SERVICE USER INTERVIEW - PARTICIPANT INFORMATION SHEET
ASSIST: Assessing the impact of online self-sampling for STIs & HIV

We are inviting you to take part in an interview for the ASSIST study (**ASS**essing the **I**mpact of online self-sampling for **ST**Is & HIV) study. Please take time to read the following information carefully. Please contact us using the phone numbers or email addresses below if anything is unclear or you would like more information.

Why is this study being done?
Online postal self-sampling for STIs & HIV involves taking your own sample using a testing kit, which is usually ordered online or collected from the clinic, and posting it back to be tested for STIs and/or HIV. Your experiences of testing for STIs & HIV are very important in helping us to understand if online postal self-sampling improves access to sexual healthcare and testing for STIs and HIV. We aim to use the findings from the ASSIST study to improve healthcare services.

Why have I been invited to take part?
We are inviting people aged 16 years and older and have accessed online and/or clinic-based services in Birmingham, Sheffield and London within the past 12 months to take part in an interview.

What would taking part involve?
Taking part involves a one-to-one interview with a trained researcher. The researcher has a lot of questions and, depending on your answers, the interview could take up to 90 minutes. However, we expect most interviews will be complete within 60 minutes. The interview is about your experiences of testing for STIs and/or HIV.

A trained researcher will contact you within a week to discuss the possibility of arranging an interview and check that you are eligible for the study using the telephone number and/or email address that you have provided.

They will explain the study and, if you agree, arrange whether to do the interview face-to-face on NHS or university premises or by telephone or video (by Teams or Skype, for example) and organise a convenient time and day for it to take place.

At the beginning of the interview, the researcher will ask if you agree to take part in the study and ask for your permission to audio-record the interview. Before you start the interview, the researcher will ask some background questions. The interview will cover your experience of testing for STIs and HIV using online postal self-sampling and/or at the clinic. At the end of the session, the researcher will ask you to confirm that you are still happy for your data to be included in the study.

Do I have to take part?
No - it is up to you to decide whether to take part - taking part is **voluntary**. If you do not wish to take part or change your mind, you do not need to give a reason and it will not affect the standard of care you receive from the NHS in any way. You can change your mind and withdraw from the study before and during the interview, and up to four weeks after your interview has taken place.

What are the possible advantages of taking part?
There are no direct benefits to you for taking part in the study. We hope you will find the interview interesting and you will benefit from sharing your experiences. We hope the results of the study will inform policy to help improve sexual healthcare services in the UK, and in so doing reduce the spread of STIs and HIV.

What are the disadvantages of taking part?
You may find some of the questions very personal. If you feel upset in the interview you must let the researcher know immediately. You do not have to answer any questions that make you feel uncomfortable. You can let the researcher know that you wish to move on to another subject or stop the interview altogether.

Who is conducting this study?
This study is being conducted by University College London (UCL). It is led by Prof Fiona Burns and Dr Jo Gibbs who are responsible for the project and all the data. The study is funded by the National Institute for Health Research. UCL is the sponsor and has overall responsibility for the conduct of the study, and for ensuring the study is carried out ethically and in the best interests of the study participants.

Who has reviewed the study?
All research in the NHS is reviewed and authorised by an independent group of people, called a Research Ethics Committee, to protect your safety, rights, wellbeing and dignity. This study has been reviewed and given favourable opinion by South Central - Berkshire B Research Ethics Committee. Additionally, the study has been granted approval from the Health Research Authority (HRA), and the Trust's Research and Development Office.

What will happen to the information about me collected during the study?
The interview is audio-recorded to make sure we do not forget or miss any important information that you tell us. At the start of the interview, we will ask for your permission to record the interview (sound only) for it to be typed up. The recording will be held on a voice recorder that is encrypted for your security. After the interview, it will be transferred to a restricted-access password-protected drive at UCL where it will be stored. The audio recording will be deleted from the audio recorder immediately after.

The audio recordings will be typed up by a professional transcription company which is subject to a confidentiality agreement. The audio recordings on the secure university drive will be deleted as soon as they are typed up. We do not ask for names, so you will not be recognised from your answers. The only people who will listen to the recorded discussion are the research team and the team typing up the notes. We remove all identifying information, such as names and places, from the typed-up discussion.

Before you start the interview, we will ask you to sign a digital consent form. If you prefer not to use the digital consent form, we will ask for your consent and audio-record it. The digital form or audio consent will be stored on a secure university server.

Will taking part in the study be kept confidential?
All information that we collect about you during the study is kept strictly confidential. This information will include your:

- first name
- personal email and/or telephone number
- postcode

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 not tell anyone that you have agreed to take part. No identifying information, such as your name, is kept with the typed-up discussion. All information is stored safely and securely, and only the research team can access it.

However, if we believe you or someone else is in danger or at risk of significant harm, this will be reported directly to Prof Fiona Burns and Dr Jo Gibbs, Co-Chief Investigators on the study and to [name], [role: Named Professional for Safeguarding]. Any allegations of poor practice discovered during the course of the study will be reported to the local Head of Service [name] and Service Manager [name].

What will happen to the information I provide?
UCL is the sponsor for this study and UCL will act as data controller. We will be using information from you in order to undertake this study and we are responsible for looking after your information and using it properly.

You can change your mind and withdraw from the study before and during, and up to four weeks after your interview has taken place, and we will remove any information about you. After four weeks, the anonymous information will be incorporated into the analysis. If you withdraw from the study after four weeks, any information already collected will be retained and used for the purpose of the study, however, no additional data will be collected.

Certain individuals from UCL and regulatory organisations may look at your research records to check the accuracy of the research study. The other universities collaborating on this study will only receive information from the study without any personally identifying information about you. This information will not contain your name or any other identifying details.

The research team keep identifiable information about you from this study for no more than 12 months after the study has finished. If you agree to take part in this study, you will have the option to take part in other research into sexual health in the future. If you agree to be contacted about future research, your name and contact details will be stored safely and securely at UCL for this purpose. Non-identifiable information for this study will be stored at a registered UCL archive facility for a minimum of 10 years after the end of the study.

You can find out more about how we use your information: www.ucl.ac.uk/jro/who-are-we/data-protection or by contacting the ASSIST project manager, Dr Alison Howarth at alison.howarth@ucl.ac.uk

What will happen to the results of the study?

The interviews will be analysed and presented in a form that does not allow any individuals to be identified. The results will be shared with healthcare services, policy makers, academics and service users. They will

be written up for publication in academic journals. If we use direct quotations from interviews when we present the results, they will be anonymous. The information will only be used for the purpose of health and care research, and cannot be used to contact you or to affect your care.

If you are interested in receiving a summary of the results, we will ask you to provide contact details so that we can send you a copy. We will also put the results on our website: www.assist-project.org and Twitter account: twitter.com/ASSIST_OPSS .

As a university we use personally identifiable information to conduct research to improve health, care and services. As a publicly funded organisation, we 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, we will use your data in the ways needed to conduct and analyse the research study. 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. To safeguard your rights, we will use the minimum personally identifiable information possible.

Health and care research should serve the public interest, which means that we have to demonstrate that our research serves the interests of society as a whole. We do this by following the UK Policy Framework for Health and Social Care Research.

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. 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) (https://ico.org.uk/ or tel: 0303 123 1113).

Expenses and payments

After the interview, the researcher will send you a £30 gift card as a thank you for taking part in the study.

What if there is a problem?

If you have any concerns about the way you have been approached or treated during the study, please contact the research team using the phone number or email address below and they will do their best to address your concerns. If you are still unhappy and wish to complain, please use the normal NHS or UCL complaints process. Please ask the researcher if you would like more information on this.

In the unlikely event that you are harmed by taking part in this study, compensation may be available.

If something goes wrong and you are harmed during the study and you suspect this is due to how the study has been designed or the result of negligence by the Sponsor (UCL) or the clinic / hospital, then you may be able to claim compensation. In such cases, please make the claim in writing to Prof Fiona Burns who is Co-Chief Investigator on the study and based at UCL. She will then pass the claim to the Sponsor's Insurers, via the Sponsor's office. You may have to bear the costs of the legal action initially, and you should consult a lawyer about this.

For any questions about your rights as a research participant, please contact:

PALS (Patient Advice and Liaison Service), Telephone: XXXXX, Email: xxx.xxx@nhs.net

Contact for further information
If you have any queries or want more information about the study either now or at any time during the course of the study, please contact:

Dr Jessica Sheringham
Email: j.sheringham@ucl.ac.uk
Tel: 07919 444064

UCL Data Protection Office
tel: 0203 108 8764
email: data-protection@ucl.ac.uk

For UCL's General Privacy Notice: https://www.ucl.ac.uk/legal-services/privacy/ucl-general-privacy-notice-participants-and-researchers-health-and-care-research-studies

You can find out more about how we use your information at: www.hra.nhs/information-about-patients

Thank you for taking the time to consider taking part in this study.

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