



UK Health  
Security  
Agency



University Hospitals Sussex  
NHS Foundation Trust



National Institute  
for Health Research

## PARTICIPANT INFORMATION SHEET

### Acceptability and feasibility of longitudinal sample collection to better understand the epidemiology of enteric infections in men who have sex with men (MSM): a pilot study

We would like to invite you to take part in our research study. Joining the study is voluntary and entirely up to you. Before you decide, we would like you to understand why the research is being done and what it would involve for you.

Please read this information sheet and ask if anything is unclear to you or if you have any concerns.

Thank you very much for taking the time to consider being involved in the study.

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### What is the study about?

There are a range of microbes (bugs) such as bacteria and viruses that live in the gut. Some of these bugs can make you sick; causing diarrhoea, stomach cramps and fever. The bugs can be passed on in a number of ways, including by small traces of faeces (poo) getting into your mouth during and after sex.

We don't know how common they are, but we think that between 1% and 10% of men who have sex with men (MSM) may have a gut bug that can make you sick. We also think that some of these bugs might occur in people who do not have any symptoms. Testing and treatment for these bugs is not usually necessary unless you have symptoms, as the bugs will often clear up on their own.

To help us to understand the extent to which these bugs are spreading, to identify who may be at higher risk of being infected and to determine how we can best treat the infections, we are conducting a research study. The study is investigating carriage of gut bugs (e.g. *Shigella*) in gay, bisexual and other MSM. We are currently recruiting to the pilot phase of our study, which will involve around 200 people and should help us to ensure that we are conducting the study in the best way.

### Why have I been invited?

We are inviting men (cisgender men assigned male at birth or transgender), trans women or gender-diverse people attending the sexual health clinic who are aged 16 years and above and who have had sex with another man (cis/transgender) or non-binary person assigned male at birth in the past 3 months, to take part in this study. You may participate, regardless of whether you have experienced any symptoms.

To be eligible for this study, you should be able to read and write in English, and be able to use a tablet, computer or smartphone and the Internet.

## **Do I have to take part?**

It is entirely your choice whether you want to take part in the study. If you agree to participate, we will ask you to complete and sign a consent form. If you decide not to participate, it will not affect the standard of care you receive. It is helpful if you can provide a reason for not participating, but you don't have to do this. If you do decide to participate, you are free to withdraw at any time, without giving a reason and it will not affect the standard of care you receive.

If you would like to withdraw, please contact the clinic on [\[email address for clinic\]](#). If you withdraw, any information or samples that have already been collected will be retained and used for the purposes for which consent was given.

## **What will happen if I take part?**

We are asking you to complete a questionnaire and to provide a rectal swab every week for up to 3 months. We are also asking you to provide one poo sample when you sign up to the study, but this is optional. After 3 months, you do not need to do anything more.

### When you sign up to the study:

It is up to you whether you complete the following steps during your clinic visit today or at home afterwards, but we would ask that you complete the following three steps on the same day.

#### *1. Complete a questionnaire*

We will ask you to complete a short online questionnaire, which will take 10 to 15 minutes to complete. We will ask you to complete this online using your personal phone, tablet, or computer. The questionnaire will ask questions about sexual behaviour, drug use, symptoms, antibiotic use and travel history.

#### *2. Provide a rectal swab*

We will ask you to collect a rectal swab. You can take the rectal swab yourself, in exactly the same way as the self-taken rectal swabs that are collected as part of routine STI testing. The swab is simple and quick to collect, but you may experience some mild discomfort. Please post the rectal swab directly to us using the pre-paid envelopes.

#### *3. Provide a poo sample (option to opt-out)*

We will also ask you to provide a small sample of poo (about the size of a walnut) in a collection pot. By providing us with a poo sample, we can tell a lot about the specific types of bugs in the gut and how many there are.

We will provide you with a sampling kit, which you can either complete at your clinic visit or can take home with you. Detailed instructions on how to take your sample will be provided in the kit. If you choose to take the poo sample kit home, we will ask you to return the sample as soon as possible after your clinic visit and you can post it to the laboratory in the pre-paid envelope. If you are not able to post it straight away, you can keep the sample in the fridge for a few hours.

Please note that it is possible to opt-out of providing a poo sample if you choose. Even if you choose to opt-out, it is still helpful if you can participate in the remainder of the study.

## After you have signed up:

### 4. Complete follow-up questionnaires and rectal swabs

We are interested in understanding any changes to the range and distribution of gut bugs over time. We will therefore ask you to collect additional self-taken rectal swabs every week for the three months following your initial clinic visit. We will give you the sample kits today, so you don't have to come back to the clinic. You can collect your samples at home and post them directly to the laboratory in the pre-paid envelopes. We'll remind you to return your samples to us by sending a text or email if you agree to this. If you forget to collect a swab, or you miss a swab for any reason (e.g. you're on holiday), you can continue to participate in the study. You can collect the missing swab at a time that is convenient and send it to the laboratory, or you can wait until your next weekly swab is due.

Each time you collect a rectal swab, we will ask you to complete a short online questionnaire with some follow-up questions, which will take 5 to 10 minutes to complete.

### 5. Attend a 1 to 1 interview (optional)

As part of the pilot phase of this study, we would like to understand more about your experiences as a participant. This will help us to make improvements for the future. Therefore, we may invite you to take part in a 1 to 1 interview to understand what your motivations and reservations were about participating and collecting samples. The interview will take place either during the 3-month period whilst you are collecting your rectal swabs, or at the end of the study once all swabs have been collected.

Please note that attending a 1 to 1 interview is optional and is not a requirement for participation in this study. If you decide to take part in a 1 to 1 interview discussion, we will ask you to complete and sign an additional consent form.

## **What will happen to the samples I give?**

All samples will be transported to the laboratory at the UK Health Security Agency (UKHSA, formerly Public Health England), London. They will be tested for a range of gut bugs including *Shigella*, *Campylobacter*, *Salmonella*, *E. coli*, *Entamoeba*, *Giardia*, *Cryptosporidium* and Hepatitis A virus. If any of these bugs are detected, the genetic material (DNA) from the organism will be analysed. We may also analyse your sample to see if any other bugs are present, what types there are and what their genetic material looks like. Your samples will be labelled with a unique study number, which is anonymous. No personal details or identifying information will be present on the sample.

## **Will I receive the results of the tests?**

It is important for you to know that we are not able to provide you with any test results. We are also not able to provide the results to your sexual health service or GP. The results from these tests cannot be used for clinical diagnosis or decisions on the care or treatment you currently receive. Whilst participating in this study, you should continue to attend the sexual health clinic for regular STI tests as normal. If you experience any symptoms during this study, you should seek care from your sexual health clinic or your GP.

## **How will we use information about you?**

We will need to use information provided by you and the clinic for this research project. Information about you will be handled in accordance with the requirements of the Data Protection Act 2018 and the General Data Protection Regulation (GDPR).

This information will include your:

- demographic information – name, age, gender, sexual orientation, ethnicity, country of birth, geographic region of residence (but not your postcode) and contact details such as your phone number and email address
- health information – clinic patient number, (a unique number that can **only** be used by staff at your clinic to identify your name or contact details), why you are attending the clinic, your symptoms, STI and HIV tests and diagnoses, and other sexual health services received
- sexual history information – recent sexual partners and sexual behaviour, drug use, and foreign travel history
- treatment information – antibiotics you have taken recently

People will use this information to do the research or to check your records to make sure that the research is being done properly.

People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number instead.

We will keep all information about you safe and secure.

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.

## **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.

## **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/](http://www.hra.nhs.uk/information-about-patients/)

- our leaflet available from [www.hra.nhs.uk/patientdataandresearch](http://www.hra.nhs.uk/patientdataandresearch)
- by asking one of the research team
- The Department of Health and Social Care has appointed a Data Protection Officer (DPO) for the Department itself and for its executive agencies, including the UKHSA. If you have any concerns or questions you can contact the DPO:
  - Write to: Data Protection Officer, Department of Health and Social Care, 1st Floor North, 39 Victoria Street, London, SW1H 0EU
  - Or email: [data\\_protection@dhsc.gov.uk](mailto:data_protection@dhsc.gov.uk)

### **How will we process and store your information?**

We will not tell your GP or anyone else that you are taking part in this study.

The questionnaire will be answered securely online and will not be seen by the healthcare professionals in the clinic. Your responses will be submitted directly to the research team at UKHSA. The questionnaire will be labelled with a unique study number, which is anonymous. No personal identifiable information such as your name, date of birth or postcode will be present on the questionnaire.

Questionnaire responses and the results from any tests carried out on your samples will be treated with strict confidentiality. We will link your questionnaire responses and test results using the unique study number. No personal identifiable information will be present on the questionnaire or samples.

We will ask your permission to link the test results and questionnaire responses to routinely collected national data on STI and HIV tests and diagnoses (sent to UKHSA by the clinic). This information will help us to understand more about the relationship between specific gut bugs and other infections transmitted through sex. The routinely collected national STI data already contain the clinic patient number. This is a unique number which cannot be used by UKHSA to identify your name, date of birth or postcode. We will link the data by using the clinic patient number and the unique study number. Once the data are linked, the clinic patient number will be removed, and the final anonymous dataset will be analysed and reported on.

You will be asked if you are happy to provide your contact information (telephone number or an email address). This information will be used by the clinic to send reminders about this study (e.g. one weekly text or email reminder to collect your rectal swab and complete the questionnaire), and to ask if you want to take part in a 1 to 1 interview. You do not have to agree to this, and you can still participate in the study if you do not agree. If you are happy to provide your contact details, these will be held securely at the clinic and separately to all other data and samples. You can opt-out of receiving email or text reminders at any point by contacting the clinic.

We will ask for your permission to store your samples and data securely at UKHSA at the end of the study long-term so that researchers can use them in the future. The data and samples will be stored anonymously for up to 10 years and may be used in future health-related research studies with ethical permission. Any researcher who uses your samples or information in the future will not know your personal details or be able to identify you. You do not have to agree to this. If you do not want your samples to be stored long-term, they will be destroyed at the end of the study.

### **What will happen if I take part in a 1 to 1 interview?**

You may be asked to participate in a 1 to 1 interview discussion with a member of the research team at University College London. If you are happy to take part, the clinic will give your name and contact details to the researcher who is conducting the interview, so that they can arrange a time to talk with you. Your details will only be used to arrange the interview and will be kept separate from all other data and samples.

We anticipate that the discussion will last approximately 1 to 1.5 hours and will take place via telephone or video call. If appropriate, the discussion may also take place face-to-face in a quiet and private space in the clinic or within a nearby community venue. The discussion will be recorded with your permission. We will not record your name or other identifiable data.

The information you provide is strictly confidential. The healthcare professionals at the clinic will not have access to the discussion details or recording. However, during the interview, if there is a disclosure of information that indicates the possibility of self-harm or harm to others, we will be obliged to report this information to appropriate clinic staff to ensure your safety.

The recordings will be stored securely by the research team and transcribed by an external agency. All recordings will be destroyed immediately after transcription.

The discussion will be analysed but the responses will not be linked to your name or any other identifiable data. Direct quotes from the interview may be used for medical journals and posters. Results from the discussion will be used to make improvements to future studies.

### **Are there any disadvantages of you participating in the study?**

There are not likely to be any disadvantages to you participating in the study. You may find some questions sensitive and personal. You are not obliged to answer any questions that make you feel uncomfortable. You may experience some mild discomfort when collecting your samples.

### **Are there any possible advantages of you participating in this study?**

Some people say they enjoy taking part in research that may help other people in the future. Although there will be no direct benefits to you, it is anticipated that the study results will help researchers and doctors understand more about the types of bugs in the gut and how they are spreading, and this in turn can help us to develop better ways of preventing and treating the bugs that make us sick.

The success of the study depends on the goodwill and co-operation of those asked to take part. The more people who do take part, the more useful the results will be. We understand that we are asking a lot of you, and we greatly value the contribution you make by collecting samples and sharing information with us.

### **What will happen to the results from the study?**

We will submit the study results to medical journals and conferences so that doctors, researchers and policy-makers can access and use the findings. The study results will not be presented in a form which can reveal your identity.

If you would like to receive a summary of the results, please let the nurse or doctor at the clinic know.

The results will also be available via our website: <http://hprugi.nihr.ac.uk/research-themes/predict-and-prevent/steim-study/>

### **Who is organising and funding this study?**

This is a research study being carried out by researchers from the UK Health Security Agency (UKHSA), University College London (UCL), University of Liverpool (UoL), and University of Warwick.

The study has received funding from the National Institute for Health Research Health Protection Research Units (NIHR HPRUs) in Blood Borne and Sexually Transmitted Infections, and in Gastrointestinal Infections.

### **Who has reviewed this study?**

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 approved by the London - South East NHS Research Ethics Committee (Reference 21/LO/0891) and University Hospitals Sussex NHS Foundation Trust Research and Development department.

### **What do I do if I have a question or any concerns about the study?**

Please ask the nurse or doctor if you have any questions or concerns. You can also contact a member of the research team using the details below. They will do their best to answer your questions.

Email: [email address] Phone: [phone number]

If you are unhappy with any aspects of this study and you wish to complain formally, you can do this with the help of the hospital's Patient Advice and Liaison service:

Email: [email address] Phone: [phone number]