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**Participant Information Leaflet**

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| **Study Title:** | Point of care diagnosis of urinary tract infections (UTIs) in pregnancy by volatile organic compound (VOC) analysis |
| **Investigator(s):** | Dr Lauren Lacey (NIHR ACL), Dr Ian Henderson (NIHR ACF), Professor James Covington (Department of Engineering), Professor Siobhan Quenby (Warwick Medical School) |

**Summary information sheet**

**Introduction**

You are invited to take part in a research study. Before you decide, you need to understand why the research is being done and what it would involve for you. Please take the time to read the following information carefully. Talk to others about the study if you wish.

Please ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part.

**Who is organising, funding and sponsoring the study?**

This study is organised by the team of investigators above who are part of Warwick Medical School and UHCW NHS Trust. The project is funded by the Warwick-Wellcome Translational Partnership. The study is sponsored by the University of Warwick. In this document, the use of the word “we” refers to the University of Warwick.

**What is the study about?**

Urinary tract infections (UTIs) are common in pregnancy affecting up to one in ten women. Some of these women have symptoms to warn them but others do not. UTIs can lead to complications in pregnancy which can affect both the mother and the baby and therefore diagnosis in a timely fashion is important. The current rapid tests used in clinics are not very accurate to diagnose UTIs. Consequently, it is currently recommended that all women provide a urine sample when they book their pregnancy with their community midwife which is sent to the laboratory to be cultured. If bacteria grow additional tests are done to determine which antibiotics will be effective at treating that bacteria which has grown. This process can be repeated several times throughout pregnancy. This is a time consuming and expensive process which can lead to delays in starting treatment.

A new technology, which mimics the human nose, has been recently shown to accurately diagnose several human diseases including various infections. We want to ascertain if this technology, which could be available as a bedside test, can diagnose UTIs in pregnancy.

**What would taking part involve?**

You will be asked to give consent to take part in the study. You will be asked to give a sample of urine from the middle of the stream (midstream urine sample) for routine laboratory analysis (this is part of your routine antenatal care). Urine left over after this analysis will be used for this study.

In this research study we will use information from you and your medical records. We will only use information that we need for the research study. We will let very few people know your name or contact details, and only if they really need it for this study.

Everyone involved in this study will keep your data safe and secure. We will also follow all privacy rules. At the end of the study we will save some of the data in case we need to check it and for future research.

We will make sure no-one can work out who you are from the reports we write.

The information pack tells you more about this.

**Study information pack**

**What would taking part involve and how we will use information about you**

We will need to use information about you when you provide the urine sample from you and your medical records. This information will include your hospital number, name, contact details, age, BMI, ethnicity, smoking status, the number of weeks you are into your pregnancy, number of previous pregnancies, current medications you are taking, if you have any allergies and if at the time of producing the sample if you had any symptoms of a urinary tract infection. People will use this information to do the research or to check your records to make sure that the research is being done properly. We will keep all information about you safe and secure.

We will also check your contact telephone number so that if your routine sample sent to the laboratory showed that you have a urinary tract infection, the clinical team can contact you about treatment.

With your consent you may be asked again later in your pregnancy for a further urine sample to repeat the process. This will only add a few minutes on to your routine visit to the hospital.

Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that you took part in the study. Data which identifies you will be stored until the end of the study.

**Do I have to take part?**

No. Participation in this study is completely voluntary and choosing not to take part will not affect your antenatal care in any way. You can also choose to withdraw your participation at any time, without giving a reason by contacting one of the research team. Further details about withdrawing from the study are provided later on in this document.

**What are the possible benefits of taking part in this study?**

There is no direct benefit to you but knowledge gained will help patients in the future. The research could lead to commercial gain for the University of Warwick and/or collaborators.

Any samples leftover after the analysis for this study will normally be discarded, however we would like your permission to donate these samples to the Tommy’s National Reproductive Health Biobank. The samples can then be used for future ethically approved research. These projects will not have access to patient identifiable data.

**What are the possible disadvantages, side effects or risks, of taking part in this study?**

There are no known risks to taking part in this study.

**Expenses and payments**

No payment will be provided for you taking part in the study

**What are your choices about how your information is used?**

You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have. We need to manage your records in specific ways for the research to be reliable. This means that we won’t be able to let you see or change the data we hold about you.

If you agree to take part in this study, you will have the option to take part in future research using your data saved from this study which will be stored by the Tommy’s BioBank.

**Will my taking part be kept confidential?**

Your information is protected under the General Data Protection Act 2018. We have a legal duty to keep your information confidential, secure and hold information only as long as necessary. As explained above, your data will be held on paper and on secure computer systems by the Tommy’s BioBank. The personal information obtained may be scrutinised by authorised persons, but information obtained will be treated as strictly confidential.

**What will happen to the data collected about me?**

As a publicly-funded organisation, the University of Warwick have to ensure that it is in the public interest when we use personally-identifiable information from people who have agreed to take part in research. This means that when you agree to take part in a research study, such as this, we will use your data in the ways needed to conduct and analyse the research study.

We (the University of Warwick) will be using information from you and your medical records in order to undertake this study and will act as the data controller for this study. We are committed to protecting the rights of individuals in line with data protection legislation. The Tommy’s Biobank will store the data for a minimum of 25 years.

Research data will be **link-anonymised** as quickly as possible after data collection. This means all direct and indirect identifiers will be removed from the research data and will be replaced with a participant number. The key to identification will be stored separately and securely to the research data to safeguard your identity. Any data used in future research will be anonymised

**Data Sharing**

Your rights to access, change or move your information are limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate. The University of Warwick has in place policies and procedures to keep your data safe.

As explained above, this data may also be used for future research, including impact activities following review and approval by an independent Research Ethics Committee and subject to your consent at the outset of this research project.

For further information, please refer to the University of Warwick Research Privacy Notice which is available here: <https://warwick.ac.uk/services/sim/privacynotices/research/> or by contacting the Legal and Compliance Services <https://warwick.ac.uk/services/legalandcomplianceservices>

**How do I stop participating in the study?**

If you wish to withdraw from the study, please contact Dr Lauren Lacey or the Biomedical Research Unit team on 02476967528.

**What will happen to the results of the study?**

Results will be published in internationally recognised journals and/or may be shared with collaborators. No identifiable patient details will be included.

**Who has reviewed the study?**

This study has been reviewed by North West Greater Manchester South Research Ethics Committee and approval given on 30th March 2021

**Who should I contact if I want further information about the study?**

Please contact Dr Lauren Lacey or the Biomedical Research Unit team on 02476 967528

### Where can you find out more about how your information is used?

You can find out more about how we use your information

* at [www.hra.nhs.uk/information-about-patients/](https://www.hra.nhs.uk/information-about-patients/)
* by asking one of the research team
* by sending an email to sponsorship@warwick.ac.uk or
* by ringing the sponsorship team on 02476 573123.

**Will anyone contact me about future research?**

We work with researchers in Reproductive Health across the UK, all who are trying to improve pregnancy outcomes for women and their babies. With your permission your contact details available to them if they have details of further studies that you may want to take part in.

**Who should I contact if I wish to make a complaint?**

Any complaint about the way you have been dealt with during the study or any possible harm you might have suffered will be addressed. Please address your complaint to the person below, who is a senior University of Warwick official entirely independent of this study:

**Head of Research Governance**

Jane Prewett

Research & Impact Services

University House

University of Warwick

Coventry

CV4 8UW

Email: [researchgovernance@warwick.ac.uk](mailto:researchgovernance@warwick.ac.uk)

Tel: 024 76 522746

If you wish to raise a complaint on how we have handled your personal data, you can contact our Data Protection Officer, who will investigate the matter: [DPO@warwick.ac.uk](mailto:DPO@warwick.ac.uk).

If you are not satisfied with our response or believe we are processing your personal data in a way that is not lawful you can complain to the Information Commissioner’s Office (ICO).

**Thank you for taking the time to read this Participant Information Leaflet**