(Form to be printed on local headed paper)

Participant Information Sheet - CONSULTEE
(Final version 1.1: date 2nd August 2023)

IRAS Project ID: 325423
Title of Study: VOICE2 Evaluation
Name of Chief Investigator: Professor Rowan Harwood
Local Researcher(s):

Invitation

Your relative (it could also be a friend or someone you care for, but for brevity this document will use the term 'relative') is being invited to take part in a research study. Before you decide whether you agree to their taking part it is important for you to understand why the research is being done and what it will involve. One of our team will go through the information sheet with you and answer any questions you have. Talk to others about the study if you wish. Ask us if there is anything that is not clear or if you would like more information.

Who can act as a consultee?

Where people cannot take the decision to consent to be involved in a research project then a consultee must be appointed. A consultee can either be 'personal' or 'nominated.' A personal consultee is someone unconnected with the research who knows the potential research participant in a personal capacity and can advise on the person's wishes or feelings. This can be a friend, family member or court appointee. A 'nominated consultee' is someone unconnected with the research, appointed by the researcher, to advise the researcher about the person's wishes and feeling in relation to the project. This can be another health-care worker, but they must not have any connection with the study. Before a nominated consultee is appointed, the researcher will take all reasonable steps to identify a personal consultee.

What is the role of the consultee?

The consultee advises the researcher on what the participant's wishes and feelings would be if they were able to consent for themselves, and on whether they should take part. The consultee does not give consent, only advice. The responsibility to decide whether the participant should be entered into the research lies with the researcher. Consultees will be provided with information about the research project and will be given

Formatted: Font color: Auto
Formatted: Font color: Auto
Formatted: Font color: Auto

the opportunity to discuss it and their role as consultee. All consultees must be able to understand their role and be willing to undertake it.

What is the purpose of the study?

Hospital staff such as nurses, doctors, therapists, and healthcare assistants often find it difficult to communicate effectively with patients with dementia when the patient is distressed. The patient might show their distress as agitation, aggression or repetitive calling out. There is little hard evidence on what communication strategies work to avoid, de-escalate or resolve patient distress. We video and audio recorded conversations between ward staff and patients with dementia and then studied them to identify which communication strategies are most effective when the patient is distressed. Using this information, we have developed a communication skills training course for ward staff and a 'train the trainers' course for hospital clinical educators to learn how to deliver this course. We want to understand whether the communication skills the ward staff learn on this course, do have a positive impact on patient care.

Why has my relative been invited?'

Your relative is being invited to take part because they have a diagnosis of dementia and at times can become distressed. We are inviting 60 patients like your relative to take part

Does my relative have to take part?

No, we would like you to think very carefully about whether your relative would have wanted to join the study. If your opinion is that he/she would have decided to take part, you will be given this information sheet to keep and be asked to sign a declaration form indicating your view allowing your relative to participate in the study. If you later decide that he/she no longer wishes to take part, please inform us and he/she will be withdrawn from the study. You do not need to give a reason and it will not affect the standard of care your relative receives.

What will happen to my relative if they take part?

If your relative takes part in the study, we will look at their medical notes to confirm they have a diagnosis of dementia. We will watch and make notes of the care your relative receives from the ward staff we have trained. There will be no changes to the care they receive, we will only be watching routine care being given to them. We may also talk to you about the care given to your relative and how well ward staff treated them when they were distressed.

Formatted: Font color: Auto

Formatted: Font color: Auto

Formatted: Font color: Auto

Your relative will be involved in this research for the time they are a patient on the ward.

What are the possible disadvantages or risks of taking part?
We are only watching the ward staff delivering the usual care to your relative and talking to you about the care your relative receives. There is little risk of harm. You might find that talking about the care your relative has received when they are distressed makes you feel distressed. Our researchers are skilled at supporting people who are distressed

What are the advantages of taking part?
We cannot promise the study will help your relative directly. We hope that the information we get will help staff to care better for people in a similar situation to your relative in the future.

What happens when the research study stops?
The information you give us will be used to understand whether the communication skills training course we have developed does improve patient care. We will write up the results of the study in medical journals and share the results with hospital staff, people with dementia and their family members and friends. If the course is shown to be of benefit, we will aim to roll it out nationally.

What if there is a problem?
If you have a concern about any aspect of this study, you should ask to speak to the researchers who will do their best to answer your questions. The researchers contact details are given at the end of this information sheet. If you remain unhappy and wish to complain formally, you can do this by contacting NHS Complaints. Details can be obtained from your hospital.

Will their taking part in this study be kept confidential?
We will follow ethical and legal practice and all information about your relative will be handled in confidence.

If your relative joins the study, we will use information collected about them and their medical records during the research. This information will be kept strictly confidential, stored in a secure and locked office, and on a password protected database at the University of Nottingham. Under United Kingdom Data Protection laws, the University is the Data Controller (legally responsible for the data security) and the Chief Investigator of this study (named above) is the Data Custodian (manages access to the data). This means we are responsible for looking after the

Formatted: Font color: Auto
Formatted: Font color: Auto
Formatted: Font color: Auto

information and using it properly. Rights to access, change or move your information are limited as we need to manage the information in specific ways to comply with certain laws and for the research to be reliable and accurate. To safeguard your relative's rights, we will use the minimum personally identifiable information possible.

You can find out more about how we use your relative's information and to read our privacy notice at:

https://www.nottingham.ac.uk/utilities/privacy.aspx.

The data collected for the study will be looked at and stored by authorised persons from the University of Nottingham who are organising the research. They may also be looked at by authorised people from regulatory organisations to check that the study is being carried out correctly. All will have a duty of confidentiality to your relative as a research participant and we will do our best to meet this duty.

All information which is collected about your relative during the research will be kept **strictly confidential**, stored in a secure and locked office, and on a password protected database. Information about your relative which leaves the [site] will have their name and address removed and a unique code will be used so that they cannot be recognised from it. By signing the consultee advice form or providing verbal agreement, you agree to the above.

Your relative's personal data (address, telephone number) will be kept for up to six months after the end of the study. All other data (research data) will be kept securely for 7 years. After this time, your relative's data will be disposed of securely. During this time, all precautions will be taken by all those involved to maintain your relative's confidentiality, only members of the research team will have access to their personal data.

In accordance with the University of Nottingham's, the Government's, and our funders' policies we may share our research data with researchers in other Universities and organisations, including those in other countries, for research in health and social care. Sharing research data is important to allow peer scrutiny, re-use (and therefore avoiding duplication of research) and to understand the bigger picture in particular areas of research. Data sharing in this way is usually anonymised (so that you could not be identified) but if we need to share identifiable information, we will seek your consent for this and ensure it is secure.

Formatted: Font color: Auto

Formatted: Font color: Auto

Formatted: Font color: Auto

You will be made aware then if the data is to be shared with countries whose data protection laws differ to those of the United Kingdom and how we will protect your confidentiality.

What will happen if I do not want my relative to carry on with the study?
Your relative's participation is voluntary, and you are free to withdraw them at any time, without giving any reason, and without their legal rights being affected. If you withdraw your relative, then the information collected so far cannot be erased and this information may still be used in the project analysis.

What will happen to the results of the study?
The results of this study will be discussed at medical research meetings and written about in research and clinical journals. Your relative will not be identified in any publication.

We will send a newsletter to all patients recruited to the study updating them on the results.

Who is organising and funding the research?
This research is being organised by the University of Nottingham and is being funded by the National Institute of Health Research.

Who has reviewed this study?
All research in the NHS is looked at by independent group of people, called a Research Ethics Committee, to protect participant's interests. This study has been reviewed and given favourable opinion by the Health and Social Care Research Ethics Committee Wales REC4.

Further information and contact details
If you have any additional questions, please contact one of the research team at the University of Nottingham or Nottingham University Hospitals. You can contact the project administrator Kasia Kowalewska who will direct you to the most appropriate person email: katarzyna.kowalewska@nottingham.ac.uk or the Chief Investigator Professor Rowan Harwood by phone 0115 8230873, or on email: rowan.harwood@nuh.nhs.uk

Thank you for reading this and considering taking part in the study

Formatted: Font color: Auto
Formatted: Font color: Auto
Formatted: Font color: Auto