

## CASCADE Collaboration

### Participant Information Sheet A

#### We are inviting you to take part in a study

- Please take time to read the following information carefully. Discuss it with friends and family, if you wish. Take time to decide whether or not you wish to take part.
- You are free to decide whether or not to take part in this study. If you choose not to take part, this will not affect your access to services or the care you receive in any way.
- You can stop taking part in any part of the study at any time, without giving a reason.
- Ask us if there is anything that is not clear or if you would like more information.

#### Important things that you need to know

- Taking part in this study is voluntary.
- In the CASCADE study we will be looking at the health, experiences and needs of people with recently-acquired HIV.
- We will need to use information from you and your clinic records for this study.
- This study is made up of four separate parts and you might be asked to take part in one or more of them:
  - collecting information from your medical notes or clinic databases.
  - completing a questionnaire, yourself.
  - taking part in an interview now and another in 12-months.
  - taking part in a photography project, in-between the interviews.
- It's up to you which parts of the study you take part in.
- We will use this information to better understand the experiences and needs of people who have recently acquired HIV.
- We will only use information that we need for the research study.

- Everyone involved in the study will keep your data safe and secure, and only study team members will have access to your data. We will follow all privacy rules and make sure no one can work out who you are from any reports we write about the project.
- The project is led by University College London (UCL). The Chief Investigator is Professor Kholoud Porter.

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#### How to contact us

If you have any questions about this project, then please contact our Study Coordinator:

**Dr Elisa Ruiz Burga**  
University College London  
Mortimer Market Centre, 3<sup>rd</sup> Floor  
Off Capper Street  
London, WC1E 6JB  
Tel: 07833 160577  
Email: Elisa.RuizBurga@nhs.net

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## 1 Why are we doing this project?

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Over recent years there has been a fall in the number of new HIV diagnoses, mainly because of better access to the medication used to treat HIV and new ways of preventing it being passed on, such as pre-exposure prophylaxis (PrEP). We now know that people who are living with HIV who are on medication and have an undetectable level of the virus in their blood can't pass it on. However, roughly 27,000 people were newly diagnosed with HIV in the Europe in 2019.

We want to understand more about the health, experiences and needs of people who have caught HIV recently (for our study, that means people who have received a positive HIV test within 12 months of a negative one). We also want to understand how we can improve HIV prevention services.

Learning from people who have recently caught HIV will help us understand new HIV infection better. This will help policymakers and healthcare providers to improve health and support services in the future.

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## 2 Why am I being asked to take part?

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You are being asked to take part because you have been diagnosed as having recently acquired HIV. For this study that means you have had an HIV-negative test within 12 months of your HIV-positive test.

It is up to you to decide whether or not to take part and your decision will not affect your access to services or the care you receive in any way.

If you do decide to take part, you will be given this information sheet to keep and be asked

to sign a consent form. If you decide to take part, you are still free to change your mind and withdraw at any time without giving a reason.

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## 3 What do I need to know about taking part in this project?

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We are inviting you to take part in CASCADE. There are four parts of the study. It is up to you which part(s) you want to be involved in.

### 1. Clinic data

We can learn a lot from blood tests that are done as part of your routine clinical care. A member of the clinic team will get your clinic data (such as CD4 count, HIV viral load, Hepatitis B and C tests, medication history) from medical records and transfer it securely to the research team at University College London. Your name will not be collected. We will ask permission to collect your Hospital/Clinic ID so we can match your clinic data with your questionnaire (if you complete this). We will use this clinical data to answer questions such as which medications are more effective, and what is the best time to start treatment.

### 2. Questionnaire

We invite you to fill in a confidential questionnaire (online or on paper) about you, and your experiences of HIV so far. The questionnaire will cover potentially sensitive areas such as your physical health, your mental health, your knowledge, attitudes and access to different methods of HIV prevention before being diagnosed with HIV, and sexual behaviour. You can miss out any questions you don't want to answer. We will **NOT** collect your name. The questionnaire will take around 15 minutes to do. If you have any difficulty with any of the questions, please feel free to ask for help.

### **3. Interview**

We invite you to take part in an interview. This will be face-to-face in a private room in your clinic, on a video-call using software such as Microsoft Teams, or by telephone. It is up to you how we do the interview.

A member of the CASCADE study team will ask you about your experiences of living with HIV, HIV testing, HIV prevention, HIV medication, well-being, and mental health. There are no right or wrong answers to the interview. We want to learn about your experiences.

You don't need to answer any questions you don't want to, and you don't need to disclose any personal information if you don't want to.

We will invite anyone who takes part in the interview to have a repeat interview 12 months later so we can find out how things have changed.

If you want to stop at any point during either of the interviews, you just need to let the interviewer know. You do not need to give a reason.

### **4. Photography/writing project**

If you have been invited for an interview, you will also be asked to take part in a photography/writing project.

This will involve taking between one and five photographs or completing a short writing task (up to 250 words) about every three months in between the two interviews. You can choose to only submit photographs, only submit completed writing tasks, or to use a mixture of the two.

We will send prompts by SMS text message or e-mail (whichever you prefer) with suggestions of what you might focus your photographs and writing on. The prompts include suggestions such as photographs or

writing that shows us how you have been getting on, how HIV affects your daily life, or something that makes you feel safe. You can choose to be guided by these prompts or send us something else. You will be asked to submit your photographs or writing tasks via a secure weblink that we will include in this message.

In the second interview at 12 months (mentioned above), you will be asked about the photographs and/or completed writing tasks that you have submitted.

You can withdraw from the photography/writing project at any time. Your photographs will not be reproduced by researchers until you have signed a participant release form, which we will ask you to fill in at the end of the study.

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## **4 What will I need to do if I take part?**

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### **1. Clinic data**

There is nothing you need to do if you agree to take part in the clinic data study. Your clinic team will send your clinic data to the research team at University College London using a secure link.

### **2. Questionnaire**

We will ask you to complete a short 15-minute questionnaire on paper or online (it's up to you). If you agree, we will invite you to complete a similar, but shorter, questionnaire again in 12-18 months after this first one.

### **3. Interview**

There is nothing in particular you need to do before the first interview, other than turn up at the scheduled time or make sure you are available for the video/phone call at the scheduled time. A member of the CASCADE study team will give you specific instructions about how to join the interview in person,

online or by telephone. You will be invited to take part in a second (and final) interview 12 months after the first one. We will send you more information about that nearer the time.

#### **4. Photography/writing project**

During the 12 months between the first and second interviews, we will ask you by SMS or email to take photographs or complete short writing tasks at approximately three month intervals and send them to the UCL research team. It is entirely your choice whether you want to respond to those prompts.

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

We think that it is unlikely that you will come to any harm through taking part in the study. We realise that some of the questionnaire, interview and photography questions may cover sensitive and personal information. Any questions that you don't want to answer, or feel unable to answer, can be missed out. We understand that some of the topics may be upsetting to you. If completing the questionnaire or taking part in the interviews or photography/writing project bring up something that's upsetting, then please let a member of the clinic team or the researcher know so we can help you get further advice and support, including access to mental healthcare resources.

If you share information that makes us concerned about harm to yourself, or to others, we may have to share with other professionals e.g. HIV clinic or GP. We would inform you before doing this.

You are free to stop the questionnaire and interviews at any time without giving a reason. If you agree to take part in the workshops, your identity may be recognised by other participants. All participants will be asked to keep what is discussed or seen in these workshops as confidential information. You can also stop participating in the

photography project at any time during the 12-month period.

### **6 What are the possible benefits of taking part in this study?**

The project is unlikely to help you personally, although some people enjoy sharing their experiences and having someone listen carefully. You may also enjoy knowing that you are helping to improve what is known about the experiences and needs of people with newly-acquired HIV. This could help to inform policy and improve services in the future and help us prevent people from catching HIV in the future.

In recognition of your time, you will receive a £10 gift voucher for completing a questionnaire, and a £20 gift voucher for participating in an interview.

### **7 More information about taking part**

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

No, it is up to you to decide whether or not to take part, and which part(s) of the study you agree to. If you decide to take part, you will be given this information sheet to keep and you will be asked to sign a consent form.

If you are interested in taking part in the interview and/or photography/writing project, we will ask you if we can pass your details on (securely) to the CASCADE study team so they can contact you to arrange this.

If you decide not to take part in any/some of the CASCADE study, this will not affect your access to services or the care you receive in any way.

## Can I stop taking part?

You can stop taking part in the study at any time. You can talk to a member of the study team first. They can advise you about any concerns you may have.

## What will happen to information about me collected during the study?

If you agree to take part, the following will happen (depending on which part(s) of the study you want to take part in). Consent forms will be kept in locked cabinets in the clinic:

- **Clinic data** will be entered into a secure study database (at your clinic). We will not be collecting names. These data will be automatically transferred to the UCL Data Safe Haven, a highly confidential and secure system to manage data from the NHS.

A dataset, **with all personal identifiers removed**, will be generated for analyses. Researchers at UCL and in collaborating institutions in EU countries will have access to this dataset.

- **Questionnaires.** If you complete the questionnaire online, this will be automatically transferred to UCL's Data Safe Haven (see above). Paper questionnaires will go into a sealed envelope and collected by a member of the local study.

No one in the clinic will know your questionnaire answers unless you have asked them to help you complete the questionnaire. Researchers at UCL and in collaborating institutions in EU countries will have access to this dataset.

As with the clinic data, a dataset with all personal identifiers removed will be generated for analyses.

- **Interviews:** We will ask for your permission to record the interview (sound only). The recording will be held on a digital voice recorder or a university computer that is encrypted for your security. After the interview, it will be transferred to UCL's Data Safe Haven.

The interview will be transcribed automatically using software or typed up by a professional transcriber (who sign a confidentiality agreement and use a secure and encrypted transfer).

The audio recording will be deleted from the computer immediately after it has been transferred to the Data Safe Haven.

We do not ask for your name during the interview, so you will not be recognised on the sound recording from your answers. The recording of your interview and the transcript generated from it will only be identified by a project number, and not your name.

The only people who will listen to the recorded discussion are the project team. The recording will be securely deleted once we have checked the typed version for accuracy.

## What will happen to information collected about me after the study?

This project is being undertaken by researchers based at University College London (UCL). Professor Kholoud Porter (UCL), is responsible for the project and all the data. We will be using information from you to undertake this project and we are responsible for looking after your information and using it properly.

You can withdraw from the clinical data part at any time until the study ends and we will not collect any further data from your clinical records.

You can withdraw your questionnaire data at any point up until the questionnaires have started to be analysed. We will delete your questionnaire record from the questionnaire database.

You can withdraw your interview/photography/writing data up to four weeks after the interview or the photography/writing project ends. We will remove any information about you.

If you withdraw from the project after it ends, we will keep the information about you that we have already obtained.

Non-identifiable information for this study will be analysed and stored at a registered UCL archive facility for a minimum of 10 years after the end of the study. Other researchers from outside UCL, in EU countries, will have access to the anonymised dataset for analyses. The funders will also be given reasonable access to this anonymised dataset.

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.

### 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/)
- by contacting the UCL Data Protection Office [data-protection@ucl.ac.uk](mailto:data-protection@ucl.ac.uk), 0203 108 8764
- by asking one of the research team
- by sending an email to [Elisa.RuizBurga@nhs.net](mailto:Elisa.RuizBurga@nhs.net), or
- by ringing us on 07833 160577.

### What are the choices about how my 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.
- If you choose to stop taking part in the study, we would like to continue collecting information about your health from your clinic records. If you do not want this to happen, tell us and we will stop.
- 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.

### What will happen to the results of the project?

When the study is completed, we will present the findings at academic conferences and publish the results in academic journals, so that healthcare professionals and researchers can see them. You can ask your clinic team for a copy of any future publications. Your identity and any personal details will be kept confidential. No named information about you will be published in any report of this study. We will make sure no-one can work out who you are from the reports we write.

The study information will not identify you and will not be combined with other information in a way that could identify you.

No sound recordings or names will be used when this research is presented at conferences and meetings. Any quotes will be anonymous. Some of the submitted photographs may be shared at conferences and in reports and articles. We will ask you for permission to use specific images.



We will also put a summary of our results on our website:

<https://www.cascadestudy.net>

And our Twitter feed: @study\_cascade

At UCL 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 this project research study, we will use your data in the ways needed to conduct and analyse the work. 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).

## Who is organising and funding the study?

The study has been designed by researchers at UCL. The project has been reviewed and is being paid for by a number of pharmaceutical companies (Janssen Pharmaceutica, ViiV Healthcare, and MSD Corp). UCL is Sponsor



and has overall responsibility for the conduct of the group discussion part of the project. They are responsible for ensuring the discussions are carried out ethically and in the best interests of participants.

## Who has reviewed the study?

The study has been reviewed and authorised by a Research Ethics Committee, the Health Research Authority (HRA), and the Trust's Research and Development Office.

## What if something goes wrong for me?

If you have any concerns about the way you have been approached or treated during the study, please talk to your doctor or nurse. If you are still unhappy, or if you wish to complain, please use the normal NHS complaints process.

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

PALS (Patient Advice and Liaison Service)

Telephone: TBC

Email: TBC

If you are harmed by taking part in the interview, or if you are harmed because of someone's negligence, then you may be able to take legal action. The Sponsor of the study, University College London, holds an insurance policy, in case anything does go wrong.

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## 8 Contacts for further information

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If you want further information about this study, contact

**CASCADE Study Coordinator**

**Dr Elisa Ruiz Burga**

University College London  
Mortimer Market Centre, 3<sup>rd</sup> Floor



Off Capper Street  
London, WC1E 6JB  
Tel: 07833 160577  
Email: [Elisa.RuizBurga@nhs.net](mailto:Elisa.RuizBurga@nhs.net)

**UCL Data Protection Office**

Tel: 0203 108 8764  
Email: [data-protection@ucl.ac.uk](mailto:data-protection@ucl.ac.uk)

UCL privacy notes for: [health or social care research](#)

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