Alternative CErvical screening (ACES) in Primary Care

Participant Information Sheet (PIS)

You are being invited to take part in a research study looking at the accuracy of urine HPV testing for cervical screening. The research forms part of one or more student projects, including a PhD thesis. Before you decide whether to take part, it is important for you to understand why the research is being conducted and what it will involve. Please take time to read the following information carefully before deciding whether to take part, and discuss it with others if you wish. Please ask if anything is not clear or if you would like more information. Thank you for taking the time to read this.

About the research

➢ **What is the purpose of the research?**

Cervical screening (also known as the 'smear test') is a test to help prevent cervical cancer and can save lives, yet only 7 in 10 eligible people in the UK attend screening, the lowest rate in 20 years. Cervical screening involves collecting cells from the cervix (neck of the womb) with a soft brush. These cells are tested for a virus known to cause cancer called human papillomavirus (HPV). If HPV is detected, the cells are examined under the microscope. If they look abnormal, you are referred to a colposcopy clinic, where cells that are found to be 'pre-cancerous' (cells with potential to become cancer cells) are identified and treated before they get a chance to turn into cervical cancer.

We have developed a urine test that can detect HPV. This test has the potential to remove many of the current barriers to screening, like embarrassment, fear of examination and inconvenience, and could substantially increase the number of people attending for cervical screening. This study will see if a urine test can accurately identify women and people with a cervix, with cervical pre-cancer and those who continue to be HPV positive after treatment, by comparing HPV detection rates in urine and cervical samples.

What would my involvement be?

➢ **Am I suitable to take part?**

You can take part if you are attending your GP Practice or other NHS clinic for routine cervical screening, also known as a 'smear test'. You cannot take part if you are pregnant or have had a hysterectomy.

➢ **What would I be asked to do if I took part?**

If you decide to take part, the study visit will take place on the same day as you attend your cervical screening appointment. Your appointment may take an extra 15 minutes. At the visit the practice staff will collect:

Your medical History. We will ask for some information about yourself including your current health and your health in the past.

A urine sample. We will give you a container and ask you to collect a urine sample. This can be collected in complete privacy.

Your thoughts about the test (optional). We would like you to complete a short questionnaire about urine and cervical tests and where you would prefer to do cervical screening in future e.g. GP practice or home.

After you have provided a urine sample, your routine cervical screening appointment (smear test) will go ahead as normal. You will be managed according to the results of your routine cervical screening test. We ask to view your medical records and collect the results of tests that are done so we can compare the results to our urine test. We will not inform you or your GP of your urine test results. We ask for your consent to keep any remaining urine, or samples that are taken during your routine clinical care for research. This will only be done after everything you need for your clinical care is finished.

Please be aware that your urine sample cannot be used as a replacement for your routine cervical screening test. If you do not wish to participate in the study, we will ask you to complete a brief questionnaire explaining your reasons. The questionnaire is entirely voluntary. It will not contain any personal identifiable information and the data may be used in scientific journals, conference presentations and PhD thesis.

If you need to attend for clinical follow up visits or repeat tests as part of your routine care, we may ask you to provide further urine and cervical samples each time you visit (up to a maximum of 3 times) for research. This will usually be within 12 months of your first appointment. Collecting further samples will help us understand how well the urine test performs during the management of abnormal smears.

- **How do I collect the urine sample?**

We would like to collect the first part of your urine. To do this you will be given instructions and a collection device called a collipee. **Please do not urinate for 1 hour before taking your urine sample**. We also ask that you avoid the use of vaginal moisturisers and lubricants and please do not bathe, shower or wash your genital area 1 hour before collecting the urine sample.

- **What happens if I do not want to take part or change my mind?**

It is up to you to decide whether or not to take part. If you do decide to take part you will be given this information sheet to keep and will be asked to sign a consent form. If you decide to take part you are still free to withdraw at any time without giving a reason and without detriment to yourself. However, it will not be possible to remove your data from the project once it has been anonymised as we will not be able to identify your specific data. This does not affect your data protection rights. If you decide not to take part you do not need to do anything further.

- **What are the possible benefits of taking part?**

There are no immediate benefits to you for taking part. The results will help us know whether urine HPV testing could be a reasonable alternative to routine cervical screening and encourage more people to attend.

- **What are the possible disadvantages and risks of taking part?**

We do not expect you to experience any side effects by taking part, though your GP appointment will take around 10 – 15 minutes longer.

- **What will happen to any samples I give?**

Your samples will be collected at the GP practice or clinic where you are having your routine cervical screening. Your samples will be stored and tested for HPV (DNA analysis) and other genetic markers, proteins and cells in MFT Clinical Sciences and University of Manchester Research Laboratories.

Some samples may also be sent for testing at GeneFirst laboratories in Oxfordshire (a molecular diagnostics company), The Queen Mary University, London or other academic institutions. Your identifiable data will be removed from your samples. We will ask for your consent to store your anonymised samples for future research at MFT Biobank to be used for research in projects led by scientists and doctors in academic institutions in the UK or abroad. Your samples may also be used in research projects led by commercial companies interested in developing new screening tests and diagnostics for cervical cancer. Any samples not required for future research will be disposed of appropriately as per NHS Trust policy. This study does not involve the use of laboratory animals.

- **Will I be compensated for talking part?**

You will not receive financial compensation for taking part in the study.

Research conduct, funding and publication

- **Who will conduct the research?**

Prof Emma Crosbie and Dr Jennifer Davies Oliveira, Division of Cancer Sciences at the University of Manchester.

- **Who is organising and funding the research?**

This study is sponsored by the University of Manchester and funded by the National Institute for Health Research (NIHR).

➢ **What if something goes wrong?**

In the unlikely event that something goes wrong and you are harmed during the research you may have grounds for a legal action for compensation against the University of Manchester but you may have to pay your legal costs. The normal National Health Service complaints mechanisms will still be available to you.

➢ **Who has reviewed the research project?**

All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee, to protect your interests. This study has been reviewed and given a favourable opinion by South West – Cornwall & Plymouth Research Ethics Committee, 22/SW/0007, IRAS project ID 309113.

➢ **Will the outcomes of the research be published?**

The results of this study will be published in a scientific journal, student dissertations and PhD theses. You will not be identified in any publication reporting the results of this study. If requested, you will be sent a summary of the results.

Data Protection and Confidentiality

➢ **What information will you collect about me?**

In order to participate in this research project we will need to collect information that could identify you, called "personal identifiable information". Specifically we will need to collect your:

- Name
- Address, Postcode, Email Address
- NHS number and GP details
- Date of birth
- Medical history/clinical investigations
- Clinical tissue sample data
- Demographics: Ethnicity, gender, sexual orientation, occupation, disability and education

Individuals from the University of Manchester, NHS Trust and GP practice will access your medical records to collect information for the study. Specifically we need to collect cervical screening test results and any treatment you are required to have (if any). The above information will help us collect your clinical outcomes, answer the study questions and to contact you with a summary of results once the study has finished. Your medical details and samples will be stored under a study specific ID that means that the research team analysing the results of the study cannot identify you. The link to your personal identifiable information will be held securely in a locked filing cabinet or secure database in a University office/computer that restricts access to members of the research team only.

➢ **Under what legal basis are you collecting this information?**

We are collecting and storing this personal identifiable information in accordance with UK data protection laws that protect your rights. These state that we must have a legal basis (specific reason) for collecting your data. For this study, the specific reason is that it is "a public interest task" and "a process necessary for research purposes".

➢ **What are my rights in relation to the information you will collect about me?**

You have a number of rights under data protection law regarding your personal information. For example you can request a copy of the information we hold about you. If you would like to know more about your rights or the way we use your personal information to ensure we follow the law, please consult our Privacy Notice for Research at http://documents.manchester.ac.uk/display.aspx?DocID=37095. Sometimes your rights may be limited if it would prevent or delay the research. If this happens you will be informed by the research team.

➢ **Will my participation in the study be confidential and my personal identifiable information be protected?**

In accordance with data protection law, the University of Manchester is the Data Controller for this project. This means that the University is responsible for making sure your personal information is kept secure, confidential and used only in the way you have been told it will be used. All researchers are trained with this in mind, and your data will be looked after appropriately. Only the research team at the University of Manchester/NHS Trust and GP Practice will have access to your personal information.

You may be given the option to provide consent and answer the questionnaire electronically or on paper. Consent forms are stored separately to research data. Your name and any other identifying information will be removed from study data and replaced with a random ID number (pseudonymised) upon entry to the study. Only the research team will access the key that links this ID number to your personal information. Your consent form will be kept for 5 years

after the study ends. Personal details will be retained for 1 year after the study results are published in order to allow us to collect the relevant medical data for the project. Your anonymised study data will be retained for 15 years. After this, the data will be destroyed in a secure manner. This includes data in both paper and electronic format. Please also note that individuals from the University of Manchester, NHS Trust, GP Practice or regulatory authorities may need to look at the data collected for this study to make sure the project is being carried out as planned. This may involve looking at identifiable data. All individuals involved in auditing and monitoring the study will have a strict duty of confidentiality to you as a research participant. Your GP practice will record your involvement in the study.

When you agree to take part in a research study and with your informed consent, the information about you may be provided to researchers running other studies here or at other organisations. With your consent your anonymised information will be shared in order to support additional research in accordance with the UK Policy Framework for Health and Social Care Research instead of the Research Privacy Notice https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/uk-policy-framework-health-social-care-research/ This information will not identify you and will not be combined with other information in a way that could identify you. The information will only be used for the purpose of cancer prevention or gynaecological health, and cannot be used to contact you regarding any other matter. It will not be used to make decisions about future services available to you. If you would like more general information on how researchers use data about patients, please visit: www.hra.nhs.uk/information-about-patients/ At the end of the project we will deposit a fully anonymised dataset in an open data repository where it will be permanently stored. Researchers at other institutions can access the anonymised data directly from the repository and use it for further research or to check our analysis and results.

If you consent for us to do so, we will keep your contact details on a separate password-protected database that can only be accessed by the research team to allow us to contact you about future research studies. You can withdraw your consent for us to contact you in this way at any time and we will not pass your contact information to others for any other purpose. If we cannot reach you, we will try one more time to get in touch. We will delete the contact information we keep for you after 15 years or upon your request.

What if I have a complaint?

- **Contact details for concerns and complaints**

If you have a concern or complaint that you wish to direct to members of the research team, please contact:

- **Suzanne Carter (Project Manager), Tel. 0161 701 6941, Email. Suzanne.carter@manchester.ac.uk**
- **Prof Emma Crosbie (Chief Investigator), Tel. 0161 701 6942, Email.emma.crosbie@manchester.ac.uk**

If you wish to make a formal complaint to someone independent of the research team or if you are not satisfied with the response you have gained from the researchers in the first instance then please contact:
Research Ethics Manager, Research Office, Christie Building, University of Manchester, Oxford Road, Manchester, M13 9PL. Email. research.complaints@manchester.ac.uk or Tel. 0161 306 8089

If you wish to contact us about your data protection rights, please email dataprotection@manchester.ac.uk or write to the Information Governance Office, Christie Building, University of Manchester, Oxford Road, M13 9PL and we will guide you through the process of exercising your rights. You also have a right to complain to the Information Commissioner's Office about complaints relating to your personal identifiable information at https://ico.org.uk/make-a-complaint/your-personal-information-concerns/ or Tel. 0303 123 1113

Contact Details - If you have any queries about the study or if you are interested in taking part contact:

	Suzanne Carter (Project Manager) **Tel. 0161 701 6941, Email. Suzanne.carter@manchester.ac.uk**
	Prof Emma Crosbie (Chief Investigator) **Tel. 0161 701 6942 Email. Emma.crosbie@manchester.ac.uk**

Thank you for taking the time to read this information and considering whether or not you would like to take part in this study.