

The Dementia Enquirers Gold Standards for Ethical Research



deep

The UK Network
of Dementia Voices



Innovations
in Dementia



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Background

What are Dementia Enquirers and DEEP?

DEEP is the UK Network of Dementia Voices¹. Between 2019 and 2022, people with dementia from over 20 groups in DEEP were supported to conduct their own small-scale research projects through a programme called Dementia Enquirers. Many groups had already been involved in research studies carried out by universities. However, this programme gave people with dementia a chance to develop/create, lead, and be in control, of their own research – on issues that are important to them. The aim was also to learn what it actually means – and takes – for them to be ‘in the driving seat’ of research. Dementia Enquirers and DEEP are delivered/ facilitated by Innovations in Dementia². We are very grateful for the support of the National Lottery Community Fund.

¹ DEEP is a network of influencing groups led by, or actively involving, people with dementia.

² A not-for-profit Community Interest Company.

What are research ethics?

‘Ethics’ can sound mysterious and scary. But ‘being ethical’ in research is really just about being honest, respectful and appropriately careful towards anyone involved in your research project.

An ethical research project:

- looks after the health, safety and wellbeing of everyone taking part
- is honest and clear
- is respectful of everyone taking part, their dignity and rights
- has a clear plan to complete the research – but stays flexible
- has a clear purpose/reason to be done
- meets any legal and ethical requirements

Why do we have Research Ethics Committees (RECs)?

In the past, bad things have sometimes been done to vulnerable people because of a lack of scrutiny. There are examples of early research that we would now see as unethical. Research Ethics Committees (often called RECs) were set up to:

- stop this type of research happening today
- help researchers show that their research puts people’s well-being first, and protects participants from harm
- identify risks the researcher hasn’t thought of... which in turn can help reduce these risks
- reassure participants that you have thought about ethics, and the right way to act.

There are more than 80 NHS Research Ethics Committees across the UK – all come under the Health Research Authority. They exist to safeguard the rights, safety, dignity and well-being of research participants. They consist of up to 15 members, a third of whom are 'lay'. The Social Care Research Ethics Committee also comes under the Health Research Authority. Most universities also have established Research Ethics Committees as part of their internal governance arrangements.

RECs review research proposals and give an opinion about whether the research is ethical. They also look at issues such as the participant involvement in the research. The committees are entirely independent of research sponsors (the organisations responsible for the management and conduct of the research), funders and the researchers themselves. This enables them to put participants at the centre of their review.

What are the problems we want to address?

Organisations that do research, such as universities and hospitals, tend to have a Research Ethics Committee, or access to one. The process of getting research approved (i.e. agreeing that it's ethical and can be done) can often feel very daunting and inaccessible (not only to people who are familiar with it, but also to people who are not!). It is often hard to know:

- Whether your work needs to go to a Research Ethics Committee
- Which Research Ethics Committees it would go to
- What kind of approval you need
- What happens during the approval process

People with dementia are often thought incapable of consenting or taking charge of research. If they want to design and lead their own research, they have no direct route to any organised Research Ethics Committee. Also, there are seemingly different (and inconsistent) processes between many of the different Research Ethics Committees (in particular universities). The processes can often feel complicated, jargon-ridden, time-consuming, resource-draining and de-skilling. There is also the question of proportionality. Where the risk is low or virtually none, processes should be very simple and quick to enable the project to proceed.

On the other hand, RECs are arguably less concerned than they should be about methods. For example, they often approve interview-based research, rather than recommending alternative, more creative methods which would make the research more truly inclusive and participatory. This perpetuates the exclusion of vulnerable people or those with cognitive difficulties or fluctuating capacity. If we really want to be inclusive we have to adapt traditional methods or use more innovative ones in order to compensate for disabilities and make the research enjoyable and non-anxiety provoking.

REC approval is important, because if it is not asked for and gained, the work may not be taken seriously by other researchers, and it may not be publishable in academic journals. This matters because publishing research in peer-reviewed journals is the most reputable way to have research read by an international academic and clinical audience, and thus to have the greatest impact. Peer reviewed research is also the currency for academic careers.

This does prevent researchers doing whatever they want and trying to publish it without considering ethics or the participants' well-being. But the options we have are currently too restrictive. Moreover, the work may not be allowed to happen at all.

What are our new Standards?

Dementia Enquirers aimed to support more people to be involved in research, not just academics and practitioner researchers. So, we piloted a new set of Standards which have been identified by people with dementia who are involved in research (or are wanting to be involved). The Standards:

- are more flexible, and can take a considered approach to some of the grey areas
- start from the assumption that being diagnosed with dementia does not mean you necessarily lack capacity
- incorporate support for people to make their own decisions
- are realistic about how we think about risk
- aim to include (not exclude), and assume that people have got capacity to be involved (unless it is shown that they don't) – in line with the Mental Capacity Act (and similar legislation in Scotland and Northern Ireland)
- respect the sense of urgency of the need for action and change that people with dementia feel
- focuses less on *why* the project is being done, and more on whether *how* it is being done is ethical
- respect the importance of equality and diversity issues, and requirements of the Equality Act for 'reasonable adjustments'

The 6 Standards are:

1

Working in real partnership
(‘co-production’)

4

Informed consent
and capacity

2

Respect and
acknowledgment

5

Confidentiality and
anonymity

3

Safety and wellbeing

6

Information that is simple,
accessible and open

These important practicalities are on some occasions overlooked by academics and practitioner researchers. The aim of the Gold Standards checklist is to provide reassurance that the project has been carefully thought through, will be carried out legally, and is in line with ethical requirements. This reassurance is important to:

- people with dementia who are involved (and their families/advocates)
- any academic partners
- policy makers, organisations and local authorities that may consider changes to policies or practices as a result of the research
- any organisations that might be involved (for example in providing access as a research ‘site’)
- journals which may consider publishing your findings

What are our hopes?

In 2020, we piloted the Dementia Enquirers Gold Standards for Ethical Research on applications we received from groups in the DEEP Network for Dementia Enquirers funding. These projects were small, mainly qualitative and did not include, for example, clinical trials. A 'Lived Experience Sounding Board', led by people with dementia, and supported by a (non-voting) external advisor, reviewed the applications and made recommendations. These aimed to help applicants with more formal ethical approvals if needed.

In time, we hope that:

- formal Research Ethics Committees and peer-reviewed journals will accept and promote the Dementia Enquirers Gold Standards for Ethical Research as evidence that a project is ethical (though this will not always obviate the need for Research Ethics Committee approval)
- following our example, Research Ethics Committees will make their own processes simpler and more accessible (though still in line with regulatory requirements)
- following the example of the Dementia Enquirers projects, Research Ethics Committees will accept that people with dementia can be in the driving seat of research
- more researchers may voluntarily decide to use the Dementia Enquirers Gold Standards for Ethical Research
- in time, funders may suggest (or require) that projects they fund follow the Standards.



The Dementia Enquirers Gold Standards for Ethical Research checklist

This checklist is intended for researchers (with or without dementia) who are planning a research project involving people with dementia.

If this is you, we suggest that you use this checklist at an early stage to ensure that you have considered all the key ethical issues. We hope it will provide the basis for useful discussions in the research team about how you will carry out your project.



Standard 1: Working in partnership ('co-production')

How will we recognise and minimise differences in power and status?

As researchers (with or without dementia) we will...	Yes/No/ Need to check
Set research agendas and priorities through discussion with people with dementia.	
Respect the views and lived experiences of people with dementia as knowledge.	
Respect that people with dementia may not want or need to have a 'carer' involved (depending on the nature of the study of course).	
Help to develop the research skills of people with dementia so that they can be involved in influencing knowledge about dementia, and as research partners when possible.	

Standard 2: Respect and acknowledgment

How will we demonstrate respect and consideration to all involved?

As researchers (with or without dementia) we will...	Yes/No/ Need to check
Use language that is not patronising, judgmental or disparaging.	
Make every effort to avoid discrimination, bias, stereotyping, prejudice and intolerance.	
Avoid over-taxing people's memory or communication skills. Always re-cap on previous conversations or interviews each time we meet with people with dementia.	
Include enough breaks – e.g. for refreshments, quiet time, toilet and re-focusing – because research involves a lot of concentration.	
Remind participants the day before that they will be meeting with us, using the communication method that they indicate is best for them.	

Standard 2: Respect and acknowledgment (continued)

How will we demonstrate respect and consideration to all involved?

As researchers (with or without dementia) we will...	Yes/No/ Need to check
Arrive and leave at the time we said we would.	
Ensure our study is worth doing i.e. that we are not wasting people's time and that any intrusion is worth it.	
Genuinely try to involve a diverse, representative group (e.g. minority populations, people experiencing low socioeconomic status, members of the LGBTQ+ community). And if we cannot do this, explain why.	
Avoid inappropriate exclusion of people, for example because of a diagnosis, deafness or language barrier. And take reasonable steps to be inclusive (such as translators, remote video conferencing or telephone where transport is not available or easily accessible, and not limiting studies to an upper age limit without good reason).	

Standard 2: Respect and acknowledgment (continued)

How will we demonstrate respect and consideration to all involved?

As researchers (with or without dementia) we will...	Yes/No/ Need to check
Ask participants (and if agreed, their families or a trusted person who they nominate) how they want feedback: at what points, and in what ways. This may need to be re-checked.	
Avoid plagiarism, by acknowledging the sources of thoughts, ideas and words and their originators in our own report ³ .	
At the end of our report, include a reference list or bibliography which directs people to where full papers are available.	

³ This is called 'citation'. If we quote directly, we will name the source, the year it was said, and which page it was written on. Or if we quote indirectly, we will use our own words, but give the name and year of the information alongside.

Standard 3: Safety and wellbeing

How will we protect participants from harm – physical and/or emotional – and minimise any potential risks?

As researchers (with or without dementia) we will...	Yes/No/ Need to check
<p>Start from the position that the person with dementia has the capacity to understand risk, and to be supported to make their own decisions about risk-taking and risk-management in relation to taking part in the research.</p>	
<p>Ensure that benefits and risks are clearly identified for the research participant, even where harm is unlikely. But keep processes simple and in proportion.</p>	
<p>Ensure that the research is conducted in a quiet, safe, private space and in keeping with the participant's wishes (if at all possible).</p>	
<p>Offer to help with travel plans, remote access, meeting people at stations etc. if they need/want this to keep them safe.</p>	

Standard 3: Safety and wellbeing (continued)

How will we protect participants from harm – physical and/or emotional – and minimise any potential risks?

As researchers (with or without dementia) we will...	Yes/No/ Need to check
Make the schedule flexible to people's preferred time of day and avoid days where other support might be limited e.g. Friday evenings.	
Find out if there is someone else they would like to have with them when they are taking part in research (but don't assume they need or want to have someone).	
Check each time – and regularly throughout the discussion – how the participant is and what support they need that day (both emotional and practical).	
Avoid irrelevant, intrusive questions which may trigger distress ⁴ . If such questions are necessary, put emotional support in place.	

⁴ For example, Sensitive personal, relationship or family issues; Sensitive cultural issues; Death, bereavement, grief, or serious traumatic loss; Sexuality; Gender identity; Race or ethnic identity; Negative aspects of dementia or other health conditions; Intrusive or potentially onerous interventions e.g. audio-visual recording of daily activities.

Standard 3: Safety and wellbeing (continued)

How will we protect participants from harm – physical and/or emotional – and minimise any potential risks?

As researchers (with or without dementia) we will...	Yes/No/ Need to check
<p>Recognise, and be open about, the fact that asking participants to describe or remember unhappy or difficult experiences could be upsetting or bring back bad memories. Use our ‘emotional intelligence’ and be ready to offer emotional support if feasible (in the moment, or later), or information about advice and support, in the way the participant wants.</p>	
<p>If there are significant risks identified in the research, there is a plan in place to support research participants and researchers. This includes the researchers having the experience or expertise to support participants themselves, if they become distressed during the research, and having the contact details of organisations and professionals who can provide help if required.</p>	
<p>Hold indemnity insurance, and follow a lone researcher policy.</p>	

Standard 3: Safety and wellbeing (continued)

How will we protect participants from harm – physical and/or emotional – and minimise any potential risks?

As researchers (with or without dementia) we will...	Yes/No/ Need to check
<p>Be aware that disclosures may be made during the course of the research e.g. about neglect or abuse – and have a clear procedure in place in case this occurs⁵. This should be made clear to the participant before they agree to take part.</p>	
<p>Consider whether DBS (Disclosure and Barring Service) checks are necessary for those carrying out the research⁶. And comply with employment-related guidance about this.</p>	

⁵ Disclosures like these could relate to an adult safeguarding concern.

The Care Act 2014 includes a section on safeguarding and, if necessary, researchers should report a concern to the local authority safeguarding team. Research confidentiality does not apply in these situations.

⁶ A standard DBS check shows spent and unspent convictions, cautions, reprimands and final warnings. Basic and enhanced checks are also available. See: <http://bit.ly/38s8Tud>

Standard 4: Informed consent and capacity

How will we ensure that consent is supported and informed?

As researchers (with or without dementia) we will...	Yes/No/ Need to check
<p>Start from the assumption (based in law) that people with dementia have capacity and can make informed decisions and give consent to participate in the research.</p>	
<p>Tailor our information so that it is fit for purpose, for the audience, and for the level of risk.</p>	
<p>Ensure that participants understand what the research involves before they agree to take part. People will be helped to weigh up the ‘pros and cons’ of being involved in the research i.e. how it might affect them. Check that they can Understand and Retain the information to make a decision about taking part, and Communicate their views and decision(s) about this.</p> <p>If they are unable to do one or more of these, they lack the capacity to consent to taking part (but see below).</p>	

Standard 4: Informed consent and capacity (continued)

How will we ensure that consent is supported and informed?

As researchers (with or without dementia) we will...	Yes/No/ Need to check
<p>Offer extra help to give informed consent e.g. by using visual props, Talking Mats, easy-read information, to help people to understand and decide whether to be involved in the work. Keep everything as simple as possible – and give people enough time to make decisions.</p>	
<p>Involve a family member, support worker from a partner organisation or other support in the consent process, where appropriate.</p>	
<p>Once someone has all the information they need to decide whether to take part, ask them to give ‘informed consent/ agreement’. They can do this by signing a form, or by us recording their agreement on video or audio, or in a ‘field note’. We will not accept a signature from a ‘proxy’.</p>	

Standard 4: Informed consent and capacity (continued)

How will we ensure that consent is supported and informed?

As researchers (with or without dementia) we will...	Yes/No/ Need to check
<p>Accept that consent is an ongoing and flexible process. If we are seeing people more than once, provide routine reminders and recaps (verbal, written or pictorial), that prompt them to reconsider and reflect on their involvement. They will be asked on each occasion whether they are still happy to take part/reconfirm consent to take part. It will be made clear that they can withdraw at any time (with no effect on them or their care/access to services/legal rights).</p>	
<p>Complete separate consent forms for films and photographs, and request the signature of the person with dementia, or record their agreement. The forms will specify what use will be made of the digital media (for example in advertising/training etc). Stress that film/photos will NOT be used for anything that is not agreed on in that form—for example, people won't see their photos on another product/video that has nothing to do with the current project they are involved in.</p>	
<p>Explain how information (data) will be stored and used (see 5), dates for withdrawal/destruction of data, and also an explicit opt-in/out for anonymity.</p>	

Standard 4: Informed consent and capacity (continued)

How will we ensure that consent is supported and informed?

As researchers (with or without dementia) we will...	Yes/No/ Need to check
<p>Take reasonable steps to identify a ‘consultee’ who can establish whether the person would have wanted to take part in the research, if they lack capacity to consent. This is usually a close family member, but could be a friend or neighbour. (Or, if one is not available, it could be a nominated consultee, provided that they have no connection with the research project.)⁷</p>	
<p>Accept responsibility to ensure anyone participating in the research has given a valid consent. Have we given all the necessary information to enable informed consent to be given? Are we confident that the person does understand this information, and is making a free choice? If not, and also if their capacity to consent fluctuates, the proposal will need to go to a specific NHS Research Ethics Committee or the Social Care Research Ethics Committee (see below).</p>	

⁷ In Scotland, if the person with dementia lacks capacity, you must get consent from a guardian or welfare attorney who has power to consent to the adult’s participant in research. If there is no such person, then consent is given by the person’s nearest relative.

Standard 5: Confidentiality and anonymity

Might we do damage to the participants or to other people by revealing sensitive information?

Can we make people feel more comfortable about sharing personal information or things they are worried about by offering anonymity?

As researchers (with or without dementia) we will...	Yes/No/ Need to check
Assume that all information collected in the research is sensitive and personal, and present it in a way that protects a person's privacy.	
Tell the truth – be transparent about the purpose of the research, who is funding it, how it will be presented, and in what formats (e.g. conference presentations, workshops, training material and resources, published papers/PhD theses etc). Also any intention to use it for future research. Who will see the 'raw data', for what purpose, and what steps (if any) will be taken to disguise identities?	
Use a storage system that is safe and only accessible to the researchers in the project. Tell participants the date when their data will be destroyed.	

Standard 5: Confidentiality and anonymity (continued)

Might we do damage to the participants or to other people by revealing sensitive information?

Can we make people feel more comfortable about sharing personal information or things they are worried about by offering anonymity?

As researchers (with or without dementia) we will...	Yes/No/ Need to check
Keep identifiable information separate to research answers e.g. name and address will be stored separately to questionnaires.	
Only share information that the person has agreed to being shared (unless there is a safeguarding concern).	
Offer participants the chance to 'withdraw' data but be clear about how and when they can do this (put a time limit on it e.g. two weeks after interview, or before publication). Put this information on any consent or information sheets.	
Offer choices to protect identity e.g. by using first name only; an identity code; or a pseudonym (a different name). But say we are willing to use real names where this is wanted and agreed.	

Standard 5: Confidentiality and anonymity (continued)

Might we do damage to the participants or to other people by revealing sensitive information?

Can we make people feel more comfortable about sharing personal information or things they are worried about by offering anonymity?

As researchers (with or without dementia) we will...	Yes/No/ Need to check
Have specific plans in place to keep participation confidential if we are researching in a small community.	
Make data Open Access, once all identifiable variables are removed, with the approval and complete understanding of what this entails from the participant.	
Stick to any other GDPR (General Data Protection Regulation) rules.	

Standard 6: Information that is simple, accessible and open

Do we provide enough information (but not too much) to enable people to make an informed decision about whether to take part in our study?

As researchers (with or without dementia) we will...	Yes/No/ Need to check
<p>Have an information sheet which summarises (but does not overload) the research we want to do, why we are doing it, how we will look after participants, and our contact details. This will be in simple accessible language.</p>	
<p>Use photos and other images if this helps to convey information explaining the research.</p>	
<p>Avoid overloading people with other (less accessible) information where it's not necessary.</p>	
<p>Present all information clearly and accessibly, making reasonable adjustments as needed (including translation/interpretation). Where necessary, slow down, and adapt to the person's own pace and preferred communication type and style.</p>	

Standard 6: Information that is simple, accessible and open (continued)

Do we provide enough information (but not too much) to enable people to make an informed decision about whether to take part in our study?

As researchers (with or without dementia) we will...	Yes/No/ Need to check
<p>Speak at a steady pace and in simple (non-academic) language. Explain research terms each time they are used and avoid using abbreviations and acronyms.</p>	
<p>Give a clear explanation of why people are included or excluded in the research.</p>	
<p>Provide a summary of the final report in simple, understandable language. Offer individuals a choice of what type of report they want (summary/ 2-sides of key points/full report?) ...and re-confirm at the end of involvement.</p>	

So... over and above all this, do we need approval from a formal Research Ethics Committees (REC)?

Our research includes people who may be lacking capacity (even if we are simply observing them)	Yes, by law	from a NHS (Health Research Authority) designated Ethics Committee
Our research involves interviewing NHS or social services staff in their place of work, or finding people to take part in our research through the NHS or social services (e.g. a doctor, social worker or health unit)	Yes	from any NHS (Health Research Authority) Ethics Committee
Our research involves changing treatment/care from accepted standards for any of the people involved	Yes	from any NHS (Health Research Authority) Ethics Committee
We will be presenting our findings as generalisable	Yes	from any NHS (Health Research Authority) Ethics Committee
Our research involves developing interventions and/or allocating people to different services, or control groups not getting a service	Yes	from any NHS (Health Research Authority) Ethics Committee

<p>We are working with a University. (Would that Committee accept an application in a more accessible format than usual? They might need to be reminded of Equality Act obligations)</p>	<p>Yes</p>	<p>from the University Ethics Committee</p>
<p>We are looking at publishing in high-impact, peer-reviewed academic journals</p>	<p>Maybe</p>	<p>check with specific journal</p>
<p>We are looking at publishing in the more mainstream journals e.g. Journal of Dementia Care, dementia newsletters, popular press etc.</p>	<p>Less likely</p>	<p>check with specific journal</p>
<p>Our research is based on focus groups or questionnaires</p>	<p>No</p>	<p>unless any of the above apply</p>
<p>Our research is a stand-alone evaluation of a service (including a survey)</p>	<p>No</p>	<p>but check you have give clear information and ask for consent</p>

Acknowledgments:

The Dementia Enquirers Gold Standards for Ethical Research draw on a range of important guidelines including:

- Health Research Authority **Decision Tools**
- Health Research Authority **Policy Framework for Health and Social Care Research**
- Health Research Authority **GDPR Guidance**
- British Society of Gerontology **Ethical Guidelines**
- British Psychological Society **Code of Human Research Ethics**
- Economic and Social Research Council **Framework for Research Ethics**
- Wellcome Trust **Policy on Research involving Human Participants**
- Scottish Dementia Working Group **Core Principles for involving People with Dementia in Research**
- Dementia Enquirers **Research Pack**

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To find out more about
Dementia Enquirers, visit
dementiaenquirers.org.uk or
contact **Rachael Litherland**
at **rachael@myid.org.uk**.

Innovations in Dementia is a not-for-profit Community Interest Company (CIC). People with dementia are at the heart and start of all our work. We promote a positive but realistic view of dementia, demonstrating that, although it is life changing, it does not have to be life ending. We support people with dementia to live with hope and keep control of their lives.

We want to influence how others engage with people with dementia, and we provide training and consultancy. We run many innovative projects, often in partnership with universities, public bodies or charitable funders.

Please also visit our websites:

Innovations in Dementia

<http://www.innovationsindementia.org.uk/>

Dementia Diaries

<https://dementiadiaries.org/>

and

Dementia Voices

<https://dementivoices-id.org.uk/>

This website includes mini-sites for five of our key projects:

- DEEP (the UK Network of Dementia Voices)
- Dementia Diaries
- Dementia Tip-share
- Dementia Creatives (including Craftivists)
- Dementia Enquirers



To find out more about Dementia Enquirers, visit dementiaenquirers.org.uk or contact **Rachael Litherland** at rachael@myid.org.uk.

