



## **CONSULTEE INFORMATION SHEET**

### **Introduction**

You are being asked to give advice about someone known to you, who is resident in a care home that is supporting research. This person is unable to decide for himself/herself whether to participate in this research study.

To help decide if he/she should join the study, we'd like to ask your opinion as to whether they would want to be involved. We'd ask you to consider what you know of their wishes and feelings, and to consider their interests. Please let us know of any advance decisions they may have made about participating in research.

Please consider the information provided about the research study. You will have the opportunity to discuss the study with the research study staff and care home staff caring for the person you know, and to ask any questions you may have about the study.

If you decide this person would have no objection to taking part, we will ask you to read and sign a Consultee Declaration Form. We will then give you a copy to keep. We will keep you fully informed during the study so you can let us know if you have any concerns or you think the person should be withdrawn.

If you decide that the person would not wish to take part it will not affect the standard of care they receive in any way.

If you are unsure about taking the role of consultee you may seek independent advice. We will understand if you do not want to take on this responsibility.

The following information about the study is the same as would have been provided to the person we are consulting you about.

## Summary

You are being asked to consider whether the person you know should join the DISCO UTI research study. To help you decide it is important that you understand why the research is being done and what it will involve for them. Please read the information below carefully and ask questions if anything is not clear or you would like more information.

### Key points:

- We are a team of researchers who are looking into how we can improve the detection of urinary tract infections (UTIs) in people who live in care homes.
- UTIs don't always cause clear symptoms for people who live in care homes and urine tests that are currently available do not give accurate or quick results.
- It can therefore be challenging for doctors to be sure whether someone has a UTI or not.
- We have some ideas about new ways that might help show us if someone really has a UTI but we don't know yet whether these will work. This study will help to explore these new ideas.
- Taking part in the study would involve the person you know giving a series of small samples of urine for research tests at the beginning of the study.
- If they get a possible UTI over the next 6 months they would give another set of small urine samples for research tests.
- They would receive care as usual from the NHS whilst they are in the study and if they got a possible UTI.
- If you decide that the person would not wish to take part it will not affect the standard of care they receive in any way.

## **1. What is the study title?**

The full title of the study is 'Feasibility cohort study on predictors of diagnosis and prognosis of urine infection in care home residents.' However, we usually refer to the study by its short name which is DISCO UTI.

## **2. Who is doing the study?**

The study is being carried out by a team of researchers from the University of Southampton, the University of Oxford and the University of Bristol, as well as other researchers from across the UK. We are interested in the health of people who live in care homes.

## **3. What is the study about?**

We are looking at how we can improve the detection of urinary tract infections (UTIs) in people who live in care homes. This is a common illness but it can be challenging for doctors to be sure whether someone in a care home has a UTI or not.

## **4. Why is it important to be sure whether someone has a UTI?**

It is important to know whether someone really has a UTI because if you don't treat an infection there can be serious consequences. However, giving antibiotic treatment when there isn't an infection can cause antibiotic resistance and side effects.

## **5. Why is it challenging to be sure whether someone in a care home has a UTI?**

There are several reasons for this:

- UTIs don't always cause clear symptoms for people who live in care homes.
- UTIs sometimes just cause symptoms like confusion which can have lots of different possible causes.
- It may be hard for people living with dementia to say how they are feeling or to easily provide a urine sample.

- Many people who live in care homes have bacteria present in their urine even when they are well, but this not harmful and does not need treatment.

## **6. Can you do any tests for UTI?**

Unfortunately, urine tests that are currently available do not give accurate or quick results. They also can't tell the difference between bacteria in the urine causing infection (needing treatment), and bacteria in the urine not causing infection (not needing treatment). As a result, many people in care homes probably get antibiotics when they don't actually need them.

## **7. How are you going to address these challenges around detecting a UTI?**

We have some new ideas that we want to test:

- Working out which symptoms or signs mean a UTI is more likely
- Detecting new markers of infection in urine samples
- Trying out new bedside tests that give rapid results

Eventually, we want to conduct a very large study collecting information and urine samples from many people living in care homes over a long period of time. However, we need to work out the best way to do such a big study. DISCO UTI will help us to do this.

## **8. Why is the person we are consulting you about eligible to take part in DISCO UTI?**

They are eligible to take part in this study because they are over 65 years of age and live in a care home. We will be including 100 people like them in DISCO UTI.

However, they will **not** be able to take part in the study for several reasons, including:

- They are not permanently living in the care home
- They have a urinary catheter, or regularly use an in-out catheter
- They have a weakened immune system

- They will not be able to provide an uncontaminated urine sample

Members of the research team will check whether they meet all of the criteria.

### **9. Do they have to take part?**

No, if you decide that this person would not wish to take part they do not have to.

### **10. What will happen if I decide to take part in the study?**

There are several stages to the study.

#### 1. Baseline assessment

The researcher will record some information about the person including their medical problems, medications and whether they have had UTIs in the past. Care home records may be used to complete this.

They will then be asked to provide a small sample of urine which will be sent for research tests. A researcher or care home worker can support them to collect the sample if needed.

#### 2. Weekly urine samples for 4 weeks

25 participants will be asked to provide another small sample of urine once a week for the next four weeks. We will select participants to ensure that we have a good mix of gender and presence or not of bacteria in the urine at baseline. We will make it clear to you and the care home whether the person you know has been selected for this part of the study. Each of these samples will be sent for research tests.

#### 3. Reassessment if they get a possible UTI

For the six months following the baseline assessment, the care home will be asked to contact the research team every time they think that the person you know might have a UTI. They will also contact their GP, who will investigate and treat them as they normally would.

We can put up a poster in the person's room to remind the care home staff to contact the research team in these instances. However, this would be visible to anyone coming into the person's room. If you would prefer there to be no poster, you do not need to sign this optional part of the consultee declaration form.

The care home will be asked to support them in collecting another urine sample which will be sent for research tests. If the GP has also asked for a urine sample, we will make sure that this is done first.

A member of the research team will also come to the care home to record more information like symptoms and whether the illness has meant that they need additional care or support. They will ask the care home whether they have had any care from their GP or other healthcare provider over this period.

A member of the research team will return to the care home 14 and 28 days later to see how they are getting on and to collect a further urine sample. They may ask to see the care home records to find out what has happened to them between the visits.

If they develop a further possible UTI over the 6 months of the study, all of these steps would be repeated again.

## **11. How will they provide a urine sample?**

If they need help providing a urine sample, the person you know will be offered support by a care home worker or a member of the research team. We only need 15ml (around 1 tablespoon) per sample of urine for all the research tests to be able to be carried out.

## **12. What are the research tests?**

We will be doing a few different research tests on each of the samples that you provide.

Some of these will be carried out in a laboratory:

- Culture test – we will see if any bacteria grow from the urine sample. This test will be carried out in the Public Health Wales laboratory in Cardiff.
- Biomarker tests – we will see if we can detect different biological molecules that may be higher in infections. These tests will be carried out in a University of Southampton research laboratory.

Some of the tests will be carried out in the care home by the research team. These will involve putting a fresh sample of urine into a machine which will look for the presence of bacteria, or other markers of infection.

### **13. Who will get the results of the research tests?**

We will not give you as consultee, the care home or the GP the results of any of the research tests. This is because we do not know how good the new tests will be at detecting a UTI. We do not want to cause harm by giving an inaccurate or unhelpful result.

Urine culture tests are available as part of usual NHS care. If the person's GP or other healthcare provider wants a culture test they will send one themselves, and will receive the result directly.

### **14. Will the results of the test be shared with anyone other than the research team?**

The central laboratory run by Public Health Wales will combine the person's study code with the results of the specialised culture tests they run. The companies who have created the new devices may also be given data about the sample tested on their device, but they will not be given any data about the person you know. Neither Public Health Wales nor device manufacturers will receive their name or any other identifiable information about them from this study.

### **15. What will happen to the urine samples after the research tests have been carried out?**

All urine tested at the care home will be safely disposed of after any tests carried out there. However, if there is any urine remaining after the

tests have been carried out in the laboratory, we will freeze and store it at a licensed facility. This means that it could potentially be used in another research project in the future. Any future research would need to have ethical approval. Future research may involve commercial organisations. Samples will be stored anonymously which means that they could not be linked back to the person you know.

**16. What are the possible benefits of taking part?**

There will be no direct benefit to the person taking part in the research. However, the information gained from the study will be useful when planning further research in care homes, which may help people like them in the future.

**17. Will they be reimbursed for taking part?**

No, they will not receive any payment for taking part in this study.

**18. Are there any possible disadvantages from taking part?**

Taking part in the study will involve some of their time – to answer questions and to provide urine samples at each of the study visits. Overall, we hope that this won't be too inconvenient.

**19. Will the person's GP be informed that they are taking part in the study?**

We will notify the GP that they are taking part in the study. There may also be instances where the research team may ask the care home to contact the GP – for example if they are worried that they are unwell when they see them at a study visit.

**20. Will taking part in the study be kept confidential?**

Yes, their participation and the information we collect about them during the course of the research will be kept strictly confidential.

Only members of the research team and responsible members of the University of Southampton and University of Oxford may be given access to data about them for monitoring purposes and/or to carry out



an audit of the study to ensure that the research is complying with applicable regulations. Individuals from regulatory authorities (people who check that we are carrying out the study correctly) may require access to the data. All of these people have a duty to keep their information, as a research participant, strictly confidential.

## **21. What will happen to their data?**

The University of Southampton conducts research to the highest standards of research integrity. As a publicly-funded organisation, the University has to ensure that it is in the public interest when we use personally-identifiable information about people who have agreed to take part in research. This means that when you agree that your friend/relative will take part in a research study, we will use information about you in the ways needed, and for the purposes specified, to conduct and complete the research project. Under data protection law, 'Personal data' means any information that relates to and is capable of identifying a living individual. The University's data protection policy governing the use of personal data by the University can be found on its website (<https://www.southampton.ac.uk/legalservices/what-we-do/data-protection-and-foi.page>).

This Consultee Information Sheet tells you what data will be collected for this project and whether this includes any personal data. Please ask the research team if you have any questions or are unclear what data is being collected about the person you know.

Our privacy notice for research participants provides more information on how the University of Southampton collects and uses personal data when you take part in one of our research projects and can be found at <http://www.southampton.ac.uk/assets/sharepoint/intranet/Is/Public/Research%20and%20Integrity%20Privacy%20Notice/Privacy%20Notice%20for%20Research%20Participants.pdf>

Any personal data we collect in this study will be used only for the purposes of carrying out our research and will be handled according to

the University's policies in line with data protection law. If any personal data is used from which the person can be identified directly, it will not be disclosed to anyone else without your consent unless the University of Southampton is required by law to disclose it.

Data protection law requires us to have a valid legal reason ('lawful basis') to process and use the Personal data of the person you know. The lawful basis for processing personal information in this research study is for the performance of a task carried out in the public interest. Personal data collected for research will not be used for any other purpose.

For the purposes of data protection law, the University of Southampton and the University of Oxford are the 'Data Controllers' for this study, which means that we are responsible for looking after the person's information and using it properly. The Universities will keep identifiable information about your friend/relative for 10 years after the study has finished after which time any link between them and their information will be removed.

To safeguard their rights, we will use the minimum personal data necessary to achieve our research study objectives. Data protection rights – such as to access, change, or transfer such information - may be limited, however, in order for the research output to be reliable and accurate. The University will not do anything with the personal data of the person you know that you would not reasonably expect.

If you have any questions about how the person's personal data is used, or wish to exercise any of your rights, please consult the University's data protection webpage (<https://www.southampton.ac.uk/legalservices/what-we-do/data-protection-and-foi.page>) where you can make a request using our online form. If you need further assistance, please contact the University's Data Protection Officer ([data.protection@soton.ac.uk](mailto:data.protection@soton.ac.uk)).

## **22. What will happen if I don't want the person I know to carry on with the study?**

You can change your mind at a later stage. Withdrawal from the study will not affect the care they receive from the care home or the NHS. If you withdraw the person you know from the study, we will destroy all identifiable samples, but will use the data we collected up to the withdrawal.

## **23. What will happen to the results of this study?**

We will publish the study findings through journal articles, reports, presentations and conference papers. We also hope to present the work to people who play an important role in care homes – like residents, staff and charities. The person you know will not be able to be identified in any written or verbal reports from the study. As a consultee, we will also send you a summary of the findings of the study if you would like this. Some of the research being undertaken will also contribute to a PhD thesis.

## **24. What if there is a problem?**

If you have a concern about any aspect of this study, you should speak to the researchers (contact details below) who will do their best to answer your questions.

If you remain unhappy or have a complaint about any aspect of this study, please contact the University of Southampton Research Integrity and Governance Manager (023 8059 5058, [rgoinfo@soton.ac.uk](mailto:rgoinfo@soton.ac.uk)).

## **25. How have patients and the public been involved in this study?**

Care home staff and relatives of those living in care homes have provided feedback on the design of the study and the information sheets that care homes and participants read. We will be asking for their help throughout the study, including how the results of the study are shared with the public.

## **26. Who is organising and funding the study?**

The research is being organised by the Primary Care Research Centre at the University of Southampton and the Nuffield Department of Primary Care Health Sciences at the University of Oxford. The research is being funded by the National Institute for Health and Care Research School for Primary Care Research. Dr Abigail Moore is completing some of this work as part of her PhD which is being funded by the Wellcome Trust.

## **27. Who has reviewed the study?**

All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee, to protect participants' interests. This study has been reviewed and given favourable opinion by Newcastle & North Tyneside 2 Research Ethics Committee Research Ethics Committee.

### **Further information and contact details:**

Please ask the research study team if you have any questions or you do not understand the information we have provided on the contact details below:

Principle Investigator: Dr Abigail Moore

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Email: [discouti@phc.ox.ac.uk](mailto:discouti@phc.ox.ac.uk)

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**Thank you for reading this information and considering taking part in this study.**