Advance Research Directives: *Dementia Researchers' Views on a Prototype Directive and Implementation Strategies*

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Appendix

Note to readers: The authors have prepared a revised version of an ARD template that incorporates the recommendations from this study. Please contact the corresponding author to request a copy of the updated template.

Sample Content for an Advance Research Directive

This is draft text only. We are interested in your views on the general content covered in each section of this draft text. It is not necessary to address specific wording.

Content area 1: General description of research
Research helps us learn new things. For example, researchers do studies with people to find new ways to prevent and treat diseases. If you take part in a study, you might not get any direct benefit. Instead, you might help researchers answer questions that could benefit other people in the future. There are sometimes risks in being part of a research study. A risk is the potential for harm, discomfort or inconvenience. For example: ☐ You might have to take time out of your day to take part in a research activity. ☐ You might feel uncomfortable about some activities, like researchers asking you personal questions or using a needle to take a small amount of your blood. ☐ You might feel sick or have side-effects from a new drug or treatment. Before researchers can ask people to be part of a study, they must get permission from an ethics committee. This is an independent committee that makes sure the research is safe (there are more benefits than risks) and it follows ethical rules. Once researchers have ethics approval for their study, they can ask people to take part in the research. Researchers tell people what the study involves, including any risks and benefits. People can then decide if they want to take part. The choice is up to them and they can say yes or no. _ *[For a facilitator - Prompts regarding decision-making capacity: Ask the person to summarise this information in their own words. Question prompts may be used, for example: (1) Why do we do research? (2) What are some benefits of research? (3) What are some risks of research? Tick boxes may be used after each paragraph to indicate the person's understanding of the information.]*

Content area 2: Advance research directive—making choices about research
To find out new ways to help people who have health problems, researchers need to include these people in studies. But sometimes people are too sick to make a choice about being part of a study. Or they might have a condition, like dementia (or Alzheimer's disease), that makes it hard for them to remember things and make decisions. People can make an **Advance Research Directive**. A Directive asks you to write down your wishes about being involved in research in the future in case you become too sick or are unable to choose later.

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 research activities. You can review and change your Directive at any time as long as you are able to make your own decisions.

If you are not able to make decisions in the future, 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 can also choose a person you trust to speak for you in the future in case you cannot make your own choices. This person will be involved in decisions about whether it is a good idea for you to take part in a research study. This person is called your **decision-maker**. You should discuss your Directive with your decision-maker so they understand your wishes.

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[For a facilitator - Prompts regarding decision-making capacity: Ask the person to summarise this information in their own words. Question prompts may be used, for example: (1) What is an Advance Research Directive? (2) What kinds of information do you put in a Directive? (3) When might an Advance Research Directive be used? (4) Can you change a Directive after you make it? Tick boxes may be used after each paragraph to indicate the person's understanding of the information.]

Content area 3: Name a decision-maker

I give permission to the person(s) named below to make decisions for me about taking part in research. The person(s) will only do so **if I am not able** to make the decision myself.

Note: It is a good idea to name two people. If your first decision-maker is not available, the second decision-maker can be contacted.

My first decision-maker	My second decision-maker
Name:	Name:
Address:	Address:
Phone number:	Phone number:

Content area 4: My values and attitudes about research

I think research is important to find out new ways to help people who have health problems.
☐ strongly agree ☐ agree ☐ disagree ☐ strongly disagree ☐ no opinion

In general, I trust researchers.
☐ strongly agree ☐ agree ☐ disagree ☐ strongly disagree ☐ no opinion

I have been part of a research study in the past.
☐ yes ☐ no ☐ not sure/can't remember

Content area 5: General wishes about research participation
If I lose the ability to make my own decisions: ☐ I do NOT want to be involved in any research. *[Skip to the end to sign the document.]* ☐ I am willing to be part of research that might help me directly. ☐ I am willing to be part of research that will not help me directly, but might help others.

Content area 6: Views about specific research activities

In the future, if I lose the ability to make my own choices, I would be willing to be included in a research study that involves:

Please initial the statements below that reflect your wishes.	**Initial**	
Asking me questions in a survey or interview (example: asking about my experiences or opinions)		
Observing my behaviour (example: watching how I act if I listen to music)		
Testing my memory or thinking (example: asking me to draw a picture or remember specific words)		
Giving me psychological therapy *(*example: counselling for anxiety or depression)		
Giving me physical therapy or exercises (example: moving my arms or legs, massaging my muscles)		
Giving me experimental medicine (example: an experimental drug that might reverse damage in my brain)		
Taking x-rays or scans of my body (example: to help researchers see how a disease is affecting my brain)		
Taking measurements about my body (example: my blood pressure)		
Putting something on my body, like a bracelet, that keeps track of information (example: how much time I spend in bed)		
Taking a sample of my blood or other body fluid for *genetic* **research** (example: to find out if I and my relatives have a gene that increases the risk of getting diseases) Note: *Genetic* research looks at diseases that can run in families. You inherit genes from your parents and you pass your genes on to your children.		
Taking a sample of my blood or other body fluid for *non-genetic* **research** (example: to find out if my blood shows I had an infection in the past that increases my risk of getting diseases)		
Looking at my personal records, such as medical records or test results stored at my doctor's office or hospital (example: to study how a past illness might be related to my current health problem)		
Accessing stored samples of my blood, body fluids or other tissues (example: If I had blood taken in the past for another reason, researchers might ask the hospital for access to that blood for study)		

Content area 7: Using your Directive in the future

Even if you lose the ability to make your own decisions, you might still be able to express your feelings about being involved in a research activity. A person doing research must check whether you are okay to go ahead. If you are **not happy** to do the activity, this should be respected, even if your Directive says you agree to that activity.

For people who are sick or who have memory problems, it is sometimes hard for them to express whether they are happy or unhappy with doing a research activity. If this happens to you, do you prefer that:

- ☐ Your wishes in this Directive are followed as much as possible.
- ☐ Your feelings—as you are able to express them in the future—are followed as much as possible.

Signatures

Person making the ARD
Name:

Signature:

Date:

Contact details (address, telephone, email):

Facilitator and/or witness (add space as needed)

Name:

Signature:

Date:

Contact details (address, telephone, email):