do some research on the care given to these people.

Some people will get 1 kind of care and others will get different care.

The doctor will see if any of the people get better.

No one knows if taking part in the research will mean the people will get better or worse.

The doctor does not know if the research will mean better care for people in the future or not.

The research is trying to find this out.

Some of the people the doctor wants to do research on cannot give **informed consent** to take part in the research.

Questions about research on people who have a brain disease

In these questions we will ask you to think about what you would want to happen if you had a brain disease.

These questions are not about you.

The questions are a made up example.

1. If you had a brain disease and could not give informed consent would you want to take part in this research?
Choose the answer that is right for you.

Yes

No

I do not have an answer

If you said yes to question 1
2. Why would you want to take part in this research?

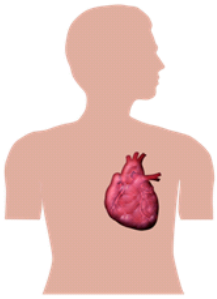
Feel it isn't invasive so would want to be able to help others

If you said no to question 1

3. Why would you not want to take part in this research?

4. Do you want to say any more about this question?

Case study 4: Research on people who are having a cardiac arrest

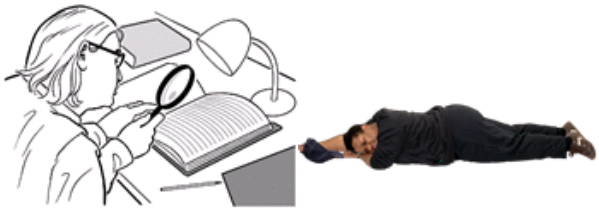


Cardiac arrest is when you have a big problem with your heart and it stops working.

Most of the time when a person's heart stops they are given a medicine.

No one knows if the medicine helps or hurts people.

In this case study a doctor wants to research whether the medicine helps people whose heart has stopped.



If somebody's heart stops working they will not be awake.

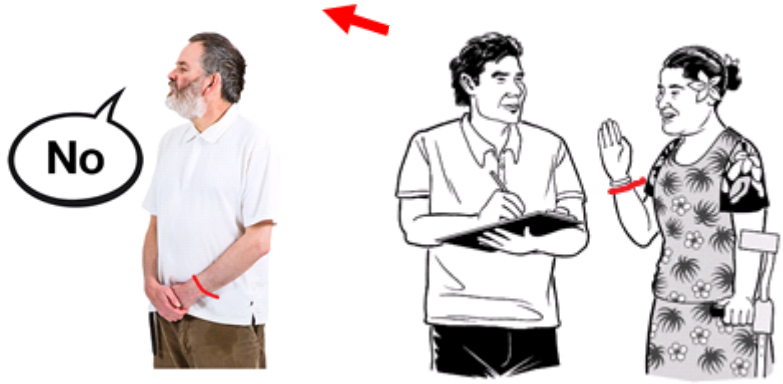
This means the doctor will not be able to ask for **informed consent** to take part in the research.

The doctor wants to give some people the medicine and others no medicine to see which group gets better.

People can choose to **opt out** of this research.

Opt out means you say you do **not** want to take part in the research if your heart stops in the future.

People who want to **opt out** of this research can wear a bracelet that says **no study** on it.



To do this people need to:

- ask for a bracelet in case their heart stops 1 day in the future
- wear the bracelet

Questions about research on people that are having a cardiac arrest

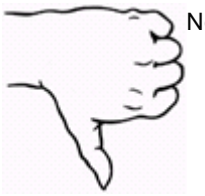
In these questions we will ask you to think about what you would want to happen if your heart stopped working.

These questions are not about you.

The questions are a made up example.

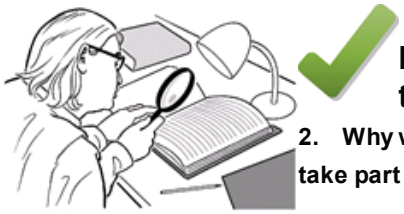
1. If your heart stopped would you want to take part in research to find out if taking this medicine is better than no medicine?
Choose the answer that is right for you.

Yes



No

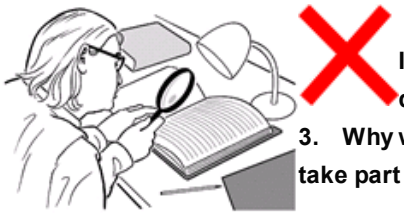
I do not have an answer



If you said yes to question 1

2. Why would you want to take part in this research?

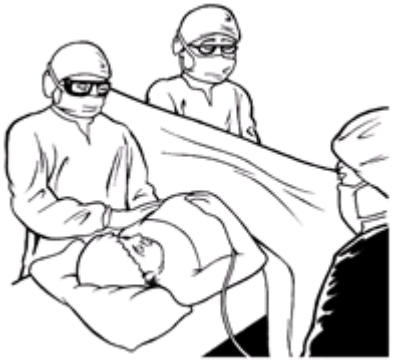
Seems to be a non-invasive research that would hopefully help others



If you said no to question 1

3. Why would you not want to take part in this research?

4. Do you want to say any more about this question?

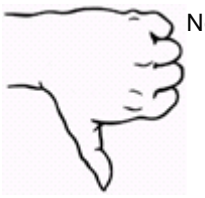


5. People who are wearing the bracelets will not be in the research if their heart stops.

Do you think it is OK for the doctors to do the research on anyone who is not wearing a bracelet when their heart stops?

Choose the answer that is right for you.

Yes



No

I do not have an answer

If you said yes to question 5:

6. Why do you think this?

Yes but only if people have been educated or told about the bracelet option

If you said no to question 5:

7. Why do you think this?

Case study 5: Research on people who have Down Syndrome

Down Syndrome is a learning disability.

In this case study a doctor wants to do some research to find out if a medicine can help people with Down Syndrome with their learning.

The medicine may make some people with Down Syndrome think sad things and want to hurt themselves.

Some people with Down Syndrome who take part in the research **will** get the medicine.

Some people with Down Syndrome who take part in the research will **not** get the medicine.

This is so that the doctor can see if the medicine is helping the people with Down Syndrome who get it.

Some people with Down Syndrome will be able to give **informed consent** to take part in the research.

Some people with Down Syndrome will **not** be able to give **informed consent** to take part in the research.

The doctor wants to have people with Down Syndrome in their research who:

- can give **informed consent** to take part
- cannot give **informed consent** to take part.

The doctor wants to be able to get **informed consent** from the family members or support workers of the people with Down Syndrome who cannot give **informed consent**.

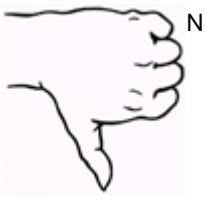
Questions about research on people with Down Syndrome

These questions are not about you.

The questions are a made up example.

1. Do you think people with Down Syndrome who cannot give informed consent should be in this research?
Choose the answer that is right for you.

Yes



No

I do not have an answer

If you said yes to question 1:

2. Why do you think people with Down Syndrome who cannot give informed consent should be in this research?

If you said no to question 1:

3. Why do you think people with Down Syndrome who cannot give informed consent should not be in this research?

Don't like the idea of this at all unless the person can fully understand what is going to happen

4. Do you want to say any more about this question?

5. Do you think other people should decide if people with Down Syndrome will be in this research?

These other people could be:

- **family / whānau**
- **support workers**

Choose the answer that is right for you.

Yes

No

I do not have an answer

If you said yes to question 5:

6. Why do you think this?

If you said no to question 5:

7. Why do you think this?

Feels like the patient's rights are being taken away

8. Do you want to say any more about this?

Questions about informed consent

Here are some more questions.

These questions will ask you what you think about **informed consent** to take part in research.

Health and Disability Commissioner
Te Toihau Hauora, Hauātanga

Your answers will help the **Health and Disability Commissioner** know what is important to you.

1. Do you think it is OK for adults who cannot give informed consent to take part in research when no one knows if it will help them or hurt them?
Choose the answer that is right for you.

Yes

No

I do not have an answer

2. When do you think it is OK for adults who cannot give informed consent to take part in research?

maybe if it is non-invasive

3. Some people doing research are not health or disability providers so they do not have to follow the Health and Disability Code of Rights.

Do you think everyone doing health and disability research should have to follow the Code?

Choose the answer that is right for you.


Yes

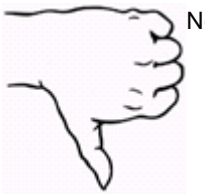
No

I do not have an answer

4. Do you think the law should say that if any person taking part in research looks like they are scared or in pain they should not be part of the research anymore?

Choose the answer that is right for you.


Yes



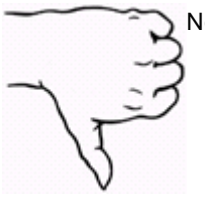
No

I do not have an answer

5. Do you think the law should change to say it is OK for people to give delayed consent to research after they wake up?

Delayed consent means asking for consent to do research on you after it has already been done. Choose the answer that is right for you.

Yes

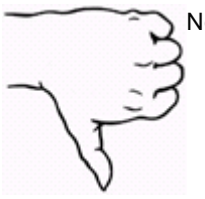


No

I do not have an answer

6. If the research can be done with people who can give informed consent is it OK to do the research with people who cannot give informed consent? Choose the answer that is right for you.

Yes

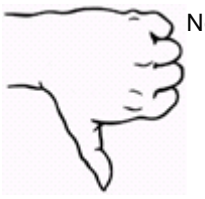


No

I do not have an answer

7. Do you think research should be done on a person that cannot give informed consent if the research may or may not help them but might help other people in the future? Choose the answer that is right for you.

Yes



No

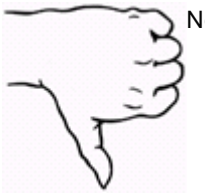
I do not have an answer

8. Why do you think this?

breach of their rights

9. Do you think all people that want to do research with adults who cannot give informed consent should have to get the OK from an ethics committee to do it?Choose the answer that is right for you.

Yes



No

I do not have an answer

10. Why do you think this?

cos they should present all research thru ethics

11. Who do you think should have a say in whether or not a person who cannot give informed consent will be part of research?

You can choose as many as you want.

- [x] Someone who is Enduring Power of Attorney or Welfare Guardian for the person
- [ ] Family / whanau of the person
- [ ] The person's doctor (if they are not part of the research)
- [ ] The person who wants to do the research
- [ ] Someone else

12. Do you think anyone else should have a say in whether or not a person who cannot give informed consent will be part of research?

no

13. Do you want to say any more about question 11?

i even question whether the person with epoa should be able to consent

What happens next?

The **Health and Disability Commissioner** will:

- think about what everyone has said about people who cannot give **informed consent** being part of research

- decide what to tell the Government about whether changes are needed to the law on **informed consent** to be in research

- decide whether the **Code** needs to be changed about **informed consent** to be in research.

If the Health and Disability Commissioner thinks the **Code** needs to be changed he will ask everyone about the changes.

Your name

Organisation (if you represent an organisation)

Thank you.

Thank you for:

- reading this information
- thinking about the hard topics

- telling the **Health and Disability Commissioner** what you think.

This will help the **Health and Disability Commissioner** to know what needs to be done.

Health and Disability Commissioner
Te Toihau Hauora, Hauātanga

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Started on 28 February 2017 at 9:07pm | Completed on 28 February 2017 at 9:52pm

some research uses people who are not able to say if they want to take part or not.

This is the form to tell the Health and Disability Commissioner what you think.

Questions and Answers

This form has **questions** to find out what you think about doing research with people who are not able to say if they want to take part or not.

Health and Disability Commissioner
Te Toihau Hauora, Hauātanga

Your **answers** will help the **Health and Disability Commissioner** know what needs to be done.

You do not have to **answer** all the questions.

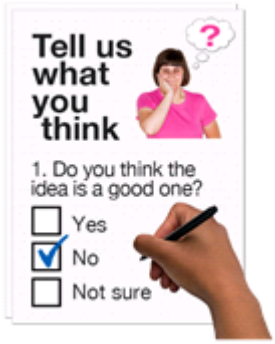
Case studies and questions

Case studies are stories that help us to understand something.

5

Here are 5 case studies that show when research cannot be done without informed consent at the moment in New Zealand.

These may help you decide if the law should change.



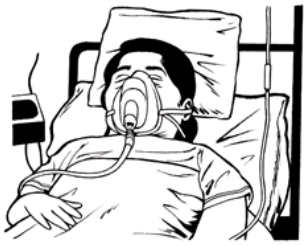
Each case study has questions that we would like you to answer.

Health and Disability Commissioner
Te Toihau Hauora, Hauātanga

Your answers to the questions will help the Health and Disability Commissioner know what is important to you.

Case study 1: Observational research on people with a bad infection

Some people with a bad infection will:



- get very sick
- not be able to tell other people what they think or feel

- have to take medicine to get healthy.

In this case study a doctor wants to do some research on people who:

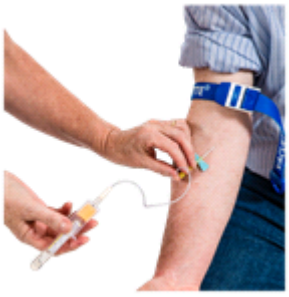
- have a bad infection

- have been given medicine.

The doctor will not change the medicine the people are getting.

The doctor:

- wants to know how much medicine these people need to take to get better



- will take samples from their bodies to find out how much medicine they need to take to get better.

The doctor wants to do this research on people who:

- cannot give informed consent to take part

- will not get better health from being part of the research
- will get the same medicine whether they take part in the research or not.

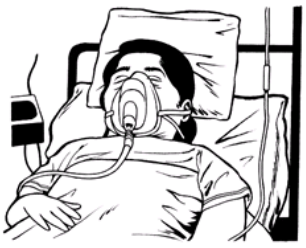
This research may help other people who get bad infections to get the medicine that will help them.

Questions about observational research on people with a bad infection

In these questions we will ask you to think about what you would choose to do if you were sick with a bad infection.

These questions are not about you.

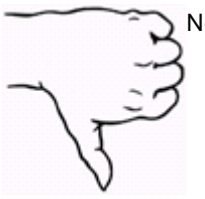
The questions are a made up example.



1. If you had a bad infection and could not give informed consent would you want to take part in research about how much medicine is needed to get better?

Choose the answer that is right for you:

Yes



No

I do not have an answer

If you said yes to question 1:

2. Why would you want to take part in this research?

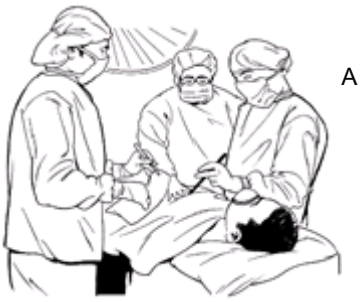
If you said no to question 1:

3. Why would you not want to take part in this research?

I would be happy that research is done post me getting better but not while I was sick. I do think your vulnerability at that stage leaves you open to some experimentation and there is probably enough of that happening while they are trying to get you better anyway.

4. Do you want to say any more about this question?

Case study 2: Research on brain operations



A person has to have a brain operation.

There are 2 things doctors use to make sure a person who has a brain operation is OK after their operation has finished.

No one knows which thing works best.

In this case study a doctor wants to do some research to find out which of the 2 things will work best for other people in the future to help them get better.

In the research the doctor will give some people 1 thing and other people a different thing.

The doctor will see which thing works best.

The people cannot say if they want to be part of the research or not.

The doctor wants to get **delayed consent** for the research from some of the people after their brain operation is done.

Delayed consent means asking for consent to do research on you after it has already been done.

Questions about research on brain operations

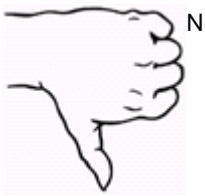
In these questions we will ask you to think about what you would choose to do if you were sick and have to have a brain operation.

These questions are not about you.

The questions are a made up example.

1. If you were not able to say yes or no to taking part in this research before your brain operation would you be OK with the doctor doing the research anyway? Choose the answer that is right for you.

Yes



No

I do not have an answer

If you said yes to question 1

2. Why would you want to take part in this research?

If you said no to question 1

3. Why would you not want to take part in this research?

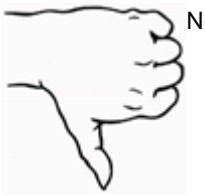
Nervousness around experimentation. I would need to know there was absolute transparency around any issues that result from the research and also strict controls/audits around practitioners involved that were available to the public, this would however not be of any use to those with those with intellectual disabilities which makes me uncomfortable.

4. Do you want to say any more about this question?

5. Do you think delayed consent is ok? Choose the answer that is right for you.

- ( ) Yes

- ( ) No



- ( ) I do not have an answer

If you said yes to question 5:

6. Why do you think delayed consent is OK?

If you said no to question 5:

7. Why do you think delayed consent is not OK?

I would feel that I was taken advantage of when vulnerable - I also wonder about recovery. if you have any issues or unexpected delays in your recovery you would be left with some doubts about what was given or done to you.

Case study 3: Research on people who have a brain disease

Sometimes people get a brain disease that makes it hard for them to:

- remember
- say what they think and feel.

In this case study a doctor wants to do some research on the care given to these people.

Some people will get 1 kind of care and others will get different care.

The doctor will see if any of the people get better.

No one knows if taking part in the research will mean the people will get better or worse.

The doctor does not know if the research will mean better care for people in the future or not.

The research is trying to find this out.

Some of the people the doctor wants to do research on cannot give **informed consent** to take part in the research.

Questions about research on people who have a brain disease

In these questions we will ask you to think about what you would want to happen if you had a brain disease.

These questions are not about you.

The questions are a made up example.

1. If you had a brain disease and could not give informed consent would you want to take part in this research?
Choose the answer that is right for you.

Yes

No

I do not have an answer

If you said yes to question 1
2. Why would you want to take part in this research?

If you said no to question 1

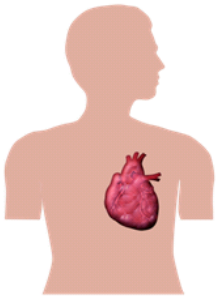
3. Why would you not want to take part in this research?

No I would not - once again you are too vulnerable to experimentation.

4. Do you want to say any more about this question?

This might be one where your Power of Attorney rep could give consent on your behalf - hopefully being aware of controls in place.

Case study 4: Research on people who are having a cardiac arrest

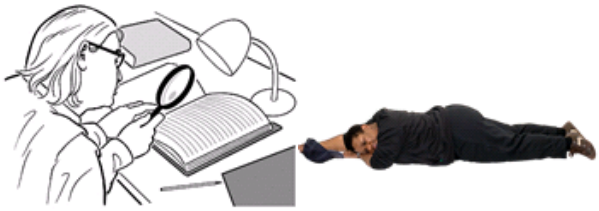


Cardiac arrest is when you have a big problem with your heart and it stops working.

Most of the time when a person's heart stops they are given a medicine.

No one knows if the medicine helps or hurts people.

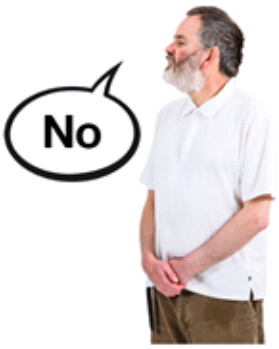
In this case study a doctor wants to research whether the medicine helps people whose heart has stopped.



If somebody's heart stops working they will not be awake.

This means the doctor will not be able to ask for **informed consent** to take part in the research.

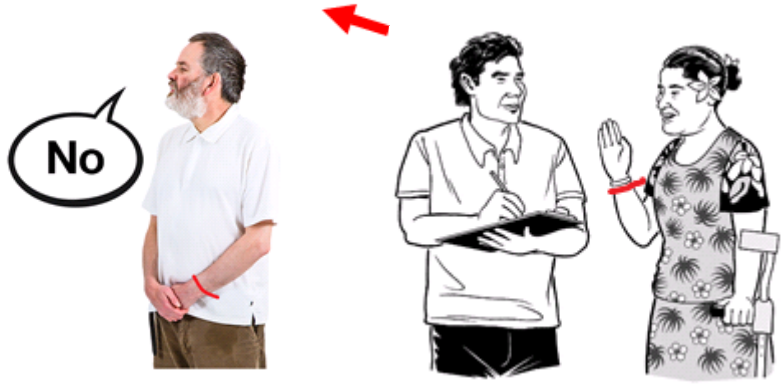
The doctor wants to give some people the medicine and others no medicine to see which group gets better.



People can choose to **opt out** of this research.

Opt out means you say you do **not** want to take part in the research if your heart stops in the future.

People who want to **opt out** of this research can wear a bracelet that says **no study** on it.



To do this people need to:

- ask for a bracelet in case their heart stops 1 day in the future
- wear the bracelet

Questions about research on people that are having a cardiac arrest

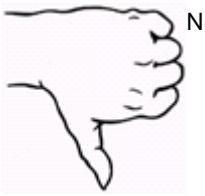
In these questions we will ask you to think about what you would want to happen if your heart stopped working.

These questions are not about you.

The questions are a made up example.

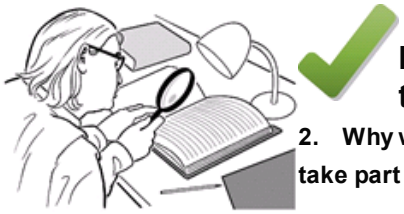
1. If your heart stopped would you want to take part in research to find out if taking this medicine is better than no medicine?
Choose the answer that is right for you.

Yes



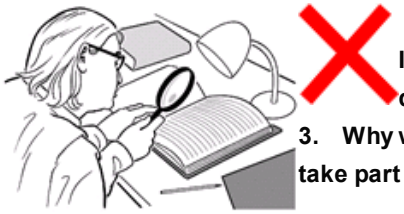
No

I do not have an answer



If you said yes to question 1

2. Why would you want to take part in this research?



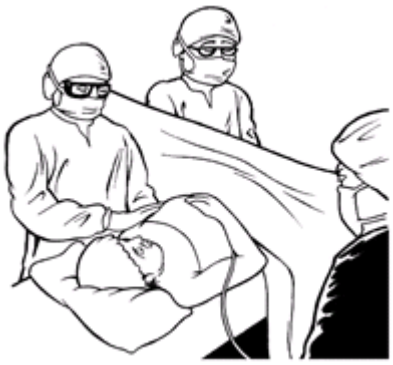
If you said no to question 1

3. Why would you not want to take part in this research?

It sounds a bit like playing Russian roulette. Surely if you were in that stage they would be giving you what is proven and tested and you will either recover or not - I would not want to be a live experiment.

4. Do you want to say any more about this question?

Having to actually wear a bracelet (that you would probably have to purchase or apply for) makes the choice of opting out harder and there are some groups (language, disability) that may not either have easy access or ability to make this kind of choice. What happens if you don't have your bracelet on you? It does not work for me.

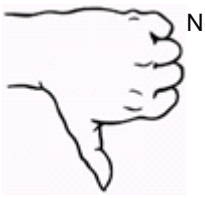


5. People who are wearing the bracelets will not be in the research if their heart stops.

Do you think it is OK for the doctors to do the research on anyone who is not wearing a bracelet when their heart stops?

Choose the answer that is right for you.

Yes



No

I do not have an answer

If you said yes to question 5:

6. Why do you think this?

If you said no to question 5:

7. Why do you think this?

See my previous answer - there are groups that may not know how or where or even understand the bracelet concept that makes this not acceptable.

Case study 5: Research on people who have Down Syndrome

Down Syndrome is a learning disability.

In this case study a doctor wants to do some research to find out if a medicine can help people with Down Syndrome with their learning.

The medicine may make some people with Down Syndrome think sad things and want to hurt themselves.

Some people with Down Syndrome who take part in the research **will** get the medicine.

Some people with Down Syndrome who take part in the research will **not** get the medicine.

This is so that the doctor can see if the medicine is helping the people with Down Syndrome who get it.

Some people with Down Syndrome will be able to give **informed consent** to take part in the research.

Some people with Down Syndrome will **not** be able to give **informed consent** to take part in the research.

The doctor wants to have people with Down Syndrome in their research who:

- can give **informed consent** to take part
- cannot give **informed consent** to take part.

The doctor wants to be able to get **informed consent** from the family members or support workers of the people with Down Syndrome who cannot give **informed consent**.

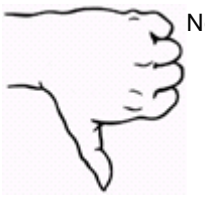
Questions about research on people with Down Syndrome

These questions are not about you.

The questions are a made up example.

1. Do you think people with Down Syndrome who cannot give informed consent should be in this research?
Choose the answer that is right for you.

Yes



No

I do not have an answer

If you said yes to question 1:

2. Why do you think people with Down Syndrome who cannot give informed consent should be in this research?

If you said no to question 1:

3. Why do you think people with Down Syndrome who cannot give informed consent should not be in this research?

Live people experimentation is not okay - side effects etc will not be able to be dealt with or understood by this group of people, so this is just simply not okay.

4. Do you want to say any more about this question?

5. Do you think other people should decide if people with Down Syndrome will be in this research?

These other people could be:

- **family / whānau**
- **support workers**

Choose the answer that is right for you.

Yes

No

I do not have an answer

If you said yes to question 5:

6. Why do you think this?

If you said no to question 5:

7. Why do you think this?

Without a real understanding of what the medicine would do, the side effects and the benefits for the person involved I would still say no to family/support workers making this decision as I assume that most would not have the clinical understanding to have a real understanding. There is no magic bullet for people born with syndromes and my discomfort would be that these vulnerable family members may see this as a "cure" without really thinking through the possible side effects or results of participation.

8. Do you want to say any more about this?

Questions about informed consent

Here are some more questions.

These questions will ask you what you think about **informed consent** to take part in research.

Health and Disability Commissioner
Te Toihau Hauora, Hauātanga

Your answers will help the **Health and Disability Commissioner** know what is important to you.

1. Do you think it is OK for adults who cannot give informed consent to take part in research when no one knows if it will help them or hurt them?
Choose the answer that is right for you.

Yes

No

I do not have an answer

2. When do you think it is OK for adults who cannot give informed consent to take part in research?

I don't think that it is okay period. All you need is one "bad egg" practitioner or someone pushing the boundaries of research into experimentation and you open up access to a very vulnerable group.

3. Some people doing research are not health or disability providers so they do not have to follow the Health and Disability Code of Rights.

Do you think everyone doing health and disability research should have to follow the Code?

Choose the answer that is right for you.


Yes

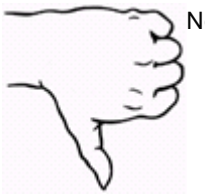
No

I do not have an answer

4. Do you think the law should say that if any person taking part in research looks like they are scared or in pain they should not be part of the research anymore?

Choose the answer that is right for you.


Yes



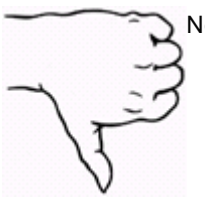
No

I do not have an answer

5. Do you think the law should change to say it is OK for people to give delayed consent to research after they wake up?

Delayed consent means asking for consent to do research on you after it has already been done. Choose the answer that is right for you.

Yes

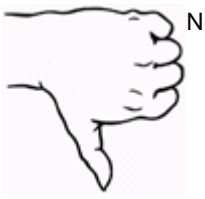


No

I do not have an answer

6. If the research can be done with people who can give informed consent is it OK to do the research with people who cannot give informed consent? Choose the answer that is right for you.

Yes

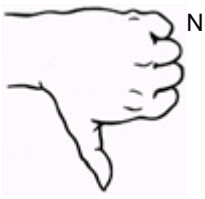


No

I do not have an answer

7. Do you think research should be done on a person that cannot give informed consent if the research may or may not help them but might help other people in the future? Choose the answer that is right for you.

Yes



No

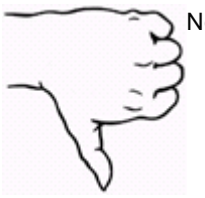
I do not have an answer

8. Why do you think this?

I reiterate previous answers around vulnerability.

9. Do you think all people that want to do research with adults who cannot give informed consent should have to get the OK from an ethics committee to do it?Choose the answer that is right for you.

Yes



No

I do not have an answer

10. Why do you think this?

This is a difficult question because answering yes means I agree, answering no means I agree with no controls.

11. Who do you think should have a say in whether or not a person who cannot give informed consent will be part of research?

You can choose as many as you want.

- Someone who is Enduring Power of Attorney or Welfare Guardian for the person
- Family / whanau of the person
- The person's doctor (if they are not part of the research)
- The person who wants to do the research
- Someone else

12. Do you think anyone else should have a say in whether or not a person who cannot give informed consent will be part of research?

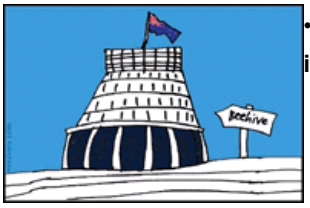
13. Do you want to say any more about question 11?

Am not choosing any option - would prefer this research did not occur with these vulnerable people/groups. As stated previously if the family/power of attorney were to have a say they would need to show that they have a true understanding of what is being researched, side effects and be able to manage the side effects. They should not be giving consent for the person to simply be a live experiment.

What happens next?

The **Health and Disability Commissioner** will:

- think about what everyone has said about people who cannot give **informed consent** being part of research



- decide what to tell the Government about whether changes are needed to the law on **informed consent** to be in research

- decide whether the **Code** needs to be changed about **informed consent** to be in research.

If the Health and Disability Commissioner thinks the **Code** needs to be changed he will ask everyone about the changes.

Your name

Organisation (if you represent an organisation)

Thank you.

Thank you for:

- reading this information
- thinking about the hard topics

- telling the **Health and Disability Commissioner** what you think.

This will help the **Health and Disability Commissioner** to know what needs to be done.

Health and Disability Commissioner
Te Toihau Hauora, Hauātanga

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some research uses people who are not able to say if they want to take part or not.

This is the form to tell the Health and Disability Commissioner what you think.

Questions and Answers

This form has **questions** to find out what you think about doing research with people who are not able to say if they want to take part or not.

Health and Disability Commissioner
Te Toihau Hauora, Hauātanga

Your **answers** will help the **Health and Disability Commissioner** know what needs to be done.

You do not have to **answer** all the questions.

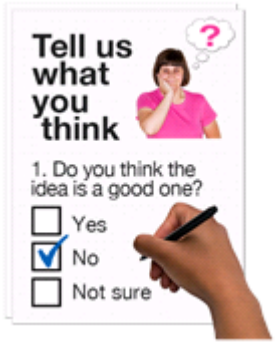
Case studies and questions

Case studies are stories that help us to understand something.

5

Here are 5 case studies that show when research cannot be done without informed consent at the moment in New Zealand.

These may help you decide if the law should change.



Each case study has questions that we would like you to answer.

Health and Disability Commissioner
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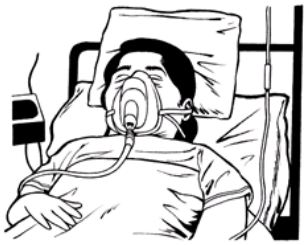
Your answers to the questions will help the Health and Disability Commissioner know what is important to you.

Case study 1: Observational research on people with a bad infection

Some people with a bad infection will:



- get very sick
- not be able to tell other people what they think or feel

- have to take medicine to get healthy.

In this case study a doctor wants to do some research on people who:

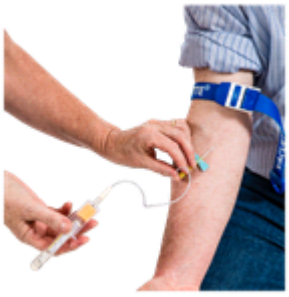
- have a bad infection

- have been given medicine.

The doctor will not change the medicine the people are getting.

The doctor:

- wants to know how much medicine these people need to take to get better



- will take samples from their bodies to find out how much medicine they need to take to get better.

The doctor wants to do this research on people who:

- cannot give informed consent to take part

- will not get better health from being part of the research
- will get the same medicine whether they take part in the research or not.

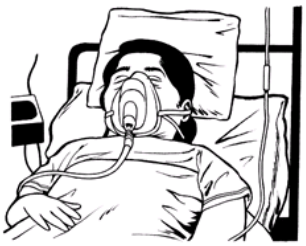
This research may help other people who get bad infections to get the medicine that will help them.

Questions about observational research on people with a bad infection

In these questions we will ask you to think about what you would choose to do if you were sick with a bad infection.

These questions are not about you.

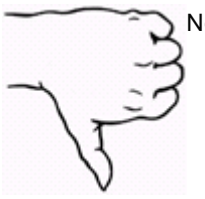
The questions are a made up example.



1. If you had a bad infection and could not give informed consent would you want to take part in research about how much medicine is needed to get better?

Choose the answer that is right for you:

Yes



No

I do not have an answer

If you said yes to question 1:

2. Why would you want to take part in this research?

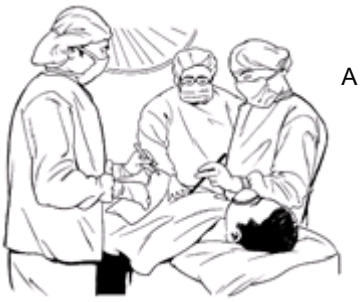
Because it is observational only (no additional risk due to being part of the research) and may help others in the future. We are all subject to ongoing observational research, e.g. from Google which collects all of our information, search histories etc.

If you said no to question 1:

3. Why would you not want to take part in this research?

4. Do you want to say any more about this question?

Case study 2: Research on brain operations



A person has to have a brain operation.

There are 2 things doctors use to make sure a person who has a brain operation is OK after their operation has finished.

No one knows which thing works best.

In this case study a doctor wants to do some research to find out which of the 2 things will work best for other people in the future to help them get better.

In the research the doctor will give some people 1 thing and other people a different thing.

The doctor will see which thing works best.

The people cannot say if they want to be part of the research or not.

The doctor wants to get **delayed consent** for the research from some of the people after their brain operation is done.

Delayed consent means asking for consent to do research on you after it has already been done.

Questions about research on brain operations

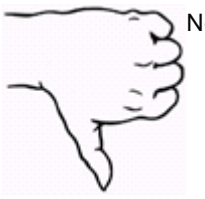
In these questions we will ask you to think about what you would choose to do if you were sick and have to have a brain operation.

These questions are not about you.

The questions are a made up example.

1. If you were not able to say yes or no to taking part in this research before your brain operation would you be OK with the doctor doing the research anyway? Choose the answer that is right for you.

Yes



No

I do not have an answer

If you said yes to question 1

2. Why would you want to take part in this research?

If you said no to question 1

3. Why would you not want to take part in this research?

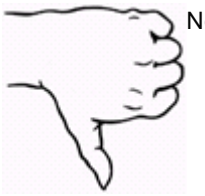
There is a potential risk as the outcome of the medicine is unknown. Research could be done with those who can give informed consent (e.g. advanced directive) or further alternative testing could be done.

4. Do you want to say any more about this question?

5. Do you think delayed consent is ok? Choose the answer that is right for you.

Yes

No



I do not have an answer

If you said yes to question 5:

6. Why do you think delayed consent is OK?

If you said no to question 5:

7. Why do you think delayed consent is not OK?

I don't believe it is ok to ask someone if it was ok that research was done on them afterwards. The risk has already been taken and we would not believe it was acceptable to do this in other aspects of our lives.

Case study 3: Research on people who have a brain disease

Sometimes people get a brain disease that makes it hard for them to:

- remember
- say what they think and feel.

In this case study a doctor wants to do some research on the care given to these people.

Some people will get 1 kind of care and others will get different care.

The doctor will see if any of the people get better.

No one knows if taking part in the research will mean the people will get better or worse.

The doctor does not know if the research will mean better care for people in the future or not.

The research is trying to find this out.

Some of the people the doctor wants to do research on cannot give **informed consent** to take part in the research.

Questions about research on people who have a brain disease

In these questions we will ask you to think about what you would want to happen if you had a brain disease.

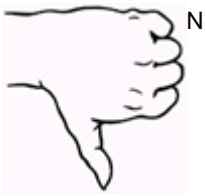
These questions are not about you.

The questions are a made up example.

1. If you had a brain disease and could not give informed consent would you want to take part in this research?
Choose the answer that is right for you.

- Yes

- No



- I do not have an answer

If you said yes to question 1
2. Why would you want to take part in this research?

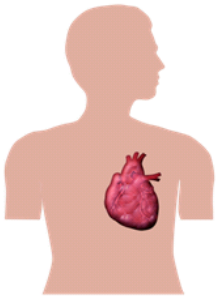
If you said no to question 1

3. Why would you not want to take part in this research?

There is a potential risk. Others who are able to give informed consent could choose to participate if they wish, however the risk should not be taken with the health of those that cannot give genuine informed consent.

4. Do you want to say any more about this question?

Case study 4: Research on people who are having a cardiac arrest

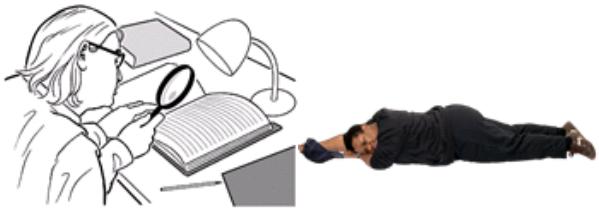


Cardiac arrest is when you have a big problem with your heart and it stops working.

Most of the time when a person's heart stops they are given a medicine.

No one knows if the medicine helps or hurts people.

In this case study a doctor wants to research whether the medicine helps people whose heart has stopped.



If somebody's heart stops working they will not be awake.

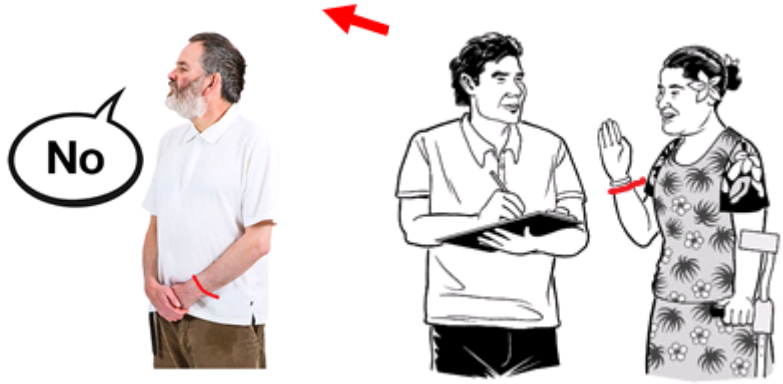
This means the doctor will not be able to ask for **informed consent** to take part in the research.

The doctor wants to give some people the medicine and others no medicine to see which group gets better.

People can choose to **opt out** of this research.

Opt out means you say you do **not** want to take part in the research if your heart stops in the future.

People who want to **opt out** of this research can wear a bracelet that says **no study** on it.



To do this people need to:

- ask for a bracelet in case their heart stops 1 day in the future
- wear the bracelet

Questions about research on people that are having a cardiac arrest

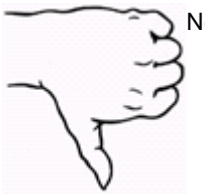
In these questions we will ask you to think about what you would want to happen if your heart stopped working.

These questions are not about you.

The questions are a made up example.

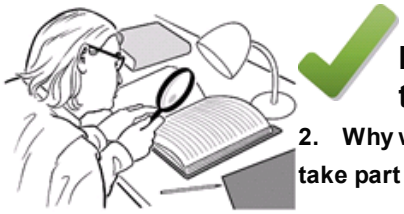
1. If your heart stopped would you want to take part in research to find out if taking this medicine is better than no medicine?
Choose the answer that is right for you.

Yes



No

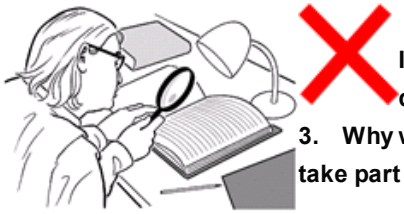
I do not have an answer



If you said yes to question 1

2. Why would you want to take part in this research?

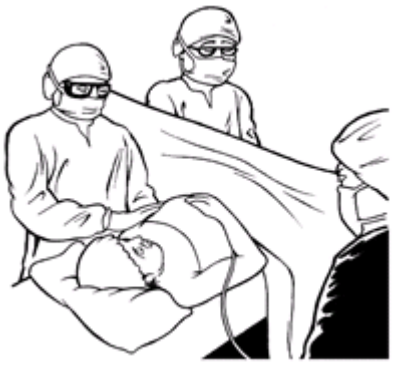
The medicine is already being given most of the time and I trust that this would not be the approved treatment if it was not effective, or carried minimal additional risk to no medicine.



If you said no to question 1

3. Why would you not want to take part in this research?

4. Do you want to say any more about this question?

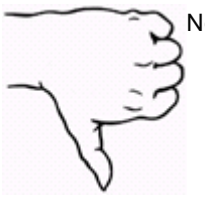


5. People who are wearing the bracelets will not be in the research if their heart stops.

Do you think it is OK for the doctors to do the research on anyone who is not wearing a bracelet when their heart stops?

Choose the answer that is right for you.

Yes



No

I do not have an answer

If you said yes to question 5:

6. Why do you think this?

If you said no to question 5:

7. Why do you think this?

In this case the doctor would have to assume that those not wearing the bracelets had consented. However, I do not think that opt-out methods are useful in these cases as people may not be aware they need to opt-out, may forget to opt-out etc and therefore the lack of a bracelet might not be a genuine consent. This would then lead to potentially requiring delayed consent from people which I do not agree with.

Case study 5: Research on people who have Down Syndrome

Down Syndrome is a learning disability.

In this case study a doctor wants to do some research to find out if a medicine can help people with Down Syndrome with their learning.

The medicine may make some people with Down Syndrome think sad things and want to hurt themselves.

Some people with Down Syndrome who take part in the research **will** get the medicine.

Some people with Down Syndrome who take part in the research will **not** get the medicine.

This is so that the doctor can see if the medicine is helping the people with Down Syndrome who get it.

Some people with Down Syndrome will be able to give **informed consent** to take part in the research.

Some people with Down Syndrome will **not** be able to give **informed consent** to take part in the research.

The doctor wants to have people with Down Syndrome in their research who:

- can give **informed consent** to take part
- cannot give **informed consent** to take part.

The doctor wants to be able to get **informed consent** from the family members or support workers of the people with Down Syndrome who cannot give **informed consent**.

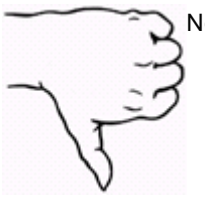
Questions about research on people with Down Syndrome

These questions are not about you.

The questions are a made up example.

1. Do you think people with Down Syndrome who cannot give informed consent should be in this research?
Choose the answer that is right for you.

Yes



No

I do not have an answer

If you said yes to question 1:

2. Why do you think people with Down Syndrome who cannot give informed consent should be in this research?

If you said no to question 1:

3. Why do you think people with Down Syndrome who cannot give informed consent should not be in this research?

There is a known serious risk with this medication so I do not believe it should be given to people who cannot give informed consent.

4. Do you want to say any more about this question?

5. Do you think other people should decide if people with Down Syndrome will be in this research?

These other people could be:

- **family / whānau**
- **support workers**

Choose the answer that is right for you.

Yes

No

I do not have an answer

If you said yes to question 5:

6. Why do you think this?

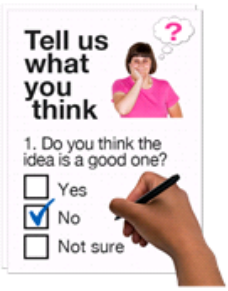
If you said no to question 5:

7. Why do you think this?

I don't think that other people have the right to make this decision for someone else considering the risk involved.

8. Do you want to say any more about this?

Questions about informed consent



Here are some more questions.

These questions will ask you what you think about **informed consent** to take part in research.

Health and Disability Commissioner
Te Toihau Hauora, Hauātanga

Your answers will help the **Health and Disability Commissioner** know what is important to you.

1. Do you think it is OK for adults who cannot give informed consent to take part in research when no one knows if it will help them or hurt them?
Choose the answer that is right for you.

Yes

No

I do not have an answer

2. When do you think it is OK for adults who cannot give informed consent to take part in research?

Only in a situation when the person will definitely definitely die without treatment. In this situation an experimental treatment might provide a chance to save their life, however the person's wishes were they able to give informed consent should be considered and taken into account.

3. Some people doing research are not health or disability providers so they do not have to follow the Health and Disability Code of Rights.

Do you think everyone doing health and disability research should have to follow the Code?

Choose the answer that is right for you.


Yes

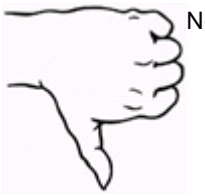

No

I do not have an answer

4. Do you think the law should say that if any person taking part in research looks like they are scared or in pain they should not be part of the research anymore?

Choose the answer that is right for you.


Yes



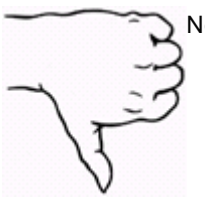
No

I do not have an answer

5. Do you think the law should change to say it is OK for people to give delayed consent to research after they wake up?

Delayed consent means asking for consent to do research on you after it has already been done. Choose the answer that is right for you.

Yes

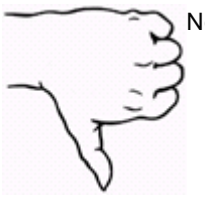


No

I do not have an answer

6. If the research can be done with people who can give informed consent is it OK to do the research with people who cannot give informed consent? Choose the answer that is right for you.

Yes

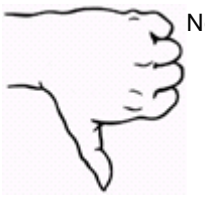


No

I do not have an answer

7. Do you think research should be done on a person that cannot give informed consent if the research may or may not help them but might help other people in the future? Choose the answer that is right for you.

Yes



No

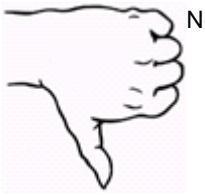
I do not have an answer

8. Why do you think this?

Because it is not acceptable to risk the life of a few people in order to potentially help others in the future. Everyone's life is of equal value.

9. Do you think all people that want to do research with adults who cannot give informed consent should have to get the OK from an ethics committee to do it?Choose the answer that is right for you.

Yes



No

I do not have an answer

10. Why do you think this?

Because there should be additional, impartial checks and balances in place to protect people who are unable to give informed consent.

11. Who do you think should have a say in whether or not a person who cannot give informed consent will be part of research?

You can choose as many as you want.

- Someone who is Enduring Power of Attorney or Welfare Guardian for the person
- Family / whanau of the person
- The person's doctor (if they are not part of the research)
- The person who wants to do the research
- Someone else

12. Do you think anyone else should have a say in whether or not a person who cannot give informed consent will be part of research?

No, only the person concerned can say if this should happen.

13. Do you want to say any more about question 11?

What happens next?

The **Health and Disability Commissioner** will:

- think about what everyone has said about people who cannot give **informed consent** being part of research

- decide what to tell the Government about whether changes are needed to the law on **informed consent** to be in research

- decide whether the **Code** needs to be changed about **informed consent** to be in research.

If the Health and Disability Commissioner thinks the **Code** needs to be changed he will ask everyone about the changes.

Your name

Organisation (if you represent an organisation)

Thank you.

Thank you for:

- reading this information
- thinking about the hard topics

- telling the **Health and Disability Commissioner** what you think.

This will help the **Health and Disability Commissioner** to know what needs to be done.

Health and Disability Commissioner
Te Toihau Hauora, Hauātanga

This information has been translated into Easy Read by People First New Zealand Inc. Ngā Tāngata Tuatahi

Started on 1 March 2017 at 10:10pm | Completed on 1 March 2017 at 10:28pm

some research uses people who are not able to say if they want to take part or not.

This is the form to tell the Health and Disability Commissioner what you think.

Questions and Answers

This form has **questions** to find out what you think about doing research with people who are not able to say if they want to take part or not.

Health and Disability Commissioner
Te Toihau Hauora, Hauātanga

Your **answers** will help the **Health and Disability Commissioner** know what needs to be done.

You do not have to **answer** all the questions.

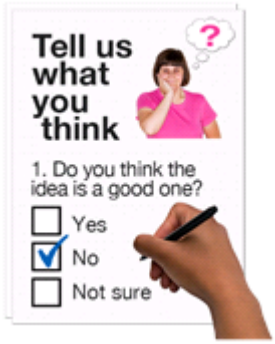
Case studies and questions

Case studies are stories that help us to understand something.

5

Here are 5 case studies that show when research cannot be done without informed consent at the moment in New Zealand.

These may help you decide if the law should change.



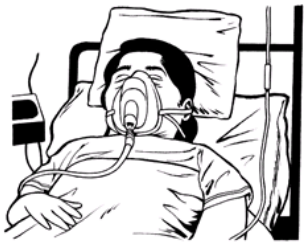
Each case study has questions that we would like you to answer.

Health and Disability Commissioner
Te Toihau Hauora, Hauātanga

Your answers to the questions will help the Health and Disability Commissioner know what is important to you.

Case study 1: Observational research on people with a bad infection

Some people with a bad infection will:



- get very sick
- not be able to tell other people what they think or feel

- have to take medicine to get healthy.

In this case study a doctor wants to do some research on people who:

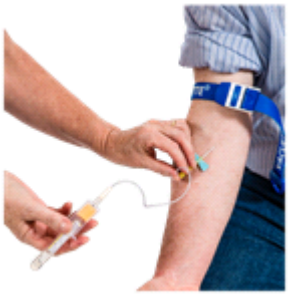
- have a bad infection

- have been given medicine.

The doctor will not change the medicine the people are getting.

The doctor:

- wants to know how much medicine these people need to take to get better



- will take samples from their bodies to find out how much medicine they need to take to get better.

The doctor wants to do this research on people who:

- cannot give informed consent to take part

- will not get better health from being part of the research
- will get the same medicine whether they take part in the research or not.

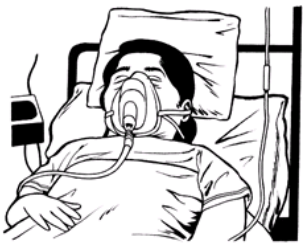
This research may help other people who get bad infections to get the medicine that will help them.

Questions about observational research on people with a bad infection

In these questions we will ask you to think about what you would choose to do if you were sick with a bad infection.

These questions are not about you.

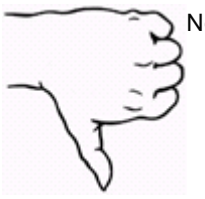
The questions are a made up example.



1. If you had a bad infection and could not give informed consent would you want to take part in research about how much medicine is needed to get better?

Choose the answer that is right for you:

Yes



No

I do not have an answer

If you said yes to question 1:

2. Why would you want to take part in this research?

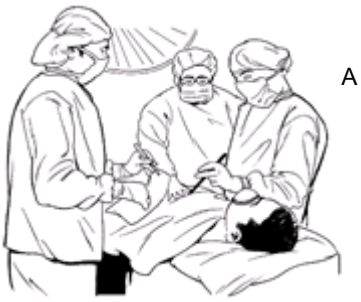
If you said no to question 1:

3. Why would you not want to take part in this research?

I need to know if this will have an adverse reaction on my health and I also would want the doctor to talk to my family first before decisions are made.

4. Do you want to say any more about this question?

Case study 2: Research on brain operations



A person has to have a brain operation.

There are 2 things doctors use to make sure a person who has a brain operation is OK after their operation has finished.

No one knows which thing works best.

In this case study a doctor wants to do some research to find out which of the 2 things will work best for other people in the future to help them get better.

In the research the doctor will give some people 1 thing and other people a different thing.

The doctor will see which thing works best.

The people cannot say if they want to be part of the research or not.

The doctor wants to get **delayed consent** for the research from some of the people after their brain operation is done.

Delayed consent means asking for consent to do research on you after it has already been done.

Questions about research on brain operations

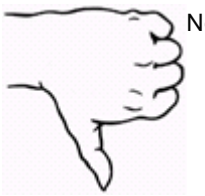
In these questions we will ask you to think about what you would choose to do if you were sick and have to have a brain operation.

These questions are not about you.

The questions are a made up example.

1. If you were not able to say yes or no to taking part in this research before your brain operation would you be OK with the doctor doing the research anyway? Choose the answer that is right for you.

Yes



No

I do not have an answer

If you said yes to question 1

2. Why would you want to take part in this research?

If you said no to question 1

3. Why would you not want to take part in this research?

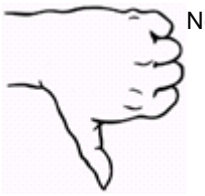
Discussion would need to take place prior in order for me to give informed consent

4. Do you want to say any more about this question?

5. Do you think delayed consent is ok? Choose the answer that is right for you.

- Yes

- No



- I do not have an answer

If you said yes to question 5:

6. Why do you think delayed consent is OK?

If you said no to question 5:

7. Why do you think delayed consent is not OK?

Apart from life saving emergency situations there is always time to give informed consent

Case study 3: Research on people who have a brain disease

Sometimes people get a brain disease that makes it hard for them to:

- remember
- say what they think and feel.

In this case study a doctor wants to do some research on the care given to these people.

Some people will get 1 kind of care and others will get different care.

The doctor will see if any of the people get better.

No one knows if taking part in the research will mean the people will get better or worse.

The doctor does not know if the research will mean better care for people in the future or not.

The research is trying to find this out.

Some of the people the doctor wants to do research on cannot give **informed consent** to take part in the research.

Questions about research on people who have a brain disease

In these questions we will ask you to think about what you would want to happen if you had a brain disease.

These questions are not about you.

The questions are a made up example.

1. If you had a brain disease and could not give informed consent would you want to take part in this research?
Choose the answer that is right for you.

Yes

No

I do not have an answer

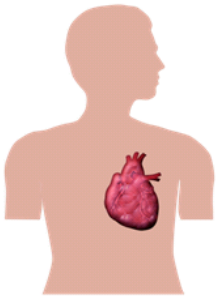
If you said yes to question 1
2. Why would you want to take part in this research?

If you said no to question 1

3. Why would you not want to take part in this research?

4. Do you want to say any more about this question?

Case study 4: Research on people who are having a cardiac arrest

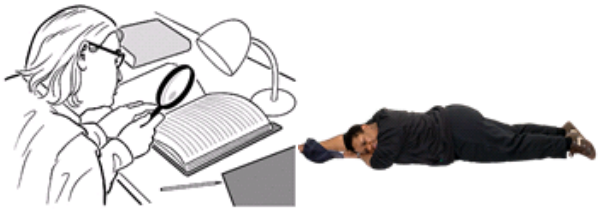


Cardiac arrest is when you have a big problem with your heart and it stops working.

Most of the time when a person's heart stops they are given a medicine.

No one knows if the medicine helps or hurts people.

In this case study a doctor wants to research whether the medicine helps people whose heart has stopped.



If somebody's heart stops working they will not be awake.

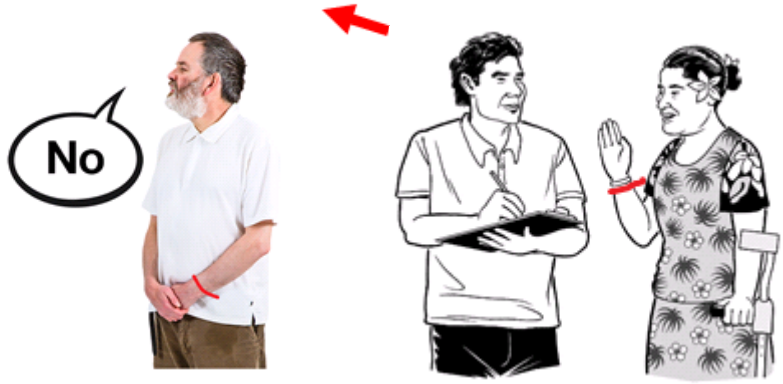
This means the doctor will not be able to ask for **informed consent** to take part in the research.

The doctor wants to give some people the medicine and others no medicine to see which group gets better.

People can choose to **opt out** of this research.

Opt out means you say you do **not** want to take part in the research if your heart stops in the future.

People who want to **opt out** of this research can wear a bracelet that says **no study** on it.



To do this people need to:

- ask for a bracelet in case their heart stops 1 day in the future
- wear the bracelet

Questions about research on people that are having a cardiac arrest

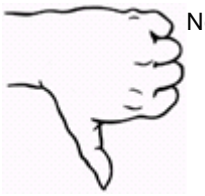
In these questions we will ask you to think about what you would want to happen if your heart stopped working.

These questions are not about you.

The questions are a made up example.

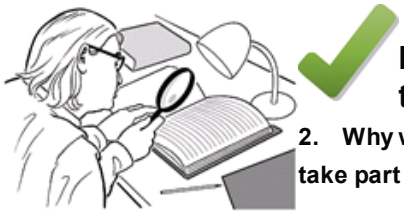
1. If your heart stopped would you want to take part in research to find out if taking this medicine is better than no medicine?
Choose the answer that is right for you.

Yes



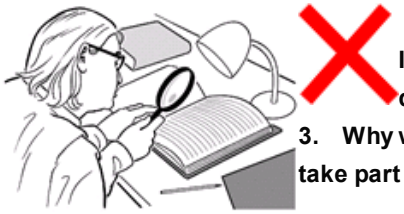
No

I do not have an answer



If you said yes to question 1

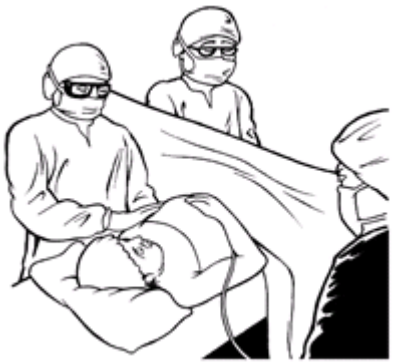
2. Why would you want to take part in this research?



If you said no to question 1

3. Why would you not want to take part in this research?

4. Do you want to say any more about this question?



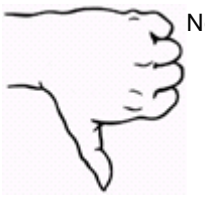
5. People who are wearing the bracelets will not be in the research if their heart stops.

Do you think it is OK for the doctors to do the research on anyone who is not wearing a bracelet when their heart stops?

Choose the answer that is right for you.

Yes

No



I do not have an answer

If you said yes to question 5:

6. Why do you think this?

If you said no to question 5:

7. Why do you think this?

No informed consent given. You must always recognise and respect the person's autonomous decision making

Case study 5: Research on people who have Down Syndrome

Down Syndrome is a learning disability.

In this case study a doctor wants to do some research to find out if a medicine can help people with Down Syndrome with their learning.

The medicine may make some people with Down Syndrome think sad things and want to hurt themselves.

Some people with Down Syndrome who take part in the research **will** get the medicine.

Some people with Down Syndrome who take part in the research will **not** get the medicine.

This is so that the doctor can see if the medicine is helping the people with Down Syndrome who get it.

Some people with Down Syndrome will be able to give **informed consent** to take part in the research.

Some people with Down Syndrome will **not** be able to give **informed consent** to take part in the research.

The doctor wants to have people with Down Syndrome in their research who:

- can give **informed consent** to take part
- cannot give **informed consent** to take part.

The doctor wants to be able to get **informed consent** from the family members or support workers of the people with Down Syndrome who cannot give **informed consent**.

Questions about research on people with Down Syndrome

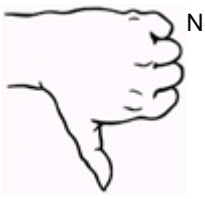
These questions are not about you.

The questions are a made up example.

1. Do you think people with Down Syndrome who cannot give informed consent should be in this research?
Choose the answer that is right for you.

Yes

No



I do not have an answer

If you said yes to question 1:

2. Why do you think people with Down Syndrome who cannot give informed consent should be in this research?

If you said no to question 1:

3. Why do you think people with Down Syndrome who cannot give informed consent should not be in this research?

People with Down's syndrome have the same human rights as any other person

4. Do you want to say any more about this question?

5. Do you think other people should decide if people with Down Syndrome will be in this research?

These other people could be:

- **family / whānau**
- **support workers**

Choose the answer that is right for you.

Yes

No

I do not have an answer

If you said yes to question 5:

6. Why do you think this?

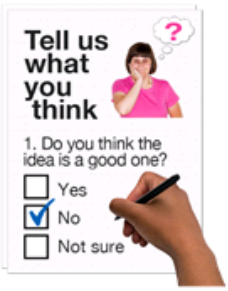
If you said no to question 5:

7. Why do you think this?

These people are entitled to respect and autonomy

8. Do you want to say any more about this?

Questions about informed consent



Here are some more questions.

These questions will ask you what you think about **informed consent** to take part in research.

Health and Disability Commissioner
Te Toihau Hauora, Hauātanga

Your answers will help the **Health and Disability Commissioner** know what is important to you.

1. Do you think it is OK for adults who cannot give informed consent to take part in research when no one knows if it will help them or hurt them?
Choose the answer that is right for you.

Yes

No

I do not have an answer

2. When do you think it is OK for adults who cannot give informed consent to take part in research?

Never

3. Some people doing research are not health or disability providers so they do not have to follow the Health and Disability Code of Rights.

Do you think everyone doing health and disability research should have to follow the Code?

Choose the answer that is right for you.


Yes

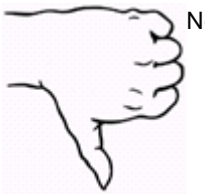

No

I do not have an answer

4. Do you think the law should say that if any person taking part in research looks like they are scared or in pain they should not be part of the research anymore?

Choose the answer that is right for you.


Yes



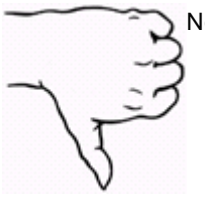
No

I do not have an answer

5. Do you think the law should change to say it is OK for people to give delayed consent to research after they wake up?

Delayed consent means asking for consent to do research on you after it has already been done. Choose the answer that is right for you.

Yes

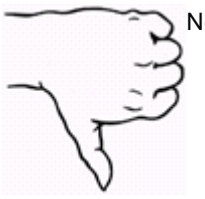


No

I do not have an answer

6. If the research can be done with people who can give informed consent is it OK to do the research with people who cannot give informed consent? Choose the answer that is right for you.

Yes

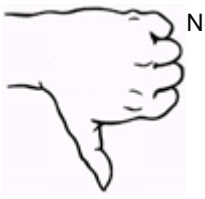


No

I do not have an answer

7. Do you think research should be done on a person that cannot give informed consent if the research may or may not help them but might help other people in the future? Choose the answer that is right for you.

Yes



No

I do not have an answer

8. Why do you think this?

Informed consent must always be given as it is a human right

9. Do you think all people that want to do research with adults who cannot give informed consent should have to get the OK from an ethics committee to do it?Choose the answer that is right for you.

Yes

No

I do not have an answer

10. Why do you think this?

This is an interesting question as I believe no ethics committee should agree with research which has this intention. Breaches Bill of Rights?

11. Who do you think should have a say in whether or not a person who cannot give informed consent will be part of research?

You can choose as many as you want.

- Someone who is Enduring Power of Attorney or Welfare Guardian for the person
- Family / whanau of the person
- The person's doctor (if they are not part of the research)
- The person who wants to do the research
- Someone else

12. Do you think anyone else should have a say in whether or not a person who cannot give informed consent will be part of research?

13. Do you want to say any more about question 11?

Unless life saving then no one but the person should give consent

What happens next?

The **Health and Disability Commissioner** will:

- think about what everyone has said about people who cannot give **informed consent** being part of research

- decide what to tell the Government about whether changes are needed to the law on **informed consent** to be in research

- decide whether the **Code** needs to be changed about **informed consent** to be in research.

If the Health and Disability Commissioner thinks the **Code** needs to be changed he will ask everyone about the changes.

Your name

Organisation (if you represent an organisation)

Thank you.

Thank you for:

- reading this information
- thinking about the hard topics

- telling the **Health and Disability Commissioner** what you think.

This will help the **Health and Disability Commissioner** to know what needs to be done.

Health and Disability Commissioner
Te Toihau Hauora, Hauātanga

This information has been translated into Easy Read
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some research uses people who are not able to say if they want to take part or not.

This is the form to tell the Health and Disability Commissioner what you think.

Questions and Answers

This form has **questions** to find out what you think about doing research with people who are not able to say if they want to take part or not.

Health and Disability Commissioner
Te Toihau Hauora, Hauātanga

Your **answers** will help the **Health and Disability Commissioner** know what needs to be done.

You do not have to **answer** all the questions.

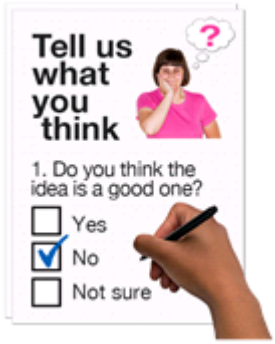
Case studies and questions

Case studies are stories that help us to understand something.

5

Here are 5 case studies that show when research cannot be done without informed consent at the moment in New Zealand.

These may help you decide if the law should change.



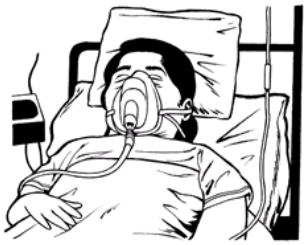
Each case study has questions that we would like you to answer.

Health and Disability Commissioner
Te Toihau Hauora, Hauātanga

Your answers to the questions will help the Health and Disability Commissioner know what is important to you.

Case study 1: Observational research on people with a bad infection

Some people with a bad infection will:



- get very sick
- not be able to tell other people what they think or feel

- have to take medicine to get healthy.

In this case study a doctor wants to do some research on people who:

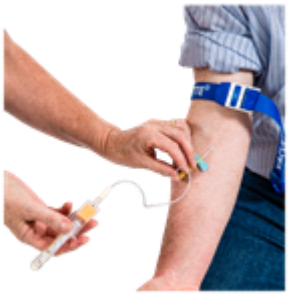
- have a bad infection

- have been given medicine.

The doctor will not change the medicine the people are getting.

The doctor:

- wants to know how much medicine these people need to take to get better



- will take samples from their bodies to find out how much medicine they need to take to get better.

The doctor wants to do this research on people who:

- cannot give informed consent to take part

- will not get better health from being part of the research
- will get the same medicine whether they take part in the research or not.

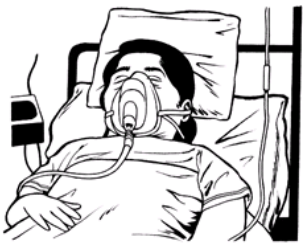
This research may help other people who get bad infections to get the medicine that will help them.

Questions about observational research on people with a bad infection

In these questions we will ask you to think about what you would choose to do if you were sick with a bad infection.

These questions are not about you.

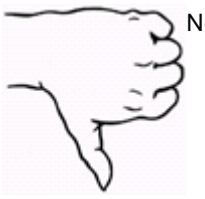
The questions are a made up example.



1. If you had a bad infection and could not give informed consent would you want to take part in research about how much medicine is needed to get better?

Choose the answer that is right for you:

Yes



No

I do not have an answer

If you said yes to question 1:

2. Why would you want to take part in this research?

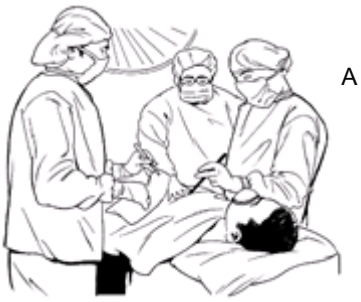
In this instance, patients would betreated the same regardless of their participation in Research or not, as doctors have to follow their treatment protocols. One way of gathering data is through research provided patients consent to the trial. When patients are unble to proved informed consent, in some instances, the relatives of these patients could consent on their behalf.
This case would allow the reseracher to eastablish the benefit of this drug at the correct dose (not under or over treat patients).
Once this patient recovers from the infection and learns about this reserach and is unwilling for the collected data to be used for the reserch purposes, he/she could withdraw the consent and request that the ata not to be used in the analysis.

If you said no to question 1:

3. Why would you not want to take part in this research?

4. Do you want to say any more about this question?

Case study 2: Research on brain operations



A person has to have a brain operation.

There are 2 things doctors use to make sure a person who has a brain operation is OK after their operation has finished.

No one knows which thing works best.

In this case study a doctor wants to do some research to find out which of the 2 things will work best for other people in the future to help them get better.

In the research the doctor will give some people 1 thing and other people a different thing.

The doctor will see which thing works best.

The people cannot say if they want to be part of the research or not.

The doctor wants to get **delayed consent** for the research from some of the people after their brain operation is done.

Delayed consent means asking for consent to do research on you after it has already been done.

Questions about research on brain operations

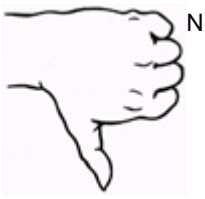
In these questions we will ask you to think about what you would choose to do if you were sick and have to have a brain operation.

These questions are not about you.

The questions are a made up example.

1. If you were not able to say yes or no to taking part in this research before your brain operation would you be OK with the doctor doing the research anyway? Choose the answer that is right for you.

Yes



No

I do not have an answer

If you said yes to question 1

2. Why would you want to take part in this research?

Yes if it will not harm me in any way

If you said no to question 1

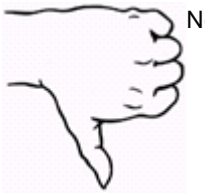
3. Why would you not want to take part in this research?

4. Do you want to say any more about this question?

5. Do you think delayed consent is ok? Choose the answer that is right for you.

- Yes

- No



- I do not have an answer

If you said yes to question 5:

6. Why do you think delayed consent is OK?

Yes. This surgery is planned which means the doctors could approach my family memebers to consent on my behalf only if the family memebers are well informed of the risks and benefits of this procedure. The patient can consent to the study upon the recovery.

If you said no to question 5:

7. Why do you think delayed consent is not OK?

Case study 3: Research on people who have a brain disease

Sometimes people get a brain disease that makes it hard for them to:

- remember
- say what they think and feel.

In this case study a doctor wants to do some research on the care given to these people.

Some people will get 1 kind of care and others will get different care.

The doctor will see if any of the people get better.

No one knows if taking part in the research will mean the people will get better or worse.

The doctor does not know if the research will mean better care for people in the future or not.

The research is trying to find this out.

Some of the people the doctor wants to do research on cannot give **informed consent** to take part in the research.

Questions about research on people who have a brain disease

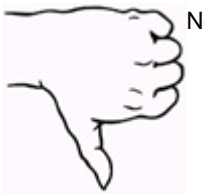
In these questions we will ask you to think about what you would want to happen if you had a brain disease.

These questions are not about you.

The questions are a made up example.

1. If you had a brain disease and could not give informed consent would you want to take part in this research?
Choose the answer that is right for you.

Yes



No

I do not have an answer

If you said yes to question 1
2. Why would you want to take part in this research?

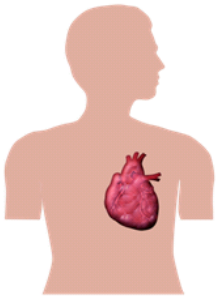
Yes provided my family memebers are well informed of risks and benefits and consent on my behalf. This reserach may help others in the future to improve their quality of life.

If you said no to question 1

3. Why would you not want to take part in this research?

4. Do you want to say any more about this question?

Case study 4: Research on people who are having a cardiac arrest

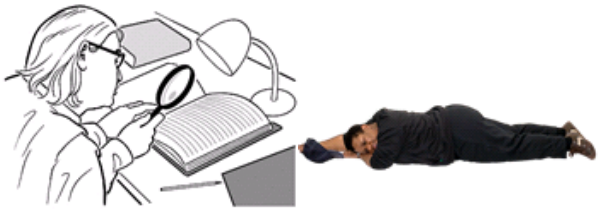


Cardiac arrest is when you have a big problem with your heart and it stops working.

Most of the time when a person's heart stops they are given a medicine.

No one knows if the medicine helps or hurts people.

In this case study a doctor wants to research whether the medicine helps people whose heart has stopped.



If somebody's heart stops working they will not be awake.

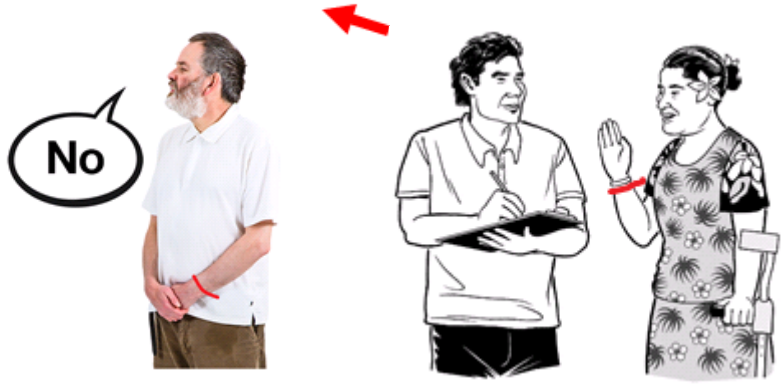
This means the doctor will not be able to ask for **informed consent** to take part in the research.

The doctor wants to give some people the medicine and others no medicine to see which group gets better.

People can choose to **opt out** of this research.

Opt out means you say you do **not** want to take part in the research if your heart stops in the future.

People who want to **opt out** of this research can wear a bracelet that says **no study** on it.



To do this people need to:

- ask for a bracelet in case their heart stops 1 day in the future
- wear the bracelet

Questions about research on people that are having a cardiac arrest

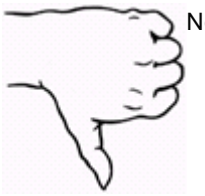
In these questions we will ask you to think about what you would want to happen if your heart stopped working.

These questions are not about you.

The questions are a made up example.

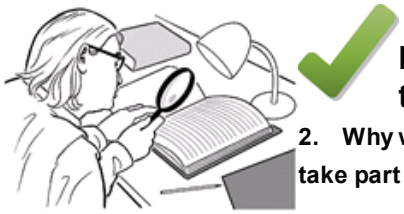
1. If your heart stopped would you want to take part in research to find out if taking this medicine is better than no medicine?
Choose the answer that is right for you.

Yes



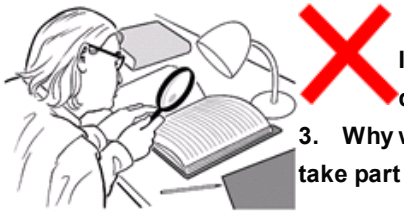
No

I do not have an answer



If you said yes to question 1

2. Why would you want to take part in this research?

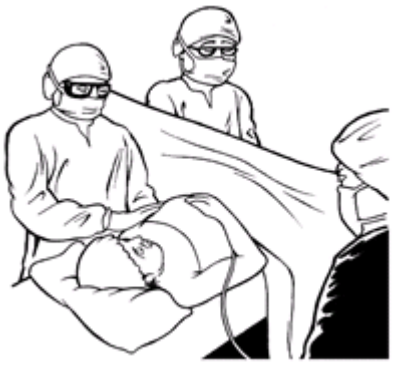


If you said no to question 1

3. Why would you not want to take part in this research?

There is something that is not right about this statement: "The doctor wants to give some people the medicine and others no medicine to see which group gets better." - Is it even ethical not to treat patients who are having a cardiac event knowing it might result in death?
I would be very suprised if there are many people who would be willing to conset to this study. If there was another drug with similar action to adrenlin, then a reserach comparing the two drugs (risks and benefits) might be of use.

4. Do you want to say any more about this question?



5. People who are wearing the bracelets will not be in the research if their heart stops.

Do you think it is OK for the doctors to do the research on anyone who is not wearing a bracelet when their heart stops?

Choose the answer that is right for you.

Yes

No

I do not have an answer

If you said yes to question 5:

6. Why do you think this?

If you said no to question 5:

7. Why do you think this?

How does one know that one will have a cardiac event tomorrow and should start wearing a braslet today?

Case study 5: Research on people who have Down Syndrome

Down Syndrome is a learning disability.

In this case study a doctor wants to do some research to find out if a medicine can help people with Down Syndrome with their learning.

The medicine may make some people with Down Syndrome think sad things and want to hurt themselves.

Some people with Down Syndrome who take part in the research **will** get the medicine.

Some people with Down Syndrome who take part in the research will **not** get the medicine.

This is so that the doctor can see if the medicine is helping the people with Down Syndrome who get it.

Some people with Down Syndrome will be able to give **informed consent** to take part in the research.

Some people with Down Syndrome will **not** be able to give **informed consent** to take part in the research.

The doctor wants to have people with Down Syndrome in their research who:

- can give **informed consent** to take part
- cannot give **informed consent** to take part.

The doctor wants to be able to get **informed consent** from the family members or support workers of the people with Down Syndrome who cannot give **informed consent**.

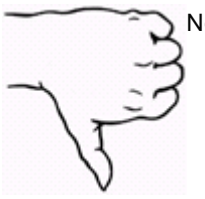
Questions about research on people with Down Syndrome

These questions are not about you.

The questions are a made up example.

1. Do you think people with Down Syndrome who cannot give informed consent should be in this research?
Choose the answer that is right for you.

Yes



No

I do not have an answer

If you said yes to question 1:

2. Why do you think people with Down Syndrome who cannot give informed consent should be in this research?

Doctors need to approach subjects' legal guardians/family members to see if they'd be interested in enrolling these people into the trial after being well informed of the trial risks, benefits etc. Subjects/caregivers must always be given an option of withdrawing patients from participation in any trial.

If you said no to question 1:

3. Why do you think people with Down Syndrome who cannot give informed consent should not be in this research?

4. Do you want to say any more about this question?

5. Do you think other people should decide if people with Down Syndrome will be in this research?

These other people could be:

- **family / whānau**
- **support workers**

Choose the answer that is right for you.

Yes

No

I do not have an answer

If you said yes to question 5:

6. Why do you think this?

If people with Down Syndrome are unable to provide informed concent, then caregivers could do it on their behalf.

If you said no to question 5:

7. Why do you think this?

8. Do you want to say any more about this?

Questions about informed consent

Here are some more questions.

These questions will ask you what you think about **informed consent** to take part in research.

Health and Disability Commissioner
Te Toihau Hauora, Hauātanga

Your answers will help the **Health and Disability Commissioner** know what is important to you.

1. Do you think it is OK for adults who cannot give informed consent to take part in research when no one knows if it will help them or hurt them?
Choose the answer that is right for you.

- Yes

- No

- I do not have an answer

2. When do you think it is OK for adults who cannot give informed consent to take part in research?

This is why it is called INFORMED consent as health professionals are obliged to list the potential risks and benefits to patients as well as what the study is all about. Then patients can decide after consulting their family memebers, friends etc. Patients will have to be provided with mple time and opportunity to think about the trial and ask questions

3. Some people doing research are not health or disability providers so they do not have to follow the Health and Disability Code of Rights.

Do you think everyone doing health and disability research should have to follow the Code?

Choose the answer that is right for you.


Yes

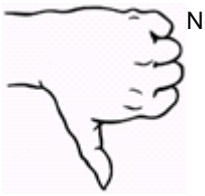
No

I do not have an answer

4. Do you think the law should say that if any person taking part in research looks like they are scared or in pain they should not be part of the research anymore?

Choose the answer that is right for you.


Yes



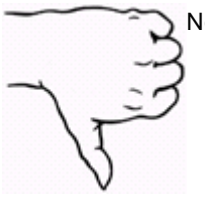
No

I do not have an answer

5. Do you think the law should change to say it is OK for people to give delayed consent to research after they wake up?

Delayed consent means asking for consent to do research on you after it has already been done. Choose the answer that is right for you.

Yes

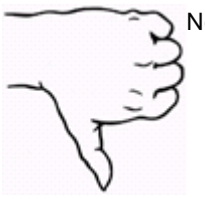


No

I do not have an answer

6. If the research can be done with people who can give informed consent is it OK to do the research with people who cannot give informed consent? Choose the answer that is right for you.

Yes

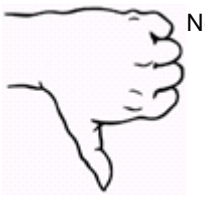


No

I do not have an answer

7. Do you think research should be done on a person that cannot give informed consent if the research may or may not help them but might help other people in the future? Choose the answer that is right for you.

Yes



No

I do not have an answer

8. Why do you think this?

If a person is unable to consent, the family memebers/whanau/caregivers can consesnt on patients' behalf after being provided with all information about the trial, risks, benefits etc. They always have an option of withdrawng the consent if the treatment, in their opinion, is detrimental to the patirnt.
This resreach MAY help others in the future!

9. Do you think all people that want to do research with adults who cannot give informed consent should have to get the OK from an ethics committee to do it?Choose the answer that is right for you.

Yes

No

I do not have an answer

10. Why do you think this?

If a person is unable to consent, the family memebers/whanau/caregivers can consesnt on patients' behalf after being provided with all information about the trial, risks, benefits etc. They always have an option of withdrawng the consent if the treatment, in their opinion, is detrimental to the patirnt.
This resreach MAY help others in the future!

11. Who do you think should have a say in whether or not a person who cannot give informed consent will be part of research?

You can choose as many as you want.

- [x] Someone who is Enduring Power of Attorney or Welfare Guardian for the person
- [x] Family / whanau of the person
- [x] The person's doctor (if they are not part of the research)
- [ ] The person who wants to do the research
- [ ] Someone else

12. Do you think anyone else should have a say in whether or not a person who cannot give informed consent will be part of research?

13. Do you want to say any more about question 11?

What happens next?

The **Health and Disability Commissioner** will:

- think about what everyone has said about people who cannot give **informed consent** being part of research

- decide what to tell the Government about whether changes are needed to the law on **informed consent** to be in research

- decide whether the **Code** needs to be changed about **informed consent** to be in research.

If the Health and Disability Commissioner thinks the **Code** needs to be changed he will ask everyone about the changes.

Your name

Organisation (if you represent an organisation)

Thank you.

Thank you for:

- reading this information
- thinking about the hard topics

- telling the **Health and Disability Commissioner** what you think.

This will help the **Health and Disability Commissioner** to know what needs to be done.

Health and Disability Commissioner
Te Toihau Hauora, Hauātanga

This information has been translated into Easy Read by People First New Zealand Inc. Ngā Tāngata Tuatahi

Started on 3 April 2017 at 9:41am | Completed on 3 April 2017 at 10:56am

some research uses people who are not able to say if they want to take part or not.

This is the form to tell the Health and Disability Commissioner what you think.

Questions and Answers

This form has **questions** to find out what you think about doing research with people who are not able to say if they want to take part or not.

Health and Disability Commissioner
Te Toihau Hauora, Hauātanga

Your **answers** will help the **Health and Disability Commissioner** know what needs to be done.

You do not have to **answer** all the questions.

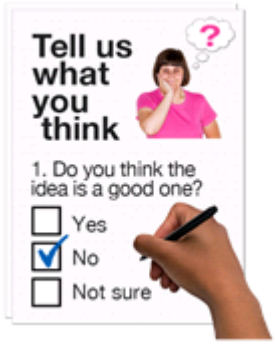
Case studies and questions

Case studies are stories that help us to understand something.

5

Here are 5 case studies that show when research cannot be done without informed consent at the moment in New Zealand.

These may help you decide if the law should change.



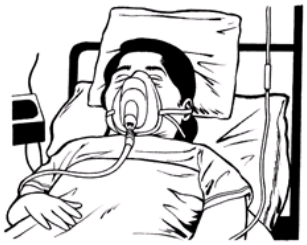
Each case study has questions that we would like you to answer.

Health and Disability Commissioner
Te Toihau Hauora, Hauātanga

Your answers to the questions will help the Health and Disability Commissioner know what is important to you.

Case study 1: Observational research on people with a bad infection

Some people with a bad infection will:



- get very sick
- not be able to tell other people what they think or feel

- have to take medicine to get healthy.

In this case study a doctor wants to do some research on people who:

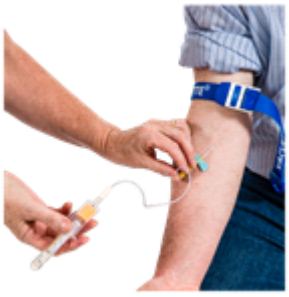
- have a bad infection

- have been given medicine.

The doctor will not change the medicine the people are getting.

The doctor:

- wants to know how much medicine these people need to take to get better



- will take samples from their bodies to find out how much medicine they need to take to get better.

The doctor wants to do this research on people who:

- cannot give informed consent to take part

- will not get better health from being part of the research
- will get the same medicine whether they take part in the research or not.

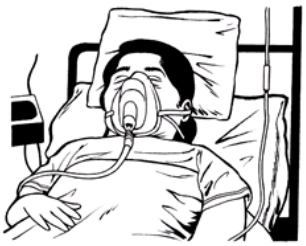
This research may help other people who get bad infections to get the medicine that will help them.

Questions about observational research on people with a bad infection

In these questions we will ask you to think about what you would choose to do if you were sick with a bad infection.

These questions are not about you.

The questions are a made up example.

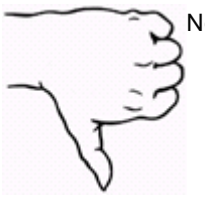


1. If you had a bad infection and could not give informed consent would you want to take part in research about how much medicine is needed to get better?

Choose the answer that is right for you:

Yes

No



I do not have an answer

If you said yes to question 1:

2. Why would you want to take part in this research?

It is fundamental that a person is given the right medicine in the right dose at the right time for them. If it is not known how much medicine to give then we need to find out.

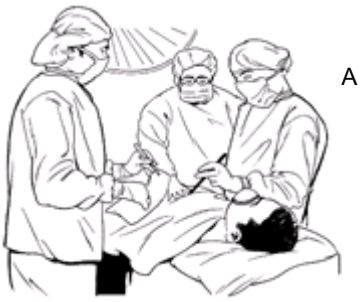
Rights entail responsibilities, so to gain the best treatment means the responsibility to find out the best answer. Responsibilities lie with both the researcher and the group being investigated

If you said no to question 1:

3. Why would you not want to take part in this research?

4. Do you want to say any more about this question?

Case study 2: Research on brain operations



A person has to have a brain operation.

There are 2 things doctors use to make sure a person who has a brain operation is OK after their operation has finished.

No one knows which thing works best.

In this case study a doctor wants to do some research to find out which of the 2 things will work best for other people in the future to help them get better.

In the research the doctor will give some people 1 thing and other people a different thing.

The doctor will see which thing works best.

The people cannot say if they want to be part of the research or not.

The doctor wants to get **delayed consent** for the research from some of the people after their brain operation is done.

Delayed consent means asking for consent to do research on you after it has already been done.

Questions about research on brain operations

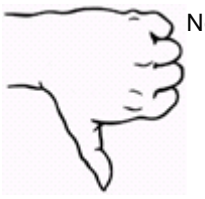
In these questions we will ask you to think about what you would choose to do if you were sick and have to have a brain operation.

These questions are not about you.

The questions are a made up example.

1. If you were not able to say yes or no to taking part in this research before your brain operation would you be OK with the doctor doing the research anyway? Choose the answer that is right for you.

Yes



No

I do not have an answer

If you said yes to question 1

2. Why would you want to take part in this research?

Both are appropriate treatments, but the outcome of each is unknown. It is entirely reasonable to determine which is best for future use. This is responsibility of one individual to a group of which they are a part.

If you said no to question 1

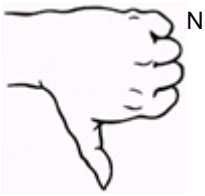
3. Why would you not want to take part in this research?

4. Do you want to say any more about this question?

This is about a standard of care, and it is likely that this group could give consent before the operation as normal informed consent. However in the situation where informed consent before hand cannot be given, then provided both are current standard praciices, this is acceptable

5. Do you think delayed consent is ok? Choose the answer that is right for you.

Yes



No

I do not have an answer

If you said yes to question 5:

6. Why do you think delayed consent is OK?

The Hawthorn effect and placebo effects are well known phenomena. Patients are likely to benefit from the research effort on the basis of that. Improved monitoring of "research" patients does result in improved standards of care for others not involved as it results in a change of clinical practice so long as it is monitored.

If you said no to question 5:

7. Why do you think delayed consent is not OK?

Case study 3: Research on people who have a brain disease

Sometimes people get a brain disease that makes it hard for them to:

- remember
- say what they think and feel.

In this case study a doctor wants to do some research on the care given to these people.

Some people will get 1 kind of care and others will get different care.

The doctor will see if any of the people get better.

No one knows if taking part in the research will mean the people will get better or worse.

The doctor does not know if the research will mean better care for people in the future or not.

The research is trying to find this out.

Some of the people the doctor wants to do research on cannot give **informed consent** to take part in the research.

Questions about research on people who have a brain disease

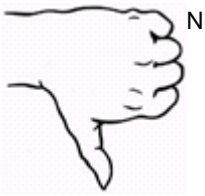
In these questions we will ask you to think about what you would want to happen if you had a brain disease.

These questions are not about you.

The questions are a made up example.

1. If you had a brain disease and could not give informed consent would you want to take part in this research?
Choose the answer that is right for you.

Yes



No

I do not have an answer

If you said yes to question 1
2. Why would you want to take part in this research?

If my mental decline was such that I could not make decisions, then my basic philosophy is that I am happy for others to learn from whatever can be determined from my plight. It is part of my contribution to my fellows who may or may not suffer the same fate.

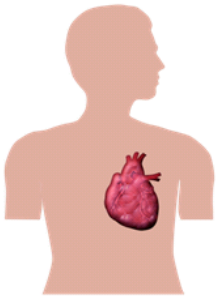
If you said no to question 1

3. Why would you not want to take part in this research?

4. Do you want to say any more about this question?

This implies a continuation of the intent and life philosophy of an idividual. It may or may not be understood by a third party. I may be quite happy to make a decision for others that family members may not. It is part of the debate about organ donation where family may over ride a persons previous decision to donate

Case study 4: Research on people who are having a cardiac arrest

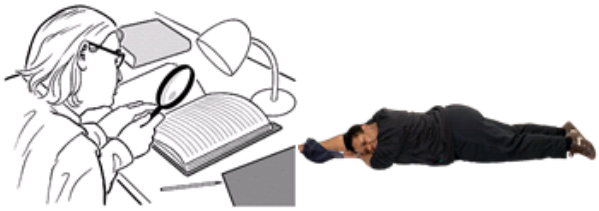


Cardiac arrest is when you have a big problem with your heart and it stops working.

Most of the time when a person's heart stops they are given a medicine.

No one knows if the medicine helps or hurts people.

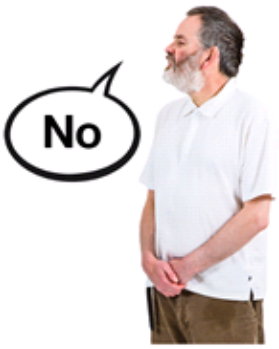
In this case study a doctor wants to research whether the medicine helps people whose heart has stopped.



If somebody's heart stops working they will not be awake.

This means the doctor will not be able to ask for **informed consent** to take part in the research.

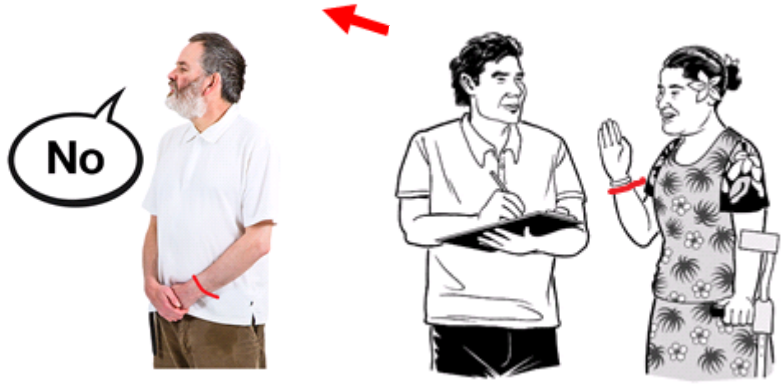
The doctor wants to give some people the medicine and others no medicine to see which group gets better.



People can choose to **opt out** of this research.

Opt out means you say you do **not** want to take part in the research if your heart stops in the future.

People who want to **opt out** of this research can wear a bracelet that says **no study** on it.



To do this people need to:

- ask for a bracelet in case their heart stops 1 day in the future
- wear the bracelet

Questions about research on people that are having a cardiac arrest

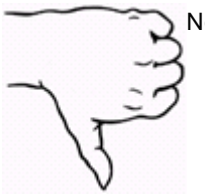
In these questions we will ask you to think about what you would want to happen if your heart stopped working.

These questions are not about you.

The questions are a made up example.

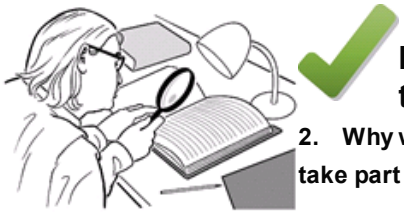
1. If your heart stopped would you want to take part in research to find out if taking this medicine is better than no medicine?
Choose the answer that is right for you.

Yes



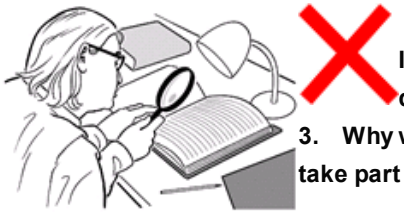
No

I do not have an answer



If you said yes to question 1

2. Why would you want to take part in this research?

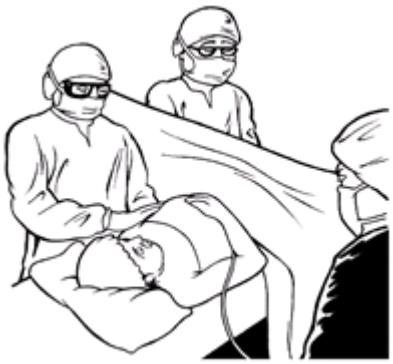


If you said no to question 1

3. Why would you not want to take part in this research?

4. Do you want to say any more about this question?

My answer depends very much on why my heart stopped working, and in what context. In the If it were an end of life event, then I would prefer to have no treatment. If however, it were part of a potentially reversible situation with few potential sequelae, that I would be happy to be part of this research.

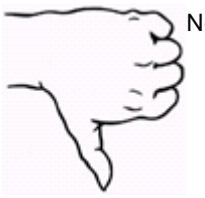


5. People who are wearing the bracelets will not be in the research if their heart stops.

Do you think it is OK for the doctors to do the research on anyone who is not wearing a bracelet when their heart stops?

Choose the answer that is right for you.

Yes



No

I do not have an answer

If you said yes to question 5:

6. Why do you think this?

This depends upon what systems are in place to ensure the information is correct and current. A wrist bracelet is used for medic alert which does not necessarily meet these criteria. Alerts on computer systems are also limited with current IT systems. It is inmany ways the same question about a potential donor databse with opt in and opt out clauses.

If you said no to question 5:

7. Why do you think this?

Case study 5: Research on people who have Down Syndrome

Down Syndrome is a learning disability.

In this case study a doctor wants to do some research to find out if a medicine can help people with Down Syndrome with their learning.

The medicine may make some people with Down Syndrome think sad things and want to hurt themselves.

Some people with Down Syndrome who take part in the research **will** get the medicine.

Some people with Down Syndrome who take part in the research will **not** get the medicine.

This is so that the doctor can see if the medicine is helping the people with Down Syndrome who get it.

Some people with Down Syndrome will be able to give **informed consent** to take part in the research.

Some people with Down Syndrome will **not** be able to give **informed consent** to take part in the research.

The doctor wants to have people with Down Syndrome in their research who:

- can give **informed consent** to take part
- cannot give **informed consent** to take part.

The doctor wants to be able to get **informed consent** from the family members or support workers of the people with Down Syndrome who cannot give **informed consent**.

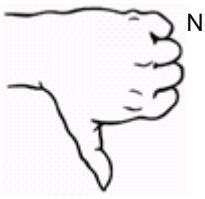
Questions about research on people with Down Syndrome

These questions are not about you.

The questions are a made up example.

1. Do you think people with Down Syndrome who cannot give informed consent should be in this research?
Choose the answer that is right for you.

Yes



No

I do not have an answer

If you said yes to question 1:

2. Why do you think people with Down Syndrome who cannot give informed consent should be in this research?

If you said no to question 1:

3. Why do you think people with Down Syndrome who cannot give informed consent should not be in this research?

It depends on the stage and phase of the study. It seems a potential answer my come from getting informed consent from part of the study group. If they have shown benefit, then I would consider it possible to include non consenting Down Syndrome people in a later study.

4. Do you want to say any more about this question?

Part of the decision would depend upon the potential benefits and how great they are. If the medication converts a happy non consenting person into an unhappy consenting person then the balance of benefit is hard to imagine.

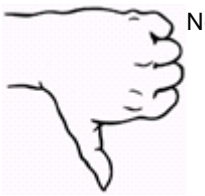
5. Do you think other people should decide if people with Down Syndrome will be in this research?

These other people could be:

- **family / whānau**
- **support workers**

Choose the answer that is right for you.

Yes



No

I do not have an answer

If you said yes to question 5:

6. Why do you think this?

If you said no to question 5:

7. Why do you think this?

8. Do you want to say any more about this?

New Zealand law about enduring powers of attorney are difficult.The Law Commission has suggested that they should be revisited, and in this situation the researcher has little evidence to allow them to make a judgement of the people making the decision.

A recent experience with enduring powers of attorney and fraught family relationships has drawn this to my attention

Questions about informed consent

Here are some more questions.

These questions will ask you what you think about **informed consent** to take part in research.

Health and Disability Commissioner
Te Toihau Hauora, Hauātanga

Your answers will help the **Health and Disability Commissioner** know what is important to you.

1. Do you think it is OK for adults who cannot give informed consent to take part in research when no one knows if it will help them or hurt them?
Choose the answer that is right for you.

Yes

No

I do not have an answer

2. When do you think it is OK for adults who cannot give informed consent to take part in research?

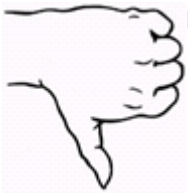
When those giving consent are well informed
Those giving consent are empowered to do so and understand the person as a potential subject of research and their wishes.
That the researchers are covered with insurance for compensation if there is shown to be a worse outcome with a therapy if it is likely to be a worse quality of life.

3. Some people doing research are not health or disability providers so they do not have to follow the Health and Disability Code of Rights.

Do you think everyone doing health and disability research should have to follow the Code?

Choose the answer that is right for you.

Yes



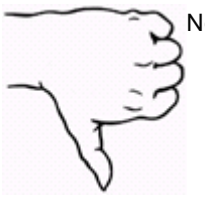
No

I do not have an answer

4. Do you think the law should say that if any person taking part in research looks like they are scared or in pain they should not be part of the research anymore?

Choose the answer that is right for you.

Yes



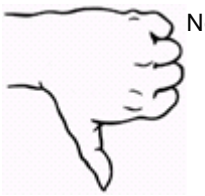
No

I do not have an answer

5. Do you think the law should change to say it is OK for people to give delayed consent to research after they wake up?

Delayed consent means asking for consent to do research on you after it has already been done. Choose the answer that is right for you.

Yes

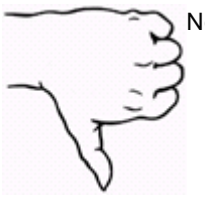


No

I do not have an answer

6. If the research can be done with people who can give informed consent is it OK to do the research with people who cannot give informed consent? Choose the answer that is right for you.

Yes

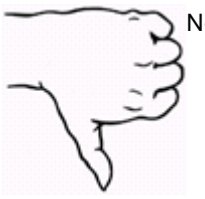


No

I do not have an answer

7. Do you think research should be done on a person that cannot give informed consent if the research may or may not help them but might help other people in the future? Choose the answer that is right for you.

Yes



No

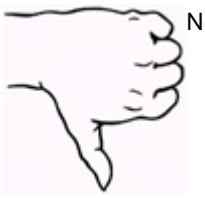
I do not have an answer

8. Why do you think this?

I commented on this in the earlier part of the questionnaire. I think it is part of a responsibility to fellow citizens who may be similarly afflicted. Hawthornand Placebo effects are benefician in themselves. There are benefits to other patients in an arena where research is carried out as standards of care rise as part of the research effort and the monitoring associated with properly conducted and audited research

9. Do you think all people that want to do research with adults who cannot give informed consent should have to get the OK from an ethics committee to do it?Choose the answer that is right for you.

Yes



No

I do not have an answer

10. Why do you think this?

Third party comment always raises the standard and may highlight concerns that had not been accounted for in initial proposals.

It also provides validation to the research effort. The difficulty arises when the ethics considerations prevent valid and reasonable questions being answered

11. Who do you think should have a say in whether or not a person who cannot give informed consent will be part of research?

You can choose as many as you want.

- [x] Someone who is Enduring Power of Attorney or Welfare Guardian for the person
- [x] Family / whanau of the person
- [ ] The person's doctor (if they are not part of the research)
- [ ] The person who wants to do the research
- [x] Someone else

12. Do you think anyone else should have a say in whether or not a person who cannot give informed consent will be part of research?

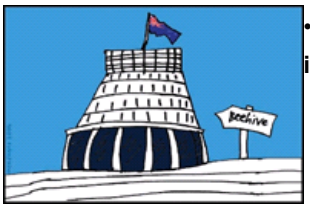
EPOAs in New Zealand need review. There is no register or character requirement. They may be formal but not enacted, or informal. There are occassions where a dependent person is estranged from family, or family is not immediately available, but the dependent has a close relationship with another person who has been caring for them. This is a very tangled web that needs some consideration, either as part of, or because of this kind of question.

13. Do you want to say any more about question 11?

What happens next?

The **Health and Disability Commissioner** will:

- think about what everyone has said about people who cannot give **informed consent** being part of research



- decide what to tell the Government about whether changes are needed to the law on **informed consent** to be in research

- decide whether the **Code** needs to be changed about **informed consent** to be in research.

If the Health and Disability Commissioner thinks the **Code** needs to be changed he will ask everyone about the changes.

Your name

Organisation (if you represent an organisation)

Thank you.

Thank you for:

- reading this information
- thinking about the hard topics

- telling the **Health and Disability Commissioner** what you think.

This will help the **Health and Disability Commissioner** to know what needs to be done.

Health and Disability Commissioner
Te Toihau Hauora, Hauātanga

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some research uses people who are not able to say if they want to take part or not.

This is the form to tell the Health and Disability Commissioner what you think.

Questions and Answers

This form has **questions** to find out what you think about doing research with people who are not able to say if they want to take part or not.

Health and Disability Commissioner
Te Toihau Hauora, Hauātanga

Your **answers** will help the **Health and Disability Commissioner** know what needs to be done.

You do not have to **answer** all the questions.

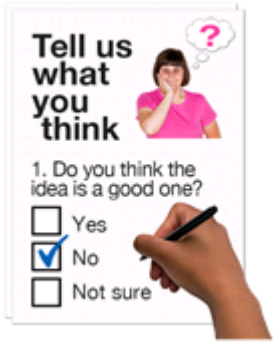
Case studies and questions

Case studies are stories that help us to understand something.

5

Here are 5 case studies that show when research cannot be done without informed consent at the moment in New Zealand.

These may help you decide if the law should change.



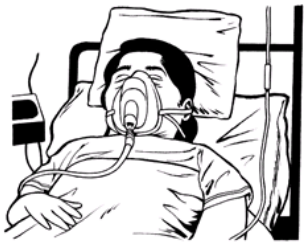
Each case study has questions that we would like you to answer.

Health and Disability Commissioner
Te Toihau Hauora, Hauātanga

Your answers to the questions will help the Health and Disability Commissioner know what is important to you.

Case study 1: Observational research on people with a bad infection

Some people with a bad infection will:



- get very sick
- not be able to tell other people what they think or feel

- have to take medicine to get healthy.

In this case study a doctor wants to do some research on people who:

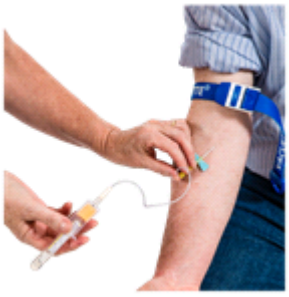
- have a bad infection

- have been given medicine.

The doctor will not change the medicine the people are getting.

The doctor:

- wants to know how much medicine these people need to take to get better



- will take samples from their bodies to find out how much medicine they need to take to get better.

The doctor wants to do this research on people who:

- cannot give informed consent to take part

- will not get better health from being part of the research
- will get the same medicine whether they take part in the research or not.

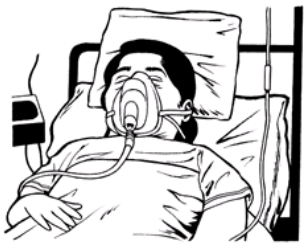
This research may help other people who get bad infections to get the medicine that will help them.

Questions about observational research on people with a bad infection

In these questions we will ask you to think about what you would choose to do if you were sick with a bad infection.

These questions are not about you.

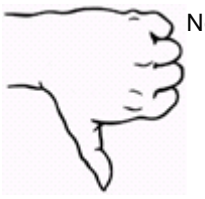
The questions are a made up example.



1. If you had a bad infection and could not give informed consent would you want to take part in research about how much medicine is needed to get better?

Choose the answer that is right for you:

Yes



No

I do not have an answer

If you said yes to question 1:

2. Why would you want to take part in this research?

To help others

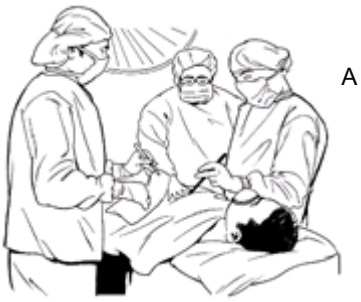
If you said no to question 1:

3. Why would you not want to take part in this research?

4. Do you want to say any more about this question?

I would do it only if it's blood or urine

Case study 2: Research on brain operations



A person has to have a brain operation.

There are 2 things doctors use to make sure a person who has a brain operation is OK after their operation has finished.

No one knows which thing works best.

In this case study a doctor wants to do some research to find out which of the 2 things will work best for other people in the future to help them get better.

In the research the doctor will give some people 1 thing and other people a different thing.

The doctor will see which thing works best.

The people cannot say if they want to be part of the research or not.

The doctor wants to get **delayed consent** for the research from some of the people after their brain operation is done.

Delayed consent means asking for consent to do research on you after it has already been done.

Questions about research on brain operations

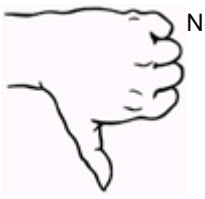
In these questions we will ask you to think about what you would choose to do if you were sick and have to have a brain operation.

These questions are not about you.

The questions are a made up example.

1. If you were not able to say yes or no to taking part in this research before your brain operation would you be OK with the doctor doing the research anyway? Choose the answer that is right for you.

Yes



No

I do not have an answer

If you said yes to question 1

2. Why would you want to take part in this research?

If you said no to question 1

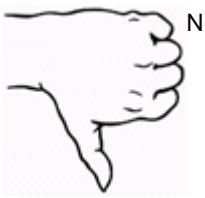
3. Why would you not want to take part in this research?

I would prefer the doctor to wait until I wake up to see if I can give consent

4. Do you want to say any more about this question?

5. Do you think delayed consent is ok? Choose the answer that is right for you.

Yes



No

I do not have an answer

If you said yes to question 5:

6. Why do you think delayed consent is OK?

That give a chance to see if the person can give consent

If you said no to question 5:

7. Why do you think delayed consent is not OK?

Case study 3: Research on people who have a brain disease

Sometimes people get a brain disease that makes it hard for them to:

- remember
- say what they think and feel.

In this case study a doctor wants to do some research on the care given to these people.

Some people will get 1 kind of care and others will get different care.

The doctor will see if any of the people get better.

No one knows if taking part in the research will mean the people will get better or worse.

The doctor does not know if the research will mean better care for people in the future or not.

The research is trying to find this out.

Some of the people the doctor wants to do research on cannot give **informed consent** to take part in the research.

Questions about research on people who have a brain disease

In these questions we will ask you to think about what you would want to happen if you had a brain disease.

These questions are not about you.

The questions are a made up example.

1. If you had a brain disease and could not give informed consent would you want to take part in this research?
Choose the answer that is right for you.

Yes

No

I do not have an answer

If you said yes to question 1
2. Why would you want to take part in this research?

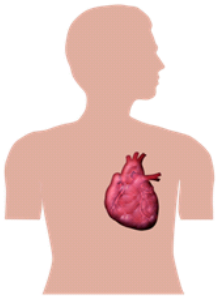
Help others

If you said no to question 1

3. Why would you not want to take part in this research?

4. Do you want to say any more about this question?

Case study 4: Research on people who are having a cardiac arrest

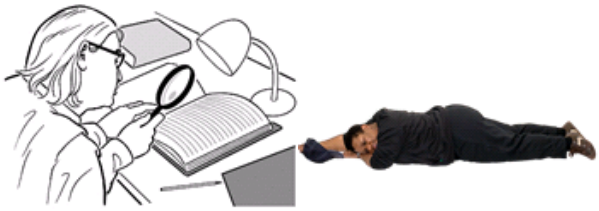


Cardiac arrest is when you have a big problem with your heart and it stops working.

Most of the time when a person's heart stops they are given a medicine.

No one knows if the medicine helps or hurts people.

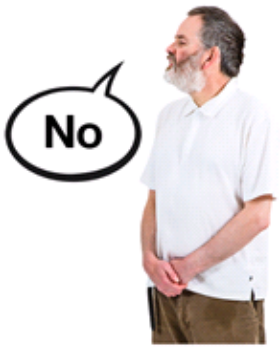
In this case study a doctor wants to research whether the medicine helps people whose heart has stopped.



If somebody's heart stops working they will not be awake.

This means the doctor will not be able to ask for **informed consent** to take part in the research.

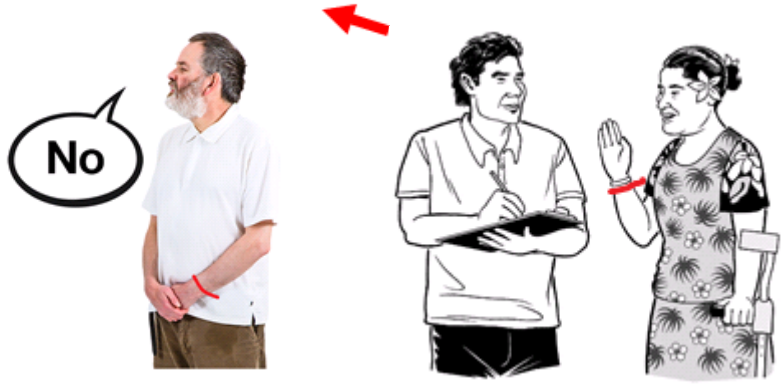
The doctor wants to give some people the medicine and others no medicine to see which group gets better.



People can choose to **opt out** of this research.

Opt out means you say you do **not** want to take part in the research if your heart stops in the future.

People who want to **opt out** of this research can wear a bracelet that says **no study** on it.



To do this people need to:

- ask for a bracelet in case their heart stops 1 day in the future
- wear the bracelet

Questions about research on people that are having a cardiac arrest

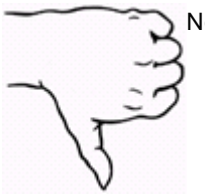
In these questions we will ask you to think about what you would want to happen if your heart stopped working.

These questions are not about you.

The questions are a made up example.

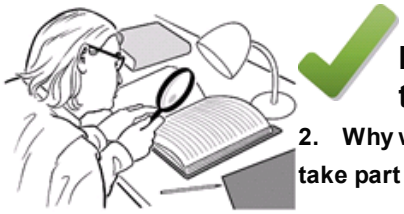
1. If your heart stopped would you want to take part in research to find out if taking this medicine is better than no medicine?
Choose the answer that is right for you.

Yes



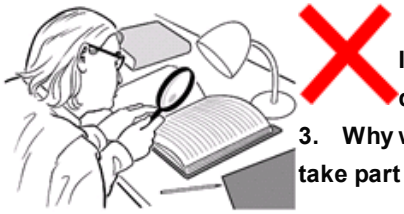
No

I do not have an answer



If you said yes to question 1

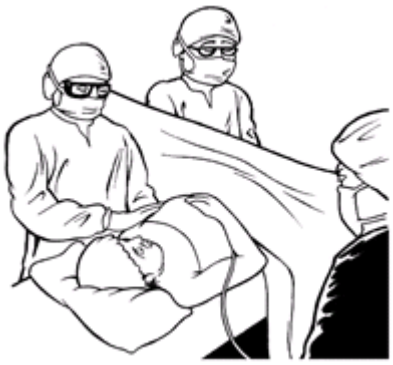
2. Why would you want to take part in this research?



If you said no to question 1

3. Why would you not want to take part in this research?

4. Do you want to say any more about this question?

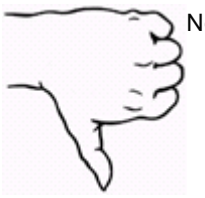


5. People who are wearing the bracelets will not be in the research if their heart stops.

Do you think it is OK for the doctors to do the research on anyone who is not wearing a bracelet when their heart stops?

Choose the answer that is right for you.

Yes



No

I do not have an answer

If you said yes to question 5:

6. Why do you think this?

Yes as long as all the patient are aware of the existence of this bracelet and research

If you said no to question 5:

7. Why do you think this?

Case study 5: Research on people who have Down Syndrome

Down Syndrome is a learning disability.

In this case study a doctor wants to do some research to find out if a medicine can help people with Down Syndrome with their learning.

The medicine may make some people with Down Syndrome think sad things and want to hurt themselves.

Some people with Down Syndrome who take part in the research **will** get the medicine.

Some people with Down Syndrome who take part in the research will **not** get the medicine.

This is so that the doctor can see if the medicine is helping the people with Down Syndrome who get it.

Some people with Down Syndrome will be able to give **informed consent** to take part in the research.

Some people with Down Syndrome will **not** be able to give **informed consent** to take part in the research.

The doctor wants to have people with Down Syndrome in their research who:

- can give **informed consent** to take part
- cannot give **informed consent** to take part.

The doctor wants to be able to get **informed consent** from the family members or support workers of the people with Down Syndrome who cannot give **informed consent**.

Questions about research on people with Down Syndrome

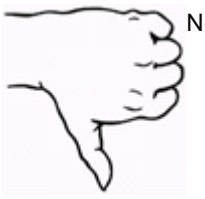
These questions are not about you.

The questions are a made up example.

1. Do you think people with Down Syndrome who cannot give informed consent should be in this research?
Choose the answer that is right for you.

Yes

No



I do not have an answer

If you said yes to question 1:

2. Why do you think people with Down Syndrome who cannot give informed consent should be in this research?

If you said no to question 1:

3. Why do you think people with Down Syndrome who cannot give informed consent should not be in this research?

4. Do you want to say any more about this question?

5. Do you think other people should decide if people with Down Syndrome will be in this research?

These other people could be:

- **family / whānau**
- **support workers**

Choose the answer that is right for you.

Yes

No

I do not have an answer

If you said yes to question 5:

6. Why do you think this?

If you said no to question 5:

7. Why do you think this?

8. Do you want to say any more about this?

Questions about informed consent

Here are some more questions.

These questions will ask you what you think about **informed consent** to take part in research.

Health and Disability Commissioner
Te Toihau Hauora, Hauātanga

Your answers will help the **Health and Disability Commissioner** know what is important to you.

1. Do you think it is OK for adults who cannot give informed consent to take part in research when no one knows if it will help them or hurt them?
Choose the answer that is right for you.

Yes

No

I do not have an answer

2. When do you think it is OK for adults who cannot give informed consent to take part in research?

When we know it will not hurt them and when the dignity of the patient stay intact

3. Some people doing research are not health or disability providers so they do not have to follow the Health and Disability Code of Rights.

Do you think everyone doing health and disability research should have to follow the Code?

Choose the answer that is right for you.

- Yes

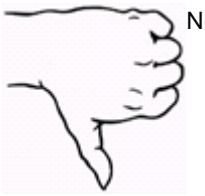
- No

- I do not have an answer

4. Do you think the law should say that if any person taking part in research looks like they are scared or in pain they should not be part of the research anymore?

Choose the answer that is right for you.

- Yes



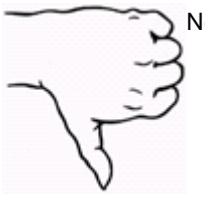
No

I do not have an answer

5. Do you think the law should change to say it is OK for people to give delayed consent to research after they wake up?

Delayed consent means asking for consent to do research on you after it has already been done. Choose the answer that is right for you.

Yes

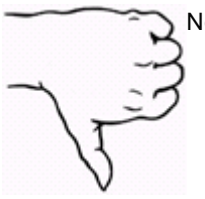


No

I do not have an answer

6. If the research can be done with people who can give informed consent is it OK to do the research with people who cannot give informed consent? Choose the answer that is right for you.


Yes

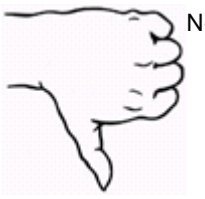

No

I do not have an answer

7. Do you think research should be done on a person that cannot give informed consent if the research may or may not help them but might help other people in the future? Choose the answer that is right for you.

Yes

No

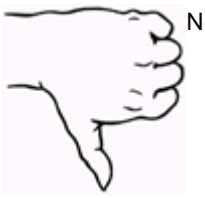


I do not have an answer

8. Why do you think this?

9. Do you think all people that want to do research with adults who cannot give informed consent should have to get the OK from an ethics committee to do it?Choose the answer that is right for you.

Yes



No

I do not have an answer

10. Why do you think this?

To avoid any type of abuse and protect the patient

11. Who do you think should have a say in whether or not a person who cannot give informed consent will be part of research?

You can choose as many as you want.

- [x] Someone who is Enduring Power of Attorney or Welfare Guardian for the person
- [x] Family / whanau of the person
- [x] The person's doctor (if they are not part of the research)
- [ ] The person who wants to do the research
- [x] Someone else

12. Do you think anyone else should have a say in whether or not a person who cannot give informed consent will be part of research?

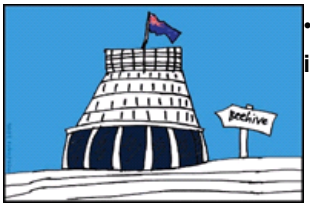
Friends and/or caregivers

13. Do you want to say any more about question 11?

What happens next?

The **Health and Disability Commissioner** will:

- think about what everyone has said about people who cannot give **informed consent** being part of research



- decide what to tell the Government about whether changes are needed to the law on **informed consent** to be in research

- decide whether the **Code** needs to be changed about **informed consent** to be in research.

If the Health and Disability Commissioner thinks the **Code** needs to be changed he will ask everyone about the changes.

Your name

Organisation (if you represent an organisation)

Thank you.

Thank you for:

- reading this information
- thinking about the hard topics

- telling the **Health and Disability Commissioner** what you think.

This will help the **Health and Disability Commissioner** to know what needs to be done.

Health and Disability Commissioner
Te Toihau Hauora, Hauātanga

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some research uses people who are not able to say if they want to take part or not.

This is the form to tell the Health and Disability Commissioner what you think.

Questions and Answers

This form has **questions** to find out what you think about doing research with people who are not able to say if they want to take part or not.

Health and Disability Commissioner
Te Toihau Hauora, Hauātanga

Your **answers** will help the **Health and Disability Commissioner** know what needs to be done.

You do not have to **answer** all the questions.

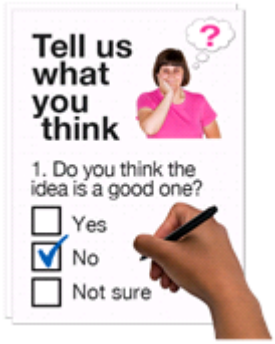
Case studies and questions

Case studies are stories that help us to understand something.

5

Here are 5 case studies that show when research cannot be done without informed consent at the moment in New Zealand.

These may help you decide if the law should change.



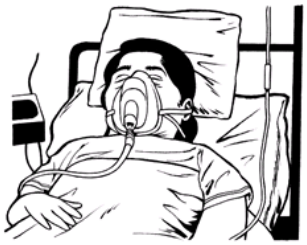
Each case study has questions that we would like you to answer.

Health and Disability Commissioner
Te Toihau Hauora, Hauātanga

Your answers to the questions will help the Health and Disability Commissioner know what is important to you.

Case study 1: Observational research on people with a bad infection

Some people with a bad infection will:



- get very sick
- not be able to tell other people what they think or feel

- have to take medicine to get healthy.

In this case study a doctor wants to do some research on people who:

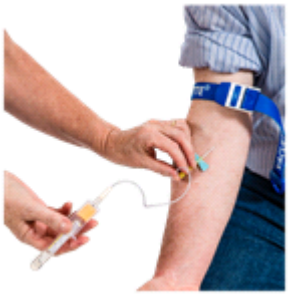
- have a bad infection

- have been given medicine.

The doctor will not change the medicine the people are getting.

The doctor:

- wants to know how much medicine these people need to take to get better



- will take samples from their bodies to find out how much medicine they need to take to get better.

The doctor wants to do this research on people who:

- cannot give informed consent to take part

- will not get better health from being part of the research
- will get the same medicine whether they take part in the research or not.

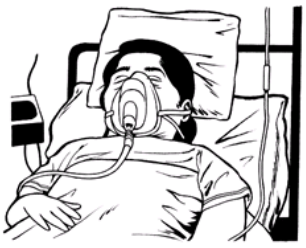
This research may help other people who get bad infections to get the medicine that will help them.

Questions about observational research on people with a bad infection

In these questions we will ask you to think about what you would choose to do if you were sick with a bad infection.

These questions are not about you.

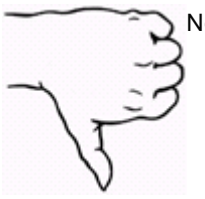
The questions are a made up example.



1. If you had a bad infection and could not give informed consent would you want to take part in research about how much medicine is needed to get better?

Choose the answer that is right for you:

Yes



No

I do not have an answer

If you said yes to question 1:

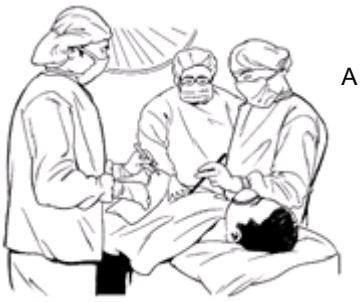
2. Why would you want to take part in this research?

If you said no to question 1:

3. Why would you not want to take part in this research?

4. Do you want to say any more about this question?

Case study 2: Research on brain operations



A person has to have a brain operation.

There are 2 things doctors use to make sure a person who has a brain operation is OK after their operation has finished.

No one knows which thing works best.

In this case study a doctor wants to do some research to find out which of the 2 things will work best for other people in the future to help them get better.

In the research the doctor will give some people 1 thing and other people a different thing.

The doctor will see which thing works best.

The people cannot say if they want to be part of the research or not.

The doctor wants to get **delayed consent** for the research from some of the people after their brain operation is done.

Delayed consent means asking for consent to do research on you after it has already been done.

Questions about research on brain operations

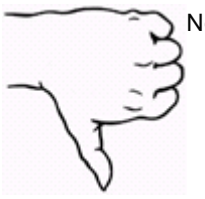
In these questions we will ask you to think about what you would choose to do if you were sick and have to have a brain operation.

These questions are not about you.

The questions are a made up example.

1. If you were not able to say yes or no to taking part in this research before your brain operation would you be OK with the doctor doing the research anyway? Choose the answer that is right for you.

Yes



No

I do not have an answer

If you said yes to question 1

2. Why would you want to take part in this research?

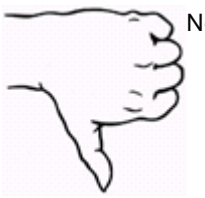
If you said no to question 1

3. Why would you not want to take part in this research?

4. Do you want to say any more about this question?

5. Do you think delayed consent is ok? Choose the answer that is right for you.

Yes



No

I do not have an answer

If you said yes to question 5:

6. Why do you think delayed consent is OK?

If you said no to question 5:

7. Why do you think delayed consent is not OK?

Case study 3: Research on people who have a brain disease

Sometimes people get a brain disease that makes it hard for them to:

- remember
- say what they think and feel.

In this case study a doctor wants to do some research on the care given to these people.

Some people will get 1 kind of care and others will get different care.

The doctor will see if any of the people get better.

No one knows if taking part in the research will mean the people will get better or worse.

The doctor does not know if the research will mean better care for people in the future or not.

The research is trying to find this out.

Some of the people the doctor wants to do research on cannot give **informed consent** to take part in the research.

Questions about research on people who have a brain disease

In these questions we will ask you to think about what you would want to happen if you had a brain disease.

These questions are not about you.

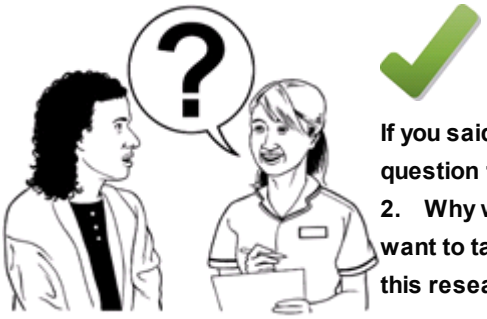
The questions are a made up example.

1. If you had a brain disease and could not give informed consent would you want to take part in this research?
Choose the answer that is right for you.

Yes

No

I do not have an answer



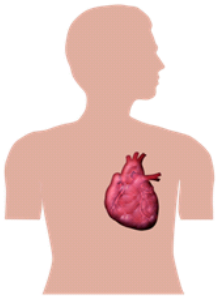
If you said yes to question 1
2. Why would you want to take part in this research?

If you said no to question 1

3. Why would you not want to take part in this research?

4. Do you want to say any more about this question?

Case study 4: Research on people who are having a cardiac arrest

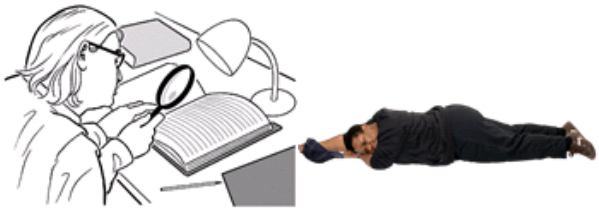


Cardiac arrest is when you have a big problem with your heart and it stops working.

Most of the time when a person's heart stops they are given a medicine.

No one knows if the medicine helps or hurts people.

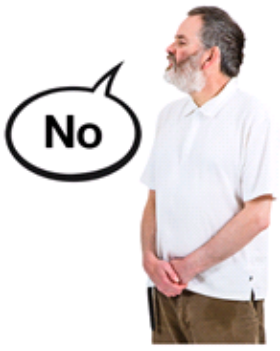
In this case study a doctor wants to research whether the medicine helps people whose heart has stopped.



If somebody's heart stops working they will not be awake.

This means the doctor will not be able to ask for **informed consent** to take part in the research.

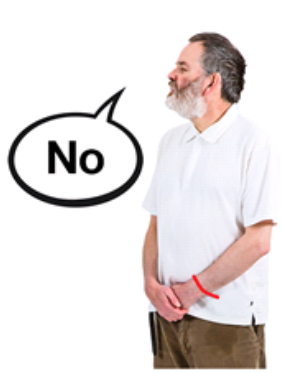
The doctor wants to give some people the medicine and others no medicine to see which group gets better.



People can choose to **opt out** of this research.

Opt out means you say you do **not** want to take part in the research if your heart stops in the future.

People who want to **opt out** of this research can wear a bracelet that says **no study** on it.



To do this people need to:

- ask for a bracelet in case their heart stops 1 day in the future
- wear the bracelet

Questions about research on people that are having a cardiac arrest

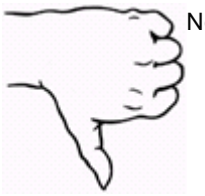
In these questions we will ask you to think about what you would want to happen if your heart stopped working.

These questions are not about you.

The questions are a made up example.

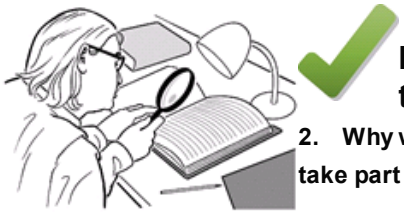
1. If your heart stopped would you want to take part in research to find out if taking this medicine is better than no medicine?
Choose the answer that is right for you.

Yes



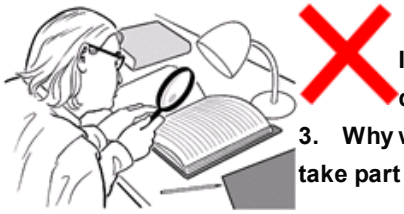
No

I do not have an answer



If you said yes to question 1

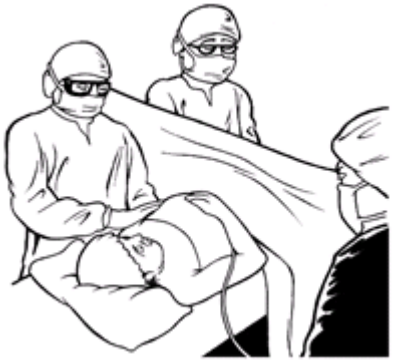
2. Why would you want to take part in this research?



If you said no to question 1

3. Why would you not want to take part in this research?

4. Do you want to say any more about this question?

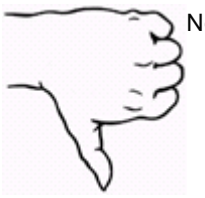


5. People who are wearing the bracelets will not be in the research if their heart stops.

Do you think it is OK for the doctors to do the research on anyone who is not wearing a bracelet when their heart stops?

Choose the answer that is right for you.

Yes



No

I do not have an answer

If you said yes to question 5:

6. Why do you think this?

If you said no to question 5:

7. Why do you think this?

Case study 5: Research on people who have Down Syndrome

Down Syndrome is a learning disability.

In this case study a doctor wants to do some research to find out if a medicine can help people with Down Syndrome with their learning.

The medicine may make some people with Down Syndrome think sad things and want to hurt themselves.

Some people with Down Syndrome who take part in the research **will** get the medicine.

Some people with Down Syndrome who take part in the research will **not** get the medicine.

This is so that the doctor can see if the medicine is helping the people with Down Syndrome who get it.

Some people with Down Syndrome will be able to give **informed consent** to take part in the research.

Some people with Down Syndrome will **not** be able to give **informed consent** to take part in the research.

The doctor wants to have people with Down Syndrome in their research who:

- can give **informed consent** to take part
- cannot give **informed consent** to take part.

The doctor wants to be able to get **informed consent** from the family members or support workers of the people with Down Syndrome who cannot give **informed consent**.

Questions about research on people with Down Syndrome

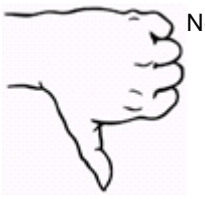
These questions are not about you.

The questions are a made up example.

1. Do you think people with Down Syndrome who cannot give informed consent should be in this research?
Choose the answer that is right for you.

Yes

No



I do not have an answer

If you said yes to question 1:

2. Why do you think people with Down Syndrome who cannot give informed consent should be in this research?

If you said no to question 1:

3. Why do you think people with Down Syndrome who cannot give informed consent should not be in this research?

4. Do you want to say any more about this question?

5. Do you think other people should decide if people with Down Syndrome will be in this research?

These other people could be:

- **family / whānau**
- **support workers**

Choose the answer that is right for you.

Yes

No

I do not have an answer

If you said yes to question 5:

6. Why do you think this?

If you said no to question 5:

7. Why do you think this?

8. Do you want to say any more about this?

Questions about informed consent

Here are some more questions.

These questions will ask you what you think about **informed consent** to take part in research.

Health and Disability Commissioner
Te Toihau Hauora, Hauātanga

Your answers will help the **Health and Disability Commissioner** know what is important to you.

1. Do you think it is OK for adults who cannot give informed consent to take part in research when no one knows if it will help them or hurt them?
Choose the answer that is right for you.

Yes

No

I do not have an answer

2. When do you think it is OK for adults who cannot give informed consent to take part in research?

3. Some people doing research are not health or disability providers so they do not have to follow the Health and Disability Code of Rights.

Do you think everyone doing health and disability research should have to follow the Code?

Choose the answer that is right for you.


Yes

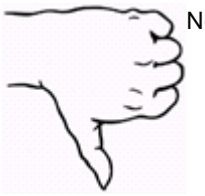

No

I do not have an answer

4. Do you think the law should say that if any person taking part in research looks like they are scared or in pain they should not be part of the research anymore?

Choose the answer that is right for you.


Yes



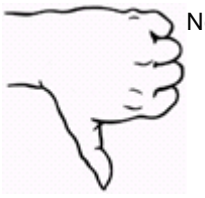
No

I do not have an answer

5. Do you think the law should change to say it is OK for people to give delayed consent to research after they wake up?

Delayed consent means asking for consent to do research on you after it has already been done. Choose the answer that is right for you.

Yes

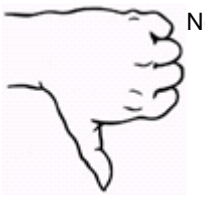


No

I do not have an answer

6. If the research can be done with people who can give informed consent is it OK to do the research with people who cannot give informed consent? Choose the answer that is right for you.

Yes

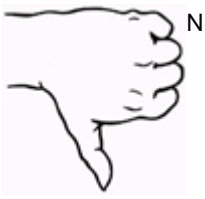


No

I do not have an answer

7. Do you think research should be done on a person that cannot give informed consent if the research may or may not help them but might help other people in the future? Choose the answer that is right for you.

Yes



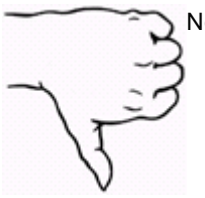
No

I do not have an answer

8. Why do you think this?

9. Do you think all people that want to do research with adults who cannot give informed consent should have to get the OK from an ethics committee to do it?Choose the answer that is right for you.

Yes



No

I do not have an answer

10. Why do you think this?

11. Who do you think should have a say in whether or not a person who cannot give informed consent will be part of research?

You can choose as many as you want.

- Someone who is Enduring Power of Attorney or Welfare Guardian for the person
- Family / whanau of the person
- The person's doctor (if they are not part of the research)
- The person who wants to do the research
- Someone else

12. Do you think anyone else should have a say in whether or not a person who cannot give informed consent will be part of research?

13. Do you want to say any more about question 11?

What happens next?

The **Health and Disability Commissioner** will:

- think about what everyone has said about people who cannot give **informed consent** being part of research

- decide what to tell the Government about whether changes are needed to the law on **informed consent** to be in research

- decide whether the **Code** needs to be changed about **informed consent** to be in research.

If the Health and Disability Commissioner thinks the **Code** needs to be changed he will ask everyone about the changes.

Your name

Organisation (if you represent an organisation)

Thank you.

Thank you for:

- reading this information
- thinking about the hard topics

- telling the **Health and Disability Commissioner** what you think.

This will help the **Health and Disability Commissioner** to know what needs to be done.

Health and Disability Commissioner
Te Toihau Hauora, Hauātanga

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some research uses people who are not able to say if they want to take part or not.

This is the form to tell the Health and Disability Commissioner what you think.

Questions and Answers

This form has **questions** to find out what you think about doing research with people who are not able to say if they want to take part or not.

Health and Disability Commissioner
Te Toihau Hauora, Hauātanga

Your **answers** will help the **Health and Disability Commissioner** know what needs to be done.

You do not have to **answer** all the questions.

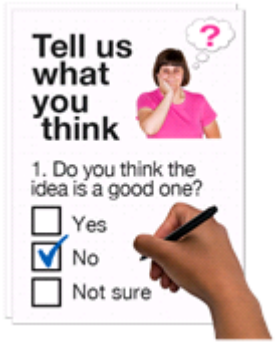
Case studies and questions

Case studies are stories that help us to understand something.

5

Here are 5 case studies that show when research cannot be done without informed consent at the moment in New Zealand.

These may help you decide if the law should change.



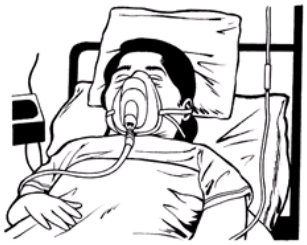
Each case study has questions that we would like you to answer.

Health and Disability Commissioner
Te Toihau Hauora, Hauātanga

Your answers to the questions will help the Health and Disability Commissioner know what is important to you.

Case study 1: Observational research on people with a bad infection

Some people with a bad infection will:



- get very sick
- not be able to tell other people what they think or feel

- have to take medicine to get healthy.

In this case study a doctor wants to do some research on people who:

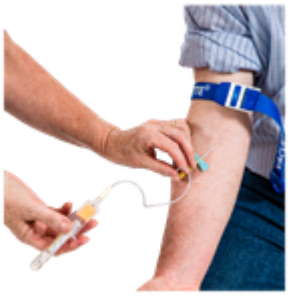
- have a bad infection

- have been given medicine.

The doctor will not change the medicine the people are getting.

The doctor:

- wants to know how much medicine these people need to take to get better



- will take samples from their bodies to find out how much medicine they need to take to get better.

The doctor wants to do this research on people who:

- cannot give informed consent to take part

- will not get better health from being part of the research
- will get the same medicine whether they take part in the research or not.

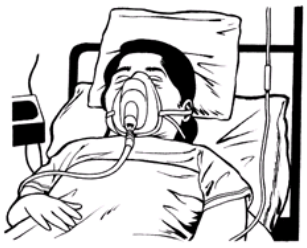
This research may help other people who get bad infections to get the medicine that will help them.

Questions about observational research on people with a bad infection

In these questions we will ask you to think about what you would choose to do if you were sick with a bad infection.

These questions are not about you.

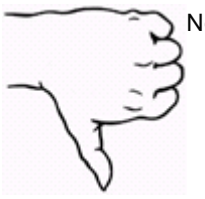
The questions are a made up example.



1. If you had a bad infection and could not give informed consent would you want to take part in research about how much medicine is needed to get better?

Choose the answer that is right for you:

Yes



No

I do not have an answer

If you said yes to question 1:

2. Why would you want to take part in this research?

Every time I have gone to 1 particular hosp they take out their own DNR, getting me well is better than letting me die like they did, god bless the guy who gave me CPR.
Am too scared to go back to that hospital now.

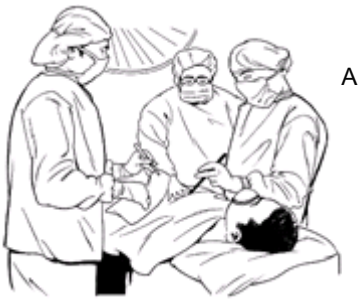
If you said no to question 1:

3. Why would you not want to take part in this research?

4. Do you want to say any more about this question?

more than the "then" dr needs to be involved in this research cos if the one is tired or too lazy to work on a patient well

Case study 2: Research on brain operations



A person has to have a brain operation.

There are 2 things doctors use to make sure a person who has a brain operation is OK after their operation has finished.

No one knows which thing works best.

In this case study a doctor wants to do some research to find out which of the 2 things will work best for other people in the future to help them get better.

In the research the doctor will give some people 1 thing and other people a different thing.

The doctor will see which thing works best.

The people cannot say if they want to be part of the research or not.

The doctor wants to get **delayed consent** for the research from some of the people after their brain operation is done.

Delayed consent means asking for consent to do research on you after it has already been done.

Questions about research on brain operations

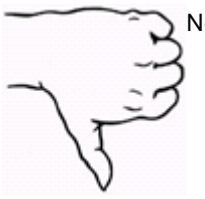
In these questions we will ask you to think about what you would choose to do if you were sick and have to have a brain operation.

These questions are not about you.

The questions are a made up example.

1. If you were not able to say yes or no to taking part in this research before your brain operation would you be OK with the doctor doing the research anyway? Choose the answer that is right for you.

Yes



No

I do not have an answer

If you said yes to question 1

2. Why would you want to take part in this research?

If you said no to question 1

3. Why would you not want to take part in this research?

we still should have the choice

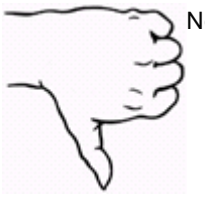
4. Do you want to say any more about this question?

information and education on these issues for patient

5. Do you think delayed consent is ok? Choose the answer that is right for you.

- Yes

- No



- I do not have an answer

If you said yes to question 5:

6. Why do you think delayed consent is OK?

at least you are given a choice

If you said no to question 5:

7. Why do you think delayed consent is not OK?

Case study 3: Research on people who have a brain disease

Sometimes people get a brain disease that makes it hard for them to:

- remember
- say what they think and feel.

In this case study a doctor wants to do some research on the care given to these people.

Some people will get 1 kind of care and others will get different care.

The doctor will see if any of the people get better.

No one knows if taking part in the research will mean the people will get better or worse.

The doctor does not know if the research will mean better care for people in the future or not.

The research is trying to find this out.

Some of the people the doctor wants to do research on cannot give **informed consent** to take part in the research.

Questions about research on people who have a brain disease

In these questions we will ask you to think about what you would want to happen if you had a brain disease.

These questions are not about you.

The questions are a made up example.

1. If you had a brain disease and could not give informed consent would you want to take part in this research?
Choose the answer that is right for you.

Yes

No

I do not have an answer

If you said yes to question 1
2. Why would you want to take part in this research?

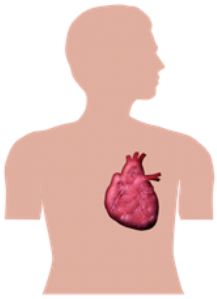
If you said no to question 1

3. Why would you not want to take part in this research?

4. Do you want to say any more about this question?

It would be for nominated person to maybe have a say

Case study 4: Research on people who are having a cardiac arrest

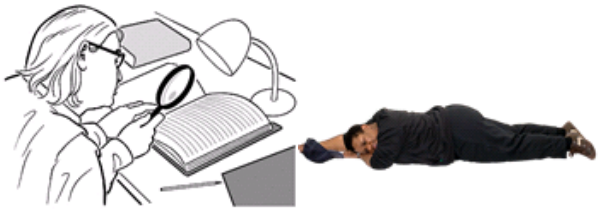


Cardiac arrest is when you have a big problem with your heart and it stops working.

Most of the time when a person's heart stops they are given a medicine.

No one knows if the medicine helps or hurts people.

In this case study a doctor wants to research whether the medicine helps people whose heart has stopped.



If somebody's heart stops working they will not be awake.

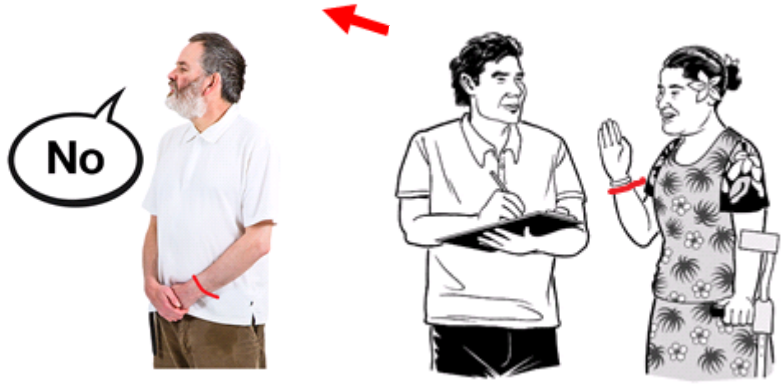
This means the doctor will not be able to ask for **informed consent** to take part in the research.

The doctor wants to give some people the medicine and others no medicine to see which group gets better.

People can choose to **opt out** of this research.

Opt out means you say you do **not** want to take part in the research if your heart stops in the future.

People who want to **opt out** of this research can wear a bracelet that says **no study** on it.



To do this people need to:

- ask for a bracelet in case their heart stops 1 day in the future
- wear the bracelet

Questions about research on people that are having a cardiac arrest

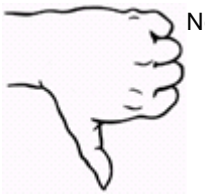
In these questions we will ask you to think about what you would want to happen if your heart stopped working.

These questions are not about you.

The questions are a made up example.

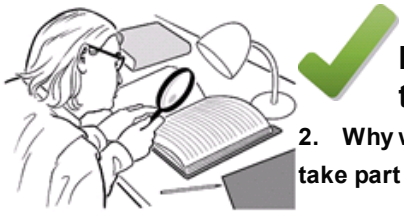
1. If your heart stopped would you want to take part in research to find out if taking this medicine is better than no medicine?
Choose the answer that is right for you.

Yes



No

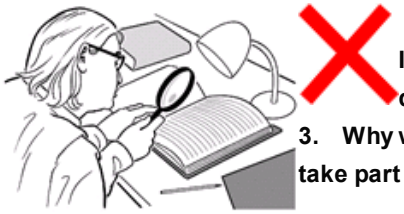
I do not have an answer



If you said yes to question 1

2. Why would you want to take part in this research?

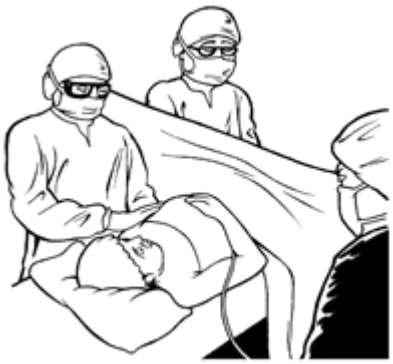
I had cardiac arrest, whatever they did apart from CPR worked



If you said no to question 1

3. Why would you not want to take part in this research?

4. Do you want to say any more about this question?

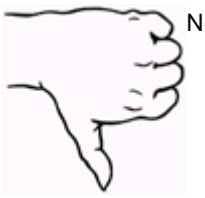


5. People who are wearing the bracelets will not be in the research if their heart stops.

Do you think it is OK for the doctors to do the research on anyone who is not wearing a bracelet when their heart stops?

Choose the answer that is right for you.

Yes



No

I do not have an answer

If you said yes to question 5:

6. Why do you think this?

as long as it is beneficial to the well being of the patient

If you said no to question 5:

7. Why do you think this?

Case study 5: Research on people who have Down Syndrome

Down Syndrome is a learning disability.

In this case study a doctor wants to do some research to find out if a medicine can help people with Down Syndrome with their learning.

The medicine may make some people with Down Syndrome think sad things and want to hurt themselves.

Some people with Down Syndrome who take part in the research **will** get the medicine.

Some people with Down Syndrome who take part in the research will **not** get the medicine.

This is so that the doctor can see if the medicine is helping the people with Down Syndrome who get it.

Some people with Down Syndrome will be able to give **informed consent** to take part in the research.

Some people with Down Syndrome will **not** be able to give **informed consent** to take part in the research.

The doctor wants to have people with Down Syndrome in their research who:

- can give **informed consent** to take part
- cannot give **informed consent** to take part.

The doctor wants to be able to get **informed consent** from the family members or support workers of the people with Down Syndrome who cannot give **informed consent**.

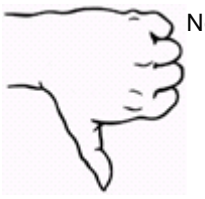
Questions about research on people with Down Syndrome

These questions are not about you.

The questions are a made up example.

1. Do you think people with Down Syndrome who cannot give informed consent should be in this research?
Choose the answer that is right for you.

Yes



No

I do not have an answer

If you said yes to question 1:

2. Why do you think people with Down Syndrome who cannot give informed consent should be in this research?

If you said no to question 1:

3. Why do you think people with Down Syndrome who cannot give informed consent should not be in this research?

4. Do you want to say any more about this question?

This is up to the family

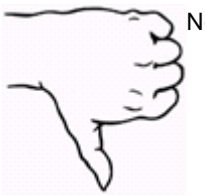
5. Do you think other people should decide if people with Down Syndrome will be in this research?

These other people could be:

- **family / whānau**
- **support workers**

Choose the answer that is right for you.

Yes



No

I do not have an answer

If you said yes to question 5:

6. Why do you think this?

family / whanau or nominated person

If you said no to question 5:

7. Why do you think this?

8. Do you want to say any more about this?

Questions about informed consent

Here are some more questions.

These questions will ask you what you think about **informed consent** to take part in research.

Health and Disability Commissioner
Te Toihau Hauora, Hauātanga

Your answers will help the **Health and Disability Commissioner** know what is important to you.

1. Do you think it is OK for adults who cannot give informed consent to take part in research when no one knows if it will help them or hurt them?
Choose the answer that is right for you.

Yes

No

I do not have an answer

2. When do you think it is OK for adults who cannot give informed consent to take part in research?

asking family or nominated persons

3. Some people doing research are not health or disability providers so they do not have to follow the Health and Disability Code of Rights.

Do you think everyone doing health and disability research should have to follow the Code?

Choose the answer that is right for you.


Yes

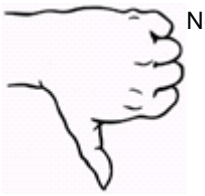
No

I do not have an answer

4. Do you think the law should say that if any person taking part in research looks like they are scared or in pain they should not be part of the research anymore?

Choose the answer that is right for you.


Yes



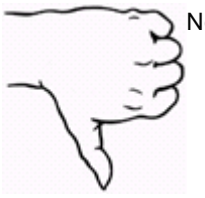
No

I do not have an answer

5. Do you think the law should change to say it is OK for people to give delayed consent to research after they wake up?

Delayed consent means asking for consent to do research on you after it has already been done. Choose the answer that is right for you.

Yes

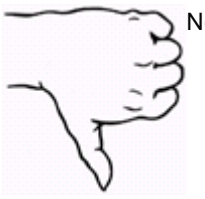


No

I do not have an answer

6. If the research can be done with people who can give informed consent is it OK to do the research with people who cannot give informed consent? Choose the answer that is right for you.

Yes

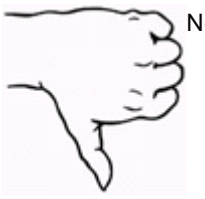


No

I do not have an answer

7. Do you think research should be done on a person that cannot give informed consent if the research may or may not help them but might help other people in the future? Choose the answer that is right for you.

Yes



No

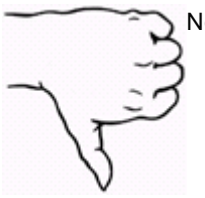
I do not have an answer

8. Why do you think this?

choice and well being

9. Do you think all people that want to do research with adults who cannot give informed consent should have to get the OK from an ethics committee to do it?Choose the answer that is right for you.

Yes



No

I do not have an answer

10. Why do you think this?

peoples choice and well being-safety

11. Who do you think should have a say in whether or not a person who cannot give informed consent will be part of research?

You can choose as many as you want.

- [x] Someone who is Enduring Power of Attorney or Welfare Guardian for the person
- [x] Family / whanau of the person
- [x] The person's doctor (if they are not part of the research)
- [ ] The person who wants to do the research
- [ ] Someone else

12. Do you think anyone else should have a say in whether or not a person who cannot give informed consent will be part of research?

no

13. Do you want to say any more about question 11?

people are not for experiment

What happens next?

The **Health and Disability Commissioner** will:

- think about what everyone has said about people who cannot give **informed consent** being part of research

- decide what to tell the Government about whether changes are needed to the law on **informed consent** to be in research

- decide whether the **Code** needs to be changed about **informed consent** to be in research.

If the Health and Disability Commissioner thinks the **Code** needs to be changed he will ask everyone about the changes.

Your name

Organisation (if you represent an organisation)

Thank you.

Thank you for:

- reading this information
- thinking about the hard topics

- telling the **Health and Disability Commissioner** what you think.

This will help the **Health and Disability Commissioner** to know what needs to be done.

Health and Disability Commissioner
Te Toihau Hauora, Hauātanga

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some research uses people who are not able to say if they want to take part or not.

This is the form to tell the Health and Disability Commissioner what you think.

Questions and Answers

This form has **questions** to find out what you think about doing research with people who are not able to say if they want to take part or not.

Health and Disability Commissioner
Te Toihau Hauora, Hauātanga

Your **answers** will help the **Health and Disability Commissioner** know what needs to be done.

You do not have to **answer** all the questions.

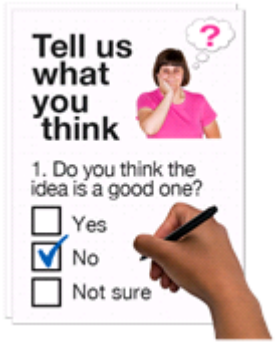
Case studies and questions

Case studies are stories that help us to understand something.

5

Here are 5 case studies that show when research cannot be done without informed consent at the moment in New Zealand.

These may help you decide if the law should change.



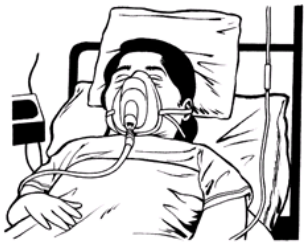
Each case study has questions that we would like you to answer.

Health and Disability Commissioner
Te Toihau Hauora, Hauātanga

Your answers to the questions will help the Health and Disability Commissioner know what is important to you.

Case study 1: Observational research on people with a bad infection

Some people with a bad infection will:



- get very sick
- not be able to tell other people what they think or feel

- have to take medicine to get healthy.

In this case study a doctor wants to do some research on people who:

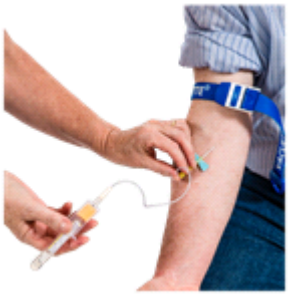
- have a bad infection

- have been given medicine.

The doctor will not change the medicine the people are getting.

The doctor:

- wants to know how much medicine these people need to take to get better



- will take samples from their bodies to find out how much medicine they need to take to get better.

The doctor wants to do this research on people who:

- cannot give informed consent to take part

- will not get better health from being part of the research
- will get the same medicine whether they take part in the research or not.

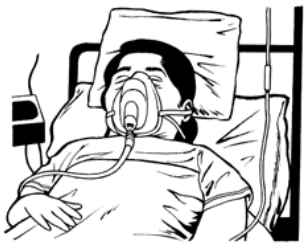
This research may help other people who get bad infections to get the medicine that will help them.

Questions about observational research on people with a bad infection

In these questions we will ask you to think about what you would choose to do if you were sick with a bad infection.

These questions are not about you.

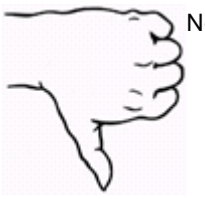
The questions are a made up example.



1. If you had a bad infection and could not give informed consent would you want to take part in research about how much medicine is needed to get better?

Choose the answer that is right for you:

Yes



No

I do not have an answer

If you said yes to question 1:

2. Why would you want to take part in this research?

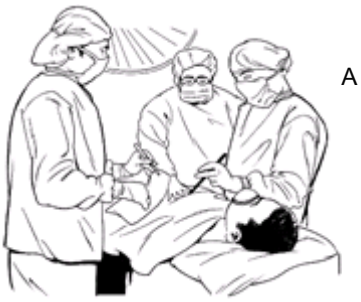
It causes me no harm and may help others in the future

If you said no to question 1:

3. Why would you not want to take part in this research?

4. Do you want to say any more about this question?

Case study 2: Research on brain operations



A person has to have a brain operation.

There are 2 things doctors use to make sure a person who has a brain operation is OK after their operation has finished.

No one knows which thing works best.

In this case study a doctor wants to do some research to find out which of the 2 things will work best for other people in the future to help them get better.

In the research the doctor will give some people 1 thing and other people a different thing.

The doctor will see which thing works best.

The people cannot say if they want to be part of the research or not.

The doctor wants to get **delayed consent** for the research from some of the people after their brain operation is done.

Delayed consent means asking for consent to do research on you after it has already been done.

Questions about research on brain operations

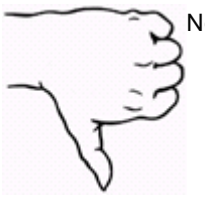
In these questions we will ask you to think about what you would choose to do if you were sick and have to have a brain operation.

These questions are not about you.

The questions are a made up example.

1. If you were not able to say yes or no to taking part in this research before your brain operation would you be OK with the doctor doing the research anyway? Choose the answer that is right for you.

Yes



No

I do not have an answer

If you said yes to question 1

2. Why would you want to take part in this research?

As long as there is true equipoise that has been well demonstrated then I would be happy to be part of the research.

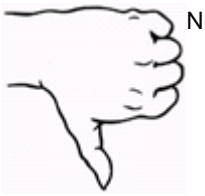
If you said no to question 1

3. Why would you not want to take part in this research?

4. Do you want to say any more about this question?

5. Do you think delayed consent is ok? Choose the answer that is right for you.

Yes



No

I do not have an answer

If you said yes to question 5:

6. Why do you think delayed consent is OK?

As long as family are involved where ever possible to represent my views, and it is made clear after that the intervention has been delivered and this is asking permission to continue in the study and use the data generated I would have no problems with this type of consent.

If you said no to question 5:

7. Why do you think delayed consent is not OK?

Case study 3: Research on people who have a brain disease

Sometimes people get a brain disease that makes it hard for them to:

- remember
- say what they think and feel.

In this case study a doctor wants to do some research on the care given to these people.

Some people will get 1 kind of care and others will get different care.

The doctor will see if any of the people get better.

No one knows if taking part in the research will mean the people will get better or worse.

The doctor does not know if the research will mean better care for people in the future or not.

The research is trying to find this out.

Some of the people the doctor wants to do research on cannot give **informed consent** to take part in the research.

Questions about research on people who have a brain disease

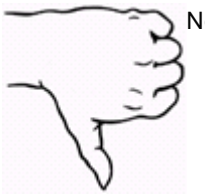
In these questions we will ask you to think about what you would want to happen if you had a brain disease.

These questions are not about you.

The questions are a made up example.

1. If you had a brain disease and could not give informed consent would you want to take part in this research?
Choose the answer that is right for you.

Yes



No

I do not have an answer

If you said yes to question 1
2. Why would you want to take part in this research?

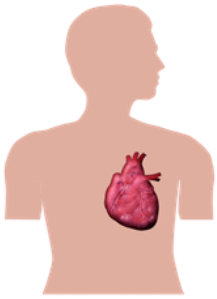
As long as family are involved in the consent process I would be happy with this consent. I may benefit from being involved.
As long as there is a data safety committee conducting an interim analysis and the patient is being protected as much as possible and the study is halted if the results demonstrate harm I would be happy to participate in the research.

If you said no to question 1

3. Why would you not want to take part in this research?

4. Do you want to say any more about this question?

Case study 4: Research on people who are having a cardiac arrest

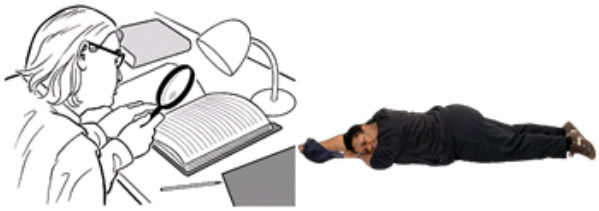


Cardiac arrest is when you have a big problem with your heart and it stops working.

Most of the time when a person's heart stops they are given a medicine.

No one knows if the medicine helps or hurts people.

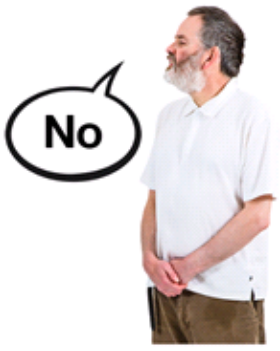
In this case study a doctor wants to research whether the medicine helps people whose heart has stopped.



If somebody's heart stops working they will not be awake.

This means the doctor will not be able to ask for **informed consent** to take part in the research.

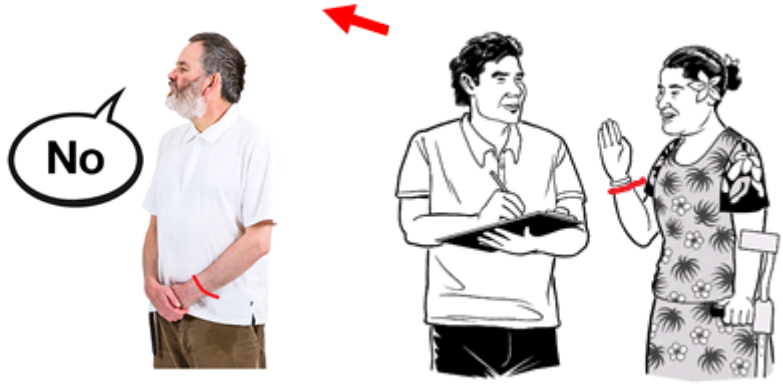
The doctor wants to give some people the medicine and others no medicine to see which group gets better.



People can choose to **opt out** of this research.

Opt out means you say you do **not** want to take part in the research if your heart stops in the future.

People who want to **opt out** of this research can wear a bracelet that says **no study** on it.



To do this people need to:

- ask for a bracelet in case their heart stops 1 day in the future
- wear the bracelet

Questions about research on people that are having a cardiac arrest

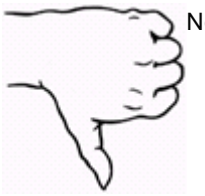
In these questions we will ask you to think about what you would want to happen if your heart stopped working.

These questions are not about you.

The questions are a made up example.

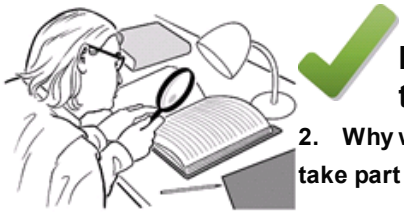
1. If your heart stopped would you want to take part in research to find out if taking this medicine is better than no medicine?
Choose the answer that is right for you.

Yes



No

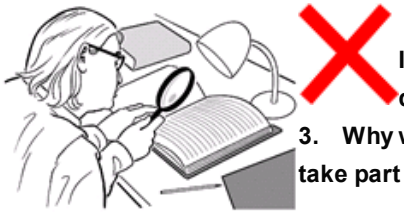
I do not have an answer



If you said yes to question 1

2. Why would you want to take part in this research?

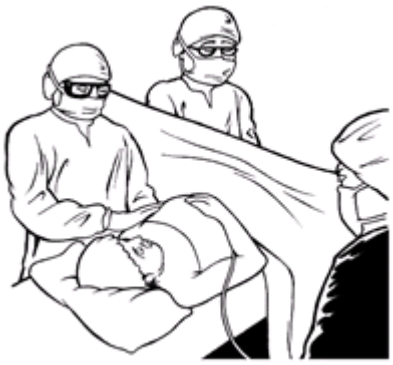
I may benefit and others may benefit in the future. I am effectively dead anyway at the point of cardiac arrest so anything that may help would be welcome. If there was the option to demonstrate equipoise prior to the study that would be important to me.



If you said no to question 1

3. Why would you not want to take part in this research?

4. Do you want to say any more about this question?

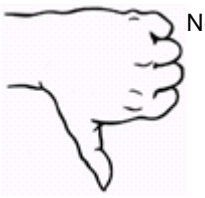


5. People who are wearing the bracelets will not be in the research if their heart stops.

Do you think it is OK for the doctors to do the research on anyone who is not wearing a bracelet when their heart stops?

Choose the answer that is right for you.

Yes



No

I do not have an answer

If you said yes to question 5:

6. Why do you think this?

As above, include families where possible and appropriate. Demonstrate clinical equipoise where possible.

If you said no to question 5:

7. Why do you think this?

Case study 5: Research on people who have Down Syndrome

Down Syndrome is a learning disability.

In this case study a doctor wants to do some research to find out if a medicine can help people with Down Syndrome with their learning.

The medicine may make some people with Down Syndrome think sad things and want to hurt themselves.

Some people with Down Syndrome who take part in the research **will** get the medicine.

Some people with Down Syndrome who take part in the research will **not** get the medicine.

This is so that the doctor can see if the medicine is helping the people with Down Syndrome who get it.

Some people with Down Syndrome will be able to give **informed consent** to take part in the research.

Some people with Down Syndrome will **not** be able to give **informed consent** to take part in the research.

The doctor wants to have people with Down Syndrome in their research who:

- can give **informed consent** to take part
- cannot give **informed consent** to take part.

The doctor wants to be able to get **informed consent** from the family members or support workers of the people with Down Syndrome who cannot give **informed consent**.

Questions about research on people with Down Syndrome

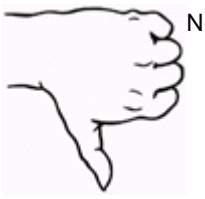
These questions are not about you.

The questions are a made up example.

1. Do you think people with Down Syndrome who cannot give informed consent should be in this research?
Choose the answer that is right for you.

Yes

No



I do not have an answer

If you said yes to question 1:

2. Why do you think people with Down Syndrome who cannot give informed consent should be in this research?

If you said no to question 1:

3. Why do you think people with Down Syndrome who cannot give informed consent should not be in this research?

4. Do you want to say any more about this question?

The risk of suicide and depression may outweigh the potential benefit. For those who can provide informed consent that could be the starting point for the study and once more data is available and a data safety committee have reviewed the interim results then maybe consider those who are unable to provide informed consent.

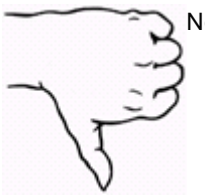
5. Do you think other people should decide if people with Down Syndrome will be in this research?

These other people could be:

- **family / whānau**
- **support workers**

Choose the answer that is right for you.

Yes



No

I do not have an answer

If you said yes to question 5:

6. Why do you think this?

If you said no to question 5:

7. Why do you think this?

8. Do you want to say any more about this?

If it can be demonstrated that the support people have the patients best interest at heart this would be acceptable

Questions about informed consent

Here are some more questions.

These questions will ask you what you think about **informed consent** to take part in research.

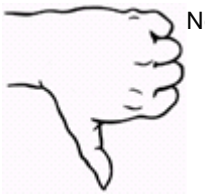
Health and Disability Commissioner
Te Toihau Hauora, Hauātanga

Your answers will help the **Health and Disability Commissioner** know what is important to you.

1. Do you think it is OK for adults who cannot give informed consent to take part in research when no one knows if it will help them or hurt them?
Choose the answer that is right for you.

- Yes

- No



- I do not have an answer

2. When do you think it is OK for adults who cannot give informed consent to take part in research?

In an acute setting, e.g. surgery, intensive care or acute stroke/heart attack etc.
Current treatments are a result of patients participating in this type of research.

3. Some people doing research are not health or disability providers so they do not have to follow the Health and Disability Code of Rights.

Do you think everyone doing health and disability research should have to follow the Code?

Choose the answer that is right for you.


Yes

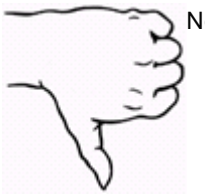

No

I do not have an answer

4. Do you think the law should say that if any person taking part in research looks like they are scared or in pain they should not be part of the research anymore?

Choose the answer that is right for you.


Yes



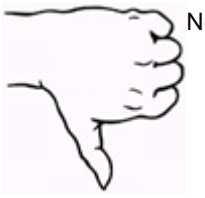
No

I do not have an answer

5. Do you think the law should change to say it is OK for people to give delayed consent to research after they wake up?

Delayed consent means asking for consent to do research on you after it has already been done. Choose the answer that is right for you.

Yes

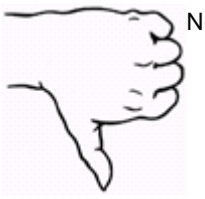


No

I do not have an answer

6. If the research can be done with people who can give informed consent is it OK to do the research with people who cannot give informed consent? Choose the answer that is right for you.

Yes

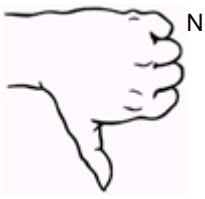


No

I do not have an answer

7. Do you think research should be done on a person that cannot give informed consent if the research may or may not help them but might help other people in the future? Choose the answer that is right for you.

Yes



No

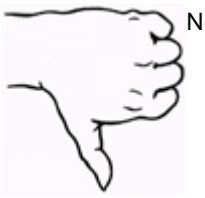
I do not have an answer

8. Why do you think this?

It will help patients in the future. As long as everything is done to protect the patient and include next of kin whether family or friends this would be acceptable.

9. Do you think all people that want to do research with adults who cannot give informed consent should have to get the OK from an ethics committee to do it?Choose the answer that is right for you.

Yes



No

I do not have an answer

10. Why do you think this?

It safeguards the patient

11. Who do you think should have a say in whether or not a person who cannot give informed consent will be part of research?

You can choose as many as you want.

- [x] Someone who is Enduring Power of Attorney or Welfare Guardian for the person
- [x] Family / whanau of the person
- [ ] The person's doctor (if they are not part of the research)
- [ ] The person who wants to do the research
- [x] Someone else

12. Do you think anyone else should have a say in whether or not a person who cannot give informed consent will be part of research?

13. Do you want to say any more about question 11?

What happens next?

The **Health and Disability Commissioner** will:

- think about what everyone has said about people who cannot give **informed consent** being part of research

- decide what to tell the Government about whether changes are needed to the law on **informed consent** to be in research

- decide whether the **Code** needs to be changed about **informed consent** to be in research.

If the Health and Disability Commissioner thinks the **Code** needs to be changed he will ask everyone about the changes.

Your name

Organisation (if you represent an organisation)

Thank you.

Thank you for:

- reading this information
- thinking about the hard topics

- telling the **Health and Disability Commissioner** what you think.

This will help the **Health and Disability Commissioner** to know what needs to be done.

Health and Disability Commissioner
Te Toihau Hauora, Hauātanga

PeopleFirst
New Zealand
Ngā Tāngata Tuatahi

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some research uses people who are not able to say if they want to take part or not.

This is the form to tell the Health and Disability Commissioner what you think.

Questions and Answers

This form has **questions** to find out what you think about doing research with people who are not able to say if they want to take part or not.

Health and Disability Commissioner
Te Toihau Hauora, Hauātanga

Your **answers** will help the **Health and Disability Commissioner** know what needs to be done.

You do not have to **answer** all the questions.

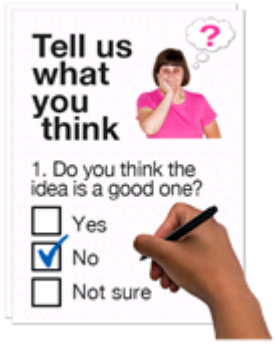
Case studies and questions

Case studies are stories that help us to understand something.

5

Here are 5 case studies that show when research cannot be done without informed consent at the moment in New Zealand.

These may help you decide if the law should change.



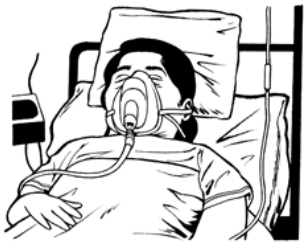
Each case study has questions that we would like you to answer.

Health and Disability Commissioner
Te Toihau Hauora, Hauātanga

Your answers to the questions will help the Health and Disability Commissioner know what is important to you.

Case study 1: Observational research on people with a bad infection

Some people with a bad infection will:



- get very sick
- not be able to tell other people what they think or feel

- have to take medicine to get healthy.

In this case study a doctor wants to do some research on people who:

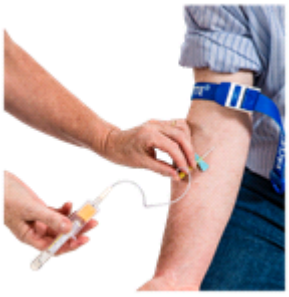
- have a bad infection

- have been given medicine.

The doctor will not change the medicine the people are getting.

The doctor:

- wants to know how much medicine these people need to take to get better



- will take samples from their bodies to find out how much medicine they need to take to get better.

The doctor wants to do this research on people who:

- cannot give informed consent to take part

- will not get better health from being part of the research
- will get the same medicine whether they take part in the research or not.

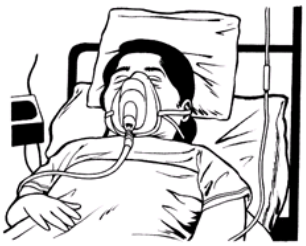
This research may help other people who get bad infections to get the medicine that will help them.

Questions about observational research on people with a bad infection

In these questions we will ask you to think about what you would choose to do if you were sick with a bad infection.

These questions are not about you.

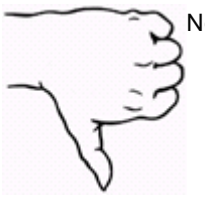
The questions are a made up example.



1. If you had a bad infection and could not give informed consent would you want to take part in research about how much medicine is needed to get better?

Choose the answer that is right for you:

Yes



No

I do not have an answer

If you said yes to question 1:

2. Why would you want to take part in this research?

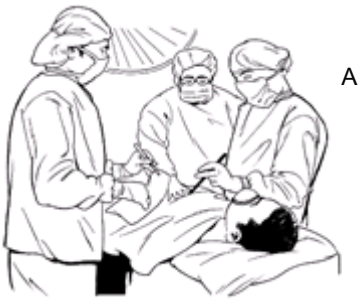
in the same way as I am a nominated donor in the case of accidental death, I would like to benefit others in the case of illness

If you said no to question 1:

3. Why would you not want to take part in this research?

4. Do you want to say any more about this question?

Case study 2: Research on brain operations



A person has to have a brain operation.

There are 2 things doctors use to make sure a person who has a brain operation is OK after their operation has finished.

No one knows which thing works best.

In this case study a doctor wants to do some research to find out which of the 2 things will work best for other people in the future to help them get better.

In the research the doctor will give some people 1 thing and other people a different thing.

The doctor will see which thing works best.

The people cannot say if they want to be part of the research or not.

The doctor wants to get **delayed consent** for the research from some of the people after their brain operation is done.

Delayed consent means asking for consent to do research on you after it has already been done.

Questions about research on brain operations

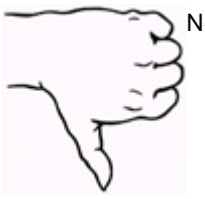
In these questions we will ask you to think about what you would choose to do if you were sick and have to have a brain operation.

These questions are not about you.

The questions are a made up example.

1. If you were not able to say yes or no to taking part in this research before your brain operation would you be OK with the doctor doing the research anyway? Choose the answer that is right for you.

Yes



No

I do not have an answer

If you said yes to question 1

2. Why would you want to take part in this research?

I am at no more real risk if i am researched while having this treatment than if I am not researched, in my opinion

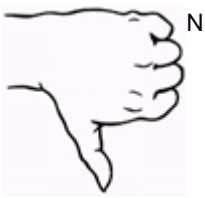
If you said no to question 1

3. Why would you not want to take part in this research?

4. Do you want to say any more about this question?

5. Do you think delayed consent is ok? Choose the answer that is right for you.

Yes



No

I do not have an answer

If you said yes to question 5:

6. Why do you think delayed consent is OK?

as a survivor, my opinion is very significant to me and possibly to others

If you said no to question 5:

7. Why do you think delayed consent is not OK?

Case study 3: Research on people who have a brain disease

Sometimes people get a brain disease that makes it hard for them to:

- remember
- say what they think and feel.

In this case study a doctor wants to do some research on the care given to these people.

Some people will get 1 kind of care and others will get different care.

The doctor will see if any of the people get better.

No one knows if taking part in the research will mean the people will get better or worse.

The doctor does not know if the research will mean better care for people in the future or not.

The research is trying to find this out.

Some of the people the doctor wants to do research on cannot give **informed consent** to take part in the research.

Questions about research on people who have a brain disease

In these questions we will ask you to think about what you would want to happen if you had a brain disease.

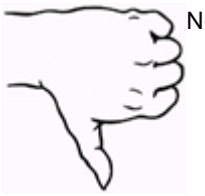
These questions are not about you.

The questions are a made up example.

1. If you had a brain disease and could not give informed consent would you want to take part in this research?
Choose the answer that is right for you.

- Yes

- No



- I do not have an answer

If you said yes to question 1
2. Why would you want to take part in this research?

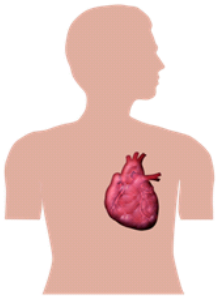
this research will increase understanding of treatment options and so I support the idea of being involved

If you said no to question 1

3. Why would you not want to take part in this research?

4. Do you want to say any more about this question?

Case study 4: Research on people who are having a cardiac arrest

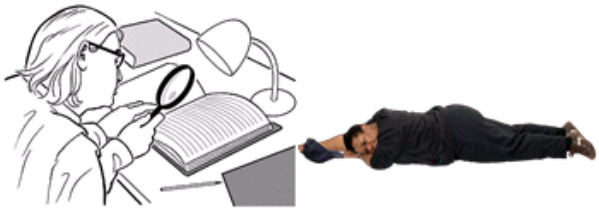


Cardiac arrest is when you have a big problem with your heart and it stops working.

Most of the time when a person's heart stops they are given a medicine.

No one knows if the medicine helps or hurts people.

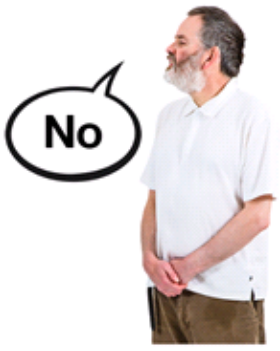
In this case study a doctor wants to research whether the medicine helps people whose heart has stopped.



If somebody's heart stops working they will not be awake.

This means the doctor will not be able to ask for **informed consent** to take part in the research.

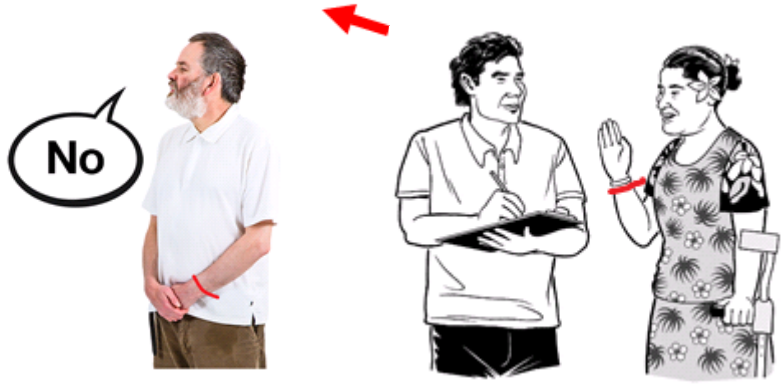
The doctor wants to give some people the medicine and others no medicine to see which group gets better.



People can choose to **opt out** of this research.

Opt out means you say you do **not** want to take part in the research if your heart stops in the future.

People who want to **opt out** of this research can wear a bracelet that says **no study** on it.



To do this people need to:

- ask for a bracelet in case their heart stops 1 day in the future
- wear the bracelet

Questions about research on people that are having a cardiac arrest

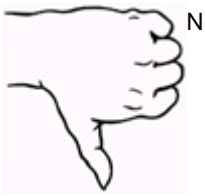
In these questions we will ask you to think about what you would want to happen if your heart stopped working.

These questions are not about you.

The questions are a made up example.

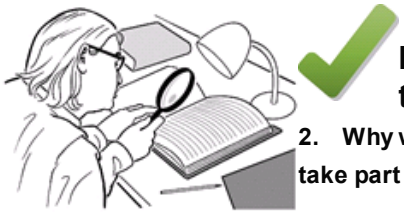
1. If your heart stopped would you want to take part in research to find out if taking this medicine is better than no medicine?
Choose the answer that is right for you.

Yes



No

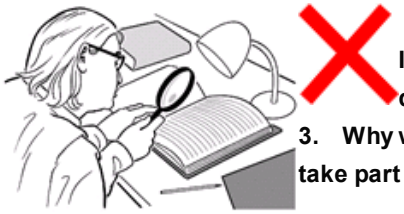
I do not have an answer



If you said yes to question 1

2. Why would you want to take part in this research?

i believe that it is important to test the effectiveness of this drug, knowing that resuscitation involves more skills and applications than just the adrenalin.

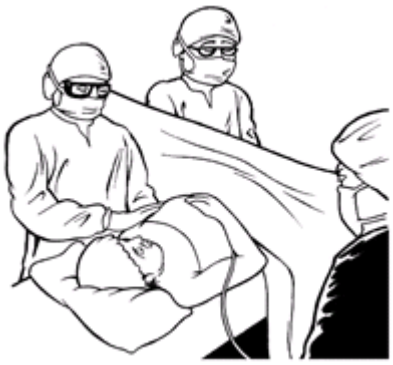


If you said no to question 1

3. Why would you not want to take part in this research?

4. Do you want to say any more about this question?

This question involved more soul searching for me than the previous ones. I like to think that being part of a pioneering study means exercising courage without being sure that i am going to benefit from the choice. I am hoping that someone else will.

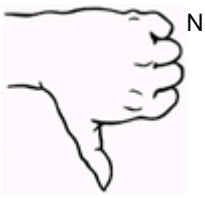


5. People who are wearing the bracelets will not be in the research if their heart stops.

Do you think it is OK for the doctors to do the research on anyone who is not wearing a bracelet when their heart stops?

Choose the answer that is right for you.

Yes



No

I do not have an answer

If you said yes to question 5:

6. Why do you think this?

If you said no to question 5:

7. Why do you think this?

Case study 5: Research on people who have Down Syndrome

Down Syndrome is a learning disability.

In this case study a doctor wants to do some research to find out if a medicine can help people with Down Syndrome with their learning.

The medicine may make some people with Down Syndrome think sad things and want to hurt themselves.

Some people with Down Syndrome who take part in the research **will** get the medicine.

Some people with Down Syndrome who take part in the research will **not** get the medicine.

This is so that the doctor can see if the medicine is helping the people with Down Syndrome who get it.

Some people with Down Syndrome will be able to give **informed consent** to take part in the research.

Some people with Down Syndrome will **not** be able to give **informed consent** to take part in the research.

The doctor wants to have people with Down Syndrome in their research who:

- can give **informed consent** to take part
- cannot give **informed consent** to take part.

The doctor wants to be able to get **informed consent** from the family members or support workers of the people with Down Syndrome who cannot give **informed consent**.

Questions about research on people with Down Syndrome

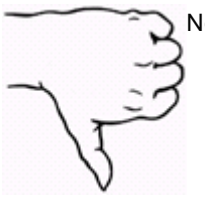
These questions are not about you.

The questions are a made up example.

1. Do you think people with Down Syndrome who cannot give informed consent should be in this research?
Choose the answer that is right for you.

Yes

No



I do not have an answer

If you said yes to question 1:

2. Why do you think people with Down Syndrome who cannot give informed consent should be in this research?

If you said no to question 1:

3. Why do you think people with Down Syndrome who cannot give informed consent should not be in this research?

If the person with Down Syndrome cannot give consent and has a negative emotional consequence to the drug, this decision has been made for them by others, and they may not even be able to communicate the adverse reaction. This is wrong, in my opinion

4. Do you want to say any more about this question?

People with Down Syndrome are often dependent on others to make decisions about a wide spectrum of things. I think that there should be more research about positive behavioral approaches in the care of people with DS

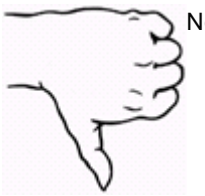
5. Do you think other people should decide if people with Down Syndrome will be in this research?

These other people could be:

- **family / whānau**
- **support workers**

Choose the answer that is right for you.

Yes



No

I do not have an answer

If you said yes to question 5:

6. Why do you think this?

With the proviso that these people have a strong attachment to the person with DS, not a distant one

If you said no to question 5:

7. Why do you think this?

8. Do you want to say any more about this?

if there is a strong attachment between the person with DS and the person making the decision on their behalf, there is liely to be ongoing involvement during the research and any adverse effects would be more likely to be identified by them than by the reseaechers, in my opinion

Questions about informed consent

Here are some more questions.

These questions will ask you what you think about **informed consent** to take part in research.

Health and Disability Commissioner
Te Toihau Hauora, Hauātanga

Your answers will help the **Health and Disability Commissioner** know what is important to you.

1. Do you think it is OK for adults who cannot give informed consent to take part in research when no one knows if it will help them or hurt them?
Choose the answer that is right for you.

Yes

No

I do not have an answer

2. When do you think it is OK for adults who cannot give informed consent to take part in research?

If the person has considered this possibility prior to becoming unable to give informed consent, of if the person has never been able to give informed consent and has a relative or caregiver in a close long term relationship which has had a positive benefit to their long term mental, emotional, spiritual and bodily health.

3. Some people doing research are not health or disability providers so they do not have to follow the Health and Disability Code of Rights.

Do you think everyone doing health and disability research should have to follow the Code?

Choose the answer that is right for you.


Yes

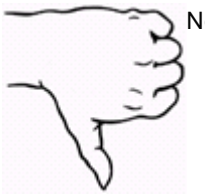

No

I do not have an answer

4. Do you think the law should say that if any person taking part in research looks like they are scared or in pain they should not be part of the research anymore?

Choose the answer that is right for you.


Yes



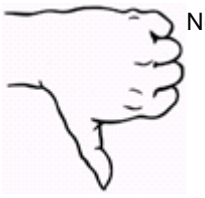
No

I do not have an answer

5. Do you think the law should change to say it is OK for people to give delayed consent to research after they wake up?

Delayed consent means asking for consent to do research on you after it has already been done. Choose the answer that is right for you.

Yes

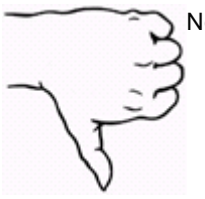


No

I do not have an answer

6. If the research can be done with people who can give informed consent is it OK to do the research with people who cannot give informed consent? Choose the answer that is right for you.

Yes

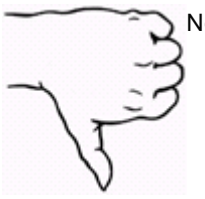


No

I do not have an answer

7. Do you think research should be done on a person that cannot give informed consent if the research may or may not help them but might help other people in the future? Choose the answer that is right for you.

Yes



No

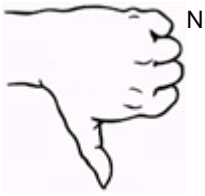
I do not have an answer

8. Why do you think this?

In this scenario, the person should have been given an opportunity to decide if they were ever able to give informed consent. Otherwise, there would need to be safeguards for those unable to give informed consent. this decision should never be made by anyone who is not closely involved in the support of the person undergoing the research

9. Do you think all people that want to do research with adults who cannot give informed consent should have to get the OK from an ethics committee to do it?Choose the answer that is right for you.

Yes



No

I do not have an answer

10. Why do you think this?

Without this approval, there is no safeguard to the well being of the participant, in my opinion

11. Who do you think should have a say in whether or not a person who cannot give informed consent will be part of research?

You can choose as many as you want.

- [x] Someone who is Enduring Power of Attorney or Welfare Guardian for the person
- [x] Family / whanau of the person
- [x] The person's doctor (if they are not part of the research)
- [x] The person who wants to do the research
- [x] Someone else

12. Do you think anyone else should have a say in whether or not a person who cannot give informed consent will be part of research?

Another person might be perceived as family/whanau of the person due to the nature of their relationship. This possibility should be part of this dialogue

13. Do you want to say any more about question 11?

In the case of non involvement by family/whanau in the care of the person, background investigations could be done to ensure that this person or group was acting in the best interests of the person

What happens next?

The **Health and Disability Commissioner** will:

- think about what everyone has said about people who cannot give **informed consent** being part of research

- decide what to tell the Government about whether changes are needed to the law on **informed consent** to be in research

- decide whether the **Code** needs to be changed about **informed consent** to be in research.

If the Health and Disability Commissioner thinks the **Code** needs to be changed he will ask everyone about the changes.

Your name

Organisation (if you represent an organisation)

Thank you.

Thank you for:

- reading this information
- thinking about the hard topics

- telling the **Health and Disability Commissioner** what you think.

This will help the **Health and Disability Commissioner** to know what needs to be done.

Health and Disability Commissioner
Te Toihau Hauora, Hauātanga

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some research uses people who are not able to say if they want to take part or not.

This is the form to tell the Health and Disability Commissioner what you think.

Questions and Answers

This form has **questions** to find out what you think about doing research with people who are not able to say if they want to take part or not.

Health and Disability Commissioner
Te Toihau Hauora, Hauātanga

Your **answers** will help the **Health and Disability Commissioner** know what needs to be done.

You do not have to **answer** all the questions.

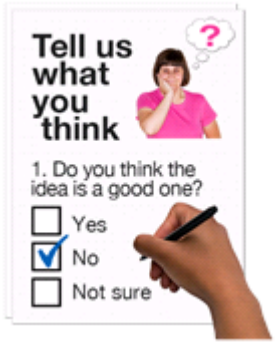
Case studies and questions

Case studies are stories that help us to understand something.

5

Here are 5 case studies that show when research cannot be done without informed consent at the moment in New Zealand.

These may help you decide if the law should change.



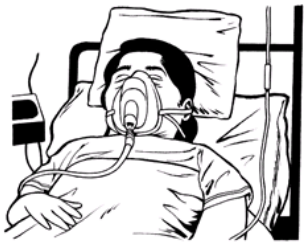
Each case study has questions that we would like you to answer.

Health and Disability Commissioner
Te Toihau Hauora, Hauātanga

Your answers to the questions will help the Health and Disability Commissioner know what is important to you.

Case study 1: Observational research on people with a bad infection

Some people with a bad infection will:



- get very sick
- not be able to tell other people what they think or feel

- have to take medicine to get healthy.

In this case study a doctor wants to do some research on people who:

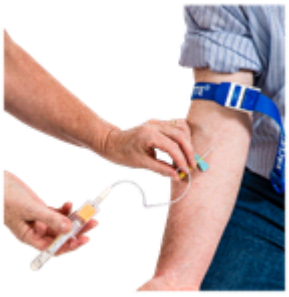
- have a bad infection

- have been given medicine.

The doctor will not change the medicine the people are getting.

The doctor:

- wants to know how much medicine these people need to take to get better



- will take samples from their bodies to find out how much medicine they need to take to get better.

The doctor wants to do this research on people who:

- cannot give informed consent to take part

- will not get better health from being part of the research
- will get the same medicine whether they take part in the research or not.

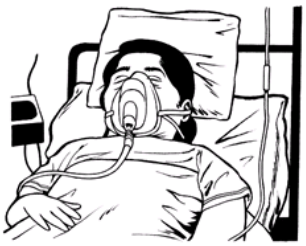
This research may help other people who get bad infections to get the medicine that will help them.

Questions about observational research on people with a bad infection

In these questions we will ask you to think about what you would choose to do if you were sick with a bad infection.

These questions are not about you.

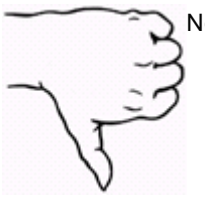
The questions are a made up example.



1. If you had a bad infection and could not give informed consent would you want to take part in research about how much medicine is needed to get better?

Choose the answer that is right for you:

Yes



No

I do not have an answer

If you said yes to question 1:

2. Why would you want to take part in this research?

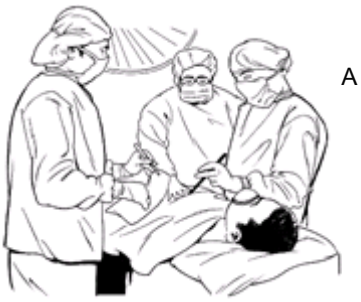
Because I would have liked it if someone had done the same for me.
Because it might be helpful.
Because it is unlikely to cause me harm.
I would like the people doing it to do it with respect.

If you said no to question 1:

3. Why would you not want to take part in this research?

4. Do you want to say any more about this question?

Case study 2: Research on brain operations



A person has to have a brain operation.

There are 2 things doctors use to make sure a person who has a brain operation is OK after their operation has finished.

No one knows which thing works best.

In this case study a doctor wants to do some research to find out which of the 2 things will work best for other people in the future to help them get better.

In the research the doctor will give some people 1 thing and other people a different thing.

The doctor will see which thing works best.

The people cannot say if they want to be part of the research or not.

The doctor wants to get **delayed consent** for the research from some of the people after their brain operation is done.

Delayed consent means asking for consent to do research on you after it has already been done.

Questions about research on brain operations

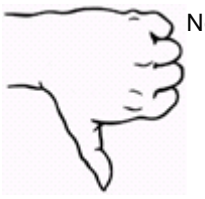
In these questions we will ask you to think about what you would choose to do if you were sick and have to have a brain operation.

These questions are not about you.

The questions are a made up example.

1. If you were not able to say yes or no to taking part in this research before your brain operation would you be OK with the doctor doing the research anyway? Choose the answer that is right for you.

Yes



No

I do not have an answer

If you said yes to question 1

2. Why would you want to take part in this research?

Because I was unable to give consent at the outset, I would be happy to go with whatever is decided, if both interventions seem to be about the same.

If I was able to give consent, I would want to have a choice, as I would use my intuition as well as reason to make the decision that seems best to me. However, as I would be unable to use my intuition, I would be happy to trust the medical team.

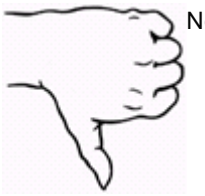
If you said no to question 1

3. Why would you not want to take part in this research?

4. Do you want to say any more about this question?

5. Do you think delayed consent is ok? Choose the answer that is right for you.

Yes



No

I do not have an answer

If you said yes to question 5:

6. Why do you think delayed consent is OK?

I think delayed consent is ok if there are not clear differences with option A or B in terms of positive outcomes / risk.
I would want it discussed with my family / whanau.

If you said no to question 5:

7. Why do you think delayed consent is not OK?

Case study 3: Research on people who have a brain disease

Sometimes people get a brain disease that makes it hard for them to:

- remember
- say what they think and feel.

In this case study a doctor wants to do some research on the care given to these people.

Some people will get 1 kind of care and others will get different care.

The doctor will see if any of the people get better.

No one knows if taking part in the research will mean the people will get better or worse.

The doctor does not know if the research will mean better care for people in the future or not.

The research is trying to find this out.

Some of the people the doctor wants to do research on cannot give **informed consent** to take part in the research.

Questions about research on people who have a brain disease

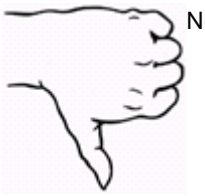
In these questions we will ask you to think about what you would want to happen if you had a brain disease.

These questions are not about you.

The questions are a made up example.

1. If you had a brain disease and could not give informed consent would you want to take part in this research?
Choose the answer that is right for you.

Yes



No

I do not have an answer

If you said yes to question 1
2. Why would you want to take part in this research?

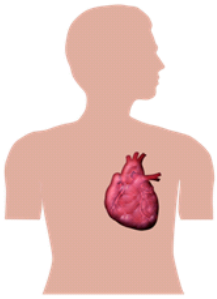
Yes because it could be helpful to people coming after me and the risk of harm is probably low. The quality of my life would be very low at this stage, and it would be good to at least help others, as at this stage I would already be receiving a lot of help from others. It would be a way of giving back.

If you said no to question 1

3. Why would you not want to take part in this research?

4. Do you want to say any more about this question?

Case study 4: Research on people who are having a cardiac arrest

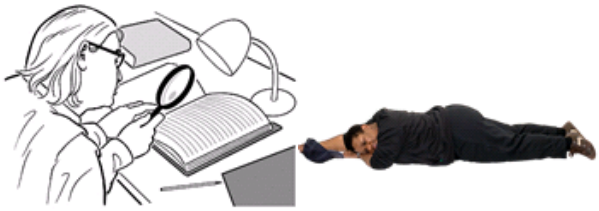


Cardiac arrest is when you have a big problem with your heart and it stops working.

Most of the time when a person's heart stops they are given a medicine.

No one knows if the medicine helps or hurts people.

In this case study a doctor wants to research whether the medicine helps people whose heart has stopped.



If somebody's heart stops working they will not be awake.

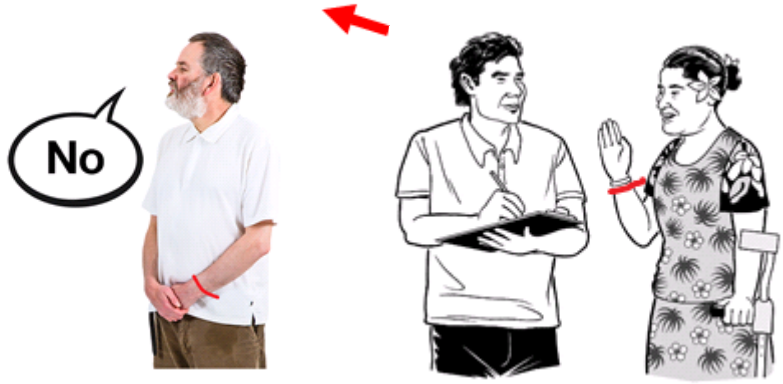
This means the doctor will not be able to ask for **informed consent** to take part in the research.

The doctor wants to give some people the medicine and others no medicine to see which group gets better.

People can choose to **opt out** of this research.

Opt out means you say you do **not** want to take part in the research if your heart stops in the future.

People who want to **opt out** of this research can wear a bracelet that says **no study** on it.



To do this people need to:

- ask for a bracelet in case their heart stops 1 day in the future
- wear the bracelet

Questions about research on people that are having a cardiac arrest

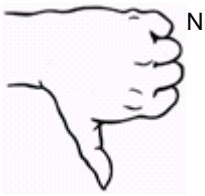
In these questions we will ask you to think about what you would want to happen if your heart stopped working.

These questions are not about you.

The questions are a made up example.

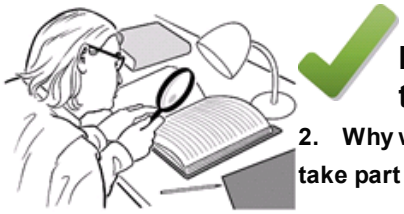
1. If your heart stopped would you want to take part in research to find out if taking this medicine is better than no medicine?
Choose the answer that is right for you.

Yes



No

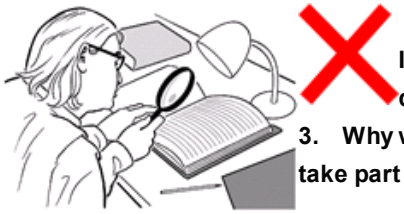
I do not have an answer



If you said yes to question 1

2. Why would you want to take part in this research?

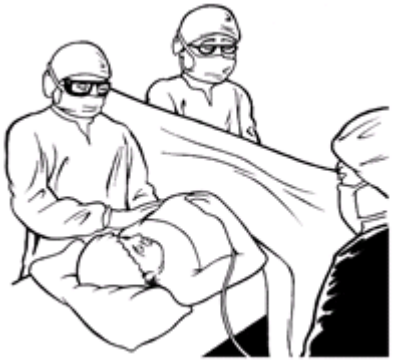
Because I would already be receiving an effective intervention. This could possibly improve the outcome, and it could help others.



If you said no to question 1

3. Why would you not want to take part in this research?

4. Do you want to say any more about this question?

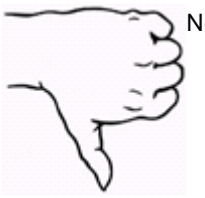


5. People who are wearing the bracelets will not be in the research if their heart stops.

Do you think it is OK for the doctors to do the research on anyone who is not wearing a bracelet when their heart stops?

Choose the answer that is right for you.

Yes



No

I do not have an answer

If you said yes to question 5:

6. Why do you think this?

If you said no to question 5:

7. Why do you think this?

I think people need to opt in for this, otherwise its asking me to forgo my ordinary way of living and change to accommodate the research project. It's quite a big ask to wear a bracelet and I may not give proper informed consent as I might not be that interested in it and it may seem irrelevant to me. That is, I might imagine I would never have a heart attack. Better to opt in.

Case study 5: Research on people who have Down Syndrome

Down Syndrome is a learning disability.

In this case study a doctor wants to do some research to find out if a medicine can help people with Down Syndrome with their learning.

The medicine may make some people with Down Syndrome think sad things and want to hurt themselves.

Some people with Down Syndrome who take part in the research **will** get the medicine.

Some people with Down Syndrome who take part in the research will **not** get the medicine.

This is so that the doctor can see if the medicine is helping the people with Down Syndrome who get it.

Some people with Down Syndrome will be able to give **informed consent** to take part in the research.

Some people with Down Syndrome will **not** be able to give **informed consent** to take part in the research.

The doctor wants to have people with Down Syndrome in their research who:

- can give **informed consent** to take part
- cannot give **informed consent** to take part.

The doctor wants to be able to get **informed consent** from the family members or support workers of the people with Down Syndrome who cannot give **informed consent**.

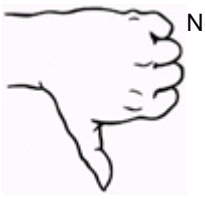
Questions about research on people with Down Syndrome

These questions are not about you.

The questions are a made up example.

1. Do you think people with Down Syndrome who cannot give informed consent should be in this research?
Choose the answer that is right for you.

Yes



No

I do not have an answer

If you said yes to question 1:

2. Why do you think people with Down Syndrome who cannot give informed consent should be in this research?

If you said no to question 1:

3. Why do you think people with Down Syndrome who cannot give informed consent should not be in this research?

Because it just doesn't seem right. Because people don't really understand Down Syndrome that well.

4. Do you want to say any more about this question?

with Down Syndrome. He is a whole person and I wouldn't say he has a learning disability
He has a whole different way of being and a very beautiful heart. So in this way his heart and mind are very healthy, more so than 'normal' people. I have spiritual beliefs that mean that I believe his life is very important on this earth to teach us about unconditional love. I also see this in others with Down's. Because these qualities are for the most part not understood by most people, I think giving someone a medicine for their 'learning disability' is not right, unless that person wanted to learn easier. It may effect that person in ways that the medical model of health does not yet understand.

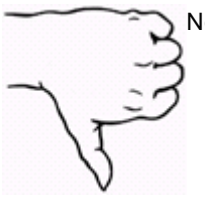
5. Do you think other people should decide if people with Down Syndrome will be in this research?

These other people could be:

- **family / whānau**
- **support workers**

Choose the answer that is right for you.

Yes



No

I do not have an answer

If you said yes to question 5:

6. Why do you think this?

If you said no to question 5:

7. Why do you think this?

Because they may not have the education to understand the perspectives of the medical model of health, the philosophical view behind this and how the medication might affect that person.

8. Do you want to say any more about this?

Questions about informed consent

Here are some more questions.

These questions will ask you what you think about **informed consent** to take part in research.

Health and Disability Commissioner
Te Toihau Hauora, Hauātanga

Your answers will help the **Health and Disability Commissioner** know what is important to you.

1. Do you think it is OK for adults who cannot give informed consent to take part in research when no one knows if it will help them or hurt them?
Choose the answer that is right for you.

Yes

No

I do not have an answer

2. When do you think it is OK for adults who cannot give informed consent to take part in research?

3. Some people doing research are not health or disability providers so they do not have to follow the Health and Disability Code of Rights.

Do you think everyone doing health and disability research should have to follow the Code?

Choose the answer that is right for you.


Yes

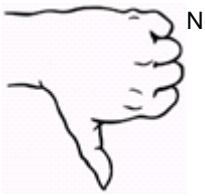
No

I do not have an answer

4. Do you think the law should say that if any person taking part in research looks like they are scared or in pain they should not be part of the research anymore?

Choose the answer that is right for you.


Yes



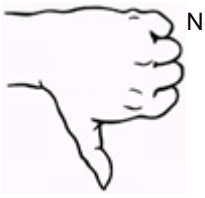
No

I do not have an answer

5. Do you think the law should change to say it is OK for people to give delayed consent to research after they wake up?

Delayed consent means asking for consent to do research on you after it has already been done. Choose the answer that is right for you.

Yes

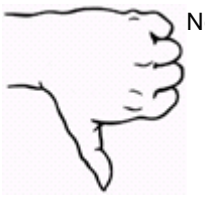


No

I do not have an answer

6. If the research can be done with people who can give informed consent is it OK to do the research with people who cannot give informed consent? Choose the answer that is right for you.

Yes

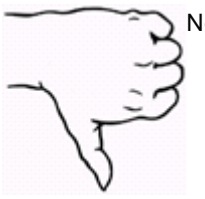


No

I do not have an answer

7. Do you think research should be done on a person that cannot give informed consent if the research may or may not help them but might help other people in the future? Choose the answer that is right for you.

Yes



No

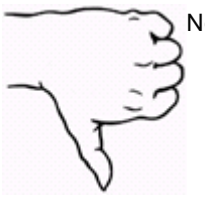
I do not have an answer

8. Why do you think this?

Because that person may recover and let you know that what was done wasn't right for them, or right for them spiritually. We need to be careful about putting 'population' needs above individual rights particularly when we have a mechanistic model of health that has an aspect of it driven by the pharmaceutical industry which has a goal of making money. We need to move to a more holistic model of health, and we may discover other methods of healing that make pharmaceutical interventions less necessary. The push by the pharmaceutical industry to have 'population' need above individual right would be strong.

9. Do you think all people that want to do research with adults who cannot give informed consent should have to get the OK from an ethics committee to do it?Choose the answer that is right for you.

Yes



No

I do not have an answer

10. Why do you think this?

Absolutely. Because the person is at an even higher risk than normal of being treated the wrong way.

11. Who do you think should have a say in whether or not a person who cannot give informed consent will be part of research?

You can choose as many as you want.

- [x] Someone who is Enduring Power of Attorney or Welfare Guardian for the person
- [x] Family / whanau of the person
- [ ] The person's doctor (if they are not part of the research)
- [ ] The person who wants to do the research
- [ ] Someone else

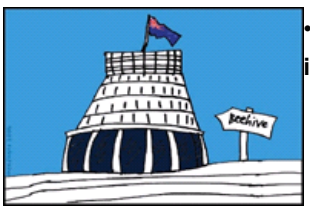
12. Do you think anyone else should have a say in whether or not a person who cannot give informed consent will be part of research?

13. Do you want to say any more about question 11?

What happens next?

The **Health and Disability Commissioner** will:

- think about what everyone has said about people who cannot give **informed consent** being part of research



- decide what to tell the Government about whether changes are needed to the law on **informed consent** to be in research

- decide whether the **Code** needs to be changed about **informed consent** to be in research.

If the Health and Disability Commissioner thinks the **Code** needs to be changed he will ask everyone about the changes.

Your name

Organisation (if you represent an organisation)

Thank you.

Thank you for:

- reading this information
- thinking about the hard topics

- telling the **Health and Disability Commissioner** what you think.

This will help the **Health and Disability Commissioner** to know what needs to be done.

Health and Disability Commissioner
Te Toihau Hauora, Hauātanga

This information has been translated into Easy Read by People First New Zealand Inc. Ngā Tāngata Tuatahi

Started on 25 April 2017 at 4:12pm | Completed on 25 April 2017 at 4:34pm

some research uses people who are not able to say if they want to take part or not.

This is the form to tell the Health and Disability Commissioner what you think.

Questions and Answers

This form has **questions** to find out what you think about doing research with people who are not able to say if they want to take part or not.

Health and Disability Commissioner
Te Toihau Hauora, Hauātanga

Your **answers** will help the **Health and Disability Commissioner** know what needs to be done.

You do not have to **answer** all the questions.

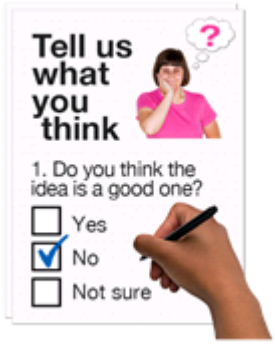
Case studies and questions

Case studies are stories that help us to understand something.

5

Here are 5 case studies that show when research cannot be done without informed consent at the moment in New Zealand.

These may help you decide if the law should change.



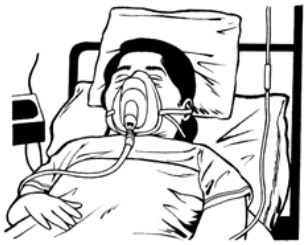
Each case study has questions that we would like you to answer.

Health and Disability Commissioner
Te Toihau Hauora, Hauātanga

Your answers to the questions will help the Health and Disability Commissioner know what is important to you.

Case study 1: Observational research on people with a bad infection

Some people with a bad infection will:



- get very sick
- not be able to tell other people what they think or feel

- have to take medicine to get healthy.

In this case study a doctor wants to do some research on people who:

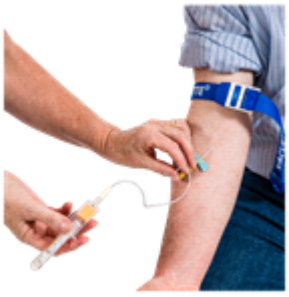
- have a bad infection

- have been given medicine.

The doctor will not change the medicine the people are getting.

The doctor:

- wants to know how much medicine these people need to take to get better



- will take samples from their bodies to find out how much medicine they need to take to get better.

The doctor wants to do this research on people who:

- cannot give informed consent to take part

- will not get better health from being part of the research
- will get the same medicine whether they take part in the research or not.

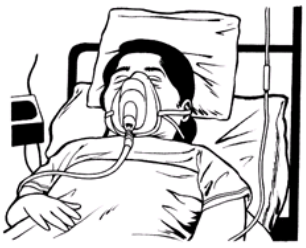
This research may help other people who get bad infections to get the medicine that will help them.

Questions about observational research on people with a bad infection

In these questions we will ask you to think about what you would choose to do if you were sick with a bad infection.

These questions are not about you.

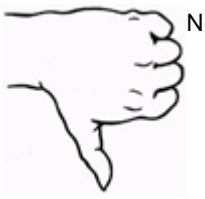
The questions are a made up example.



1. If you had a bad infection and could not give informed consent would you want to take part in research about how much medicine is needed to get better?

Choose the answer that is right for you:

Yes



No

I do not have an answer

If you said yes to question 1:

2. Why would you want to take part in this research?

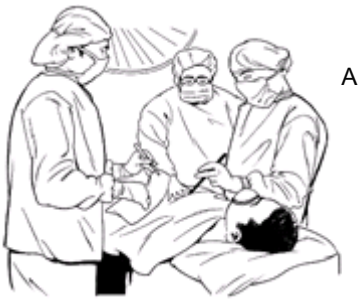
Clinical practice is changing all the time so if there is anything that may improve health care, then would be happy for this. I however, would expect consultation to take part with my next of kin. I would not be in a position to respond, so they would need to do so on my behalf.

If you said no to question 1:

3. Why would you not want to take part in this research?

4. Do you want to say any more about this question?

Case study 2: Research on brain operations



A person has to have a brain operation.

There are 2 things doctors use to make sure a person who has a brain operation is OK after their operation has finished.

No one knows which thing works best.

In this case study a doctor wants to do some research to find out which of the 2 things will work best for other people in the future to help them get better.

In the research the doctor will give some people 1 thing and other people a different thing.

The doctor will see which thing works best.

The people cannot say if they want to be part of the research or not.

The doctor wants to get **delayed consent** for the research from some of the people after their brain operation is done.

Delayed consent means asking for consent to do research on you after it has already been done.

Questions about research on brain operations

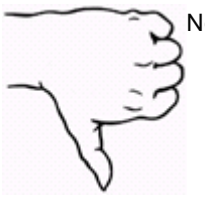
In these questions we will ask you to think about what you would choose to do if you were sick and have to have a brain operation.

These questions are not about you.

The questions are a made up example.

1. If you were not able to say yes or no to taking part in this research before your brain operation would you be OK with the doctor doing the research anyway? Choose the answer that is right for you.

Yes



No

I do not have an answer

If you said yes to question 1

2. Why would you want to take part in this research?

I would agree, but once again, it is dependant on my next of kin. they would need to make the decision for me.

If you said no to question 1

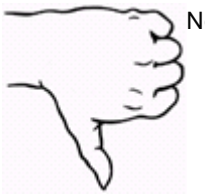
3. Why would you not want to take part in this research?

4. Do you want to say any more about this question?

Would need to know the research has passed through a formal ethics committee.

5. Do you think delayed consent is ok? Choose the answer that is right for you.

Yes



No

I do not have an answer

If you said yes to question 5:

6. Why do you think delayed consent is OK?

It may help to provide so useful information. It also allows an option to stop if need be. Would need to know the research had passed through an ethics committee.

If you said no to question 5:

7. Why do you think delayed consent is not OK?

Case study 3: Research on people who have a brain disease

Sometimes people get a brain disease that makes it hard for them to:

- remember
- say what they think and feel.

In this case study a doctor wants to do some research on the care given to these people.

Some people will get 1 kind of care and others will get different care.

The doctor will see if any of the people get better.

No one knows if taking part in the research will mean the people will get better or worse.

The doctor does not know if the research will mean better care for people in the future or not.

The research is trying to find this out.

Some of the people the doctor wants to do research on cannot give **informed consent** to take part in the research.

Questions about research on people who have a brain disease

In these questions we will ask you to think about what you would want to happen if you had a brain disease.

These questions are not about you.

The questions are a made up example.

1. If you had a brain disease and could not give informed consent would you want to take part in this research?
Choose the answer that is right for you.

Yes

No

I do not have an answer

If you said yes to question 1
2. Why would you want to take part in this research?

I would be happy to take part as long as by taking part, I was not coming to any harm.

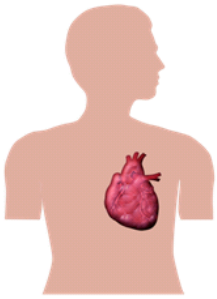
If you said no to question 1

3. Why would you not want to take part in this research?

4. Do you want to say any more about this question?

Research would need to have had approval through formal ethics committee.

Case study 4: Research on people who are having a cardiac arrest

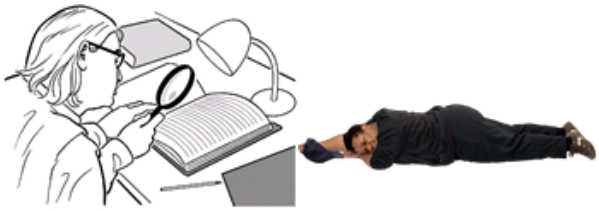


Cardiac arrest is when you have a big problem with your heart and it stops working.

Most of the time when a person's heart stops they are given a medicine.

No one knows if the medicine helps or hurts people.

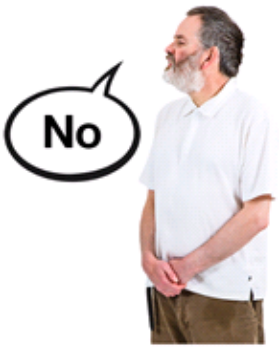
In this case study a doctor wants to research whether the medicine helps people whose heart has stopped.



If somebody's heart stops working they will not be awake.

This means the doctor will not be able to ask for **informed consent** to take part in the research.

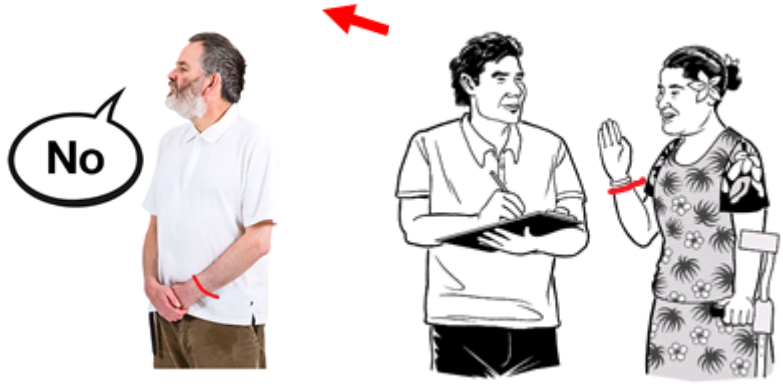
The doctor wants to give some people the medicine and others no medicine to see which group gets better.



People can choose to **opt out** of this research.

Opt out means you say you do **not** want to take part in the research if your heart stops in the future.

People who want to **opt out** of this research can wear a bracelet that says **no study** on it.



To do this people need to:

- ask for a bracelet in case their heart stops 1 day in the future
- wear the bracelet

Questions about research on people that are having a cardiac arrest

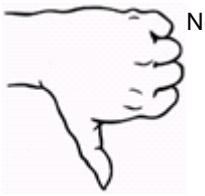
In these questions we will ask you to think about what you would want to happen if your heart stopped working.

These questions are not about you.

The questions are a made up example.

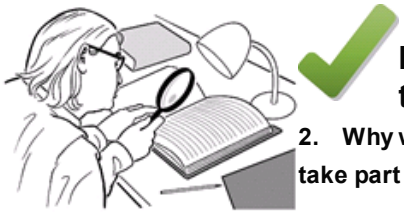
1. If your heart stopped would you want to take part in research to find out if taking this medicine is better than no medicine?
Choose the answer that is right for you.

Yes



No

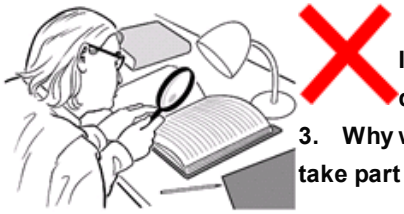
I do not have an answer



If you said yes to question 1

2. Why would you want to take part in this research?

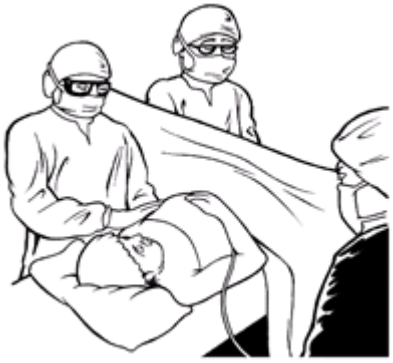
It is a life saving measure so I would want everything to be done to save me.



If you said no to question 1

3. Why would you not want to take part in this research?

4. Do you want to say any more about this question?

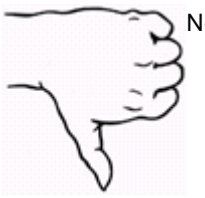


5. People who are wearing the bracelets will not be in the research if their heart stops.

Do you think it is OK for the doctors to do the research on anyone who is not wearing a bracelet when their heart stops?

Choose the answer that is right for you.

Yes



No

I do not have an answer

If you said yes to question 5:

6. Why do you think this?

Many people do not get around to applying for bracelets. However, family involvement is also important as part of the decision.

If you said no to question 5:

7. Why do you think this?

Case study 5: Research on people who have Down Syndrome

Down Syndrome is a learning disability.

In this case study a doctor wants to do some research to find out if a medicine can help people with Down Syndrome with their learning.

The medicine may make some people with Down Syndrome think sad things and want to hurt themselves.

Some people with Down Syndrome who take part in the research **will** get the medicine.

Some people with Down Syndrome who take part in the research will **not** get the medicine.

This is so that the doctor can see if the medicine is helping the people with Down Syndrome who get it.

Some people with Down Syndrome will be able to give **informed consent** to take part in the research.

Some people with Down Syndrome will **not** be able to give **informed consent** to take part in the research.

The doctor wants to have people with Down Syndrome in their research who:

- can give **informed consent** to take part
- cannot give **informed consent** to take part.

The doctor wants to be able to get **informed consent** from the family members or support workers of the people with Down Syndrome who cannot give **informed consent**.

Questions about research on people with Down Syndrome

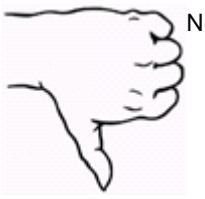
These questions are not about you.

The questions are a made up example.

1. Do you think people with Down Syndrome who cannot give informed consent should be in this research?
Choose the answer that is right for you.

Yes

No



I do not have an answer

If you said yes to question 1:

2. Why do you think people with Down Syndrome who cannot give informed consent should be in this research?

If you said no to question 1:

3. Why do you think people with Down Syndrome who cannot give informed consent should not be in this research?

4. Do you want to say any more about this question?

Not sure as I would think if a person who has Downs Syndrome is not in a position to give informed consent, then their family needs to speak for them. Their family knows them best.

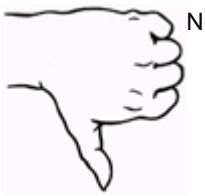
5. Do you think other people should decide if people with Down Syndrome will be in this research?

These other people could be:

- **family / whānau**
- **support workers**

Choose the answer that is right for you.

Yes



No

I do not have an answer

If you said yes to question 5:

6. Why do you think this?

See answer to qs 4

If you said no to question 5:

7. Why do you think this?

8. Do you want to say any more about this?

Questions about informed consent

Here are some more questions.

These questions will ask you what you think about **informed consent** to take part in research.

Health and Disability Commissioner
Te Toihau Hauora, Hauātanga

Your answers will help the **Health and Disability Commissioner** know what is important to you.

1. Do you think it is OK for adults who cannot give informed consent to take part in research when no one knows if it will help them or hurt them?
Choose the answer that is right for you.

Yes

No

I do not have an answer

2. When do you think it is OK for adults who cannot give informed consent to take part in research?

When it is part of Health and Disability Code

3. Some people doing research are not health or disability providers so they do not have to follow the Health and Disability Code of Rights.

Do you think everyone doing health and disability research should have to follow the Code?

Choose the answer that is right for you.


Yes

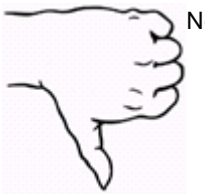
No

I do not have an answer

4. Do you think the law should say that if any person taking part in research looks like they are scared or in pain they should not be part of the research anymore?

Choose the answer that is right for you.


Yes



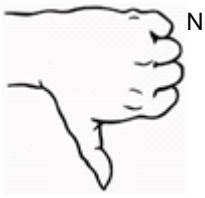
No

I do not have an answer

5. Do you think the law should change to say it is OK for people to give delayed consent to research after they wake up?

Delayed consent means asking for consent to do research on you after it has already been done. Choose the answer that is right for you.

Yes

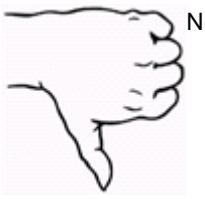


No

I do not have an answer

6. If the research can be done with people who can give informed consent is it OK to do the research with people who cannot give informed consent? Choose the answer that is right for you.

Yes

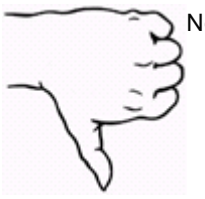


No

I do not have an answer

7. Do you think research should be done on a person that cannot give informed consent if the research may or may not help them but might help other people in the future? Choose the answer that is right for you.

Yes



No

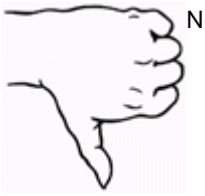
I do not have an answer

8. Why do you think this?

It would depend on what the research is for and there would need to be family involvement or have someone else acting on behalf of the person who is not able to give their informed consent to research.

9. Do you think all people that want to do research with adults who cannot give informed consent should have to get the OK from an ethics committee to do it?Choose the answer that is right for you.

Yes



No

I do not have an answer

10. Why do you think this?

Ethics committees have processes for assessing research to ensure it will not cause harm to people.

11. Who do you think should have a say in whether or not a person who cannot give informed consent will be part of research?

You can choose as many as you want.

- [x] Someone who is Enduring Power of Attorney or Welfare Guardian for the person
- [x] Family / whanau of the person
- [ ] The person's doctor (if they are not part of the research)
- [ ] The person who wants to do the research
- [ ] Someone else

12. Do you think anyone else should have a say in whether or not a person who cannot give informed consent will be part of research?

Possibly the person's doctor, if they know the patient well and feel they could make a decision on their behalf.

13. Do you want to say any more about question 11?

What happens next?

The **Health and Disability Commissioner** will:

- think about what everyone has said about people who cannot give **informed consent** being part of research

- decide what to tell the Government about whether changes are needed to the law on **informed consent** to be in research

- decide whether the **Code** needs to be changed about **informed consent** to be in research.

If the Health and Disability Commissioner thinks the **Code** needs to be changed he will ask everyone about the changes.

Your name

Organisation (if you represent an organisation)

Thank you.

Thank you for:

- reading this information
- thinking about the hard topics

- telling the **Health and Disability Commissioner** what you think.

This will help the **Health and Disability Commissioner** to know what needs to be done.

Health and Disability Commissioner
Te Toihau Hauora, Hauātanga

This information has been translated into Easy Read
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some research uses people who are not able to say if they want to take part or not.

This is the form to tell the Health and Disability Commissioner what you think.

Questions and Answers

This form has **questions** to find out what you think about doing research with people who are not able to say if they want to take part or not.

Health and Disability Commissioner
Te Toihau Hauora, Hauātanga

Your **answers** will help the **Health and Disability Commissioner** know what needs to be done.

You do not have to **answer** all the questions.

Case studies and questions

Case studies are stories that help us to understand something.

5

Here are 5 case studies that show when research cannot be done without informed consent at the moment in New Zealand.

These may help you decide if the law should change.

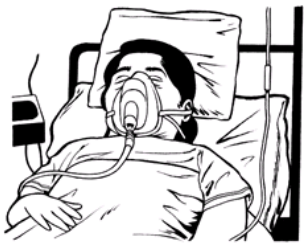
Each case study has questions that we would like you to answer.

Health and Disability Commissioner
Te Toihau Hauora, Hauātanga

Your answers to the questions will help the Health and Disability Commissioner know what is important to you.

Case study 1: Observational research on people with a bad infection

Some people with a bad infection will:



- get very sick
- not be able to tell other people what they think or feel

- have to take medicine to get healthy.

In this case study a doctor wants to do some research on people who:

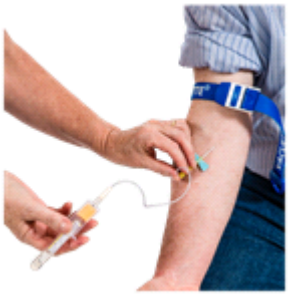
- have a bad infection

- have been given medicine.

The doctor will not change the medicine the people are getting.

The doctor:

- wants to know how much medicine these people need to take to get better



- will take samples from their bodies to find out how much medicine they need to take to get better.

The doctor wants to do this research on people who:

- cannot give informed consent to take part

- will not get better health from being part of the research
- will get the same medicine whether they take part in the research or not.

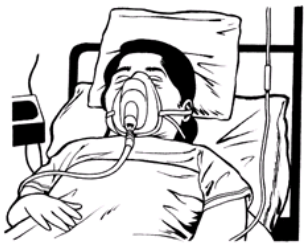
This research may help other people who get bad infections to get the medicine that will help them.

Questions about observational research on people with a bad infection

In these questions we will ask you to think about what you would choose to do if you were sick with a bad infection.

These questions are not about you.

The questions are a made up example.



1. If you had a bad infection and could not give informed consent would you want to take part in research about how much medicine is needed to get better?

Choose the answer that is right for you:

Yes

No

I do not have an answer

If you said yes to question 1:

2. Why would you want to take part in this research?

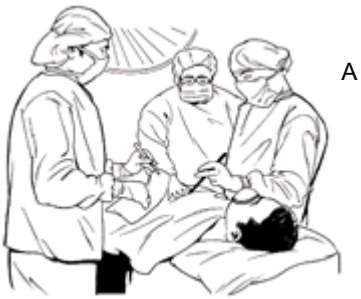
in the long term it would be for the good of other sick persons

If you said no to question 1:

3. Why would you not want to take part in this research?

4. Do you want to say any more about this question?

Case study 2: Research on brain operations



A person has to have a brain operation.

There are 2 things doctors use to make sure a person who has a brain operation is OK after their operation has finished.

No one knows which thing works best.

In this case study a doctor wants to do some research to find out which of the 2 things will work best for other people in the future to help them get better.

In the research the doctor will give some people 1 thing and other people a different thing.

The doctor will see which thing works best.

The people cannot say if they want to be part of the research or not.

The doctor wants to get **delayed consent** for the research from some of the people after their brain operation is done.

Delayed consent means asking for consent to do research on you after it has already been done.

Questions about research on brain operations

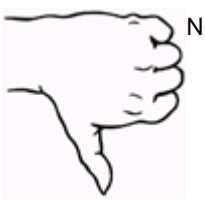
In these questions we will ask you to think about what you would choose to do if you were sick and have to have a brain operation.

These questions are not about you.

The questions are a made up example.

1. If you were not able to say yes or no to taking part in this research before your brain operation would you be OK with the doctor doing the research anyway?
Choose the answer that is right for you.

Yes



No

I do not have an answer

If you said yes to question 1

2. Why would you want to take part in this research?

If you said no to question 1

3. Why would you not want to take part in this research?

I would need to know that this was just a trial and error operation, has this proceedure been carried out before, what is therisk factor,

4. Do you want to say any more about this question?

5. Do you think delayed consent is ok? Choose the answer that is right for you.

Yes

No

I do not have an answer

If you said yes to question 5:

6. Why do you think delayed consent is OK?

If you said no to question 5:

7. Why do you think delayed consent is not OK?

IF IT WAS AN EMERGENCY PROCEEDURE ON ME AND i ONLY HAD A 1.1 CHANCE OF SURVIAL, IT WOULD BE OK IF THE SURGON CARRIED OUT A NEW technique, yes ok. If it was a chance to survive and I WAS likely to die, ok. If it failed it would be inconclusive evidence. On REFLECTION a half yes

Case study 3: Research on people who have a brain disease

Sometimes people get a brain disease that makes it hard for them to:

- remember
- say what they think and feel.

In this case study a doctor wants to do some research on the care given to these people.

Some people will get 1 kind of care and others will get different care.

The doctor will see if any of the people get better.

No one knows if taking part in the research will mean the people will get better or worse.

The doctor does not know if the research will mean better care for people in the future or not.

The research is trying to find this out.

Some of the people the doctor wants to do research on cannot give **informed consent** to take part in the research.

Questions about research on people who have a brain disease

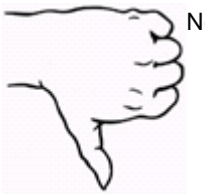
In these questions we will ask you to think about what you would want to happen if you had a brain disease.

These questions are not about you.

The questions are a made up example.

1. If you had a brain disease and could not give informed consent would you want to take part in this research?
Choose the answer that is right for you.

Yes



No

I do not have an answer

If you said yes to question 1

2. Why would you want to take part in this research?

I am stroke surviour and it could help any person to improve.good.

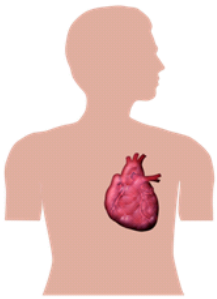
If you said no to question 1

3. Why would you not want to take part in this research?

4. Do you want to say any more about this question?

Case study 4: Research on people who are having a cardiac arrest

Cardiac arrest is when you have a big problem with your heart and it stops working.



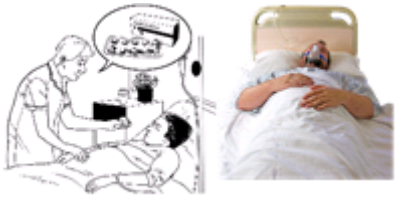
Most of the time when a person's heart stops they are given a medicine.

No one knows if the medicine helps or hurts people.

In this case study a doctor wants to research whether the medicine helps people whose heart has stopped.

If somebody's heart stops working they will not be awake.

This means the doctor will not be able to ask for **informed consent** to take part in the research.



The doctor wants to give some people the medicine and others no medicine to see which group gets better.

People can choose to **opt out** of this research.

Opt out means you say you do **not** want to take part in the research if your heart stops in the future.

People who want to **opt out** of this research can wear a bracelet that says **no study** on it.

To do this people need to:

- ask for a bracelet in case their heart stops 1 day in the future
- wear the bracelet

Questions about research on people that are having a cardiac arrest

In these questions we will ask you to think about what you would want to happen if your heart stopped working.

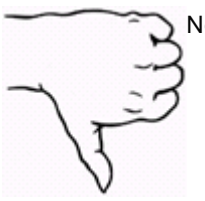
These questions are not about you.

The questions are a made up example.

1. If your heart stopped would you want to take part in research to find out if taking this medicine is better than no medicine?
Choose the answer that is right for you.

Yes

No



I do not have an answer

If you said yes to question 1

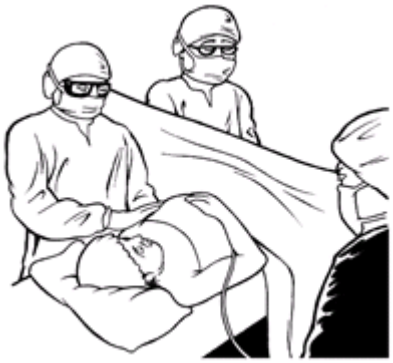
2. Why would you want to take part in this research?

to help other people

If you said no to question 1

3. Why would you not want to take part in this research?

4. Do you want to say any more about this question?

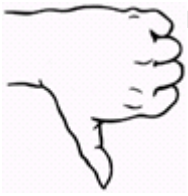


5. People who are wearing the bracelets will not be in the research if their heart stops.

Do you think it is OK for the doctors to do the research on anyone who is not wearing a bracelet when their heart stops?

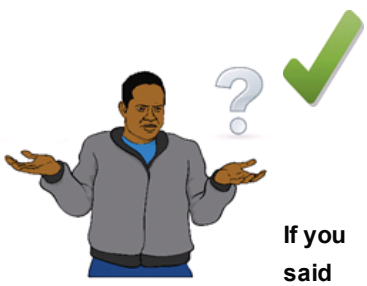
Choose the answer that is right for you.

Yes



No

I do not have an answer



If you said yes to question 5:

6. Why do you think this?

I have considered having tatooed on my chesT
Do not revive

If you said no to question 5:

7. Why do you think this?

Case study 5: Research on people who have Down Syndrome

Down Syndrome is a learning disability.

In this case study a doctor wants to do some research to find out if a medicine can help people with Down Syndrome with their learning.

The medicine may make some people with Down Syndrome think sad things and want to hurt themselves.

Some people with Down Syndrome who take part in the research **will** get the medicine.

Some people with Down Syndrome who take part in the research will **not** get the medicine.

This is so that the doctor can see if the medicine is helping the people with Down Syndrome who get it.

Some people with Down Syndrome will be able to give **informed consent** to take part in the research.

Some people with Down Syndrome will **not** be able to give **informed consent** to take part in the research.

The doctor wants to have people with Down Syndrome in their research who:

- can give **informed consent** to take part
- cannot give **informed consent** to take part.

The doctor wants to be able to get **informed consent** from the family members or support workers of the people with Down Syndrome who cannot give **informed consent**.

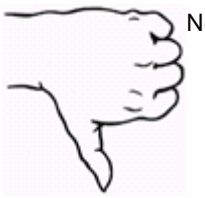
Questions about research on people with Down Syndrome

These questions are not about you.

The questions are a made up example.

1. Do you think people with Down Syndrome who cannot give informed consent should be in this research? Choose the answer that is right for you.

Yes



No

I do not have an answer

If you said yes to question 1:

2. Why do you think people with Down Syndrome who cannot give informed consent should be in this research?

If you said no to question 1:

3. Why do you think people with Down Syndrome who cannot give informed consent should not be in this research?

I HAVE had experience with down syndrome persons and mostI know lead a very simpleand happy life, not comparing it to our own lifestyle

4. Do you want to say any more about this question?

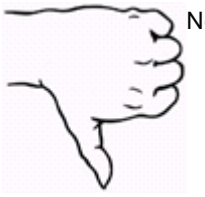
5. Do you think other people should decide if people with Down Syndrome will be in this research?

These other people could be:

- **family / whānau**
- **support workers**

Choose the answer that is right for you.

Yes



No

I do not have an answer

If you said yes to question 5:

6. Why do you think this?

If you said no to question 5:

7. Why do you think this?

I think that family should have no say in treatment, it is up to the doctors

8. Do you want to say any more about this?

Questions about informed consent

Here are some more questions.

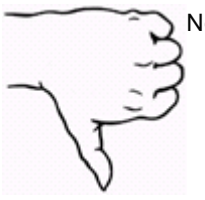
These questions will ask you what you think about **informed consent** to take part in research.

Health and Disability Commissioner
Te Toihau Hauora, Hauātanga

Your answers will help the **Health and Disability Commissioner** know what is important to you.

1. Do you think it is OK for adults who cannot give informed consent to take part in research when no one knows if it will help them or hurt them?
Choose the answer that is right for you.

Yes



No

I do not have an answer

2. When do you think it is OK for adults who cannot give informed consent to take part in research?

they have a poor quality of life. Have advanced dementia

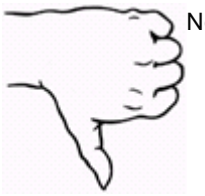
3. Some people doing research are not health or disability providers so they do not have to follow the Health and Disability Code of Rights.

Do you think everyone doing health and disability research should have to follow the Code?

Choose the answer that is right for you.

- Yes

- No



- I do not have an answer

4. Do you think the law should say that if any person taking part in research looks like they are scared or in pain they should not be part of the research anymore?

Choose the answer that is right for you.

Yes

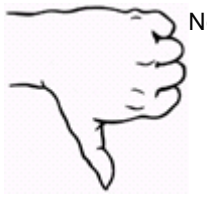
No

I do not have an answer

5. Do you think the law should change to say it is OK for people to give delayed consent to research after they wake up?

Delayed consent means asking for consent to do research on you after it has already been done. Choose the answer that is right for you.

Yes

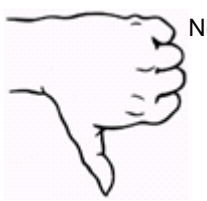


No

I do not have an answer

6. If the research can be done with people who can give informed consent is it OK to do the research with people who cannot give informed consent? Choose the answer that is right for you.

Yes

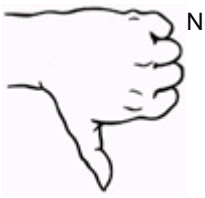


No

I do not have an answer

7. Do you think research should be done on a person that cannot give informed consent if the research may or may not help them but might help other people in the future? Choose the answer that is right for you.

Yes



No

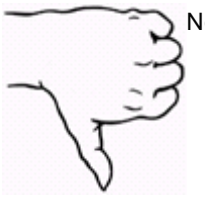
I do not have an answer

8. Why do you think this?

too much like the cervitial cancer experiment

9. Do you think all people that want to do research with adults who cannot give informed consent should have to get the OK from an ethics committee to do it?Choose the answer that is right for you.

Yes



No

I do not have an answer

10. Why do you think this?

ethics committee will make the right decision

11. Who do you think should have a say in whether or not a person who cannot give informed consent will be part of research?

You can choose as many as you want.

- [x] Someone who is Enduring Power of Attorney or Welfare Guardian for the person
- [x] Family / whanau of the person
- [ ] The person's doctor (if they are not part of the research)
- [x] The person who wants to do the research
- [ ] Someone else

12. Do you think anyone else should have a say in whether or not a person who cannot give informed consent will be part of research?

13. Do you want to say any more about question 11?

What happens next?

The **Health and Disability Commissioner** will:

- think about what everyone has said about people who cannot give **informed consent** being part of research

- decide what to tell the Government about whether changes are needed to the law on **informed consent** to be in research

- decide whether the **Code** needs to be changed about **informed consent** to be in research.

If the Health and Disability Commissioner thinks the **Code** needs to be changed he will ask everyone about the changes.

Your name

Organisation (if you represent an organisation)

Thank you.

Thank you for:

- reading this information
- thinking about the hard topics

- telling the **Health and Disability Commissioner** what you think.

This will help the **Health and Disability Commissioner** to know what needs to be done.

Health and Disability Commissioner
Te Toihau Hauora, Hauātanga

This information has been translated into Easy Read by People First New Zealand Inc. Ngā Tāngata Tuatahi

Started on 30 April 2017 at 9:07am | Completed on 30 April 2017 at 10:20am

some research uses people who are not able to say if they want to take part or not.

This is the form to tell the Health and Disability Commissioner what you think.

Questions and Answers

This form has **questions** to find out what you think about doing research with people who are not able to say if they want to take part or not.

Health and Disability Commissioner
Te Toihau Hauora, Hauātanga

Your **answers** will help the **Health and Disability Commissioner** know what needs to be done.

You do not have to **answer** all the questions.

Case studies and questions

Case studies are stories that help us to understand something.

5

Here are 5 case studies that show when research cannot be done without informed consent at the moment in New Zealand.

These may help you decide if the law should change.

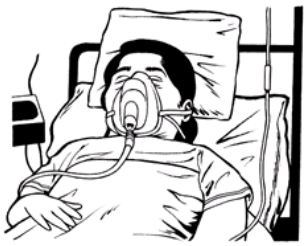
Each case study has questions that we would like you to answer.

Health and Disability Commissioner
Te Toihau Hauora, Hauātanga

Your answers to the questions will help the Health and Disability Commissioner know what is important to you.

Case study 1: Observational research on people with a bad infection

Some people with a bad infection will:



- get very sick
- not be able to tell other people what they think or feel

- have to take medicine to get healthy.

In this case study a doctor wants to do some research on people who:

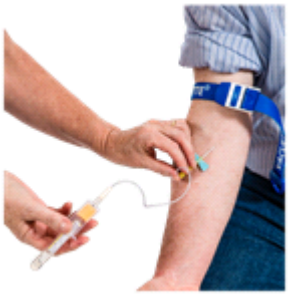
- have a bad infection

- have been given medicine.

The doctor will not change the medicine the people are getting.

The doctor:

- wants to know how much medicine these people need to take to get better



- will take samples from their bodies to find out how much medicine they need to take to get better.

The doctor wants to do this research on people who:

- cannot give informed consent to take part

- will not get better health from being part of the research
- will get the same medicine whether they take part in the research or not.

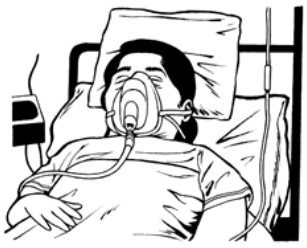
This research may help other people who get bad infections to get the medicine that will help them.

Questions about observational research on people with a bad infection

In these questions we will ask you to think about what you would choose to do if you were sick with a bad infection.

These questions are not about you.

The questions are a made up example.



1. If you had a bad infection and could not give informed consent would you want to take part in research about how much medicine is needed to get better?

Choose the answer that is right for you:

Yes

No

I do not have an answer

If you said yes to question 1:

2. Why would you want to take part in this research?

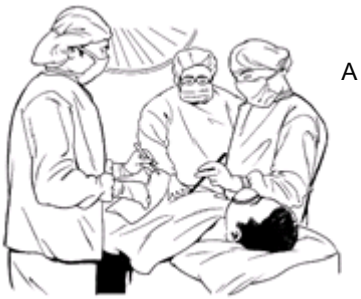
As per the full case study document, there is currently no information available regarding the rate at which specirfic forms of dialysis remove the antibiotics used to treat sepsis. I believe anonymised data should be allowed to be collected (without "informed consent" as currently defined) in order to provided better insight that will help to provide better individualised care and to improve the efficacy, efficiency and economy of future healthcare treatments.

If you said no to question 1:

3. Why would you not want to take part in this research?

4. Do you want to say any more about this question?

Case study 2: Research on brain operations



A person has to have a brain operation.

There are 2 things doctors use to make sure a person who has a brain operation is OK after their operation has finished.

No one knows which thing works best.

In this case study a doctor wants to do some research to find out which of the 2 things will work best for other people in the future to help them get better.

In the research the doctor will give some people 1 thing and other people a different thing.

The doctor will see which thing works best.

The people cannot say if they want to be part of the research or not.

The doctor wants to get **delayed consent** for the research from some of the people after their brain operation is done.

Delayed consent means asking for consent to do research on you after it has already been done.

Questions about research on brain operations

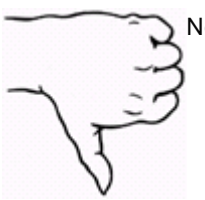
In these questions we will ask you to think about what you would choose to do if you were sick and have to have a brain operation.

These questions are not about you.

The questions are a made up example.

1. If you were not able to say yes or no to taking part in this research before your brain operation would you be OK with the doctor doing the research anyway?
Choose the answer that is right for you.

Yes



No

I do not have an answer

If you said yes to question 1

2. Why would you want to take part in this research?

I would like to personally contribute to a better understanding of which drug is better - especially if this information is currently unavailable.

If you said no to question 1

3. Why would you not want to take part in this research?

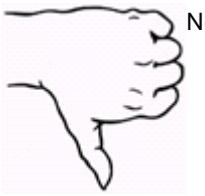
4. Do you want to say any more about this question?

Page 13 of the HDC Consultation Document states that currently "authorised representatives" are unable to consent activities with the goal of generating generalisable knowledge to benefit people in the future; they can only consent to acts that focus on saving the incompetent person's life/preventing serious damage. I believe the power/jurisdiction of the "authorised representative" needs to be reviewed so that generalisable data can be collected and used to benefit other people.

5. Do you think delayed consent is ok?

Choose the answer that is right for you.

Yes



No

I do not have an answer

If you said yes to question 5:

6. Why do you think delayed consent is OK?

Given that there is currently no information available on which of the two drugs is superior - it wouldn't have mattered which drug I was given either way. So being told afterward / consent sought afterwards is just as meaningful as prior consent.

If you said no to question 5:

7. Why do you think delayed consent is not OK?

Case study 3: Research on people who have a brain disease

Sometimes people get a brain disease that makes it hard for them to:

- remember
- say what they think and feel.

In this case study a doctor wants to do some research on the care given to these people.

Some people will get 1 kind of care and others will get different care.

The doctor will see if any of the people get better.

No one knows if taking part in the research will mean the people will get better or worse.

The doctor does not know if the research will mean better care for people in the future or not.

The research is trying to find this out.

Some of the people the doctor wants to do research on cannot give **informed consent** to take part in the research.

Questions about research on people who have a brain disease

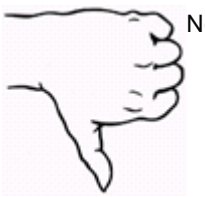
In these questions we will ask you to think about what you would want to happen if you had a brain disease.

These questions are not about you.

The questions are a made up example.

1. If you had a brain disease and could not give informed consent would you want to take part in this research?
Choose the answer that is right for you.

Yes



No

I do not have an answer

If you said yes to question 1

2. Why would you want to take part in this research?

The case study states that there is currently very little evidence about the benefits or risks of "interactive care". The only way to gather more evidence / data is to conduct further experiments to add to the knowledge. In order to do so in a "controlled" setting is to allow doctors to randomly assign patients to the different treatment groups. How else would we challenge the status quo?

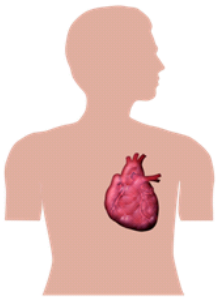
If you said no to question 1

3. Why would you not want to take part in this research?

4. Do you want to say any more about this question?

Case study 4: Research on people who are having a cardiac arrest

Cardiac arrest is when you have a big problem with your heart and it stops working.



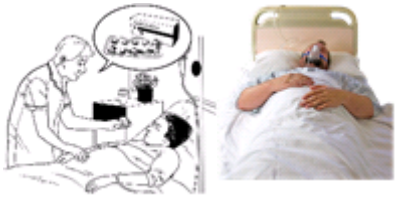
Most of the time when a person's heart stops they are given a medicine.

No one knows if the medicine helps or hurts people.

In this case study a doctor wants to research whether the medicine helps people whose heart has stopped.

If somebody's heart stops working they will not be awake.

This means the doctor will not be able to ask for **informed consent** to take part in the research.



The doctor wants to give some people the medicine and others no medicine to see which group gets better.

People can choose to **opt out** of this research.

Opt out means you say you do **not** want to take part in the research if your heart stops in the future.

People who want to **opt out** of this research can wear a bracelet that says **no study** on it.

To do this people need to:

- ask for a bracelet in case their heart stops 1 day in the future
- wear the bracelet

Questions about research on people that are having a cardiac arrest

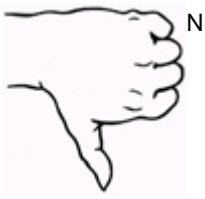
In these questions we will ask you to think about what you would want to happen if your heart stopped working.

These questions are not about you.

The questions are a made up example.

1. If your heart stopped would you want to take part in research to find out if taking this medicine is better than no medicine?
Choose the answer that is right for you.

Yes



No

I do not have an answer

If you said yes to question 1

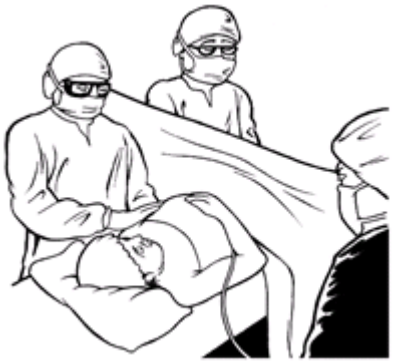
2. Why would you want to take part in this research?

Prior to reading the case study, I was not aware that the standard treatment has not been thoroughly studied, and may have long term consequences on other body systems. I can understand why the standard practice has persisted, but this status quo can only be improved if the health professionals are given the opportunity to robustly test and challenge the current thinking/process. I would want to personally contribute to that wider investigation/review.

If you said no to question 1

3. Why would you not want to take part in this research?

4. Do you want to say any more about this question?

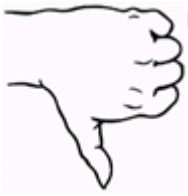


5. People who are wearing the bracelets will not be in the research if their heart stops.

Do you think it is OK for the doctors to do the research on anyone who is not wearing a bracelet when their heart stops?

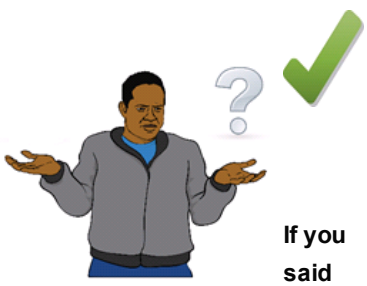
Choose the answer that is right for you.

Yes



No

I do not have an answer



If you said yes to question 5:

6. Why do you think this?

I think if the "opt out" option is adequately promoted through education via primary health care professionals, then people will have been given appropriate opportunity to make an informed decision as to whether they wish to partake or not. The

study participants have to come from somewhere - so my view is if people do not actively opt out then they've forfeited the right to do so.

If you said no to question 5:

7. Why do you think this?

Case study 5: Research on people who have Down Syndrome

Down Syndrome is a learning disability.

In this case study a doctor wants to do some research to find out if a medicine can help people with Down Syndrome with their learning.

The medicine may make some people with Down Syndrome think sad things and want to hurt themselves.

Some people with Down Syndrome who take part in the research **will** get the medicine.

Some people with Down Syndrome who take part in the research will **not** get the medicine.

This is so that the doctor can see if the medicine is helping the people with Down Syndrome who get it.

Some people with Down Syndrome will be able to give **informed consent** to take part in the research.

Some people with Down Syndrome will **not** be able to give **informed consent** to take part in the research.

The doctor wants to have people with Down Syndrome in their research who:

- can give **informed consent** to take part
- cannot give **informed consent** to take part.

The doctor wants to be able to get **informed consent** from the family members or support workers of the people with Down Syndrome who cannot give **informed consent**.

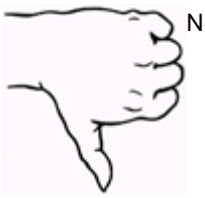
Questions about research on people with Down Syndrome

These questions are not about you.

The questions are a made up example.

1. Do you think people with Down Syndrome who cannot give informed consent should be in this research? Choose the answer that is right for you.

Yes



No

I do not have an answer

If you said yes to question 1:

2. Why do you think people with Down Syndrome who cannot give informed consent should be in this research?

If you said no to question 1:

3. Why do you think people with Down Syndrome who cannot give informed consent should not be in this research?

4. **Do you want to say any more about this question?**

The case study example highlights significant risks that I'm not certain the healthcare system is adequately prepared for in terms of monitoring/preventing/intervening (e.g. increased likelihood of suicidal thoughts). I think any participation by people with Down Syndrome will need to be on the proviso that the family / carer is fully on board and can give robust reassurance of support.

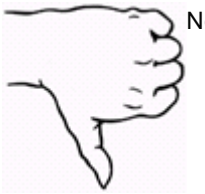
5. **Do you think other people should decide if people with Down Syndrome will be in this research?**

These other people could be:

- **family / whānau**
- **support workers**

Choose the answer that is right for you.

Yes



No

I do not have an answer

If you said yes to question 5:

6. Why do you think this?

I think this is an important research area that has the potential of improving the quality of life of Down Syndrome patients in the long run, hence I would like to support it. However I think the family / support workers need to be fully on board with the monitoring of the potential side effects to ensure that the study is not to the patient's detriment.

If you said no to question 5:

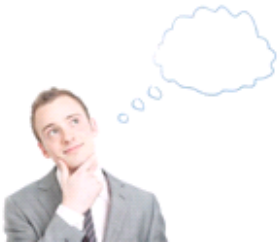
7. Why do you think this?

8. Do you want to say any more about this?

Perhaps another fail-safe might be to allow consenting family / whanau / support workers to choose to discontinue / cease participation, if during the study they deem the drug to be having unacceptably adverse changes / affects on the mental / physical wellbeing of their DS patient? This data would still be a valuable contribution toward the literature.

Questions about informed consent

Here are some more questions.



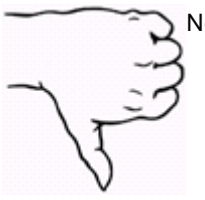
These questions will ask you what you think about **informed consent** to take part in research.

Health and Disability Commissioner
Te Toihau Hauora, Hauātanga

Your answers will help the **Health and Disability Commissioner** know what is important to you.

1. Do you think it is OK for adults who cannot give informed consent to take part in research when no one knows if it will help them or hurt them?
Choose the answer that is right for you.

Yes



No

I do not have an answer

2. When do you think it is OK for adults who cannot give informed consent to take part in research?

When the research treatment offers a potential improvement from the baseline default that would otherwise be available by default to the patient.

When the data is anonymised to protect the privacy of the participant.

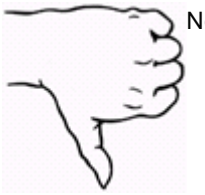
When the data arising from the research will ultimately contribute to the greater good (from an Utilitarian perspective).

3. Some people doing research are not health or disability providers so they do not have to follow the Health and Disability Code of Rights.

Do you think everyone doing health and disability research should have to follow the Code?

Choose the answer that is right for you.

Yes



No

I do not have an answer

4. Do you think the law should say that if any person taking part in research looks like they are scared or in pain they should not be part of the research anymore?

Choose the answer that is right for you.

Yes

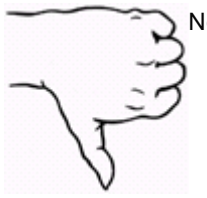
No

I do not have an answer

5. Do you think the law should change to say it is OK for people to give delayed consent to research after they wake up?

Delayed consent means asking for consent to do research on you after it has already been done. Choose the answer that is right for you.

Yes

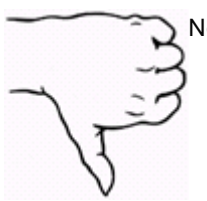


No

I do not have an answer

6. If the research can be done with people who can give informed consent is it OK to do the research with people who cannot give informed consent? Choose the answer that is right for you.

Yes

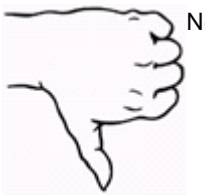


No

I do not have an answer

7. Do you think research should be done on a person that cannot give informed consent if the research may or may not help them but might help other people in the future? Choose the answer that is right for you.

Yes



No

I do not have an answer

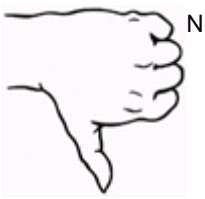
8. Why do you think this?

A lot of the valuable medical knowledge available to us now have originally arisen from past studies where the idea of "informed consent" wasn't necessarily around, let alone enforced. I think in order for future progress to be made,

researchers must be allowed to conduct experiments and access data sources that they need. I think the research need to be supported, as long as their design is ethically sound. From an utilitarian perspective I believe "authorised representatives" should be permitted to consent to participation in research that may help people in the future / extend human knowledge, not just those that concern the immediate health status of the incompetent person.

9. Do you think all people that want to do research with adults who cannot give informed consent should have to get the OK from an ethics committee to do it?Choose the answer that is right for you.

Yes



No

I do not have an answer

10. Why do you think this?

I think it ultimately depends on the nature of the research being conducted. For example, I believe observational, non-intrusive, retrospective or low-risk studies should be permitted without official consent as long as the privacy and anonymity of the participants are guaranteed. This would allow progress to be made at a much faster pace, without any negative impact on the participants.

11. Who do you think should have a say in whether or not a person who cannot give informed consent will be part of research?

You can choose as many as you want.

- [x] Someone who is Enduring Power of Attorney or Welfare Guardian for the person
- [x] Family / whanau of the person
- [x] The person's doctor (if they are not part of the research)
- [ ] The person who wants to do the research
- [ ] Someone else

12. Do you think anyone else should have a say in whether or not a person who cannot give informed consent will be part of research?

13. Do you want to say any more about question 11?

What happens next?

The **Health and Disability Commissioner** will:

- think about what everyone has said about people who cannot give **informed consent** being part of research

- decide what to tell the Government about whether changes are needed to the law on **informed consent** to be in research

- decide whether the **Code** needs to be changed about **informed consent** to be in research.

If the Health and Disability Commissioner thinks the **Code** needs to be changed he will ask everyone about the changes.

Your name

Organisation (if you represent an organisation)

Thank you.

Thank you for:

- reading this information
- thinking about the hard topics

- telling the **Health and Disability Commissioner** what you think.

This will help the **Health and Disability Commissioner** to know what needs to be done.

Health and Disability Commissioner
Te Toihau Hauora, Hauātanga

This information has been translated into Easy Read by People First New Zealand Inc. Ngā Tāngata Tuatahi

Started on 30 April 2017 at 9:50pm | Completed on 30 April 2017 at 10:52pm

some research uses people who are not able to say if they want to take part or not.

This is the form to tell the Health and Disability Commissioner what you think.

Questions and Answers

This form has **questions** to find out what you think about doing research with people who are not able to say if they want to take part or not.

Health and Disability Commissioner
Te Toihau Hauora, Hauātanga

Your **answers** will help the **Health and Disability Commissioner** know what needs to be done.

You do not have to **answer** all the questions.

Case studies and questions

Case studies are stories that help us to understand something.

5

Here are 5 case studies that show when research cannot be done without informed consent at the moment in New Zealand.

These may help you decide if the law should change.

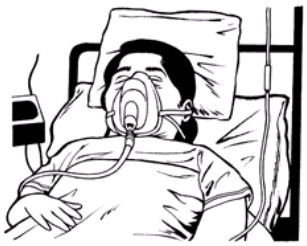
Each case study has questions that we would like you to answer.

Health and Disability Commissioner
Te Toihau Hauora, Hauātanga

Your answers to the questions will help the Health and Disability Commissioner know what is important to you.

Case study 1: Observational research on people with a bad infection

Some people with a bad infection will:



- get very sick
- not be able to tell other people what they think or feel

- have to take medicine to get healthy.

In this case study a doctor wants to do some research on people who:

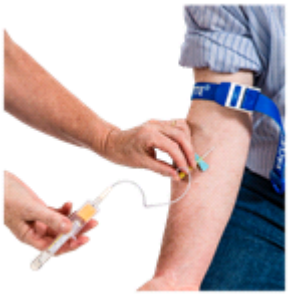
- have a bad infection

- have been given medicine.

The doctor will not change the medicine the people are getting.

The doctor:

- wants to know how much medicine these people need to take to get better



- will take samples from their bodies to find out how much medicine they need to take to get better.

The doctor wants to do this research on people who:

- cannot give informed consent to take part

- will not get better health from being part of the research
- will get the same medicine whether they take part in the research or not.

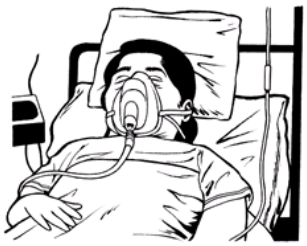
This research may help other people who get bad infections to get the medicine that will help them.

Questions about observational research on people with a bad infection

In these questions we will ask you to think about what you would choose to do if you were sick with a bad infection.

These questions are not about you.

The questions are a made up example.



1. If you had a bad infection and could not give informed consent would you want to take part in research about how much medicine is needed to get better?

Choose the answer that is right for you:

Yes

No

I do not have an answer

If you said yes to question 1:

2. Why would you want to take part in this research?

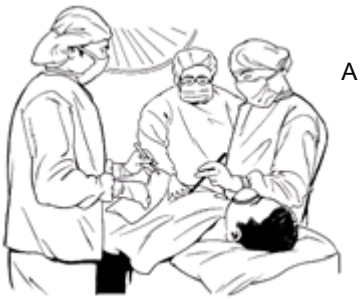
An infection could take hold very quickly - even with a reasonably healthy person before he / she could give consent.

If you said no to question 1:

3. Why would you not want to take part in this research?

4. Do you want to say any more about this question?

Case study 2: Research on brain operations



A person has to have a brain operation.

There are 2 things doctors use to make sure a person who has a brain operation is OK after their operation has finished.

No one knows which thing works best.

In this case study a doctor wants to do some research to find out which of the 2 things will work best for other people in the future to help them get better.

In the research the doctor will give some people 1 thing and other people a different thing.

The doctor will see which thing works best.

The people cannot say if they want to be part of the research or not.

The doctor wants to get **delayed consent** for the research from some of the people after their brain operation is done.

Delayed consent means asking for consent to do research on you after it has already been done.

Questions about research on brain operations

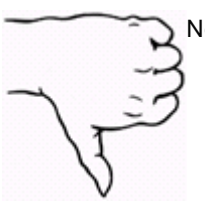
In these questions we will ask you to think about what you would choose to do if you were sick and have to have a brain operation.

These questions are not about you.

The questions are a made up example.

1. If you were not able to say yes or no to taking part in this research before your brain operation would you be OK with the doctor doing the research anyway?
Choose the answer that is right for you.

Yes



No

I do not have an answer

If you said yes to question 1

2. Why would you want to take part in this research?

If you said no to question 1

3. Why would you not want to take part in this research?

Would wish to know before hand what the percentage of success would be. Up in the 90 to 100% would be acceptable - wouldn't want to become a vegetable or some totally frustrated.

4. Do you want to say any more about this question?

5. Do you think delayed consent is ok? Choose the answer that is right for you.

Yes

No

I do not have an answer

If you said yes to question 5:

6. Why do you think delayed consent is OK?

Only if the doctor /surgeon is totally confident that he/she is totally confident and well practiced at rectifying the problem.
Also whereby quick action can save the patient and return him/her to a very good state of health.
Not to have a shot in the dark type of experiment.

If you said no to question 5:

7. Why do you think delayed consent is not OK?

Case study 3: Research on people who have a brain disease

Sometimes people get a brain disease that makes it hard for them to:

- remember
- say what they think and feel.

In this case study a doctor wants to do some research on the care given to these people.

Some people will get 1 kind of care and others will get different care.

The doctor will see if any of the people get better.

No one knows if taking part in the research will mean the people will get better or worse.

The doctor does not know if the research will mean better care for people in the future or not.

The research is trying to find this out.

Some of the people the doctor wants to do research on cannot give **informed consent** to take part in the research.

Questions about research on people who have a brain disease

In these questions we will ask you to think about what you would want to happen if you had a brain disease.

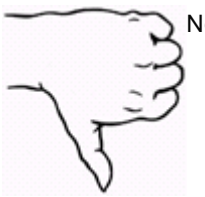
These questions are not about you.

The questions are a made up example.

1. If you had a brain disease and could not give informed consent would you want to take part in this research?
Choose the answer that is right for you.

- Yes

- No



- I do not have an answer

If you said yes to question 1

2. Why would you want to take part in this research?

If you said no to question 1

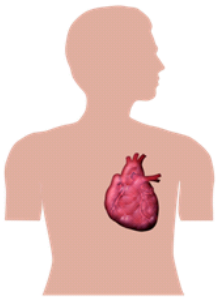
3. Why would you not want to take part in this research?

This tends to suggest an experiment on a non consenting person. This should be referred to the chosen person- enduring power of attorney or welfare Guardian.
However, once certified totally dead - may take brain for research.

4. Do you want to say any more about this question?

Case study 4: Research on people who are having a cardiac arrest

Cardiac arrest is when you have a big problem with your heart and it stops working.



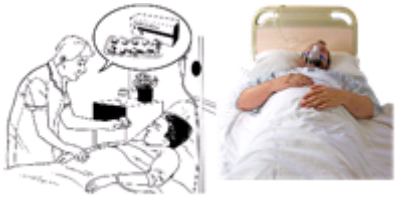
Most of the time when a person's heart stops they are given a medicine.

No one knows if the medicine helps or hurts people.

In this case study a doctor wants to research whether the medicine helps people whose heart has stopped.

If somebody's heart stops working they will not be awake.

This means the doctor will not be able to ask for **informed consent** to take part in the research.



The doctor wants to give some people the medicine and others no medicine to see which group gets better.

People can choose to **opt out** of this research.

Opt out means you say you do **not** want to take part in the research if your heart stops in the future.

People who want to **opt out** of this research can wear a bracelet that says **no study** on it.

To do this people need to:

- ask for a bracelet in case their heart stops 1 day in the future
- wear the bracelet

Questions about research on people that are having a cardiac arrest

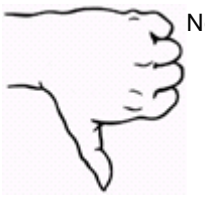
In these questions we will ask you to think about what you would want to happen if your heart stopped working.

These questions are not about you.

The questions are a made up example.

1. If your heart stopped would you want to take part in research to find out if taking this medicine is better than no medicine?
Choose the answer that is right for you.

Yes



No

I do not have an answer

If you said yes to question 1

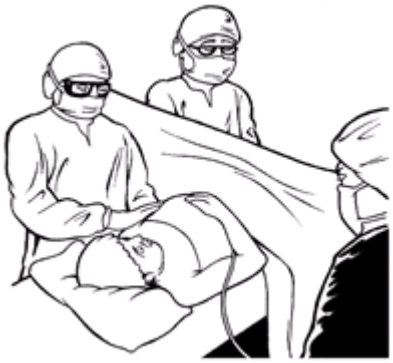
2. Why would you want to take part in this research?

If you said no to question 1

3. Why would you not want to take part in this research?

4. Do you want to say any more about this question?

This depends. If you are young and other known body functions are good, by all means do the best.
If you are old and have other diseases or disabilities or, a do not resuscitate note then do not waste time.
Try the use of a defibrillator and consider the two suggestions above.
I am not in favour of any thing that has the faintest suggestion of experimentation.

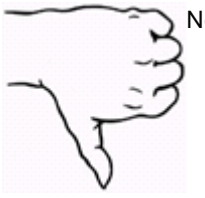


5. People who are wearing the bracelets will not be in the research if their heart stops.

Do you think it is OK for the doctors to do the research on anyone who is not wearing a bracelet when their heart stops?

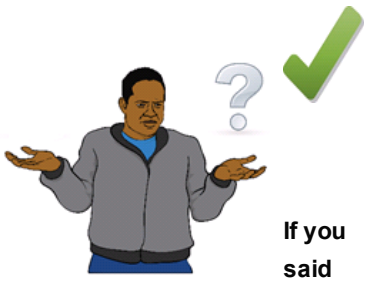
Choose the answer that is right for you.

Yes



No

I do not have an answer



If you said yes to question 5:

6. Why do you think this?

If you said no to question 5:

7. Why do you think this?

Case study 5: Research on people who have Down Syndrome

Down Syndrome is a learning disability.

In this case study a doctor wants to do some research to find out if a medicine can help people with Down Syndrome with their learning.

The medicine may make some people with Down Syndrome think sad things and want to hurt themselves.

Some people with Down Syndrome who take part in the research **will** get the medicine.

Some people with Down Syndrome who take part in the research will **not** get the medicine.

This is so that the doctor can see if the medicine is helping the people with Down Syndrome who get it.

Some people with Down Syndrome will be able to give **informed consent** to take part in the research.

Some people with Down Syndrome will **not** be able to give **informed consent** to take part in the research.

The doctor wants to have people with Down Syndrome in their research who:

- can give **informed consent** to take part
- cannot give **informed consent** to take part.

The doctor wants to be able to get **informed consent** from the family members or support workers of the people with Down Syndrome who cannot give **informed consent**.

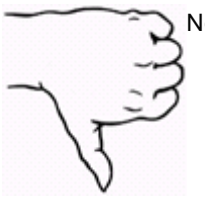
Questions about research on people with Down Syndrome

These questions are not about you.

The questions are a made up example.

1. Do you think people with Down Syndrome who cannot give informed consent should be in this research? Choose the answer that is right for you.

Yes



No

I do not have an answer

If you said yes to question 1:

2. Why do you think people with Down Syndrome who cannot give informed consent should be in this research?

If you said no to question 1:

3. Why do you think people with Down Syndrome who cannot give informed consent should not be in this research?

They need informed consent with family and doctor and a Down syndrome specialist in a stable discussion with ALL options being exposed.

4. Do you want to say any more about this question?

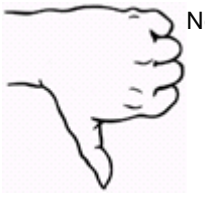
5. Do you think other people should decide if people with Down Syndrome will be in this research?

These other people could be:

- **family / whānau**
- **support workers**

Choose the answer that is right for you.

Yes



No

I do not have an answer

If you said yes to question 5:

6. Why do you think this?

If you said no to question 5:

7. Why do you think this?

8. Do you want to say any more about this?

Questions about informed consent

Here are some more questions.

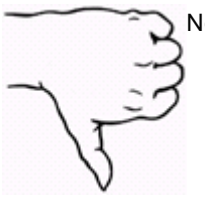
These questions will ask you what you think about **informed consent** to take part in research.

Health and Disability Commissioner
Te Toihau Hauora, Hauātanga

Your answers will help the **Health and Disability Commissioner** know what is important to you.

1. Do you think it is OK for adults who cannot give informed consent to take part in research when no one knows if it will help them or hurt them?
Choose the answer that is right for you.

Yes



No

I do not have an answer

2. When do you think it is OK for adults who cannot give informed consent to take part in research?

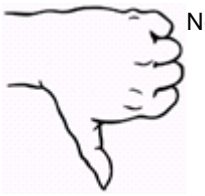
Never

3. Some people doing research are not health or disability providers so they do not have to follow the Health and Disability Code of Rights.

Do you think everyone doing health and disability research should have to follow the Code?

Choose the answer that is right for you.

Yes



No

I do not have an answer

4. Do you think the law should say that if any person taking part in research looks like they are scared or in pain they should not be part of the research anymore?

Choose the answer that is right for you.

Yes

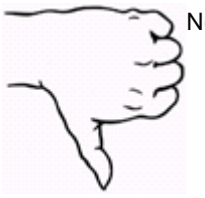
No

I do not have an answer

5. Do you think the law should change to say it is OK for people to give delayed consent to research after they wake up?

Delayed consent means asking for consent to do research on you after it has already been done. Choose the answer that is right for you.

Yes

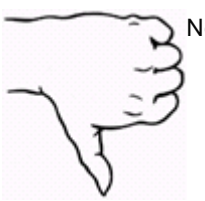


No

I do not have an answer

6. If the research can be done with people who can give informed consent is it OK to do the research with people who cannot give informed consent? Choose the answer that is right for you.

Yes

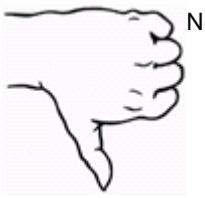


No

I do not have an answer

7. Do you think research should be done on a person that cannot give informed consent if the research may or may not help them but might help other people in the future? Choose the answer that is right for you.

Yes



No

I do not have an answer

8. Why do you think this?

Because they are still a person and still have rights.
They may be so sick, fed up, worn out and frustrated that they may just wish to pass away.

9. Do you think all people that want to do research with adults who cannot give informed consent should have to get the OK from an ethics committee to do it?Choose the answer that is right for you.

Yes

No

I do not have an answer

10. Why do you think this?

As from previous answer.

Let one of the ethics committee volunteer to have the experiments done on them.

11. Who do you think should have a say in whether or not a person who cannot give informed consent will be part of research?

You can choose as many as you want.

- [x] Someone who is Enduring Power of Attorney or Welfare Guardian for the person
- [x] Family / whanau of the person
- [x] The person's doctor (if they are not part of the research)
- [ ] The person who wants to do the research
- [ ] Someone else

12. Do you think anyone else should have a say in whether or not a person who cannot give informed consent will be part of research?

The North Korean dictator. (Bad Joke!)
My answer is no.

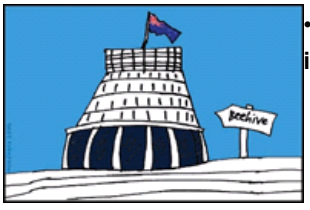
13. Do you want to say any more about question 11?

By having a group of people close to the patient a consensus of the person's wishes with surface and be carried out as stated.

What happens next?

The **Health and Disability Commissioner** will:

- think about what everyone has said about people who cannot give **informed consent** being part of research



- decide what to tell the Government about whether changes are needed to the law on **informed consent** to be in research

- decide whether the **Code** needs to be changed about **informed consent** to be in research.

If the Health and Disability Commissioner thinks the **Code** needs to be changed he will ask everyone about the changes.

Your name

Organisation (if you represent an organisation)

Thank you.

Thank you for:

- reading this information
- thinking about the hard topics

- telling the **Health and Disability Commissioner** what you think.

This will help the **Health and Disability Commissioner** to know what needs to be done.

Health and Disability Commissioner
Te Toihau Hauora, Hauātanga

This information has been translated into Easy Read by People First New Zealand Inc. Ngā Tāngata Tuatahi