**CASCADE Collaboration**

**Participant Information Sheet C: for participants acquiring HIV more than 12 months ago**

**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 who had recently-acquired HIV at the time of HIV diagnosis.
* We will need to use information from your clinic records for this study.
* It’s up to you if you wish to take part.
* We will use this information to better understand the experiences of people who engaged with health services shortly following acquiring 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, 3rd 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?** |

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.

Learning from people that have a clear timeline of when they acquired HIV allows us to understand which medications are more effective in the long run, and exactly how early treatment needs to be initiated. 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?** |

You are being asked to take part because you had recently acquired HIV at the time of your diagnosis. For this study that means you had an HIV-negative test within 12 months of your HIV-positive test or had other laboratory criteria of recently-acquiring HIV.

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?** |

We are inviting you to take part in CASCADE.

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 liaise with clinic staff should any queries arise about your clinical or laboratory data. 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.

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

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

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| 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.

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

The project is unlikely to help you personally, although you may enjoy knowing that you are helping to improve the experience of people with HIV. This could help to inform policy, improve services, and help us prevent people from catching HIV in the future.

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| 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. 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, your 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.

Consent forms will be kept in locked cabinets in the clinic.

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 at any time until the study ends, and we will not collect any further data from your clinical records.

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/](https://www.hra.nhs.uk/information-about-patients/)
* by contacting the UCL Data Protection Office data-protection@ucl.ac.uk, 0203 108 8764
* by asking one of the research team
* by sending an email to 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.
* 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.

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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 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** |

If you want further information about this study, contact

**CASCADE Study Coordinator**

**Dr Elisa Ruiz Burga**

University College London

Mortimer Market Centre, 3rd Floor

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London, WC1E 6JB

Tel: 07833 160577

Email: Elisa.RuizBurga@nhs.net

**UCL Data Protection Office**
Tel: 0203 108 8764
Email: data-protection@ucl.ac.uk

UCL privacy notes for: [health or social care research](https://www.ucl.ac.uk/legal-services/privacy/ucl-general-privacy-notice-participants-and-researchers-health-and-care-research-studies)

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