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

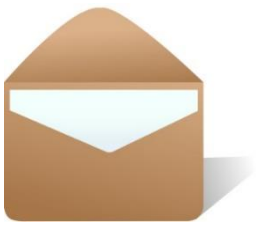
The Health and Disability Commissioner wants to know what you think about this

Easy Read

24 February 2017

What is in this book?

Health and Disability Commissioner
Te Toihau Hauora, Hauātanga



Thank you 81

Before you start

This is a long document.

While it is written in Easy Read it can be hard for some people to read a document this long.

Some things you can do to make it easier are:

- read it a few pages at a time
- have someone to assist you to understand it.

Some of the information in this document may make people upset when they are reading it.

This information is:

- not meant to scare anyone
- not true for everyone with learning disability.

This information **does not mean that these things will happen** to you or someone you know.

If you are worried about your health after reading this document, talk about it with your:

- family
- friends
- doctor.

About the Code

Health and Disability Commissioner
Te Toihau Hauora, Hauātanga

The **Code of Health and Disability Services Consumers' Rights** is a list of **10 rights** that people have when they are getting a health or disability service.

These rights are also called **the Code**.

The Code says that people who use health and disability services must be treated in a good way.

You can find the Easy Read Code of Rights here:

http://www.hdc.org.nz/the-act--code/the-code-of-rights

About the Health and Disability Commissioner

Health and Disability Commissioner
Te Toihau Hauora, Hauātanga

The **Health and Disability Commissioner** is in charge of making sure the **Code**:

- is followed by health and disability service providers
- looks after people's rights.

Health or disability research

Research is when you have a question about something and you are trying to find an answer.

Health or disability research means trying to find answers to questions about health or disability.

Health or disability research tries to get more information on how to make things better for people that:

- have health problems
- have disabilities.

It is important to know that research does not always help people to get better.

Sometimes the only way to find out if a medicine or treatment helps people is to try it to see if it works.

In some research:

- some of the people taking part get the treatment or medicine and other people do not

- the treatment or medicine they are testing may end up not helping people
- the treatment or medicine they are testing may end up hurting some people.

Health and Disability Commissioner
Te Toihau Hauora, Hauātanga

The **Health and Disability Commissioner** can only control **health and disability research** done by people who provide:

- health services
- disability services.

Health and Disability Commissioner
Te Toihau Hauora, Hauātanga

The **Health and Disability Commissioner** cannot control any **health and disability studies** that are not done by people who provide:

- health services
- disability services.

The Code says people have the right to:

- be asked if they want to take part in health or disability research
- get all of the information they need to decide if they want to take part or not
- say yes or no to taking part in health or disability research.

Health or disability research done by health or disability service providers must follow the rules of **the Code**.

Health or disability research done by people who are not health or disability service providers **does not** have to follow the rules of **the Code**.

Nothing about us without us

Every person who uses health and disability services is different.

Some people who use health and disability services may want to take part in research.

Some people who use health and disability services may not want to take part in research.

Everyone has the right to choose if they want to be in research or not.

Informed Consent

Health and Disability Commissioner
Te Toihau Hauora, Hauātanga

The Code says you have the right to give **informed consent**.

To give **informed consent** to be in research you:

- **get** information about the research
- **understand** the information about the research
- **agree** to be in the research
- sign your name to say **yes**.

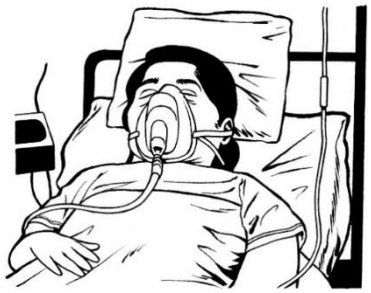
It is OK to change your mind about taking part in research.

This means:

- you do not give your **consent** anymore
- you will not be part of the research anymore.

Sometimes it is OK to treat someone without informed consent

Sometimes it is OK to give health and disability services to someone without **informed consent**.



For example it is OK to save the life of a person who is sick or hurt and not able to wake up.

Sometimes it is also OK to do health and disability research on people without informed consent

This is not allowed very often.

There are many rules about when this can happen.

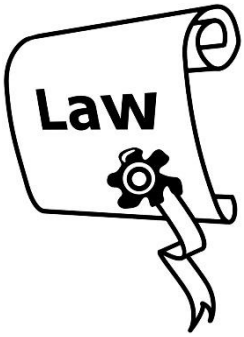
These rules are there to protect people who cannot understand the information about the research or say what they think or feel.

It is important to make sure that bad things do not happen to people who cannot:

- give **informed consent**
- speak for themselves
- say how they feel.

So what is the problem?

Some people think:



- the law in New Zealand makes it too hard to do research on people who cannot give **informed consent**

- we could learn a lot about how to help people if we do research using people who cannot give **informed consent**

- the law needs to change to make it easier to do research using people who cannot give **informed consent**.

Before we think about changing the laws we need to think about these things:

- people's rights are important

- some people can be harmed by research
- some people who are part of research may not get any better from it

- some people may be helped by being part of research
- research can help find ways to make treatment or services better.

Message from the Health and Disability Commissioner

Health and Disability Commissioner
Te Toihau Hauora, Hauātanga

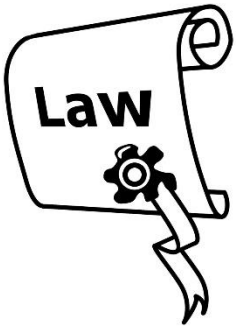
The **Health and Disability Commissioner** wants to know what you think about:

- doing research on people who cannot give **informed consent**
- whether the law on this should be changed.

We are not asking about what you think about doing research on children.

Health and Disability Commissioner
Te Toihau Hauora, Hauātanga

The **Health and Disability Commissioner** only wants to know what you think about doing research on **adults** that cannot give **informed consent** to research.



The **Health and Disability Commissioner** wants to know if you think the law about **informed consent** to be in research:

- is good
- is bad
- should change
- should stay the same.

The **Health and Disability Commissioner** wants to know what can be done to make the law about **informed consent** in research better.

In New Zealand people who cannot give **informed consent** to be in research come from many different cultures.

The Treaty of Waitangi is important to think about when working with Māori people.

Health and Disability Commissioner
Te Toihau Hauora, Hauātanga

The **Health and Disability Commissioner** wants to hear what people from **all cultures** think about **informed consent** in research.

Health and Disability Commissioner
Te Toihau Hauora, Hauātanga

The **Health and Disability Commissioner** wants to hear from:

- people who use health services
- people who use disability services
- friends of people who use services

- family of people who use services
- people who provide health services
- people who provide disability services

- people who do research
- people who want to do research.

How to tell the Health and Disability Commissioner what you think

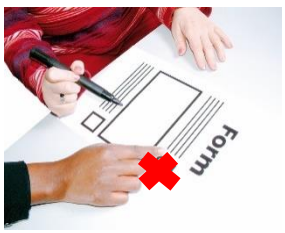
We want to hear what you think about doing research with people who cannot give informed consent.

You can:

- fill in the form on the website

or

- print out the form and send it in.



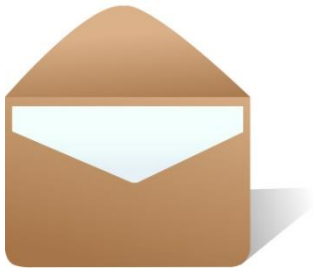
You do not have to answer all of the questions.

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

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

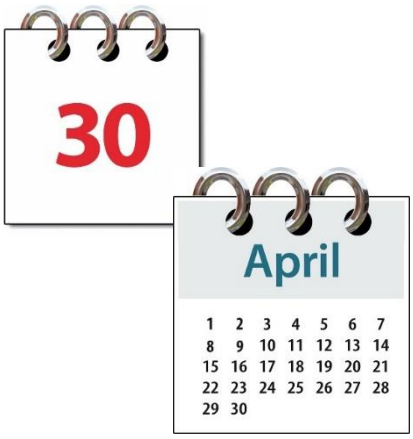
If you want to print out the form you can find it here:

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



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

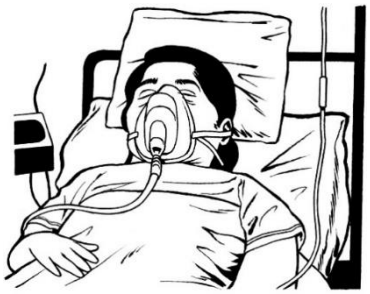
Health and Disability Commissioner
PO Box 11934
Wellington 6142



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

People who cannot give informed consent

Here are some people who cannot give **informed consent**:



1. People who are sick or hurt and are asleep and cannot wake up

2. People who cannot understand the information about research

3. People who have no way of telling other people what they think about the research.

The **Health and Disability Commissioner** wants to find out what you think about doing research with these people.

What kinds of research are we talking about?

2

This document is talking about **2** kinds of health or disability research:

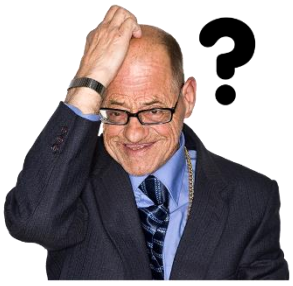
1. Interventional research

In this kind of research a change is made to the care given to a person.

The person doing the research wants to find out if the change:

- is good or bad for the person getting the care
- does not make any difference.

Some **interventional research** helps the person in the research get better health or better care.



Some **interventional research** does not help the person in the research get better health or better care.

Some **interventional research** may hurt the person taking part in the research.

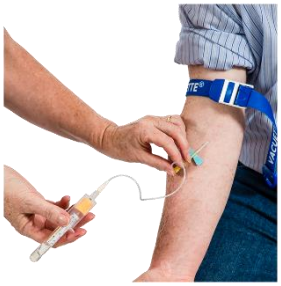
Interventional research may or may not help other people who are not taking part in the research to get better health or better care.

2. Observational research

In this kind of research there is no change made to the care that people are getting.

The person doing the research gets information from people by:

- talking to people
- watching
- writing things down
- getting samples from their bodies.



Observational research may or may not help other people who are not in the research to get better health or better care.

About advance consent

Advance consent is also known as an **advance directive**.

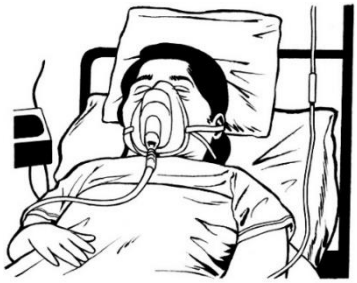
Advance consent or **advance directive** means you:

- think that 1 day you may not be able to speak for yourself
- think that 1 day you may not be able to give **informed consent**
- understand the information about the research that will be done at a time when you cannot speak for yourself

- give **informed consent** to take part in research that will be done at a time when you cannot speak for yourself.

About delayed consent

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



For example:

Sometimes people have an accident or get very sick and they are asleep and cannot wake up.

When this happens they cannot say yes or no to taking part in research.

Some people doing research want to be able to ask for **informed consent:**

- when the person gets better and wakes up
- after the research has already been done.

In New Zealand **delayed consent** is not allowed because the law says the person has to give **informed consent** before they are part of research.

When the people wake up they can make choices about whether they want to keep being part of the research.

Research with no informed consent

There are times when people who cannot give **informed consent** can still be part of research.

Here is a list of **3 times** when adults in New Zealand can be part of research even if they have not given **informed consent**:

1. Enduring Power of Attorney

Enduring Power of Attorney means you have decided that if you are ever not able to make decisions for yourself anymore **someone else can make decisions for you**.

2. Welfare Guardian

The Court can say who is able to make decisions for you.

The person who is the **Enduring Power of Attorney** or **Welfare Guardian** can say **yes** to research to:

- save your life

or

- stop your health from being harmed.

Your family / whānau or support people can only give **informed consent** to research about you if they are your:

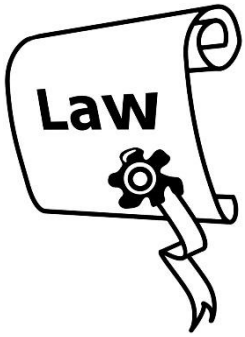
- Enduring Power of Attorney
- Welfare Guardian.

3. Court order

The Court can say you have to take some medicine or have treatment to help you.

Sometimes the medicine or treatment may be part of research that is being done.

Best interests



The law says if you cannot give **informed consent** to research you are not allowed to take part unless it is **in your best interests.**

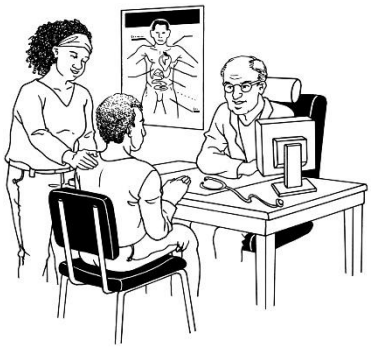
In your best interests mean it is better for you to take part in the research than the other choices.

To decide if being part of research is in a person's best interests other people in that person's life will be asked:

- **what that person would want**

or

- **what they think** if they do not know what the person would want.



The provider giving the care will then decide if it is **in the person's best interests** to be part of the research.

Ethics

If somebody wants to do research they can ask an **ethics committee** if the research is OK to do.

An **ethics committee** is a group of people who will make sure the research:

- is fair
- treats the people who take part in a good way
- does not break the law.

People doing research **do not have to** ask an ethics committee if the research is OK to do.

Most people doing research **do ask** an ethics committee if the research is OK to do.

They give information about the research to an ethics committee.

Most research cannot be done if the ethics committee does not think it is OK to do.

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.

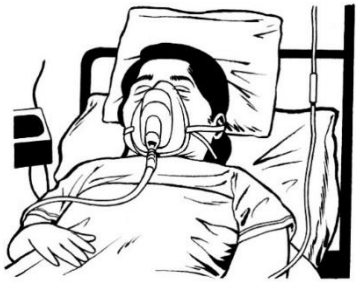
The questions are also on this website:

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

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.

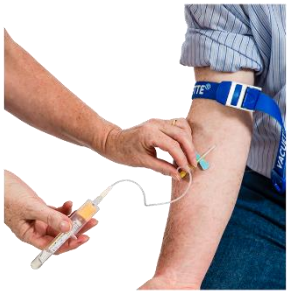
In this case study a doctor wants to do some research on people who:

- 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.

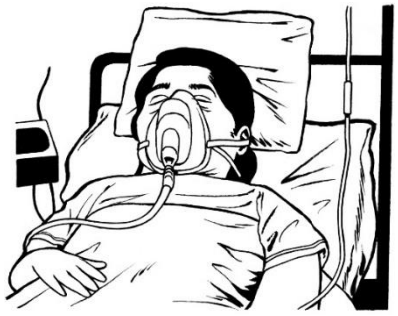
This research may help other people that get bad infections to get the medicine that will help them.

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?

If you said yes to question 1:

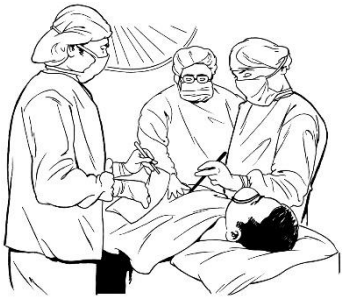
2. Why would you want to take part in this research?

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

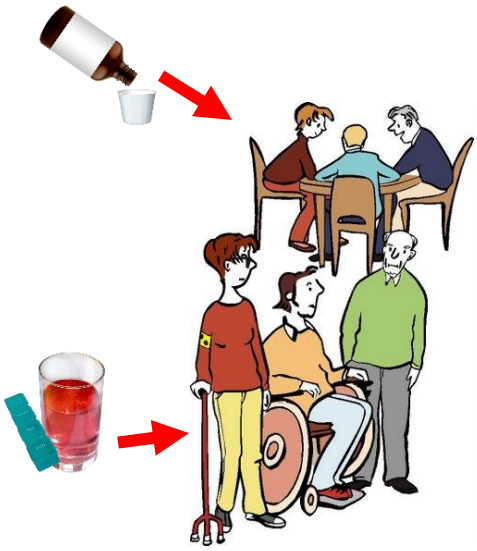


A person has to have a brain operation.

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.

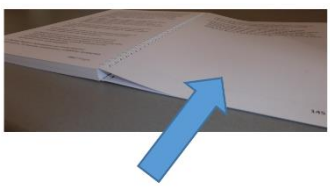


In the research the doctor will give some people 1 thing and other people a different thing.

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.



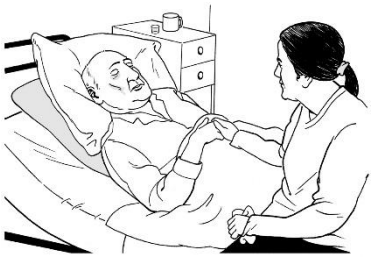
Go back to **page 35** to see what **delayed consent** is.

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 had to have a brain operation.

These questions are not about you.

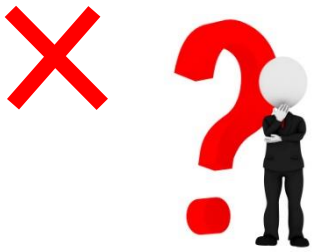
The questions are a made up example.



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?

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?

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?

If you said yes to question 1:

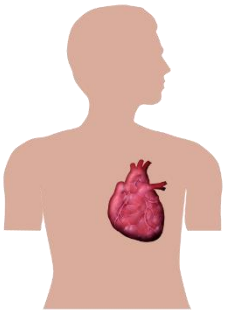
2. Why would you want to take part in this research?

If you said no to question 1:

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

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

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



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

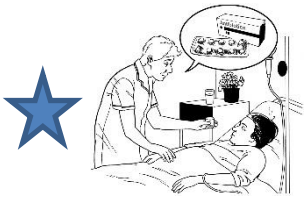
Most of the time when a person's heart stops they are given a medicine.

No one knows if the medicine helps or hurts people.

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

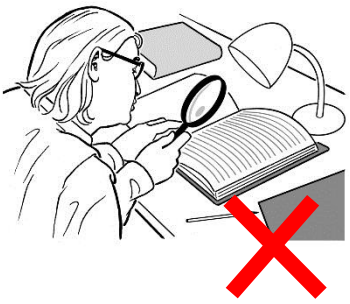
If somebody's heart stops working they will not be awake.

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



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

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



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

People 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 who 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.

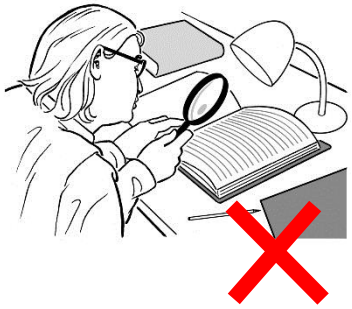
These questions are not about you.

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?

If you said yes to question 1:

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

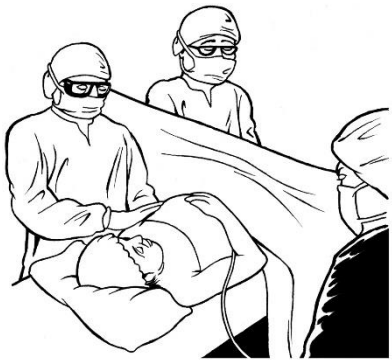


If you said no to question 1:

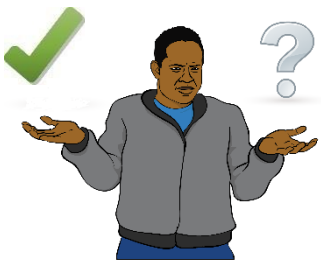
3. Why would you not want to take part in this research?

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?



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 that take part in the research **will** get the medicine.

Some people with Down Syndrome that 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?

If you said yes to question 1:

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

If you said no to question 1:

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

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

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

These other people could be:

- family / whānau
- support workers.

If you said yes to question 5:

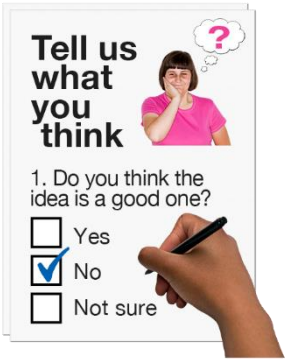
6. Why do you think this?

If you said no to question 5:

7. Why do you think this?

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

Questions about informed consent



Here are some more questions.

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

Health and Disability Commissioner
Te Toihau Hauora, Hauātanga

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

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

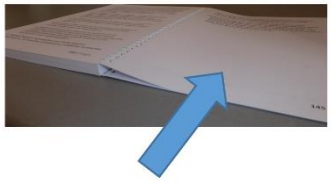
2. When do you think it is OK for adults who cannot give **informed consent** to take part in research?

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**.

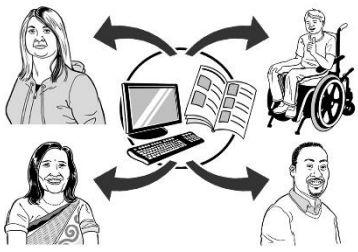
Do you think everyone doing health and disability research should have to follow the **Code**?

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?

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?



Go back to **page 35** to see what **delayed consent** is.



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**?

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?

8. Why do you think this?

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

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?

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

12. Do you think anyone else should have a say?

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

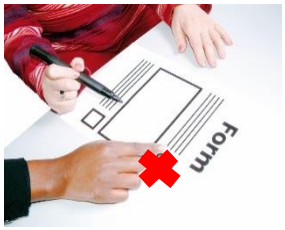
What happens next?

You can:

- fill in the form on the website

or

- print out the form and send it in.



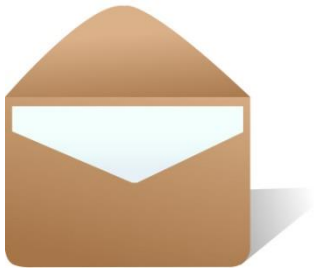
You do not have to answer all of the questions.

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

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

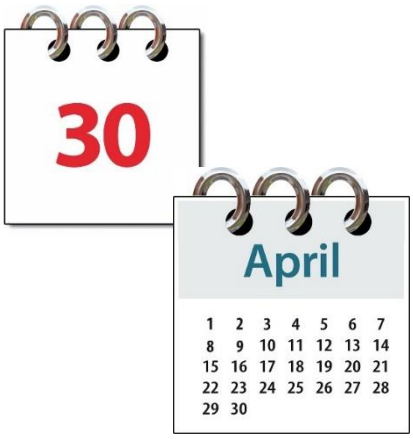
If you want to print out the form you can find it here:

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



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

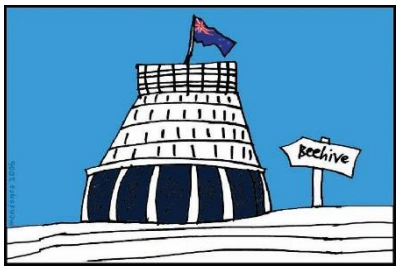
Health and Disability Commissioner
PO Box 11934
Wellington 6142



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

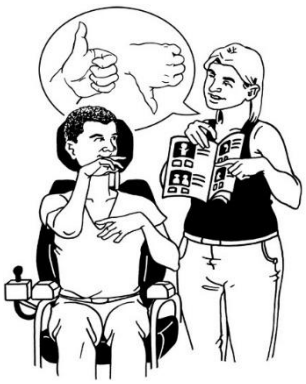
The **Health and Disability Commissioner** will:

- 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.

Health and Disability Commissioner
Te Toihau Hauora, Hauātanga

Health and Disability Commissioner

PO Box 11934, Wellington 6142

Free phone: 0800 11 22 33

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Website: www.hdc.org.nz

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