



Learning more about health-related research

The information in this document will help
you fill out the Advance Research Directive form

More information about research

The information in this document will help you fill out the Advance Research Directive form.

Getting started

You can read this document at your own pace. You may wish to discuss the information with a family member or friend.

This document has three sections:

- **Section 1:** Health-related Research – page 4
- **Section 2:** Examples of Research Studies – page 6
- **Section 3:** Making and Using an Advance Research Directive – page 12

There is a short quiz at the end of this document. You can check what you have learned.

ACKNOWLEDGEMENTS

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For more information about this project, contact Nola Ries, nola.ries@uts.edu.au

Section 1: Health-related research

This section answers these questions:

- What is the goal of research?
- How is health research different from health care?
- Why do people choose to take part in health research?
- Who makes sure a research study is safe and ethical?
- What are ethical standards for research?

What is the goal of research?

Research helps us learn new things. By doing studies, researchers can find out new ways to:

- Prevent and treat diseases
- Provide better care for people who are sick
- Improve quality of life and wellbeing for people with illnesses and disabilities

How is health research different from health care?

Health care and health research have different goals. When you receive **health care**, the goal is to help you personally – for example, by treating your specific medical condition.

The goal of **research** is to find out new and better ways of helping people – for example, by finding out how to cure or prevent diseases or to improve health care services. If you take part in a research study, you might not get any benefit personally.

Why do people choose to take part in health research?

People take part in research studies for different reasons:

- To help researchers find out answers to important questions
- To improve care for others
- To share information about their own experiences
- To try a new treatment to find out if it works

Who makes sure a research study is safe and ethical?

Before researchers can involve people in a study, they must get approval from a **Human Research Ethics Committee**. This is an independent committee that reviews the research project to make sure it is safe and follows ethical rules.

As part of its review process, an Ethics Committee looks at:

- The qualifications of the researchers doing the study
- How researchers will select and invite people to be part of the study
- The information researchers will give to people to explain the study
- The study activities, especially to check that these are safe and ethical
- What information researchers will collect about people
- How people's privacy will be protected

What are ethical standards for research?

In Australia, an important document is the **National Statement on Ethical Conduct in Human Research**. The National Statement sets standards for ethically good research:

- **Respect** is a key value – This means that people must be treated with respect. For example, people have a right to make choices about being involved in research. People who take part in studies should be protected from risks of harm.
- Research must have **merit** – This means research studies must ask important questions that are worth answering.
- Researchers must have **integrity** – This means researchers must act honestly and follow rules for doing good research.
- Research must meet principles of **justice** – This means that people must have fair opportunities to be involved in, and to benefit from, research.
- Research must be done with **benefits** in mind - The benefits of research must outweigh risks.

Section 2: Examples of research studies

This section answers these questions:

- What might a research study involve?
- What are examples of research studies?
- What is a clinical trial?

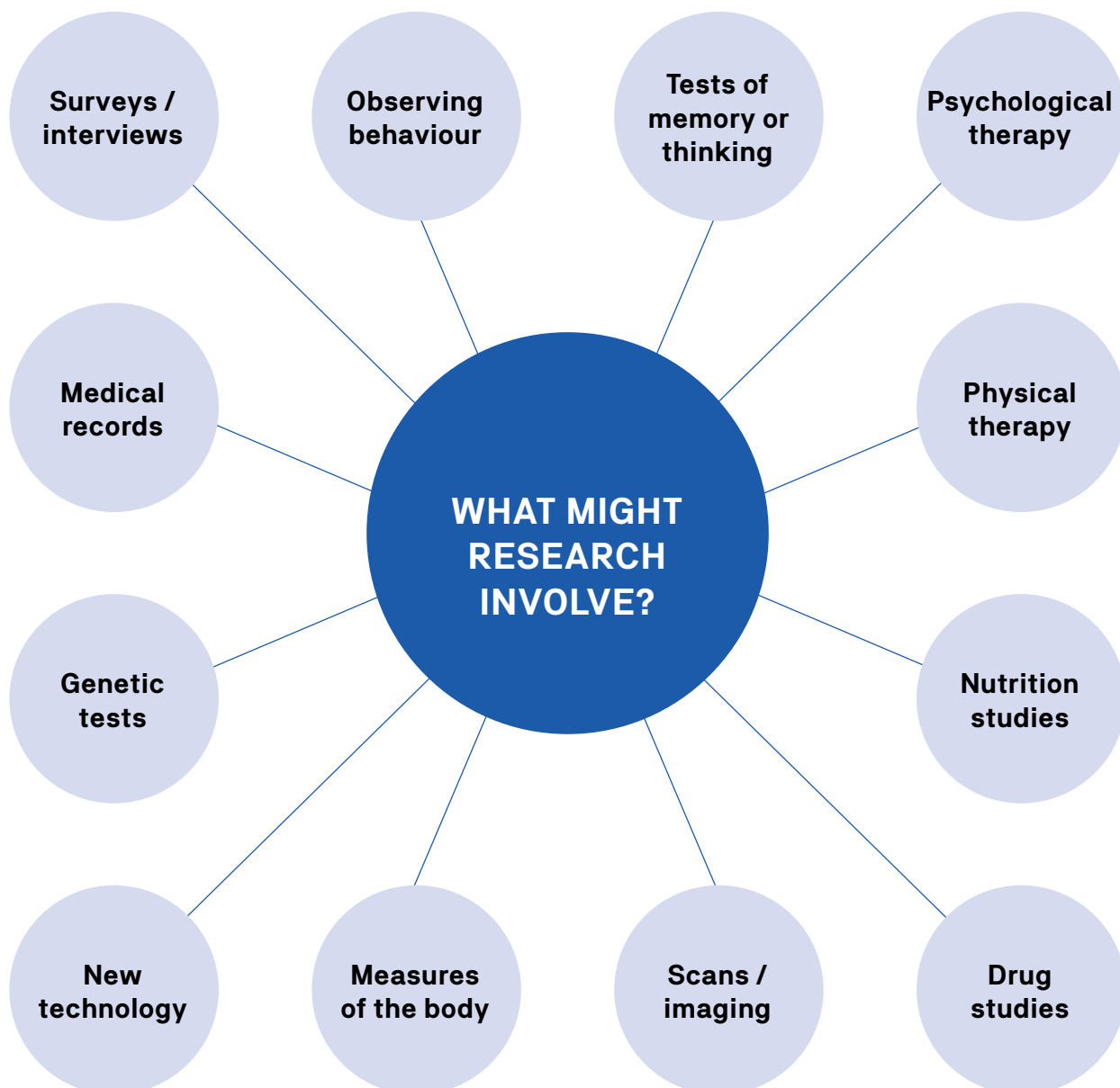
What might a research study involve?

Research involves asking questions about health problems, then designing ways to find out answers. To find out answers to questions about health, wellbeing and illness, researchers use a variety of methods and activities.

On the next pages you will learn more about what a research study might involve. You will read examples of how research can help answer questions about dementia.

This picture shows what research might involve.

The Advance Research Directive form gives short examples of these different research activities (see pages 6 and 7 of the form).



What are examples of research studies?

Here are some examples of questions that researchers can answer using different research activities or methods.



Question: How do people with younger onset dementia (before age 65) manage in their jobs?

Researchers might do **interviews** to talk to people to find out how having dementia at a younger age affects their ability to work.

Surveys/interviews – involves asking people questions to find out about their opinions and experiences. Surveys are usually in writing and interviews are done by talking.

Question: How does listening to music affect people with dementia who live in nursing homes (aged care facilities)?

Researchers might involve nursing home residents in a music group. Researchers would **observe** how the people act when they listen to music. Do they smile? Do they sing along?

Observing behaviour – involves observing people to see how they act. Observations can be written in notes or they could be video-recorded. When observing behaviour, researchers must respect people's **privacy**.

Question: For people with dementia, does taking part in a fitness program (walking and strength exercises) help improve memory and thinking?

At the start of the fitness program, people would do **tests of their memory and thinking**. After doing fitness activities for 12 weeks, they would do the same tests. Their 'before' and 'after' results can be compared to find out if the fitness program had an impact.

Tests of memory or thinking – involves asking people to do things like remember words, do basic maths or draw simple pictures.

Some research projects involve several activities – like a study of a new drug

A person with dementia might take part in a study to find out if a new drug helps them. Researchers might do several activities:

- Take **blood samples** to check how the drug is affecting the person's body
- Take **scans** of the person's brain
- Look at the person's **medical records**
- Ask the person (or a carer) to fill out **survey questions** about how the person is feeling and how they are going with daily activities

What is a clinical trial?

A clinical trial is a type of research study.

A clinical trial helps to show whether something new – like a new drug or a new way of providing care – is safe and works better than what people usually get.

People who take part in a clinical trial are often divided into **two groups**. One group gets the new (experimental) treatment or service. The other group gets the care they would normally receive. This is so that researchers can look at whether the new treatment has any benefits compared to the care that is normally provided.

A **random** process is used to assign people to the two groups. This is like picking numbers out of a hat and is done by a computer. People in a clinical trial do not get to pick their group. This means they do not choose whether they get the new treatment or the usual care.

It is important to remember that the research is being done because we do not know whether the new care is better than usual care.

Example of a clinical trial – Can a new drug help to improve memory among people with Alzheimer’s disease?

Alzheimer’s disease is the most commonly diagnosed cause of dementia. People with Alzheimer’s disease often have memory difficulties.

Improving memory function is important for people with Alzheimer’s disease and their carers.

Researchers believe a new drug could help to improve memory function in people with Alzheimer’s disease. They are doing a clinical trial.

The trial involves 200 people diagnosed with Alzheimer’s disease who experience memory difficulties.

100 people receive the new drug. They take a tablet (pill) once each day for 8 weeks.

The other 100 people take a placebo. A placebo is a tablet that looks like the real drug but does not contain the medicine.

The researchers do memory tests and brain scans of people in the trial.

The people who take the new drug have better memory function than people who take the placebo. People in the trial do not have any harmful side effects from the drug.

This clinical trial shows that the new drug works to improve memory function for people with Alzheimer’s disease.

Would you like to read more examples of studies?

If you would like to learn more about dementia research studies, visit the following websites:

- **Step Up for Dementia Research:**
stepupfordementiaresearch.org.au/types-of-research
- **Dementia Australia:**
dementia.org.au/about-dementia/dementia-research

If you would like to learn more about cancer research studies, visit the following website:

- **Cancer Council:**
cancer.org.au/cancer-information/treatment/clinical-trials

This website has lots of information about clinical trials.

Section 3: Making and using an Advance Research Directive

This section answers these questions:

- Why is it important to think ahead about being involved in research?
- Why make an Advance Research Directive?
- What is the role of a person I name as a supporter or decision-maker?
- What if I already have documents like an Enduring Guardian or Enduring Power of Attorney?
- Is an Advance Research Directive like an Advance Care Directive?
- What is the legal status of an Advance Research Directive?
- Can I change a Directive after I make it?
- What do I do with my Advance Research Directive after I complete it?

This section also tells the **story of Alice**, a person with dementia who made an Advance Research Directive.



Why is it important to think ahead about being involved in research?

To improve care for people with health problems, such as dementia or cancer, researchers need to do studies with people who have these conditions.

People have a right to decide whether or not they want to take part in research. But sometimes people are too unwell to make a choice about being part of a study. Or having a condition like dementia might make it hard for people to remember things and make decisions.

By planning ahead, you can think about your views about research. You can make choices while you are well and able to do so.

Why make an Advance Research Directive?

An Advance Research Directive is a document where you write down your wishes about being involved in health-related research.

In the future, if you become unwell and are not able to make decisions, your Directive will tell people your wishes, such as your family, your doctor or a researcher. Your Directive will help them know whether or not you want to be involved in research activities.

You make your Advance Research Directive at a time when you are able to think through your options and make choices. You can say whether you agree or disagree to being involved in research activities.

You can also name people you would like to be involved in decisions about your participation in research.

What is the role of a person I name as a supporter or decision-maker?

In your Advance Research Directive, you can choose people you trust to be your supporter or decision-maker (see page 9 of the Directive form).

A **supporter** helps you to make your **own decisions** as long as you are able. For example, they could help you talk to your doctor or a researcher about being part of a study. They could help you read and understand information about a research study.

A **decision-maker** is involved in decisions about you in case you are too unwell to make your own choices. For example, the person you name in your Advance Research Directive could discuss your wishes with researchers. Your decision-maker can let them know whether or not you would want to be part of a study.

It is okay to leave this section of the Advance Research Directive blank if you do not have someone you wish to name as your supporter/decision-maker.

Who should I choose as my supporter/decision-maker? The questions on the next page will help you consider who would be best suited to being your supporter or decision-maker.

- Have you already made a legal document to appoint someone as your Health Care Decision-Maker (such as an Enduring Guardian document)? If so, it is best to name this person as your supporter/decision-maker in your Advance Research Directive.
- Is the person someone you can talk to, rely on and trust?
- Does the person understand your values, wishes and beliefs?
- Can the person communicate well with other people?
- If called on to do so, will the person make responsible decisions on your behalf and act in your interests?
- Is the person likely to be available to support you and act as your decision-maker if necessary? As a practical matter, it is a good idea to choose someone who lives nearby and can assist you to take part in research, if that is your wish. For example, the person you choose might go with you to appointments at a medical research clinic.

What if I already have documents like an Enduring Guardian or Enduring Power of Attorney?

You might already have made legal documents to appoint people as your decision-maker for health care or financial decisions.

Making an Advance Research Directive does not replace or override these types of legal documents.

A **Health Care Decision-Maker** is someone who is responsible for making health care decisions for you if you are too unwell to do so. As noted above, if you have made a legal document to appoint a health care decision-maker (such as an **Enduring Guardian** document), you should talk to this person about your Advance Research Directive. It is best to name this person in your Advance Research Directive. You should also talk with them about your wishes for taking part in research.

An **Enduring Financial Power of Attorney** is someone who is responsible for your money and making financial decisions, if you are not able to do so.

If you would like to know more about these different types of legal roles:

- Get information from Dementia Australia – see the website dementia.org.au/information/about-dementia/planning-ahead-start2talk or ring 1800 100 500
- Talk to a solicitor.

Is an Advance Research Directive like an Advance Care Directive?

You might have heard of Advance Care Directives (sometimes called Living Wills). Or maybe you have already made your own Advance Care Directive.

An Advance Care Directive is a document where you write down your preferences for future health care. For example, if you have a serious injury or illness and cannot make your own choices, an Advance Care Directive tells people what kinds of medical treatment you would want.

If you would like to know more about Advance Care Planning you can:

- Get information from Advance Care Planning Australia – see their website advancecareplanning.org.au or ring 1300 208 582
- Talk to your doctor

An Advance Care Directive is about your future **health care**. An Advance Research Directive is about whether or not you are interested in taking part in **health research** in the future.

What is the legal status of an Advance Research Directive?

Across Australia, the states and territories have various legal rules that apply to health-related research. The status of Advance Research Directives will vary. As a general principle, if you are not able to make your own decisions in the future, your Directive should guide and inform decisions that other people may make about whether or not you take part in research studies.

On the next pages you will read Alice's story. This case study explains how an Advance Research Directive can be used to guide and inform decisions in the future.

Can I change a Directive after I make it?

Yes, you can review and change your Directive at any time as long as you are well enough to make your own decisions.

It is a good idea to review your Directive from time to time to make sure it still says what you want.

If your wishes have changed, you can update your Directive. You should also talk to your supporter/decision-maker named in your Directive so they know your current wishes.

This applies to both an Advance Research Directive and an Advance Care Directive.

What do I do with my Advance Research Directive after I complete it?

After you complete the Advance Research Directive form:

- Make sure other people know your wishes. Share copies of your Directive with anyone you named as a supporter/decision-maker, your family members or other people who you think should know your wishes.
- Keep your original Directive form with your other important documents.
- It is a good idea to keep all your 'planning ahead' documents in one place. These are documents like an Enduring Power of Attorney and an Advance Care Directive.
- You can store your 'planning ahead' documents in a clearly marked file or folder. Make sure people - your supporter/decision-maker, family members - know where to find these documents.



Case study: Alice's story

Alice was recently diagnosed with Alzheimer's disease, the most common form of dementia. She has some memory problems and it is sometimes hard for her to follow conversations.

Her husband, Bill, helps Alice manage around their home. Alice and Bill go to a dementia support group at their local community centre. They attend a session on dementia research, where Alice learns about Advance Research Directives.

Alice is interested in being part of research studies, especially to help improve care for people with Alzheimer's disease. She is also a breast cancer survivor and is interested in cancer research.

Alice knows she is likely to have more problems with memory and thinking as her Alzheimer's disease progresses. She feels it is a good idea to make a Research Directive now, while she is able to do so.

Alice makes an Advance Research Directive

In her Directive, Alice states that she is willing to be involved in research in the future. She notes her special interest in research on Alzheimer's disease and cancer.

Alice lists Bill, her husband, and her granddaughter, Clara, as her supporters/decision-makers. Alice has a close relationship with Clara, who is a nurse.

Clara visits Alice and Bill. They all read and discuss Alice's Advance Research Directive. This helps to make sure that Bill and Clara understand Alice's wishes. Alice gives Clara a copy of the Directive.

At Alice's next medical appointment, she gives her doctor a copy of her Advance Research Directive. The doctor keeps it on file. Researchers sometimes contact the medical clinic to connect with patients who are interested in taking part in research studies.

How might Alice's Advance Research Directive be used in the future?

It is now a few years later. Researchers at a local University Medical School would like to involve people with Alzheimer's disease in an important research study. The researchers contact Alice's doctor with information about the study. The doctor gives this information to Alice and Bill.

Lately Alice has had a lot more trouble with her memory and thinking. Bill and Clara talk with Alice about the study. Alice finds it hard to concentrate and make a decision.

Bill and Clara want to respect Alice's wishes as stated in her Advance Research Directive. They agree she would want to be part of the new study. They contact the researchers and give them a copy of Alice's Directive, so they are aware of Alice's interest in being involved in research.

Alice and the research study

Alice is involved in the study. The researchers wish to collect a small sample of blood from Alice. They would also like to do a scan (MRI) to take a detailed picture of her brain. In her Advance Research Directive, Alice noted she would be willing to have scans and give blood samples for research studies.

Clara takes Alice to a medical centre. A research nurse explains the two procedures to Alice. The nurse shows Alice the needle for taking blood and describes how the MRI machine works.

Even though Alice agreed to the procedures in her Research Directive, it is important for the nurse to check that Alice is okay to go ahead. If Alice was scared of the needle or the MRI machine, the nurse would not go ahead with these procedures. However, Alice is not scared. She smiles and says “Okay.”

Self-quiz: Checking what you have learned

This self-quiz lets you check what you have learned. The answers are at the end.

Choose the best answer to each question.

1. What is an Advance Research Directive?

- It tells people my wishes for medical treatment in the future.
- It tells people my preferences for taking part in research in the future.

2. What kinds of information do you write down in an Advance Research Directive?

- Whether I am willing to be part of research in the future.
- The types of research activities I find acceptable or not acceptable.
- The names of people I trust to be involved in research decisions.
- All of the above.

3. Can you change a Directive after you make it?

- Yes, I can change my Directive any time as long as I am able to do so.
- No, once I make my Directive it cannot be changed.

4. Which statement about research is TRUE?

- Research helps to find new ways to treat, prevent or cure illnesses.
- Only healthy people can take part in research studies.

5. What is the role of a Human Research Ethics Committee?

- It gives money to researchers to do studies.
- It reviews research projects to make sure they are safe and ethical.

6. Researchers must follow standards for doing good research. What are examples of these standards?

- Researchers must treat people with respect.
- Researchers must protect people's privacy.
- Researchers must minimise the risks involved in a study.
- All of the above.

Answers to the self-quiz

Below are the answers to the self-quiz. If you did not know an answer, it may be helpful to go back and review the information on the suggested page.

1. What is an Advance Research Directive?

- It tells people my wishes for medical treatment in the future.
[Note: This answer describes an Advance Care Directive.]
- It tells people my preferences for taking part in research in the future.

See page 13.

2. What kinds of information do you write down in an Advance Research Directive?

- Whether I am willing to be part of research in the future.
- The types of research activities I find acceptable or not acceptable.
- The names of people I trust to be involved in research decisions.
- All of the above.

See pages 13 and 14.

3. Can you change a Directive after you make it?

- Yes, I can change my Directive any time as long as I am able to do so.
[Note: It is important to know that you can change your Directive. It is a good idea to review it regularly to make sure it states your current wishes.]
- No, once I make my Directive it cannot be changed.

See page 15.

4. Which statement about research is TRUE?

- Research helps to find new ways to treat, prevent or cure illnesses.
- Only healthy people can take part in research studies.
[Note: It is important for researchers to involve people who have medical conditions or health problems in studies. This helps to find out new ways of providing care.]

See pages 4 and 13.

5. What is the role of a Human Research Ethics Committee?

- It gives money to researchers to do studies.
[Note: Ethics Committees do not fund research studies. Researchers get funding from other sources. These sources could be the government, charities or companies.]
- It reviews research projects to make sure they are safe and ethical.

See page 5.

6. Researchers must follow standards for doing good research. What are examples of these standards?

- Researchers must treat people with respect.
- Researchers must protect people's privacy.
- Researchers must minimise the risks involved in a study.
- All of the above.

See page 5.



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