



Participant Information Sheet

Title	Prevalence of Mycoplasma genitalium in Asymptomatic Patients
Project Sponsor	Manx Care
Principal Investigator	Debashis Mandal
Co-Investigator(s)	Professor Hugo van Woerden, Priya Pulickal, Gaynor Roberts, Chris Helm, Sarena Bhargava and Jordan Watson

Part 1 What does my participation involve?

1. Introduction

You will be invited to take part in this research project when you attend for your appointment. The project is called Prevalence of Mycoplasma genitalium in asymptomatic patients. You will be invited because you have an appointment at GUM Clinic at Noble's Hospital and are not currently experiencing any genital symptoms.

This Participant Information Sheet tells you about the research project. It explains the processes involved with taking part. Knowing what is involved beforehand will help you to decide if you wish to take part in this research.

Please read this information carefully. When you attend, please ask questions about anything that you do not understand or want to know more about. Before deciding whether or not to take part, you might want to talk about it with a relative or friend.

Participation in this research is voluntary. If you do not wish to take part, you do not have to and your care will not be affected in any way. If you decide NOT to take part in the research project, please indicate to the doctor or nurse you are going to see that you wish to opt out. By not opting out you are telling us that you:

- Understand what you have read
- Consent to take part in the research project
- Consent to be involved in the research described
- Consent to the use of your personal and health information as described.



You will be given a copy of this Participant Information Sheet to keep.

2. What is the purpose of this research?

The aim of the project is to determine whether testing for *Mycoplasma genitalium*, which is a sexually transmitted bacteria, should be included within routine screening tests in the future, regardless of whether someone has symptoms. Currently, this test is undertaken in all patients with genital symptoms. Knowing how many people come to the clinic and have this bacteria without knowing will help to determine whether it is worth including a test for this infection in our routine screening.

This research has been initiated by the researcher, Dr Debashis Mandal.

This research is being conducted by Dr Debashis Mandal.

This research is sponsored by Manx Care.

3. What does participation in this research involve?

Participation in this study involves for us adding a test for *Mycoplasma genitalium* onto the routine set of tests for Sexually Transmitted Infections (STI). No extra procedures will have to be carried out, as the infection can be picked up in the same sample we test for chlamydia or gonorrhoea, which you are going to have today. If you test positive for the infection, we will let you know and you will be given an antibiotic to treat it. This infection is curable.

You are able to participate in this study if you are currently experiencing NO genital symptoms, such as pain on urinating, unusual discharge, bleeding in-between periods, bleeding after sex or abdominal pain. If you are unsure about any symptoms you may be experiencing you can talk about them with the clinician before being tested.

If you wish to opt out of this study please let the clinician know in your appointment. Please feel free to ask any questions before, during, or after the appointment regarding the study.

If you are currently participating or recently taken part in any other forms of research please let a member of staff know.

When you attend GUM, you will complete a routine screening questionnaire which is given to all patients. If you confirm in the questionnaire that you have NO symptoms, you will be eligible to take part. If you not wish to opt out from the research project, you do not have to do anything more.

4. Additional costs and reimbursement

There are no costs associated with participating in this research project, nor will you be paid.

5. Other relevant information about the research project

The project has been set up to question whether the national guidelines need to be reviewed and changed accordingly. Smaller studies have been carried out in the past, but there is now a need for a study with participants from Isle of Man.

6. Do I have to take part in this research project?

Participation in any research project is entirely voluntary. If you do not wish to take part, you do not have to and your care will not be affected in any way. If you decide to take part and later change your mind, you are free to withdraw from the project until the finding of this research project has been published.

If you do decide to take part, you will be given this Participant Information Sheet to keep.

7. What are the possible benefits of taking part?

Possible benefits may include additional diagnosis leading to treatment and cure. Treatment will also stop the infection spreading to others.

8. What are the possible risks and disadvantages of taking part?

The risks of this study are the same as other diagnostic tests. The possibility of a positive result may result in emotional distress and partner notification will be strongly encouraged. Additionally, antibiotic treatment has the possibility of causing resistance to that antibiotic.

9. What if I withdraw from this research project?

If you do consent to participate, you may withdraw at any time prior to the publication of the finding of this research project. This is usually months to years after data collection. If you decide to withdraw from the project, please notify a member of the research. A member of the research team will inform you if there are any special requirements linked to withdrawing.

If you decide to leave the research project, the researchers will not collect additional information from you, although personal information already collected will be retained to ensure that the results of the research project can be measured properly and to comply with law. You should be aware that data collected up to the time you withdraw may form part of the research project results. If you do not want your data to be included, you must tell the researchers when you withdraw from the research project.

10. Could this research project be stopped unexpectedly?

This research project may be stopped unexpectedly for a variety of reasons. These may include reasons such as failure to obtain enough participants.

11. What happens when the research project ends?

We will get in-touch with you if the results of the test come back positive and call you in for further treatment with antibiotics. You will receive SMS message if the test is negative.

Once the research project has ended and results have been determined we will disseminate the anonymised summary of results of the study through social media publish in Manx Care website www.manxcare.im.

Part 2 How is the research project being conducted?

12. What will happen to information about me?

All of your personal information including the results of the study will be confidential as per the same practice as for other screening tests in GUM clinic setting. Only the small research team members who are GUM staff will have access to your test results. Please note that risk factors for considering secondary outcomes will be collected during history taking and significant findings will be reported on completely anonymously. No patient identifiable information will be included in research documents. The research data will only be kept until no longer needed for the research and you will remain anonymous to the research team throughout the research project.

By not opting out, you consent to the research team collecting and using personal information about you for the research project. Any information obtained in connection with this research project that can identify you will remain confidential. Participant samples will only be labelled with a special clinic number and your date of birth. Your information will be stored electronically in the computer network, as is the practice for all other GUM patients. Anonymised information will only be used for the purpose of this research project. The personal information that the research team collects and use is whether you have tested positive or negative for mycoplasma genitalium. All information about you will be anonymised from then onwards.

The GUM clinic records are kept separate from your GP records and any other hospital medical records. So results will not be able to be seen by any healthcare professional outside the GUM department.

Your health records and any information obtained during the research project are subject to inspection (for the purpose of verifying the procedures and the data) by the relevant authorities and authorised representatives, Manx Care the institution relevant to this Participant Information Sheet, or as required by law. By not opting out, you authorise release of, or access to, this confidential information to the relevant research personnel and regulatory authorities as noted above.

It is anticipated that the results of this research project will be published and/or presented in a variety of forums. In any publication and/or presentation, information will be provided in such a way that you cannot be identified. You will remain anonymous in the publication of this research, with no identifiable features being included.



Any information obtained for the purpose of this research project that can identify you will be treated as confidential and securely stored. It will be disclosed only with your permission, or as required by law.

13. Complaints and compensation

If you suffer any distress or psychological injury as a result of this research project, you should contact the research team as soon as possible. You will be assisted with arranging appropriate treatment and support.

14. Who is organising and funding the research?

This research project is being organised by Dr Debashis Mandal

This research is sponsored by Manx Care.

You will not benefit financially from your involvement in this research project even if, for example, knowledge acquired from your information proves to be of commercial value to Manx Care.

In addition, if knowledge acquired through this research leads to discoveries that are of commercial value to Manx Care, the researchers or their institutions, there will be no financial benefit to you or your family from these discoveries.

No member of the research team will receive a personal financial benefit from your involvement in this research project (other than their ordinary wages).

15. Further information and who to contact

List the names and contact phone numbers of other appropriate persons involved in the project including researchers and study coordinators.

Research contact person

Name	<i>Dr Debashis Mandal</i>
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