**Patient Information Sheet**

**STRINGS – Storage, Transport & Incubation for Neisseria Gonorrhoea Sampling**

You are being invited to take part in a research study. Before you decide it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with others if you wish. Ask us if there is anything that is not clear or if you would like more information.

**Who is carrying out the study and why?**

This study has been developed and is carried out by the North Cumbria Integrated Care NHS Foundation Trust and is in progress across Sexual Health clinics in Cumbria. The Chief Investigator is Dr Matt Phillips, Clinical Director of Sexual Health Services Cumbria. The research takes place at two Sexual Health clinics – Carlisle (Solway clinic) and Workington (Derwent clinic) – with support and oversight from research staff.

This study aims to assess the accuracy of the novel Sigma VCM swab processing kit compared to current methods to detect *Neisseria Gonorrhoea* in Cumbrian sexual health clinics and to assess the potential cost-effectiveness and benefits in terms of storage, transport and incubation time.

**Why have I been invited?**

You are being asked to participate in this research study because you are identified as someone at risk of a Gonorrhoea infection.

**Do I have to take part?**

You do not have to take part; it is entirely up to you to decide whether you would like to be involved in our study. Regardless of whether you decide to take part or not, your clinical treatment will not be affected by your decision. You are free to withdraw at any time without explanation and this will not affect the standard of care you receive in any way.

**What will happen to me if I take part?**

If you decide that you may want to take part in the study, one of the research staff, which may be the nurse or a colleague, will take written consent from you. We ask permission to access your medical records to record some demographic details (such as age/gender), medical details (such as symptoms/contraception) and your test results. You will be asked to provide samples (vaginal/cervix swabs for women and a urine sample for men) as per normal practice. The samples will be processed using the standard methods and additionally in the Sigma VCM kit. You may be asked to provide a second vaginal/cervix/urethral swab, to ensure we have enough material for the existing standard kit and the new kit. You will be cared for in the same matter as you normally would. The results of the tests will be communicated as per normal practice by the clinical team.

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

There is no intended clinical benefit from taking part in this study. However, if the novel Sigma VCM shows significant benefits over the current practice, meaning higher detection rates of Gonorrhoea, then the clinical team can use these results for the management of patients. This means that patients may be treated more optimally if the new sample transport kit that is being tested outperforms the current standard transport method. As a result, this study may then also lead to higher quality of gonorrhoea sampling and testing in the future. This is not guaranteed, and that is why we are undertaking this research study to determine which transport process for sexual health samples is best. You cannot claim payments, reimbursement of expenses or any other benefits or incentives for taking part in this research.

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

There is no significant increased personal safety risk anticipated for patients who take part in this study. To obtain sufficient material, patients may be swabbed a second time (using a same type of swab they would normally be swabbed with). This may feel a bit uncomfortable for a very brief period of a few seconds. If your nurse or the research team learns of important new information that might affect your desire to remain in the study, he or she will tell you. Appropriate precautions are in place to ensure your medical and personal information is kept safe (see next sections).

 **What will happen to the information that I give?**

All data will be held in secure environments. The requirements of the Data Protection Act and NHS Code of Confidentiality will be followed at all times. All researchers will be fully trained in NHS Confidentiality. Data released (e.g. by publication) will contain no information that could lead to the identification of an individual participant.

**Will my participation in the study be kept confidential?**

All your personal details will be treated as STRICTLY CONFIDENTIAL, in line with the Data Protection Act and General Data Protection Regulation for health and care research. Your data collected during your participation will be entered into a password-protected database and analysed – using only NHS computers and servers. None of your study data will be identified by your name – only by study number. Appropriate measures will be enforced to protect your identity in all presentations and publications, as required by United Kingdom regulations. The Sponsor’s clinical research staff, consultants, one or more nominated research organisation(s) working on behalf of Sponsor, Sponsor’s auditors or their representatives, the NHS representatives and regulatory authorities may have direct access to your medical records in order to make sure that the study is conducted correctly and to verify the results of the study. You authorise such direct access to your medical records by signing the informed consent form.

North Cumbria Integrated Care NHS Foundation Trust is the sponsor for this study based in the United Kingdom. We 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. This means that we are responsible for looking after your information and using it properly. North Cumbria Integrated Care NHS Foundation Trust will keep identifiable information about you for 15 years after the study has finished.

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. If you withdraw from the study, we will keep the information about you that we have already obtained. To safeguard your rights, we will use the minimum personally-identifiable information possible. You can find out more about how we use your information at <https://www.ncic.nhs.uk/trust/freedom-information/accessing-your-health-care-records> or by contacting research@ncic.nhs.uk.

North Cumbria Integrated Care NHS Foundation Trust will use your name, and contact details to contact you about the research study, and make sure that relevant information about the study is recorded for your care, and to oversee the quality of the study. Individuals from North Cumbria Integrated Care NHS Foundation Trust and regulatory organisations may look at your medical and research records to check the accuracy of the research study. The only people in North Cumbria Integrated Care NHS Foundation Trust who will have access to information that identifies you will be people who need to contact you to audit the data collection process. The people who analyse the information will not be able to identify you and will not be able to find out your name, or contact details.

**What if something goes wrong?**

If you have any concerns at any stage of your involvement in this research project, please feel free to discuss these with the research team. We will do our best to resolve any problems quickly. If you are still unhappy and wish to complain about any aspect of the way you have been approached, the normal National Health Service (NHS) complaints mechanisms are available to you (Patient Experience Team contact details below).

**What will happen if I don’t want to carry on with the study?**

Your participation in the study is voluntary. You can refuse to take part, or you can withdraw at any time. If you choose to withdraw, your clinician will simply ask you why you are withdrawing, and will continue treating you as he or she normally would. Any data collected up to the point where you withdraw will be retained for analysis as part of the study.

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

The study is run by North Cumbria Integrated Care NHS Foundation Trust, through the University of Cumbria; this Trust is also the study sponsor for indemnity purposes. A grant has been awarded by the manufacturer of the Sigma VCM kit, Medical Wire (MWE), to receive the kits for free for this study. The study has been reviewed and approved by the National Ethics Research Service, Dulwich Research Ethics Committee (ref 18/LO/1936), the Health Research Authority and the NHS Trusts where the study is conducted.

The research team acts as a contact point and coordinator for patients requiring information and support. If concerns are raised, referral of patients/families on to other professional agencies will be done as appropriate and according to the Trust guideline.

**Contact for further information**

You can get more information or answers to your questions about the study, your participation in the study, and your rights, from the STRINGS research team:

* Name: Ms Sarah Thornthwaite, Ms Rachel Hardy and Dr Matt Phillips
* Phone number: 07747760492 or 01228 603145.
* Email: Research@ncic.nhs.uk

Generic information on taking part in clinical research can be obtained from the Patient Experience Team, tel 0800 633 5547 or PET@ncic.nhs.uk , or from websites such as the NHS Choices website, <http://www.nhs.uk/Conditions/Clinical-trials/Pages/Introduction.aspx>

***Thank you for taking the time to read this information sheet***