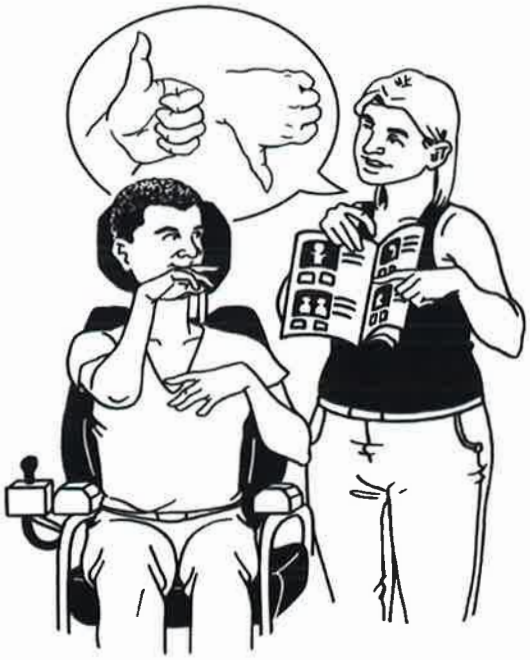
Health and Disability Commissioner
Te Toihau Hauora, Hauātanga

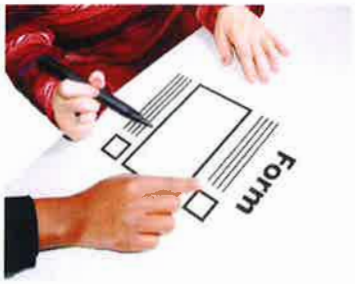
Some research involves people who are not able to say if they want to take part or not



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

Easy Read

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

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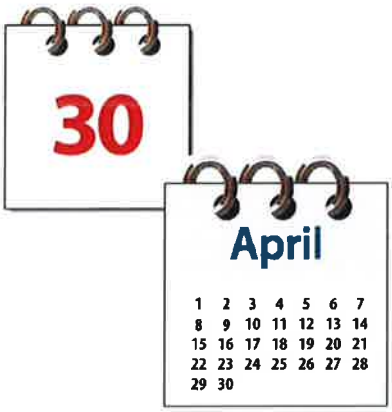

The last day to give feedback to the **Health and Disability Commissioner** on informed consent to be in research is **Sunday 30 April 2017**.

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

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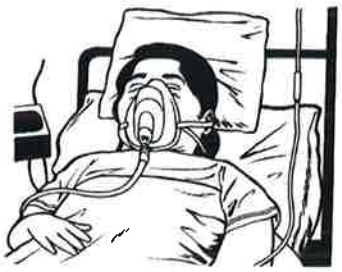
Case study 1: Observational research on people with a bad infection



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.

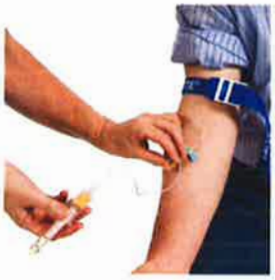
In this case study a doctor wants to do some research on people who:

- 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:

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- 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.

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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.

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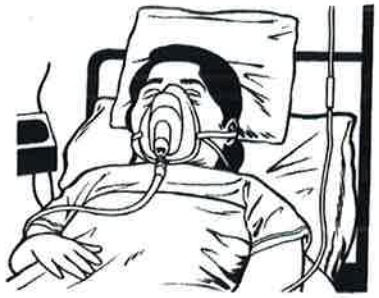


1. If you had a bad infection and could not give **informed consent** would you want to take part in research about how much medicine is needed to get better?

Tick 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?

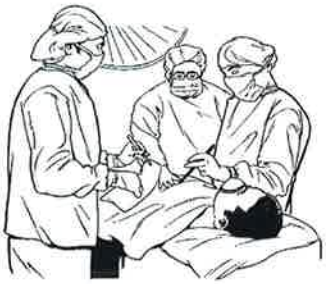
If you said no to question 1:

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

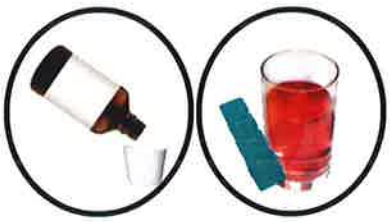
4. Do you want to say any more about this question?

I don't want to answer because it is a personal question.

Case study 2: Research on brain operations



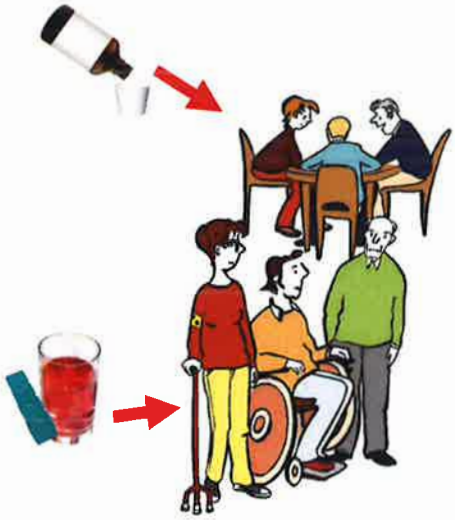
A person has to have a brain operation.



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.

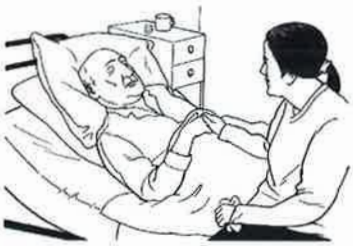
Delayed consent means asking for consent to do research on you after it has already been done.

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?

Tick 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?

I don't know because it is too hard to answer. I don't think that they should ask for consent after it has been done because it has already been done.

5. Do you think **delayed consent** is OK?

Tick the answer that is right for you:

○ Yes

☑ No

○ I do not have an answer

If you said yes to question 5:

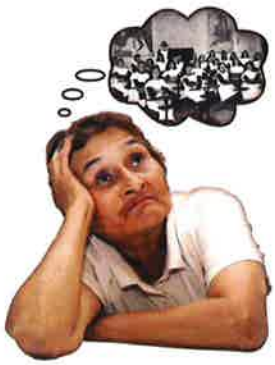
6. Why do you think **delayed consent** is OK?

If you said no to question 5:

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

See answer for Question 5

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?

Tick 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?

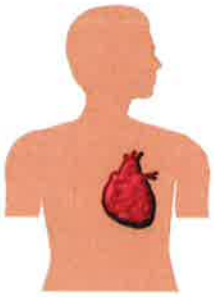
If you said no to question 1:

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

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

It's too hard to understand

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 that 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 the medicine is better than no medicine?

Tick the answer that is right for you:

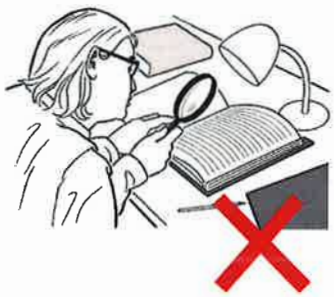
○ Yes

○ 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?

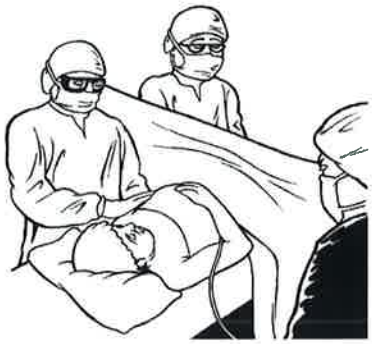


If you said no to question 1:

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

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

I feel this is too personal for me to answer.



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?

Tick 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?

It's ok so long as the person is told once they have woken up.

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?

Tick 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?

I think that family members can be trusted to make decisions that are in peoples best interests.

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.

Tick 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 Question 2.

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?

Tick 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 people who know & love the person can make a decision in their best interests.

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**?

Tick 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?

Tick 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.

Tick 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**?

Tick 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 who cannot give **informed consent** if the research may or may not help them but might help other people in the future?

Tick the answer that is right for you:

○ Yes

○ No

I do not have an answer

8. Why do you think this?

I don't know because it is too hard to answer

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

Tick 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 do as many ticks as you want.

- [x] Someone who is **Enduring Power of Attorney** or **Welfare Guardian** for the person
- [x] Family / whānau 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.

Thank you

Thank you for:

- reading this information

- thinking about the hard topics
- telling the **Health and Disability Commissioner** what you think.

Health and Disability Commissioner
Te Toihau Hauora, Hauātanga

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

Your name_ _____

Organisation (if you represent an organisation)_____

_ _____

Health and Disability Commissioner
Te Toihau Hauora, Hauātanga

Health and Disability Commissioner

PO Box 11934, Wellington 6142

Free phone: 0800 11 22 33

Fax: 04 494 7901

Email: hdc@hdc.org.nz

Website: www.hdc.org.nz

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

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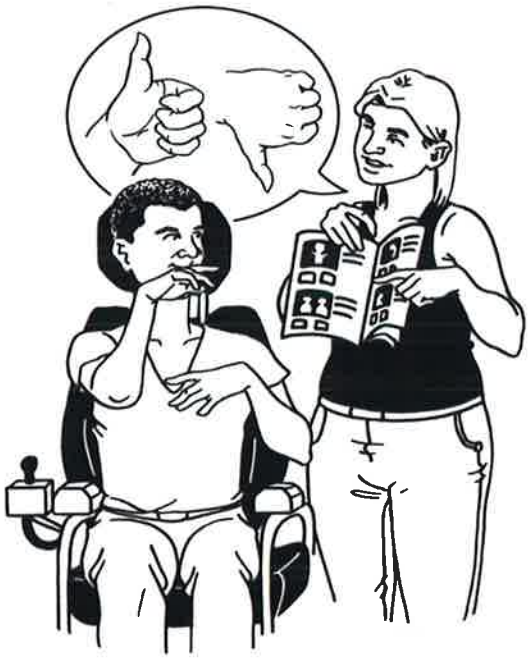

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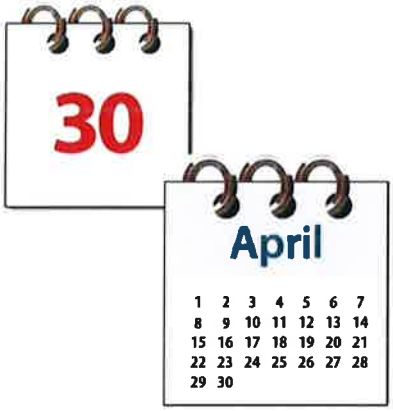

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These may help you decide if the law should change.

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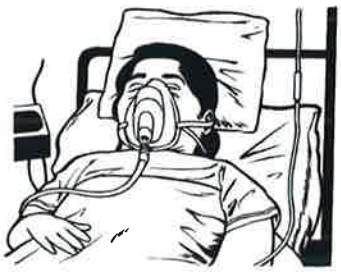


Some people with a bad infection will:

- get very sick
- not be able to tell other people what they think or feel
- have to take medicine to get healthy.

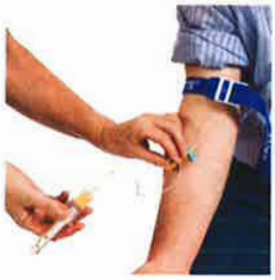
In this case study a doctor wants to do some research on people who:

- 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.

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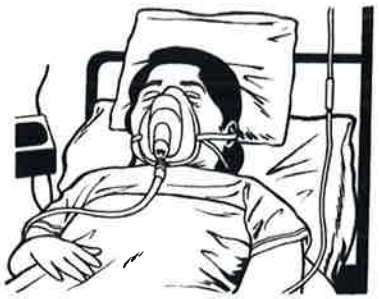


1. If you had a bad infection and could not give **informed consent** would you want to take part in research about how much medicine is needed to get better?

Tick the answer that is right for you:

○ Yes

○ No

○ I do not have an answer

If you said yes to question 1:

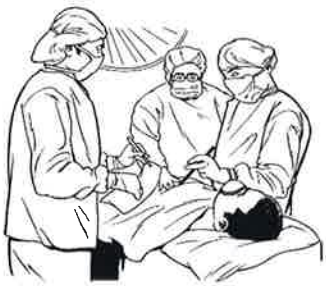
2. Why would you want to take part in this research?

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

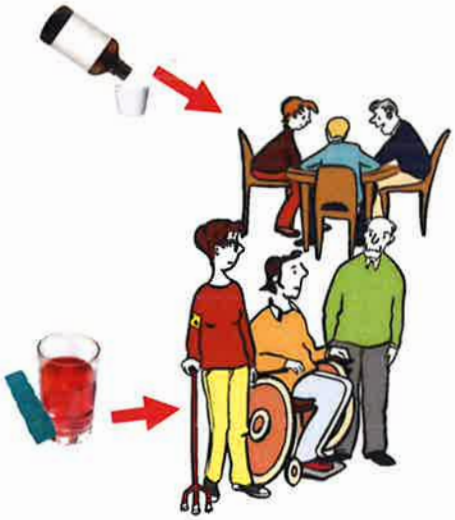


A person has to have a brain operation.

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.

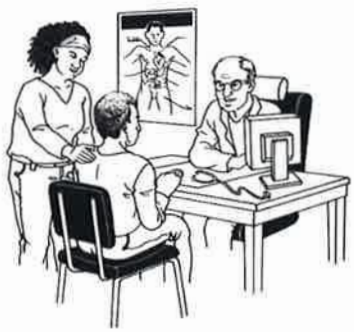


In the research the doctor will give some people 1 thing and other people a different thing.

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?

Tick 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?

Tick 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?

Tick 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 could get an allergic reaction from the research.

I don't know what is in it.

I don't want to harm my body.

I dont want bad side effects and reactions.

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

I worry that the government wouldn't pay for the medicine after the research. It is important that people can get access to things that can help them.

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 that 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 the medicine is better than no medicine?

Tick the answer that is right for you:

○ Yes

○ No

○ I do not have an answer

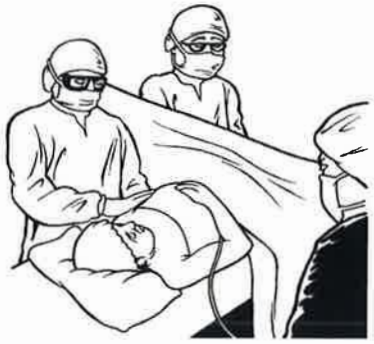
If you said yes to question 1:

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?

Tick 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?

Tick 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 do bad things to themselves when they feel bad.

Main problem is that the medicine can make them feel bad. Bad side effects or allergic reaction. When people feel bad, they could hurt other people.

People should be protected. and the notes should be locked up to protect their privacy.

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

Research notes should be locked up for privacy.

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.

Tick 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, it is only okay if someone thinks about what the person with down Syndrome would want. They speak for them. They look at them to get their facial expressions so they know what they want.

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?

Tick 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 have an answer.

People should be protected from harm

People should be safe

It is only okay for other people to agree for you to take part in research if they think about what you want.

The person should look at you and talk to you to try find out what you want.

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**?

Tick 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?

Tick 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?

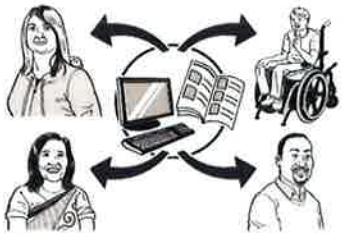
Delayed consent means asking for consent to do research on you after it has already been done.

Tick 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**?

Tick 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 who cannot give **informed consent** if the research may or may not help them but might help other people in the future?

Tick the answer that is right for you:

○ Yes

☑ No

○ I do not have an answer

8. Why do you think this?

They should look at what you want, that should be the key factor.

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

Tick the answer that is right for you:

☑ Yes

○ No

○ I do not have an answer

10. Why do you think this?

because researchers need to rethink what they say and want to do.

People (researchers) should follow rules and standards that protect 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 do as many ticks as you want.

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

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?

It should only happen if they give you eye contact and figure out what you want.

If I do know the person, and they know me well, then it is okay.

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.

Thank you

Thank you for:

- reading this information

- thinking about the hard topics
- telling the **Health and Disability Commissioner** what you think.

Health and Disability Commissioner
Te Toihau Hauora, Hauātanga

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

Your name_____

Organisation (if you represent an organisation)_____

_____

Health and Disability Commissioner
Te Toihau Hauora, Hauātanga

Health and Disability Commissioner

PO Box 11934, Wellington 6142

Free phone: 0800 11 22 33

Fax: 04 494 7901

Email: hdc@hdc.org.nz

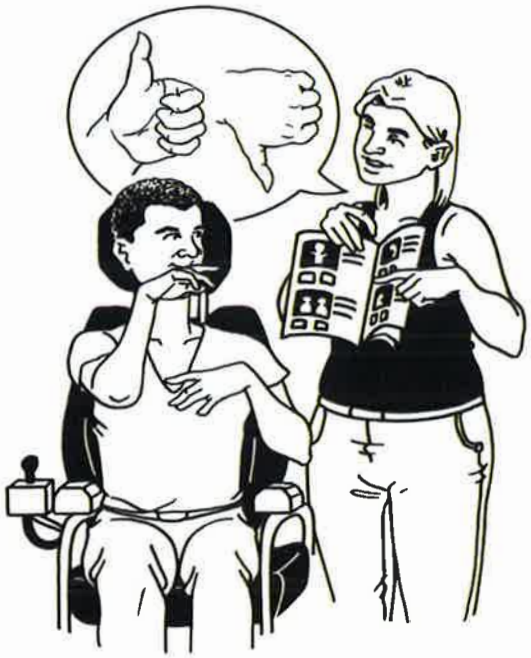
Website: www.hdc.org.nz

PeopleFirst
New Zealand
Ngā Tāngata Tuatahi

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

Health and Disability Commissioner
Te Toihau Hauora, Hauātanga

Some research involves 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

Easy Read

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 of the questions.

If you want to fill in the form online you can find it here:

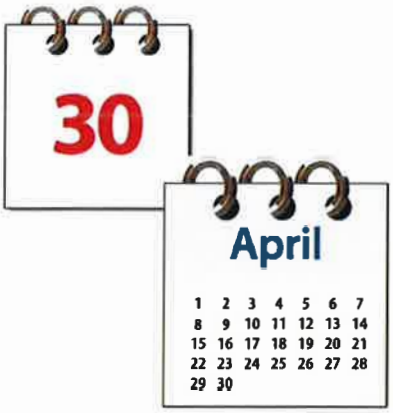
http://online.hdc.org.nz/surveys/ysi9n3Tpq0uAhQjUUA89OQ

If you want to print out the form you can find it here:

http://hdc.org.nz/the-act--code/right-7(4)-consultation/easy-read-right-7(4)-consultation

If you print out this form you should send it to:

Health and Disability Commissioner
PO Box 11934
Wellington 6142



The last day to give feedback to the **Health and Disability Commissioner** on informed consent to be in research is **Sunday 30 April 2017**.

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.

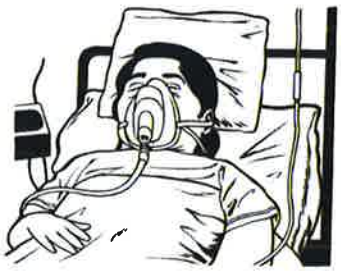
These may help you decide if the law should change.

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.

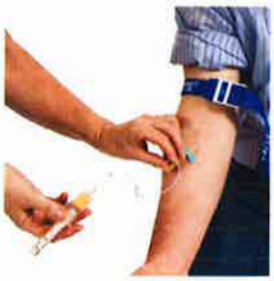
In this case study a doctor wants to do some research on people who:

- 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.

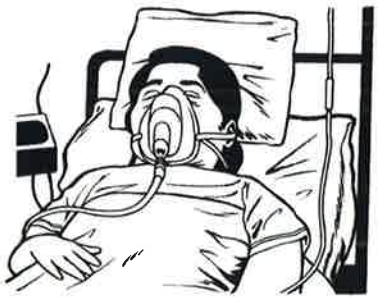
This research may help other people who get bad infections to get the medicine that will help them.

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.

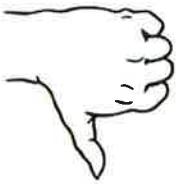
The questions are a made up example.



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?

Tick 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:

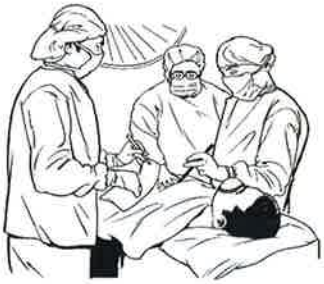
3. Why would you not want to take part in this research?

I can't give consent because I am too sick. The research would mean that I had extra things like blood tests and urine tests.

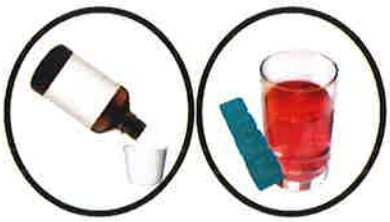
I think the research should happen with people who can still give consent because it is an important topic for research as it might stop superbugs / the overuse of antibiotics in the future.

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?

Tick 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 think that the research should only include people who are having brain surgery who can give their consent before the surgery happens.

Even if you say no when you are asked to give delayed consent after surgery — the research has already happened!

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

5. Do you think **delayed consent** is OK?

Tick 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?

Because even if you say no, the research has already happened, and you have already been part of it. Saying no afterwards doesn't change that you have been through the research processes.

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?

Tick 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?

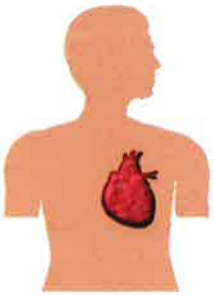
I would say yes but only if someone had talked to me about my will and preferences about my health treatment and my involvement in research. That way I could make my own decisions about the type of research that I would want to take part in.

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 that 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 the medicine is better than no medicine?

Tick the answer that is right for you:

☑ Yes

○ No

○ I do not have an answer

If you said yes to question 1:

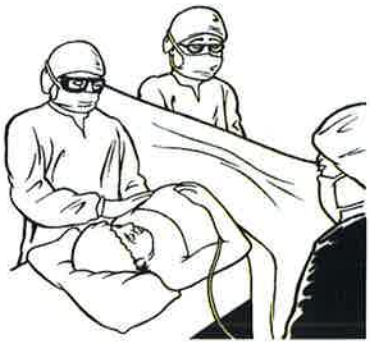
2. Why would you want to take part in this research?

I would only want to take part in this study if I had been made aware of it, and had made my own decision not to say no (opt out) by wearing the bracelet.

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?

Tick 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 lots of people may not have heard about the research and that is why they are not wearing the bracelet,

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?

Tick 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 of the risks of this study - that they might have suicidal thoughts, feel depressed, angry. If people can't consent, they wouldn't be able to express these side effects and that makes it even more dangerous for them to take part.

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.

Tick 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 + support worker might not know about how you feel about your body, and whether you want to take part.

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?

Tick 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 want the current rules to stay.

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**?

Tick 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?

Tick 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.

Tick 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**?

Tick 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 who cannot give **informed consent** if the research may or may not help them but might help other people in the future?

Tick 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 who want to do research with adults that cannot give **informed consent** should have to get the OK from an **ethics committee** to do it?

Tick 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 do as many ticks as you want.

- ○ Someone who is **Enduring Power of Attorney** or **Welfare Guardian** for the person
- ○ Family / whānau 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?

If another person is involved in making a decision they need to know the person really well, and think about that person's will and preference.

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.

Thank you

Thank you for:

- reading this information

- thinking about the hard topics
- telling the **Health and Disability Commissioner** what you think.

Health and Disability Commissioner
Te Toihau Hauora, Hauātanga

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

Your name_ _____

Organisation (if you represent an organisation)_____

_____

Health and Disability Commissioner
Te Toihau Hauora, Hauātanga

Health and Disability Commissioner

PO Box 11934, Wellington 6142

Free phone: 0800 11 22 33

Fax: 04 494 7901

Email: hdc@hdc.org.nz

Website: www.hdc.org.nz

PeopleFirst
New Zealand
Ngā Tāngata Tuatahi

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

Health and Disability Commissioner
Te Toihau Hauora, Hauātanga

Some research involves 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

Easy Read

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 of the questions.

If you want to fill in the form online you can find it here:

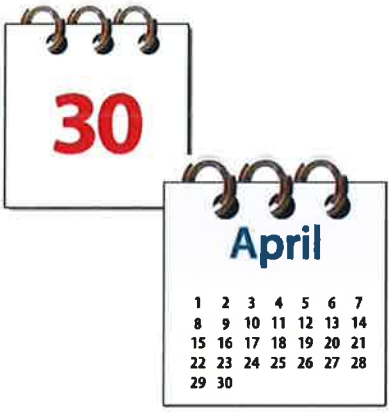
http://online.hdc.org.nz/surveys/ysi9n3Tpq0uAhQjUUA89OQ

If you want to print out the form you can find it here:

http://hdc.org.nz/the-act--code/right-7(4)-consultation/easy-read-right-7(4)-consultation

If you print out this form you should send it to:

Health and Disability Commissioner
PO Box 11934
Wellington 6142



The last day to give feedback to the **Health and Disability Commissioner** on informed consent to be in research is **Sunday 30 April 2017**.

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.

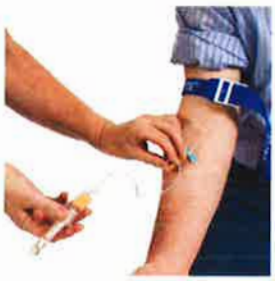
In this case study a doctor wants to do some research on people who:

- 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.

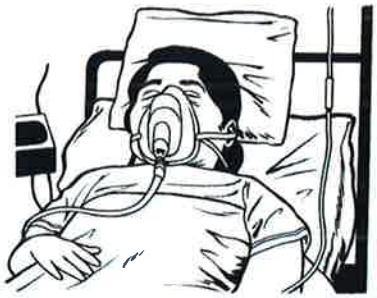
This research may help other people who get bad infections to get the medicine that will help them.

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?

Tick 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:

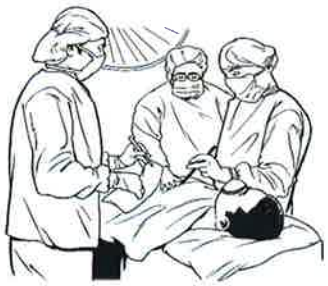
3. Why would you not want to take part in this research?

Won't be able to clearly express changes in progress through Recovery, eg: discomfort Give Feedback. further consideration

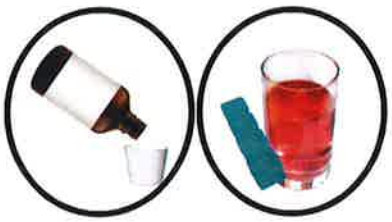
future - more focus on to now

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.

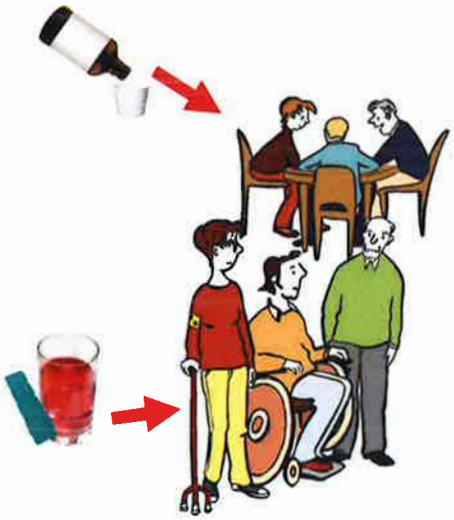


There are 2 things doctors use to make sure a person who has a brain operation is OK after their operation has finished.

two solutions

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.

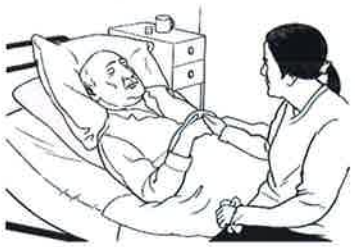
Delayed consent means asking for consent to do research on you after it has already been done.

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?

Tick 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?

Consent should only be
shared before surgery research
with delayed consent
It only really provides permission
to enter name into study or
not, not a meaningful Authentic
opion to say if you didnt want
be into study

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

5. Do you think **delayed consent** is OK?

Tick the answer that is right for you:

○ Yes

○ No

○ I do not have an answer

If you said yes to question 5:

~~6~~ 7. Why do you think **delayed consent** is not OK?

Once study complete the only
consent that you were giving
is permission to have name in
all I see it is as after post on
accrued event/treatment and say
you've been Ignored your right
of

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?

Tick the answer that is right for you:

○ Yes

○ No

○ I do not have an answer

pre enrolled
test

If you said yes to question 1:

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

I was aware early

as long as if only if my preference

were expressed before my injury got

Severe.

I can make my own choice to

select my contactable in [illegible]

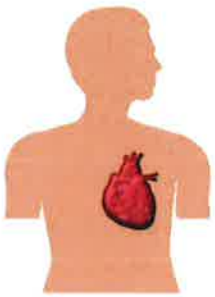
If you said no to question 1:

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

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

Emotional/social is provided for my sense of belonging. Eg Reablee in Routines!

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.

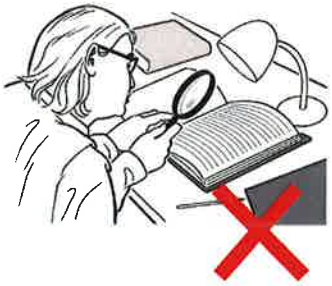
In this case study a doctor wants to research whether the medicine helps people whose heart has stopped.

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 that 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.

autonomic
Enclosure 1

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

Tick 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?

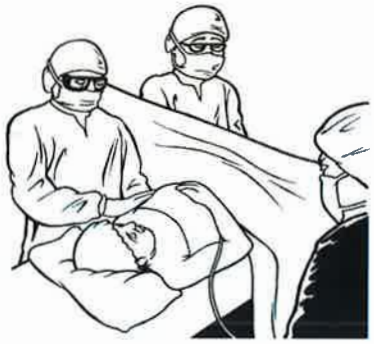
If you said no to question 1:

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

opt out gives me the automatic impression of Evidence that is with the process team's secretive/hidden perception

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

Being informed and having awareness of option of study



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?

Tick 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?

not aware of the process

of all

give options of the

study to complex to

Indicate the patience

of consent

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?

Tick 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?

Fairness and potential risk to discomfort

Research continue may not have a neg eg funds or support to recover what the young die to study outcomes

Emotionally worthless If by tele put (Risk)

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

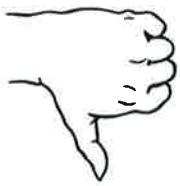
5. Do you think other people should decide if people with Down Syndrome will be in this research?

These other people could be:

- family / whānau
- support workers.

Tick 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?

if someone's happen then

FW/SW can feel like they

may have let into uncomfortable

situation then may need to

make one like to initiate recovery

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?

Tick the answer that is right for you:

○ Yes

☑ No

○ I do not have an answer

uncertaints or Rikes
un/Identified unclear no

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

only ok to save lifes

chance of survival.

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**?

Tick 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?

Tick the answer that is right for you:

☑ Yes

○ No

○ I do not have an answer

Included / collective

Need / everyone educate / ethic / researchers
Interpreter.

Include Intention.

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.

Tick 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**?

Tick the answer that is right for you:

○ Yes

⊘ No

○ I do not have an answer

Split/exclude.

7. Do you think research should be done on a person who cannot give **informed consent** if the research may or may not help them but might help other people in the future?

Tick the answer that is right for you:

○ Yes

○ No

○ I do not have an answer

8. Why do you think this?

if risk chances weigh out protected and of best wishes, I would call why the research should take place at

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

Tick the answer that is right for you:

Yes

No

I do not have an answer

10. Why do you think this?

it checked 80 sdeys and

wellbeing check of visits

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 do as many ticks as you want.

- ○ Someone who is **Enduring Power of Attorney** or **Welfare Guardian** for the person
- ○ Family / whānau 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

Should know Person Best

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?

Interpret / trust / faith / — = Best with

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

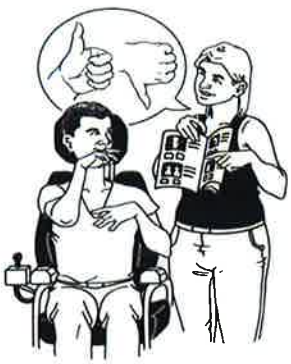
What happens next?

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.

Thank you

Thank you for:

- reading this information

- thinking about the hard topics
- telling the **Health and Disability Commissioner** what you think.

Health and Disability Commissioner
Te Toihau Hauora, Hauātanga

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

Your name_____

Organisation (if you represent an organisation)_____

_____

Health and Disability Commissioner
Te Toihau Hauora, Hauātanga

Health and Disability Commissioner

PO Box 11934, Wellington 6142

Free phone: 0800 11 22 33

Fax: 04 494 7901

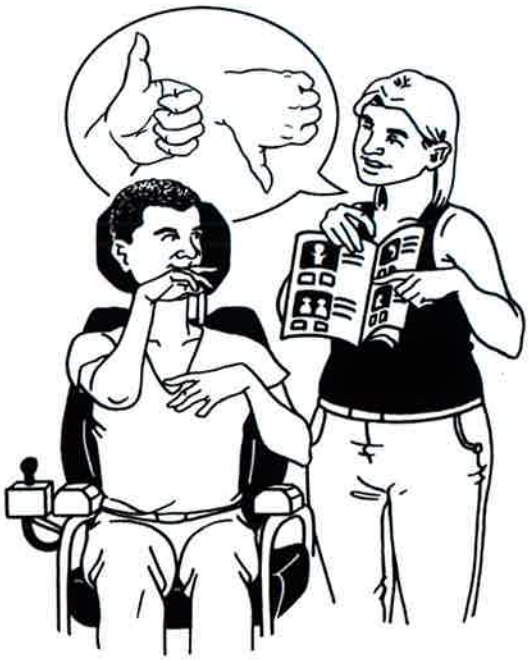
Email: hdc@hdc.org.nz

Website: www.hdc.org.nz

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

Health and Disability Commissioner
Te Toihau Hauora, Hauātanga

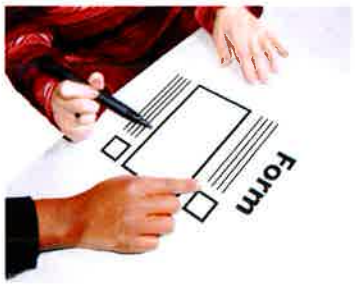
Some research involves people who are not able to say if they want to take part or not



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

Easy Read

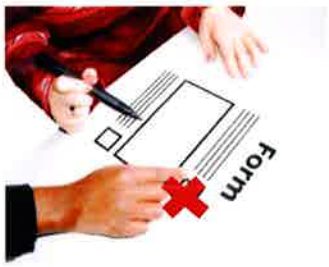
Questions and Answers



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.



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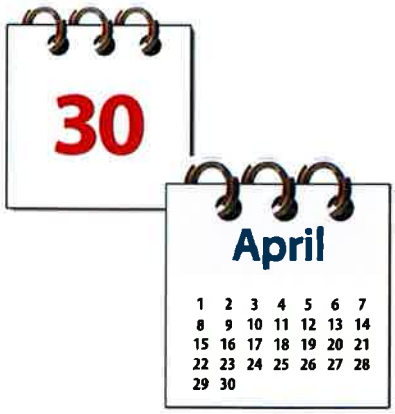
Health and Disability Commissioner
PO Box 11934
Wellington 6142



The last day to give feedback to the **Health and Disability Commissioner** on informed consent to be in research is **Sunday 30 April 2017**.

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

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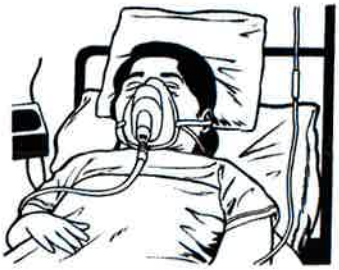
Case study 1: Observational research on people with a bad infection



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.

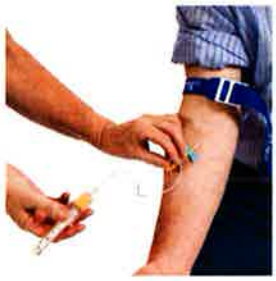
In this case study a doctor wants to do some research on people who:

- 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.

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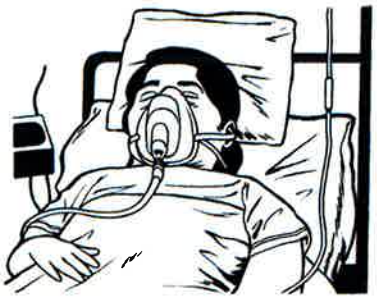


1. If you had a bad infection and could not give **informed consent** would you want to take part in research about how much medicine is needed to get better?

Tick the answer that is right for you:

○ Yes

☑ No

○ I do not have an answer

If you said yes to question 1:

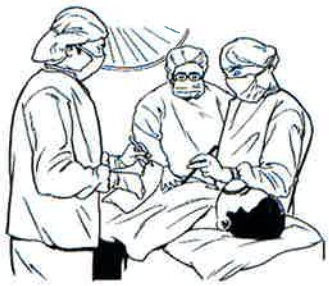
2. Why would you want to take part in this research?

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

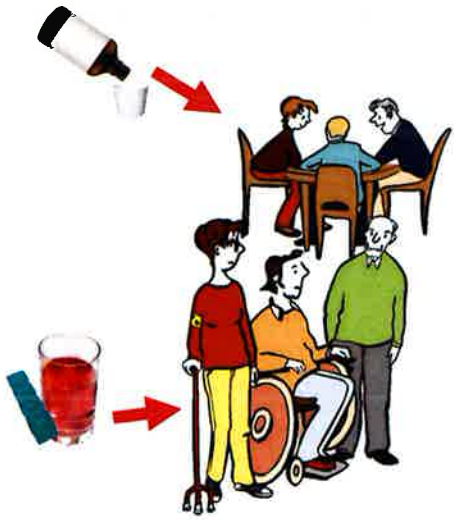


A person has to have a brain operation.

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.

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:

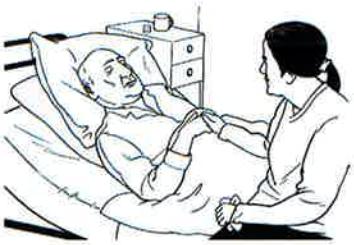
3. Why would you not want to take part in this research?

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?

Tick the answer that is right for you:

○ Yes

○ No

○ I do not have an answer

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

5. Do you think **delayed consent** is OK?

Tick 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?

Because the research has already happened. The person can't say no.

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.

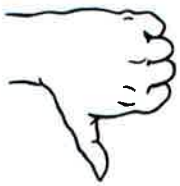
These questions are not about you.

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?

Tick 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 not a medical study.

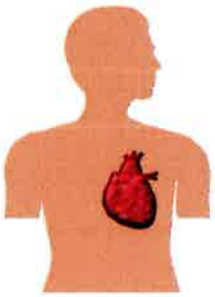
It could lead to good support.

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.

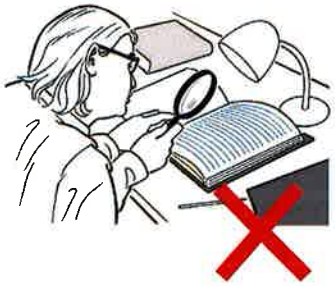
In this case study a doctor wants to research whether the medicine helps people whose heart has stopped.

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 that 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 the medicine is better than no medicine?

Tick the answer that is right for you:

○ Yes

☑ No

○ I do not have an answer

If you said yes to question 1:

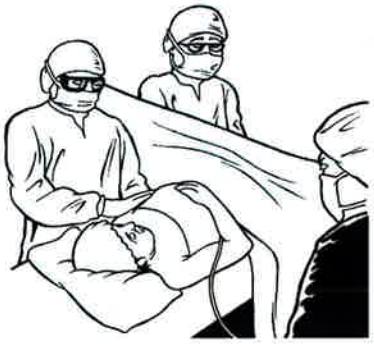
2. Why would you want to take part in this research?

If you said no to question 1:

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

It might be a risk to my health

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?

Tick 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 people might not be wearing the bracelet because they don't know about the study - not because they want to take-part.

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?

Tick 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 might make them depressed.

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.

Tick 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?

It depends on how close the person is to other people. Other people might help people make decisions, or make decisions for them. They need to be thinking about the person – not what they think.

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?

Tick 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 won't hurt them in any way.

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**?

Tick 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?

Tick 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?

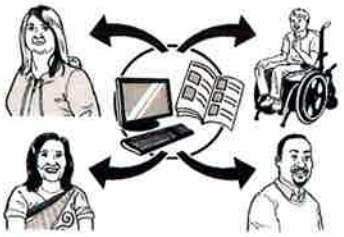
Delayed consent means asking for consent to do research on you after it has already been done.

Tick 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**?

Tick 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 who cannot give **informed consent** if the research may or may not help them but might help other people in the future?

Tick 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 who want to do research with adults that cannot give **informed consent** should have to get the OK from an **ethics committee** to do it?

Tick 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 do as many ticks as you want.

- ☑ Someone who is **Enduring Power of Attorney** or **Welfare Guardian** for the person
- ☑ Family / whānau 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?

Sometimes

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

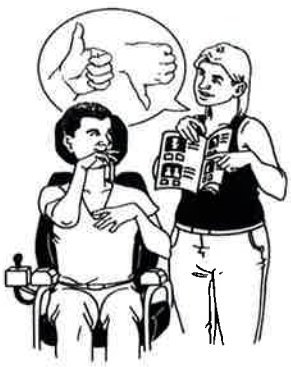
What happens next?

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.

Thank you

Thank you for:

- reading this information

- thinking about the hard topics
- telling the **Health and Disability Commissioner** what you think.

Health and Disability Commissioner
Te Toihau Hauora, Hauātanga

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

Your name__ _____

Organisation (if you represent an organisation)_____

_____

Health and Disability Commissioner
Te Toihau Hauora, Hauātanga

Health and Disability Commissioner

PO Box 11934, Wellington 6142

Free phone: 0800 11 22 33

Fax: 04 494 7901

Email: hdc@hdc.org.nz

Website: www.hdc.org.nz

This information has been translated into Easy Read

by People First New Zealand Inc. Ngā Tāngata Tuatahi

Health and Disability Commissioner
Te Toihau Hauora, Hauātanga

Some research involves 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

Easy Read

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.

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http://hdc.org.nz/the-act--code/right-7(4)-consultation/easy-read-right-7(4)-consultation

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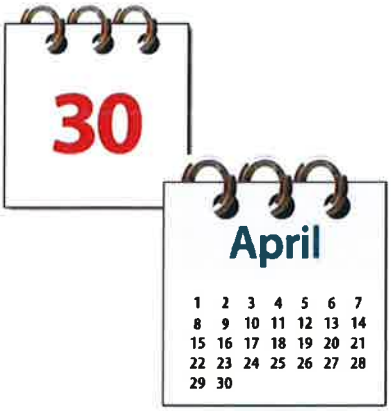

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These may help you decide if the law should change.

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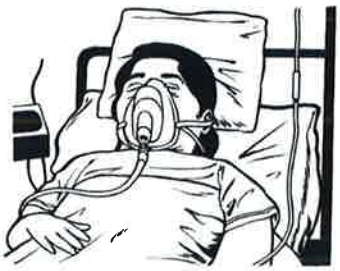
Case study 1: Observational research on people with a bad infection



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.

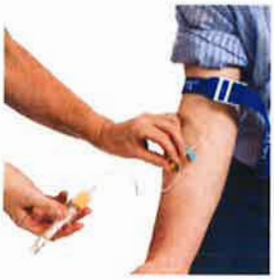
In this case study a doctor wants to do some research on people who:

- 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.

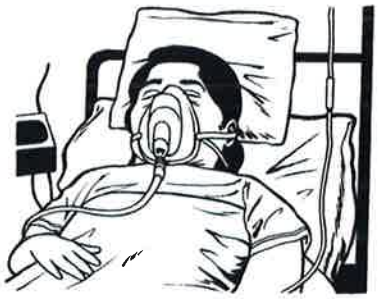
This research may help other people who get bad infections to get the medicine that will help them.

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?

Tick the answer that is right for you:

○ Yes

○ No

○ I do not have an answer

If you said yes to question 1:

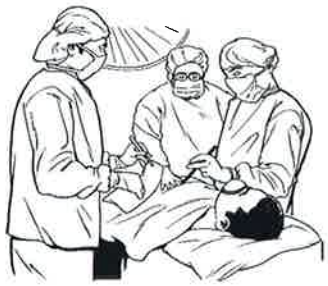
2. Why would you want to take part in this research?

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

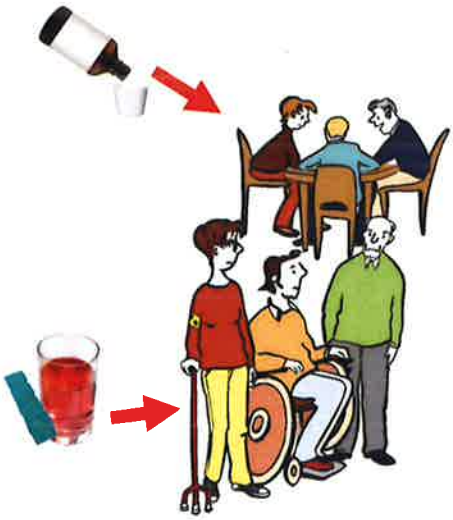


A person has to have a brain operation.

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.

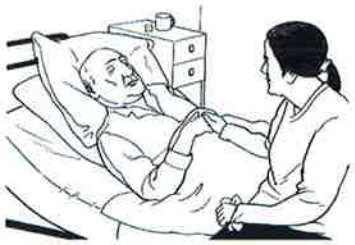
Delayed consent means asking for consent to do research on you after it has already been done.

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?

Tick 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?

Tick 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?

Tick 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?

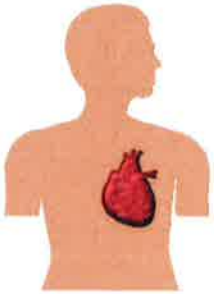
If you said no to question 1:

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

Thay may not
aderstand What is
and may may not
know how to say
yes or no to this
Treetment

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 that 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 the medicine is better than no medicine?

Tick the answer that is right for you:

○ Yes

○ No

○ I do not have an answer

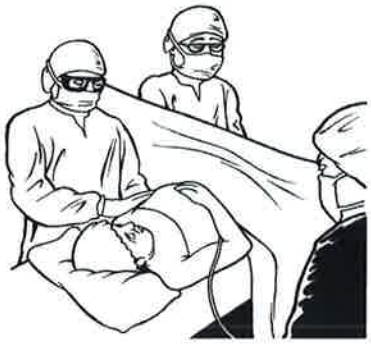
If you said yes to question 1:

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?

Tick 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

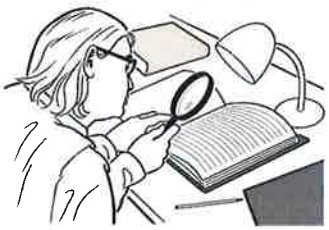
Down Syndrome is a learning disability.

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?

Tick 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 mite fell sade and upset or felling Down

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.

Tick 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?

I'm between yes and no because I think it could hurm them or put them at riste

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?

Tick 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?

Not okay.

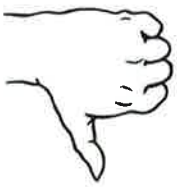
Because no one should make a decision for you to participate instead of you.

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**?

Tick the answer that is right for you:

○ Yes



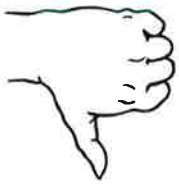
○ No

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?

Tick 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?

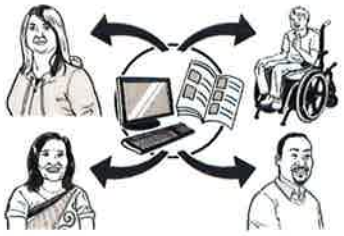
Delayed consent means asking for consent to do research on you after it has already been done.

Tick 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**?

Tick 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 who cannot give **informed consent** if the research may or may not help them but might help other people in the future?

Tick the answer that is right for you:

Yes

No

I do not have an answer

8. Why do you think this?

Because Thay could get hurf by the researsh

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

Tick 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 do as many ticks as you want.

- ○ Someone who is **Enduring Power of Attorney** or **Welfare Guardian** for the person
- ○ Family / whānau 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 because thay are not forlling their Rights

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.

Thank you

Thank you for:

- reading this information

- thinking about the hard topics
- telling the **Health and Disability Commissioner** what you think.

Health and Disability Commissioner
Te Toihau Hauora, Hauātanga

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

Your name_____

Organisation (if you represent an organisation)_____

_____

Health and Disability Commissioner
Te Toihau Hauora, Hauātanga

Health and Disability Commissioner

PO Box 11934, Wellington 6142

Free phone: 0800 11 22 33

Fax: 04 494 7901

Email: hdc@hdc.org.nz

Website: www.hdc.org.nz

This information has been translated into Easy Read

by People First New Zealand Inc. Ngā Tāngata Tuatahi

Health and Disability Commissioner
Te Toihau Hauora, Hauātanga

Some research involves 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

Easy Read

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 of the questions.

If you want to fill in the form online you can find it here:

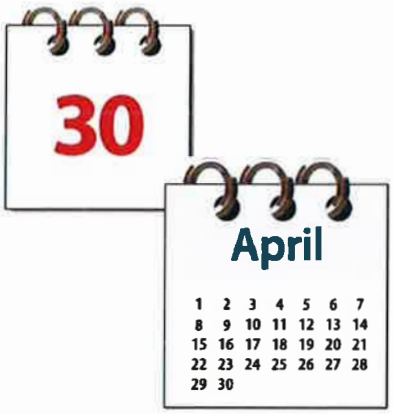
http://online.hdc.org.nz/surveys/ysi9n3Tpq0uAhQjUUA89OQ

If you want to print out the form you can find it here:

http://hdc.org.nz/the-act--code/right-7(4)-consultation/easy-read-right-7(4)-consultation

If you print out this form you should send it to:

Health and Disability Commissioner
PO Box 11934
Wellington 6142



The last day to give feedback to the **Health and Disability Commissioner** on informed consent to be in research is **Sunday 30 April 2017**.

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.

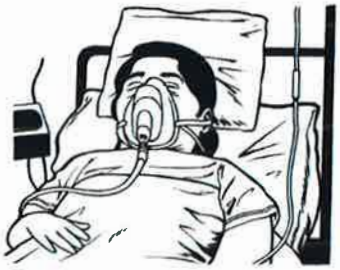
These may help you decide if the law should change.

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.

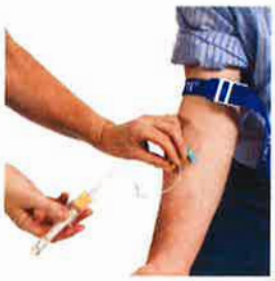
In this case study a doctor wants to do some research on people who:

- 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.

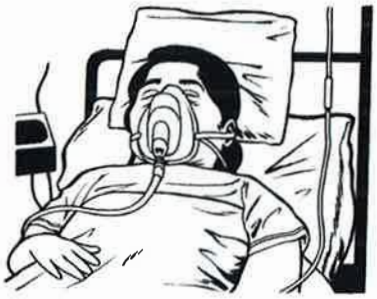
This research may help other people who get bad infections to get the medicine that will help them.

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?

Tick 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?

No

The person cannot consent, so people should not make consent on their behalf. The potential future benefits don't outweigh the people in the present. If the people could choose and consent, then the research could include them.

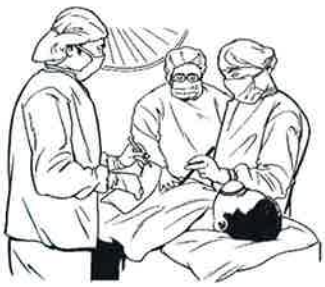
If you said no to question 1:

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

← See other page

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

Case study 2: Research on brain operations

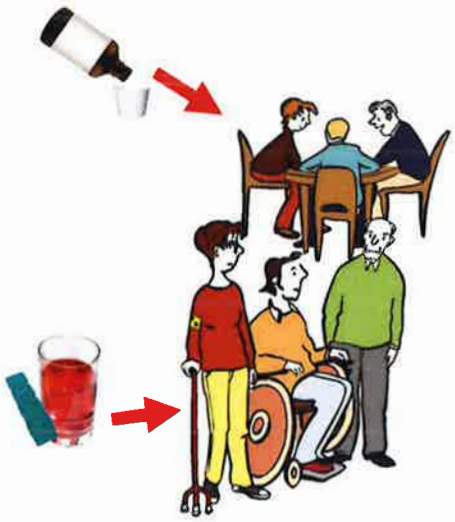


A person has to have a brain operation.

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.

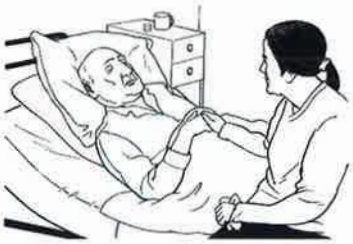
Delayed consent means asking for consent to do research on you after it has already been done.

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?

Tick 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?

The person has a right to refuse before the research happens.

People have a right to say yes or no.

They have a right to choose what happens to them.

It is important that research respects people's dignity.

Some people abuse research and don't respect people's dignity. Requiring consent can protect people's dignity.

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

Delayed consent: the research has already happened and you cant make a meaningful choice about what happens to you if the research has already happened.

5. Do you think **delayed consent** is OK?

Tick 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?

Because you cant make a meaningful choice about participating in research if it has already happened 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?

Tick 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, only if you talk to the people beforehand before they got too sick.

If people can't consent at the time and are in the research and they get stressed because of the research, then it should stop.

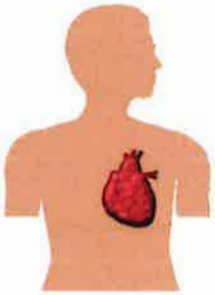
If you said no to question 1:

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

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

~~###~~ People should be talked to before they get sick and can't consent. They should be talked to about research or care they would be okay with in the future.

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 that 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 the medicine is better than no medicine?

Tick 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?

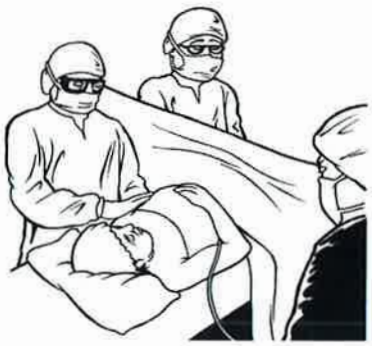
If you said no to question 1:

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

People are entitled to choose what treatment they get. The problem with this study is that they don't directly ask people what they want. And they don't talk each person through the different options and inform them

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

If possible, when someone attends doctors appointments, they should be talked to about their interests, will and preference so that we can get an idea of what the person would want in the future, if something happened.



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?

Tick 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?

Tick 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 have a right to choose

They have a right to know what medicines they are taking.

The person has a right to know what risks they are taking.

They have a choice.

It is important that we dont underestimate people and their ability to grasp important information.

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.

Tick 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 you have asked that person beforehand who they trust to make decisions for them.

Put who they trust in medical records and continuously check in with the person themselves.

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?

Tick 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**?

Tick 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?

Tick 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?

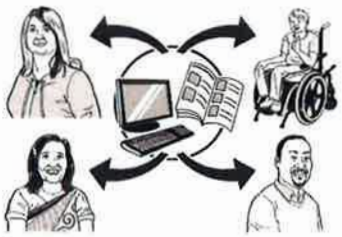
Delayed consent means asking for consent to do research on you after it has already been done.

Tick 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**?

Tick 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 who cannot give **informed consent** if the research may or may not help them but might help other people in the future?

Tick the answer that is right for you:

○ Yes

☑ No

○ I do not have an answer

8. Why do you think this?

It is important to respect the person themselves in the present. (personally) It is not about people in the future.

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

Tick the answer that is right for you:

☑ Yes

○ No

○ I do not have an answer

10. Why do you think this?

To protect people's rights.
(including people's right to
choose and have dignity).

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 do as many ticks as you want.

☑ Someone who is **Enduring Power of Attorney** or **Welfare Guardian** for the person

☑ Family / whānau 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?

Only if the person themselves has said they trust particular people. This should be in their medical records and doctors should check-in and ask who they trust.

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.

Thank you

Thank you for:

- reading this information

- thinking about the hard topics
- telling the **Health and Disability Commissioner** what you think.

Health and Disability Commissioner
Te Toihau Hauora, Hauātanga

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

Your name_

Organisation (if you represent an organisation)_____

_____

Health and Disability Commissioner
Te Toihau Hauora, Hauātanga

Health and Disability Commissioner

PO Box 11934, Wellington 6142

Free phone: 0800 11 22 33

Fax: 04 494 7901

Email: hdc@hdc.org.nz

Website: www.hdc.org.nz

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New Zealand
Ngā Tāngata Tuatahi

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