

Dementia-friendly consent in research:

study information



**About the project**

# Why have I been invited?

You are invited to take part in research study on the design of dementia friendly consent forms and the process of gaining consent in the UK – please note that this project has not covered the issues of identifying mental capacity as we focused on what participants reported affected their experience of taking part in research. Before you decide whether you wish to participate, it is important for you to understand why the study is being conducted and what it will involve. Please take some time to read the information provided and discuss it with others if you wish. Please ask if there is anything that is not clear, or if you would like more information.

# What is the purpose of the study?

The original aim was to develop a dementia-friendly consent form that would allow research to be more accessible and allow participants with dementia to provide consent with greater ease and understanding. Participants of projects that we have worked with before, have told us that consent forms can be confusing. It is important for us that the forms we use are clear for the people that we work with. We wanted to make our forms accessible at the same time as making sure that we include all the information that we need to. As part of the first stage of this project we spoke with people living with dementia, family members, dementia service staff and dementia researchers. The findings of this stage have been analysed and identified a number of recommendations for the design of the form, alongside some procedural recommendations relating to the way a project is introduced and how family or services are involved in supporting consent, where possible.

# Why have I been chosen?

We would like to ask for your feedback on elements of both the design and procedure for gaining consent for research. As a member of a research ethics committee, we would like to gain your feedback on the design, wording and overall ethical fit for this consent form.

# Do I have to take part?

Taking part is entirely voluntary. If you decide to take part, you will be asked to complete an anonymous online survey. Due to the nature of the anonymity, you will not be able to withdraw your answers at a later date. You are free to stop taking part prior to pressing submit and your responses to that point will not be recorded.

# What will my participation involve?

Below is link to an online questionnaire. This contains questions regarding the developed consent form and questions relating to the process of gaining consent via three short scenarios. This should take no longer than 30 minutes to complete.

<https://northampton.onlinesurveys.ac.uk/dementia-friendly-consent-rec-feedback-3>

After this information page you will see an example consent form (Page 2) that has been developed following recommendations from the first phase of our research. A second version follows this which differs in the style of phrasing (Page 3). One is in the form of statements and the second as questions about consent. Our research identified that questions may be easier to understand than statements. Page 4 of this document contains notes to show what changes were made and why. Page 5 contains the three consent process scenarios. Please can you read through these before completing the online survey. Please note that these are examples that focus on consent, rather than the methods.

# What are the possible benefits of taking part?

The information obtained from this study will be used to finalise our recommendations for the design of and process of gaining consent, to ensure that these meet with REC guidance. The outcomes of this research aims to encourage more people with dementia to make independent decisions about being involved in research, with the aim to make an easier to read and understand form and supported process.

# What are the possible risks or disadvantages of taking part?

The research team do not envisage there being any risks or disadvantages in taking part. However, if you are worried or experience any problems during the study, let us know or you can speak with:

Dementia UK: 0800 888 6678                              OR

Alzheimer’s Society Helpline: 0300 222 1122

# What if something goes wrong?

If you have any concerns about any aspect of the way you have been approached or treated during the course of this study, then please contact John Horton, Faculty of Health, Society and Education Research Lead, University of Northampton

Tel: 01604 892993 Email: john.horton@northampton.ac.uk

# Will my information be kept confidential?

All the information collected for this study will be anonymised and stored securely on a password-protected computer for a period of 10 years.

# What will happen to the results of the study?

The results from this study will be used in the following ways: We would like to share what we have learnt with other people. This will be in an article for journals and conference presentations.  We may also use anything we have learned in health and social care professional education.

# Who has reviewed the study?

This study has been reviewed and approved by the Faculty of Health, Society and Education’s Research Ethics Committee.

# Contact for further information

If you have any questions about this study or your possible involvement then please contact me using the contact details below.

*Alison Ward, Associate Professor, University of Northampton, Tel: 01604 893559 Email:* *alison.ward@northampton.ac.uk*

**Consent form – Statement Version**

[insert logo here]

**CONSENT FORM**

Title of project: Dementia Friendly Consent Focus Groups

Yes, I agree

Please tick box

1. I agree to take part in the research.
2. I have read and understood information about

the research.

1. I have been able to ask questions.
2. I can stop taking part if I want to.
3. (if appropriate) The interview can be recorded.
4. (If appropriate) People from [company name] can

have access to my records.

1. (if appropriate) The things I say can be used in

other research.

1. The research results can be shared with others.
2. (if appropriate) My GP can be told that I am taking

part/ I agree my GP can be involved.

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Name of participant Signature Date

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_

Name of researcher Signature Date

**Consent form – Question Version**

[insert logo here]

**CONSENT FORM**

Title of project: Dementia Friendly Consent Focus Groups

Yes, I agree

Please tick box

1. Do you agree to take part in the research?
2. Have you read and understood information

about the research?

1. Have you been able to ask questions?
2. Do you know you can stop taking part if you want to?
3. (If appropriate) Can the interview be recorded?
4. (If appropriate) Can people from [company name] have

access to your records?

1. (If appropriate) Can what you say be used in other research?
2. Can the research results be shared with others?
3. (If appropriate) Can your GP be told that you are taking

part?/ Do you agree your GP can be involved?

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Name of participant Signature Date

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Name of researcher Signature Date

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**Consent Scenarios for Research with People Living with Dementia**

# Scenario1:

**Title:** Singing and wellbeing for people with dementia and their relatives

**Methods:** Quantitative methods; pre and post questionnaire on wellbeing, and collection of saliva samples to assess cortisol level of stress

**Recruitment:** Via an established dementia service that regularly delivers a choir for people with dementia and their relative.

**Informed consent process:** Information sheet about the study introduced in person the week before a new cohort of singers joins the choir. Consent for the research taken by the research team with a carer present face to face. Single consent form incorporating consent for data collection. Consent form designed for both the person with dementia and their relative to sign on the same from as they are both attending the group together and participating in the research. Researcher also signs to confirm process has been completed as per protocol. Capacity to consent will be discussed with the service and relative as part of the initial research project introduction before an approach is made for research participation. If person with dementia is deemed not to have capacity to consent, they will not be approached to participate in the study. Data collection completed by the research team.

# Scenario 2:

**Title:** Pilot of a new intervention to support healthy eating in care homes for people living with dementia

**Methods:** Mixed methods: pre and post in person paper recorded observations and eating audit questionnaire of eating patterns/habits and interviews with care home staff. No direct input from residents.

**Recruitment:** Via care homes

**Informed consent process:** Researchers to visit care homes on several occasions prior to commencement of data collection, to meet with staff and residents. Researchers to share information with care homes initially about the project, and then speak informally about the project with residents to assess individual needs and interest in taking part. A participant information sheet will be shared during these discussions. Screening for capacity to consent for the research will be undertaken by staff at the care homes, training will be provided on assessing capacity. Care home staff will be asked to complete the consent form with participants prior to observations taking place. Care home staff will be provided with the inclusion and exclusion criteria and copy of the protocol. Care home staff will be invited to take part in one-to-one interviews and if they participate will be asked to provide written consent at the start of the interview.

**Scenario 3:**

**Title:** Understanding people with dementia’s experience of taking part in an online 'buddy' programme

**Methods:** Qualitative methods: Four interviews with people living with dementia conducted over a 6-month period (pre programme, and every successive 2 months).

**Recruitment:** Via a dementia charity

**Informed consent process:** All participants taking part in the programme are invited to take part in the research via the programme lead. Participants will be recruited through the 'buddy' programme. Researchers will visit the home, at an agreed time, to meet with participants to assess their capacity to consent (asking participant to explain in their own words about the project) and to complete the written consent form if appropriate. The Researcher will then conduct the initial interview that will last about 30 mins. The researcher will then arrange the next interview. At each successive interview verbal consent will be recorded, via Dictaphone, at the start of the interview with a verbal reminder of the consent and project at the start of each interview.  Capacity assessment will be ongoing using Dewings (2007) Process Consent method whereby the researcher assesses them against their initial visit and taking into consideration verbal and nonverbal cues.

To support engagement in the research, the interview guide provides indicative wording for the questions. The research team may need to adapt these in situ to enable a participant to be able to respond fully.