

## CASCADE Collaboration

### Participant Information Sheet B

#### 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 have already taken part in one or more of them:
  - collecting data from medical notes or clinic databases.
  - a questionnaire that you complete yourself.
  - an interview and photography project.
- In addition to this, we are now inviting you to take part in a second interview.
- If you have taken part in the photography project, we will also invite you to take part in two 2-hour workshops.
- It's up to you which parts of the study you take part in.
- We will use the information we gather in this study 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 Research Fellow

##### **Dr Emily Nicholls**

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

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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 2017.

We want to understand more about the health, experiences and needs of people who have caught HIV recently (for our study, which 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.

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. You have also already participated in the CASCADE study by agreeing to be interviewed and possibly also participating in a photography project. We are inviting you to a second

interview. If you did participate in the photography project, we will also invite you to participate in two 2-hour workshops.

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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### *i. Interview*

We will invite you to a second interview around 12-months after the first one. 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 how you've been getting on since the first interview, and also about your experiences of living with HIV, well-being, mental health. If you have participated in the photography project, you will also be asked about the photographs that you have sent us. 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.

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.

## **ii. Workshops**

If you have participated in the photography project, we will invite you to participate in two 2-hour workshops. They will be conducted online using software such as Microsoft Teams they will be held around one week apart.

The workshops will be co-facilitated by two CASCADE researchers. Everyone else in attendance will have also participated in the photography project and will be living with HIV. A maximum of 10 people will participate in each workshop.

During the workshops you will be invited to think about and share your experiences of living with HIV and of participating in the project. You will also be asked to show and discuss the photographs you have taken with others. This will include discussions as a whole group and in pairs or threes.

Between the two workshops you will be asked to take an additional photograph to show the group.

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

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### **i. 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.

## **ii. Workshops**

We will invite you to participate in two 2-hour workshops, which will be conducted online using software such as Microsoft Teams. Everyone who has participated in the CASCADE photography project will be invited to take part (maximum 10 people). The workshops will be co-facilitated by two researchers. Everyone else in attendance will be living with HIV and will have been participating in the study.

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

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We think that it is unlikely that you will come to any harm through taking part in the study. 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. We realise that the interview questions and workshops may cover sensitive and personal information. Any questions during the interview that you don't want to answer, or feel unable to answer, can be missed out. If there are discussions during the workshop that you do not want to contribute to, then you do not have to. We understand that some of the topics may be upsetting to you. If taking part in the interview or workshops bring up something that's upsetting, then please let one of the researchers 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 interview or leave the workshops at any time without giving a reason.

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

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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 £20 gift voucher for participating in an interview and a £20 for each workshop you participate in.

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## 7 More information about taking part

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### 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 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:

- **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.

- **Workshops:** The workshops will include working in pairs or threes and also having

discussions as a whole group. The whole-group discussions will be audio-recorded on a digital voice recorder or a university computer that is encrypted for your security. These recordings 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).

As soon as a transcript has been created, the audio recordings will be deleted. Any names that have been used during the workshops will be removed from the transcript.

During the workshops, the facilitators will also take notes of the discussion, and these will also be anonymised.

### 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 in order 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. We will delete all your data from the clinical database.

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/photograph/writing/workshop data up to four weeks after the interview, workshop, or four weeks after 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 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.

If you have any questions about how data are handled in this study, please speak to the CASCADE Study Coordinator. You may also contact the UCL Data Protection Office. The contact details for Coordinator and the UCL Data Protection Office are provided at the end of this information sheet.

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, but only the ones you have told us that we can use and have signed a form saying so.

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 Pharmaceuticals, ViiV Healthcare & 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.



## Contacts for further information

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If you want further information about this study, contact

**Research Fellow**

### Dr Emily Nicholls

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Off Capper Street  
London, WC1E 6JB  
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email: emily.nicholls4@nhs.net

### UCL Data Protection Office

Tel: 0203 108 8764  
Email: data-protection@ucl.ac.uk

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