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THISTLE DOWN
project

A Short Guide to Ethical Practice and
Governance for Ethnographic Research
with People who have Dementia

Written by
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Glossary of terms

- AWI** Adults with Incapacity (Scotland) Act 2000
- REC** Research Ethics Committee
- REC A** The Scottish Research Ethics Committee that reviews studies recruiting adults with incapacity
- HRA** Health Research Authority that oversees research governance in the UK
- IRAS** Integrated Research Application System. Application covers all ethics and other permissions for health and social care research in the UK

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Introduction

This booklet provides evidence based information and advice for researchers about conducting ethnographic research with people who have dementia and who lack capacity. The booklet is based on evidence from literature, policy documents and findings from the Thistledown Project.

Please note: We discuss research conducted in Scotland, under Scots Law. However, many of the ethical issues will be relevant to researchers in other countries.

The Thistledown Project

The Thistledown Project (funded by the Chief Scientist Office Catalytic Research Grant) was carried out by the authors between April and September 2017. The project aimed to provide insight into the conduct of ethnographic research with a population of individuals who have dementia, and who may lack capacity.

This was a mixed methods study, collecting data via documentary analysis and semi-structured interviews. Three groups of key informants were interviewed, see breakdown of sample below:

Interviewees	No.
Service users with a diagnosis of dementia and experience of participation in research, research governance and political activism	4
Specialists with knowledge of Scottish government policy making, and different aspects of the HRA research ethics system	7
Researchers who have experience of conducting research relevant to the project	6
Total	17

The document analysis examined 101 published articles and 30 REC applications. The analysis sought to identify: the research methodologies used; stated and inferred study participants; the study setting; ethical review processes; processes of consent; and practical conduct of the study. The range of topics addressed through the research question, and the distribution of these studies over time and geographical location were also identified.

For further detail about the Thistledown study methods and findings please see our website:

www.ed.ac.uk/health/research/e-cred/projects/thistle-down-project

About Dementia

“We, the people with dementia, need researchers to be listening to us, to hear our stories and our lived experience.”
(Interviewee)

In the UK over 850,000 people are living with dementia¹, yet less is known about dementia than illnesses like cancer², and dementia care has been identified as a key area for improvement³. More research is therefore crucial to improve the experience and care of people with dementia.

Dementia is often associated mainly with cognitive impairment, but can also affect a person’s mood, sensory perceptions and behaviour. *“The word ‘dementia’ describes a set of symptoms that may include memory loss and difficulties with thinking, problem-solving or language.”*¹

As dementia becomes more advanced the person affected may have greater difficulty understanding and recalling information, and communicating with others, and may also become more physically frail. We believe that researchers should have the skills necessary to meaningfully engage with participants who have dementia, and to support their welfare during research.

About Ethnography

Ethnography is a research methodology that has its origins in anthropology and is widely used throughout the social sciences.

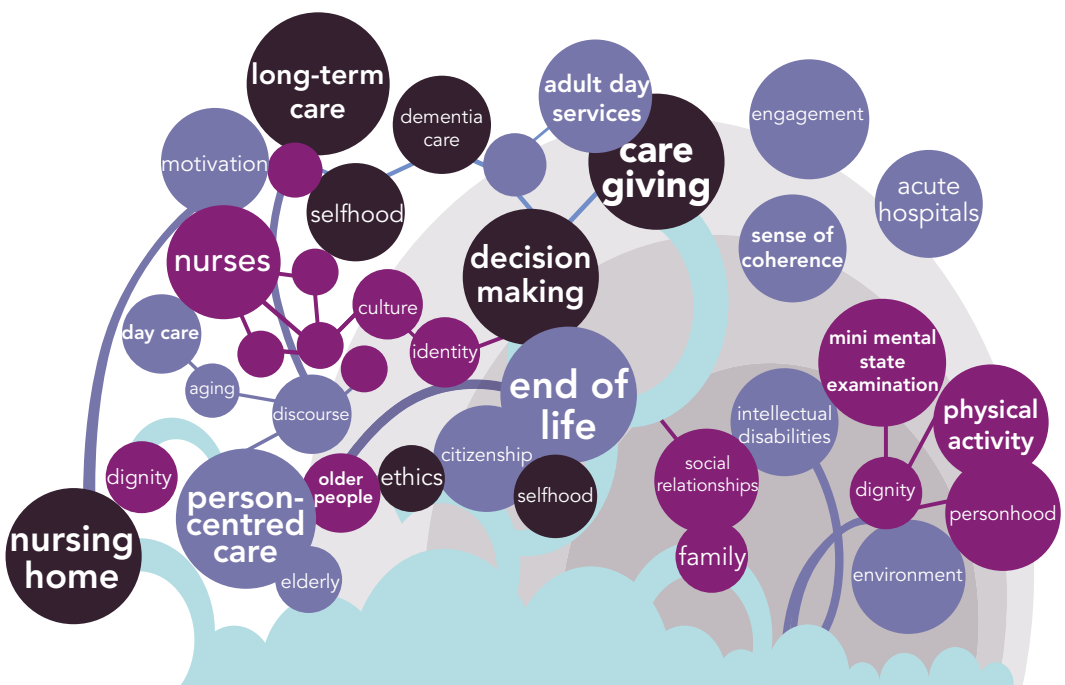
*“In terms of data collection ethnography usually involves the researcher participating overtly or covertly, in people’s daily lives for an extended period of time, watching what happens, listening to what is said, and/or asking questions through informal and formal interviews, collecting documents and artefacts – in fact, gathering whatever data are available to throw light on the issues that are the emerging focus of inquiry.”*²

Using Ethnography in Research About Dementia

Ethnography may be a particularly helpful research method when working with people who have dementia, especially more advanced dementia. Ethnographic methods allow time for communication, and can accommodate creative research approaches, responding to the needs of a vulnerable population.

As illustrated below, our content analysis of published research literature identified some common areas of focus for ethnographic research with people with dementia.

Our analysis shows that there is a lot of dementia research taking place in long term care in institutional settings. Ethnographic methods may be especially helpful in this field as they can illuminate the interactions between people and their social and cultural environment.



Conducting Research With People Who Have More Advanced Dementia

Participants in the ThistleDown Project study identified the following as important for the conduct of ethical research with people who have advanced dementia.

Knowledge and skills for dementia researchers:

- Relationship building
- Responsive observation of body language
- Creative approaches to verbal and non-verbal communication
- Understanding of how time, place and other activities and events may affect participants
- Knowledge of how people with dementia may appear and act, and what needs they may have.
- Ability to recognise fluctuations in capacity

Key finding

It is important to 'get to know' a person with dementia who may take part in research. This is because everyone experiences dementia differently, and may have different needs regarding information giving and different styles of communication. Personal knowledge is also invaluable to ensuring that a participant's welfare is maintained throughout the course of the study.

Ethical Conduct – Assessing Capacity

Under the Adults with Incapacity (Scotland) Act 2000 (AWI), some people with dementia are legally declared 'adults with incapacity', and have a legal proxy appointed to make certain decisions on their behalf.

A diagnosis of dementia is not, in itself, reason to assume incapacity, and a central principle of the Act is that individuals are presumed to have capacity unless there is evidence to the contrary. However, people with dementia can lose capacity as their condition progresses, and may have periods of fluctuating capacity. This can pose challenges for the researcher, who is responsible for recruiting the appropriate population in terms of their capacity.

When recruiting adults with incapacity the researcher must gain informed consent from a legal proxy before approaching the participant. Alternatively, researchers may encounter adults who are not legally designated as lacking capacity, but who are described by others or appear to them as not having capacity. In this case, our evidence suggests that researchers will assess capacity to participate in the research, using the following methods:

- Presenting information in different, dementia friendly formats.
- Seeking an informed opinion by talking to participant's significant others and care staff.
- Building a relationship with potential participants to enable the researcher to better assess their understanding.
- Allowing time and ensuring that the context in which the researcher approaches the participant is conducive to their best cognitive functioning.

Ethical Conduct – Process Consent

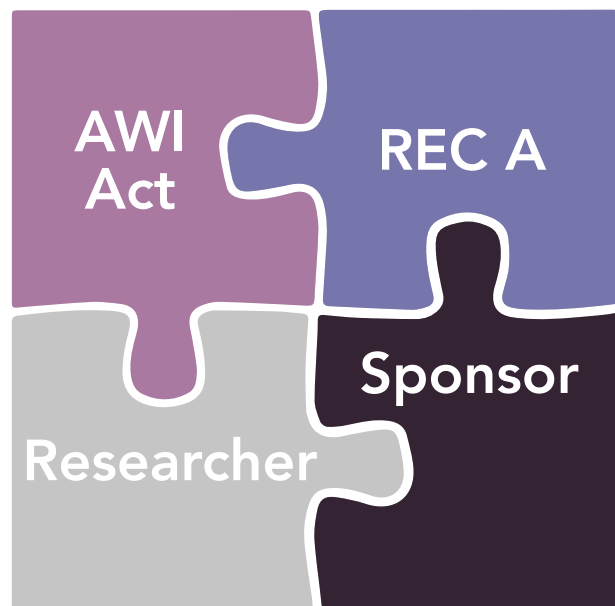
Once the sample has been recruited, and the participants (or proxy decision makers) have given consent, the legal requirement for consent has been satisfied. However, our study found that for researchers, ethically sound practice will involve ongoing process consent⁵ throughout data collection.

Process consent need not be written. Researchers can ask participants to verbally consent, or allow opportunities for participants to dissent using body language as well as direct and indirect verbal cues. This could include observing participants for signs of fatigue or distress; observing fluctuations in participants' capacity; and re-confirming willingness to participate as the research progresses.



Supporting Ethical Research

There are four key elements that support the ethical design and conduct of research with adults with incapacity:



The Sponsor

The sponsor is the organisation that is responsible for *“ensuring that the design of the study meets appropriate standards and that arrangements are in place to ensure appropriate conduct and reporting.”*⁷. The sponsor is typically a university or other employer. All research involving the NHS or adults with incapacity requires a sponsor, and some funding bodies also require a sponsor. The sponsor should ensure that the study is methodologically and legally sound.

AWI Act

In Scotland, all research involving adults with incapacity is governed by the Adults with Incapacity (Scotland) Act 2000 (AWI). Part 5, Section 51, Items 1-4 of the Act describe the circumstances under which research cannot be conducted with adults with incapacity.

REC A

The AWI stipulates that a Research Ethics Committee (REC) be established to review research with adults with incapacity. This committee is called Scotland REC A, and is governed by the Health Research Authority (HRA). The role of HRA RECs is to: *“review research proposals to assess formally if the research is ethical. This means the research must conform to recognised ethical standards, which includes respecting the dignity, rights, safety and well-being of the people who take part.”*⁶

It is not the remit of RECs to decide the legality of a study, nor to engage in peer review of a research design. However, our evidence indicates that in practice, RECs will take into consideration legal issues, the perceived quality of a study design, and the significance of the topic, as well as anticipated risks and benefits.

The Researcher

When designing a project the researcher must anticipate ethical issues and formulate appropriate responses to them. No research is risk-free, but researchers are expected to be aware of risk and to manage it accordingly. They will be asked to demonstrate this to the satisfaction of the REC. The responsibility for managing risk and responding to ethical issues continues throughout the research, and our findings suggest that the emergent nature of ethical dilemmas can be the most complex part of research ethics.

Structural Issues in Research Governance

Our study illuminated a number of issues related to two of the structures that support ethical research, the AWI and REC A.

Three Key Findings about the AWI

1. The AWI requires that research not be carried out with adults with incapacity if similar research can be carried out with adults who have capacity.

This requirement tends to restrict research to samples consisting solely of adults with capacity or solely of adults without capacity, avoiding mixed samples.

2. Research should relate to the “causes, diagnosis, treatment or care”⁸ of the adult’s incapacity.

For example, one interviewee told us about a study which promised to have benefit for a population of adults with incapacity. While the study design was considered to be ethical by the reviewing Committee, the issue to be researched was not directly related to the cause of incapacity, and therefore the research could not legally be carried out.

3. That the research should be of “real and direct benefit to the adult [who is participating in the study].”⁵

Our findings show that in practice very little research can demonstrate real and direct benefit for the participant, but studies can meet an alternative requirement in the Act, that the research will contribute to knowledge that will lead to benefit for other persons with the same incapacity.

Three Key findings about REC A

1. Composition of the Committee (which is set out in the AWI) is largely of a natural science background, with experience in biomedical research and quantitative research. Interviewees identified that the membership of the committee creates a particular knowledge culture within the committee. It may be helpful for this committee to broaden their understanding of social and qualitative research methods.
2. Our evidence suggests that there are areas of misunderstanding between researchers and REC A. Interviewees identified that researchers could better understand the remit of the REC, the legal limitations on research with adults who lack capacity, and the expectations of the REC for this kind of research.

Our data show that it is common for researchers to find attending a Committee meeting intimidating and stressful.

3. Our data show that it is common for researchers (especially novice researchers) to find attending a Committee meeting extremely stressful. There may be aspects of this that are unavoidable (e.g. having fifteen people reviewing one’s work is likely to be anxiety provoking).

Equally, interviewees suggest that the Committee could create a less intimidating atmosphere by ensuring that researchers are informed about the Committee process and aims; allowing researchers time to familiarise themselves with the Committee environment; and treating the researcher with respect.

Making a submission to the REC

“The committee by and large wants to help the researcher but the researcher has to help the committee.”

(Interviewee)

Based on our findings we have formulated the following advice for researchers:

Research with adults with incapacity

Interpretations of the AWI often seem to preclude recruiting a research sample that includes both adults with and without capacity. However, our evidence shows that there are conflicting interpretations on this point.

We identified one ethnographic study in which the researcher was given permission to recruit participants with and without capacity, while in other cases researchers were asked specifically to exclude one or other population from the sample.

Interviewees identified that where a research population contains a large proportion of adults with incapacity, the REC may take the question of representativeness into account.

Research with mixed capacity populations may also be deemed acceptable where the research aim is to compare and contrast between a population with capacity, and a population without. As with any research involving adults with incapacity, the other conditions of the AWI must still be met, and the inclusion of adults with incapacity must be essential in order to answer the research question.

Lay language

Researchers should write their IRAS application in lay language. The REC is not intended to be a committee of scientific peers, and the researcher cannot assume that REC members have any specialist knowledge about the researcher’s field. Our interviewees observed that writing in lay language can be challenging for academics. For example, academics often use the passive voice, but this can make it difficult for REC members to work out who is doing what to whom in a research study.

Presenting your research

Our findings indicate that the research question and description of methods in the IRAS form are key for the REC’s evaluation of the proposal. The research question must clearly demonstrate why including adults with incapacity is essential in order to answer the question. The description of methods must show how the methodology is appropriate for answering the research question.

Attending the REC Meeting

Our data indicate that the presence of the researcher is crucial in the REC decision making process. The researcher should attend the Committee in person in order to allow Committee members to ask them questions. In the case of PhD students, interviewees emphasised that they should be accompanied by their supervisor to demonstrate that they are properly supported.

Interviewees argued that the researcher’s experience, qualifications and skills, are important in demonstrating to the REC that they are capable of carrying out the research in an ethical manner, responding to emergent ethical issues. Personal comportment during the Committee meeting is also important in demonstrating to the REC that the researcher is competent and able to relate to research participants in a sensitive and respectful manner.

Areas for Development

Our findings suggest that there are three important ethical issues that aren't being addressed within current guidance in relation to ethnographic research with people who have dementia.

Individual Consent and Research in Communal Spaces

Ethnographic research involves understanding interactions within a social context. How do we decide who is a participant and who should be asked to consent?

Key findings

The guidance and decisions from RECs can be inconsistent on the issue of individual consent and the presence of a researcher within a community, and there are multiple different practices described in the published research.

Interviewees also identified that one problem may be that REC members lack knowledge about ethnographic research and so find it difficult to evaluate the requirements for consent.

Process consent for people with dementia

Currently the AWI focuses research governance on the beginning of the research process, and in particular who can be approached to participate, who can consent, and the gaining of informed consent. While this first stage of research is clearly essential, process consent is also important when people have fluctuating capacity and memory.

Key finding

Very few of the research papers examined in our study reported undertaking process consent in their methodological descriptions. However, in interviews, researchers described careful and sensitive process consent as central to their work and this was also evident in the IRAS applications analysed as part of this study.

Protection and Inclusion

The AWI and HRA guidance build on the 1964 Declaration of Helsinki⁹ and emphasise protection of participants. This is in response to historical abuses of participants in research studies.

Key finding

Interviewees suggested that this emphasis on protection is sometimes to the detriment of inclusivity, and silences people who are already marginalised and who have historically received poor quality care. Interviewees argued that inclusion of these people in research is important in order to build knowledge about their experiences of illness and the quality of health and social care they receive.

The Scottish Government is currently considering amending the AWI including the provisions for research. We have been informed that amendments may include a move towards more inclusive decision making with adults with incapacity, which may influence recruitment to research.

Summary

The Thistledown Project has illuminated the complexity of the ethics of conducting ethnographic research with people who have more advanced dementia. We have generated evidence based advice for how researchers can approach this challenging area. However, there remain intractable issues related to the current legislation. Research ethics structures could also be developed in recognition of the value of qualitative and social research, in order to achieve more effective scrutiny of these kinds of studies.



The advice in this booklet presents findings from the Thistledown Project. Researchers seeking specific legal or ethical advice should consult the appropriate authorities.

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- ⁹The World Medical Association Declaration Of Helsinki – Ethical Principles For Medical Research Involving Human Subjects.
www.wma.net/policies-post/wma-declaration-of-helsinki-ethical-principles-for-medical-research-involving-human-subjects/

Other useful resources

- The Research Ethics Guidebook. A resource for social scientists.
www.ethicsguidebook.ac.uk/The-Adults-with-Incapacity-Scotland-Act-188
- The UN Convention on disability rights: www.un.org/development/desa/disabilities/convention-on-the-rights-of-persons-with-disabilities.html
- The Scottish Dementia Working Group Core Principles for Involving People with Dementia in Research <http://dementivoices.org.uk/wp-content/uploads/2014/06/Involving-people-with-dementia-in-research1.pdf>

About the Authors



Professor Heather Wilkinson is the director of the Edinburgh Centre for Research on the Experience of Dementia (ECRED). Her work focuses on the inclusion of people with dementia in a range of research areas. Heather's work has contributed to service development in Scotland with several of her projects having a direct influence on policy and practice. Heather is also a co-founder of the Scottish Dementia Working Group.



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