

Participant Information Sheet

We are inviting you to take part in the Haus study. Before you make your decision, we would like you to understand the study, and what is being asked of you. You can talk to the person who gave you this sheet about any questions you may have.

What is the purpose of the study?

In the UK, people of black African heritage make up about one in three of all the people with HIV. Unfortunately many are unaware that they have HIV and only find out when they become sick. We are looking into the best ways that people can find out whether or not they have HIV. One of the ways to find out is to use a self-sampling kit such as the TINY collection device, which lets you take your own small sample of blood. You then send the kit in the envelope provided to a laboratory be tested for HIV. You are contacted with the results a few days later. We want to find out whether people are happy to be given these tests in GP surgeries and in the community.

Why have I been invited?

We have selected some GP practices and community based organisations in London and Greater Glasgow to take part. All black African people who are 18 years or above; who are not known to have HIV and are attending these services are being asked to take part. We would like as many people as possible to take part.

Do I have to take part?

It is entirely up to you to decide whether or not to take part. If you decide to take part and are eligible you will be asked to provide written consent. You can still change your mind at any point and withdraw from the study and you do not need to give a reason for this. Only essential patient information will be kept by the NHS if you return a kit.

What will taking part involve?

If you do decide to take part, this is what will happen:

1. You will need to provide contact information (including mobile phone number). We will only use this to contact you by phone or by text to send reminders about this study and for delivery of your results once the sample is tested. Any messages sent will not mention your name or HIV. Your contact information will be held securely on the UCL University database by the research team until your results are delivered to you. After this, your contact details will be destroyed unless you will be taking part in a follow up interview. If you agree to an interview now but change your mind later, you can reply to any message and ask us to remove you from the contact list.
2. You will be asked to complete a short questionnaire before you leave. You can complete this on your own. It takes less than 5 minutes to complete.

3. You will be given the TINY self-sampling kit for HIV testing to take away. You will be able to use it at a time and place that suits you. The kit has detailed instructions on how to collect the blood sample and how to return the sample. The instruction sheet also has a link to an online video where you can see how to collect the sample. Only 0.4ml of blood is required, which is a very small amount. The sample will only be used for HIV testing. You need to complete a form confirming your initials, date of birth, and contact number, which you enclose with the sample when you return it. You will also need to write your initials, date of birth and date of collection on the vial label. Your sample cannot be processed without this information.
4. After you collect the sample, we would like you to complete a short questionnaire about how you have found the process. You enclose the completed questionnaire in the same envelope which you use to return your sample. This questionnaire is optional and you do not have to do it.
5. You have the option to take part in a further telephone interview. These are to find out what you thought about the study and using the kit. The interviews will be audio recorded and will last no more than 30 minutes. They will not include your name. Though the research team may publish direct quotes provided by those who are interviewed, they will not publish any identifying information whatsoever (as such, it would be impossible for a reader to tell who said what). Those who have an interview will be provided a £10 voucher. We will only interview 30 people so even if you consent to this you may not be asked to participate.
6. The research team (which includes staff outside of the direct healthcare team) needs to be able to collect the outcomes from this study. This means they will be informed of your anonymised (no name) test results including confirmatory testing and linkage to appropriate care where relevant. However, they will not have access to your medical records. The University College London Hospitals NHS Foundation Trust will be the NHS organisation responsible for providing care for all participants who return a kit. The Central & North West London NHS Foundation Trust will be responsible for contacting everyone who needs to be contacted by phone rather than by text as they already provide this service routinely.
7. If you collected your kit at a GP practice, you will be asked for permission to let your GP know about your result.

How will I get my test results?

1. If your HIV test is “negative”:

If your test is negative you will be given the result by phone. If you have a mobile phone this will be by text message, otherwise we will contact you on your landline. The TINY test is extremely reliable however it may not always indicate very recently acquired infection (within past 4 weeks). If you think you have been at risk of HIV in the last 4 weeks you may need to take another test after the four weeks have passed.

2. If your result is “reactive”

If you have a reactive result this suggests that you may have been exposed to HIV. This is a first result and needs checking. A reactive result means there is about a 90% chance that you have HIV, so you will need to attend a clinic for further testing. You will be contacted over the phone and given information and support

to attend a local specialist clinic where they will undertake a blood test to check whether or not you are HIV positive (diagnosed with HIV). If you are found to be HIV positive than it is much better to know sooner rather than later, as early access to treatment and care will help ensure a full and healthy life, and help prevent further spread.

If for some reason there is a problem with your sample and the laboratory is unable to do the test you will be contacted and the reason explained.

You can find further information and links to support organisations that specialise in HIV prevention on our study website: www.haus.org.uk

What are the possible disadvantages of taking part?

You may experience stress and anxiety while waiting for your HIV test results. This information sheet details where you may access further support. While the kit we use is extremely reliable it will not pick up very recently acquired infection. If you think you may have been exposed to HIV less than 4 weeks ago, you may need to take another test after the 4 weeks have passed.

What are the possible advantages of taking part?

Information provided in this study could be of use to you in the future. You may benefit from this personally through your test results. Most people will find out that they do not have HIV and this may help you evaluate your own decisions. If you are diagnosed with HIV then it is much better to know sooner rather than later, as early treatment and care will help ensure a full and healthy life, and help prevent further spread. This study aims to further medical knowledge and may support future wider availability of self-sampling kits for Black Africans. Many people find it beneficial to know that their participation will help others, as well as themselves.

Will my taking part in this study be kept confidential?

Yes. All information will be kept strictly confidential. We will remove all identifying details from the questionnaire responses and from interviews. If we use direct quotations from the interviews when we present the study results, they will be anonymous. We will keep all the study information securely at University College London. Your anonymised responses will be added to everyone else's responses. The data will only be analysed for groups and not for individuals. Anonymised data from this study may be made available to other genuine researchers in the future for further research, but that would be overseen by the University College London, in line with their strict rules of confidentiality.

A confidential record of your test results will be kept by University College London Hospitals NHS Foundation Trust and where relevant, Central & North West London NHS Foundation Trust.

What will happen to the results of the study?

The results will be presented in a form that does not allow any individual to be identified. They will be shared with health care services to help improve HIV related care and with community based organisations and service users. We will also publish the findings from this study in academic journals. If you are interested, copies of the study results will be available from the research team and we will post a summary of the findings on the study website www.haus.org.uk

What if there is a problem?

If you wish to complain, or have any concerns about how you have been approached or treated by members of staff you may have experienced due to your participation in the research, the National Health Service or UCL complaints mechanisms are available to you. Please ask the person who is approached you about the study. Otherwise, you can contact the study manager directly at the numbers below. In the unlikely event that you are harmed by taking part in this study, compensation may be available. If you suspect that the harm is the result of the Sponsor's (University College London) or the organisations' negligence then you may be able to claim compensation. After discussing with the person who has enrolled you into the study, please make the claim in writing to Dr Fiona Burns who is the Chief Investigator for the research and is based at the UCL Centre for Sexual Health & HIV Research. The Chief Investigator 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.

Should you want to withdraw from the study then they will have two options: 1. Withdraw from the study, and not be approached for further information. Samples and data already obtained however may still be retained and used, and 2. Request no further contact, and for your samples and data to be destroyed. However if you have already returned your self-sampling kit then a clinical record of the result will be retained by the University College London Hospital NHS Foundation Trust (UCLH), or by Central and North West London NHS Foundation Trust (for those with reactive results). This information belongs to the NHS and will not be destroyed even if you decide to withdraw from the research component of the study.

Who is organising and funding this research?

This study is funded by the National Institute for Health Research, UK which is part of the NHS. It is being led by researchers based at University College London (UCL), London School of Hygiene & Tropical Medicine, Glasgow Caledonian University, Glasgow University, and Central and North West London NHS Foundation Trust. Dr Fiona Burns from UCL is leading the project. Ethical approval for the study has been obtained from Cambridge South Research Ethics Committee (Project ID Number): 15/EE/E0412; IRAS # 184223.

Further information

Advice and information about HIV is available from the NHS Choices website:

<http://www.nhs.uk/Conditions/HIV>

or any of the following:

www.avert.org

<http://www.waverleycare.org>

<http://www.naz.org.uk/>

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

If you would like to speak to someone about issues raised by this study please feel free to ask us.

For further information contact:

Ms. Maureen Seguin Phone: 020 3108 2073 Email: m.seguin@ucl.ac.uk

Dr Fiona Burns Phone: 020 3108 2060 Email: f.burns@ucl.ac.uk