**Appendix E: Accelerated Partner Therapy (APT) Process Evaluation Study**

**Participant Information Sheet**

**PE Study 4**

**Focus Groups with Healthcare Professionals**

LUSTRUM is a five-year programme of research led by Professor Claudia Estcourt, from Central & North West London NHS Trust and University College London and Glasgow Caledonian University. LUSTRUM aims to improve the sexual health of heterosexual people and men who have sex with men (MSM). The programme aims to achieve this by preventing transmission of sexually transmitted infections (STIs) and reducing undiagnosed HIV.

We are inviting you to take part in the *Accelerated Partner Therapy Process Evaluation Study.* The study is part of the LUSTRUM Accelerated Partner Therapy (APT) Chlamydia Partner Notification Trial. We will be conducting focus groups with health care professionals, who delivered APT during the LUSTRUM APT Chlamydia Partner Notification Trial to talk about intervention delivery and their experiences.

Before you decide whether or not to take part, it is important for you to understand what participation in the study will involve for you. Please take time to read the following information carefully. Please contact us at the phone number or email address below if you have any further questions or concerns regarding the study.

**What is the purpose of the study?**

This study forms part of the LUSTRUM Accelerated Partner Therapy (APT) Chlamydia Partner Notification Trial. These discussions will help us understand in detail health care professionals’ experiences and perspectives when delivering APT. Findings of this study will be presented in reports, at academic and/or professional conferences and may be published in academic journals.

**Who is organising and funding this research?**

The LUSTRUM programme including the *Accelerated Partner Therapy Process Evaluation Study*, are funded by the National Institute for Health Research (NIHR), UK. The sponsor of the LUSTRUM Accelerated Partner Therapy (APT) Chlamydia Partner Notification Trial is Central and North West London NHS Trust. The *Accelerated Partner Therapy Process Evaluation Study* is led by Professor Paul Flowers at Glasgow Caledonian University.

**Who has reviewed the project?**

All research that takes place within the NHS is looked at by an independent group called the National Research Ethics Committee, to protect your interests. The *Accelerated Partner Therapy Process Evaluation Study* has been reviewed and given Favourable Opinion (23rd July 2018) by London – Chelsea Research Ethics Committee.

**Why have I been invited?**

We are inviting health care professionals, including those who delivered APT during the LUSTRUM APT Chlamydia Partner Notification Trial to take part in focus groups. The focus group discussions will focus upon your perspectives of APT and details of how it was delivered.

**Do I have to take part?**

It is up to you to decide whether or not to take part. Participation is voluntary and you can withdraw from the study at any time, without giving a reason. If you decide to leave the study any information already collected will be retained and used for the purpose of the study, however, no additional data will be collected.

**What will happen if you decide to take part in the study?**

If you agree to take part in the study, you will need to complete an expression of interest form and email it to the research team. It includes some basic background and demographic questions and also asks about your involvement with APT. You will also be asked to provide your contact details (first name, mobile number and email). Your contact details will be used only by the research team and used to arrange your participation in the study. You can contact the research team directly by returning the expression of interest form electronically via email. Members of the research team will then contact you to confirm participation.

When we contact you we will explain about the study, and make sure you received the participant information sheet. You will be invited to participate in a focus group discussion about your views and experiences of APT*.* If you choose to participatein a focus group we will seek written consent and we will ask you to complete a consent form on the day of the focus group.The focus group discussion will last approximately two hours. If you feel uncomfortable during this process you are free to withdraw from the study, at this or any further point. At the end of the session, we will ask you to confirm that you are still happy for your data to be included in the study.

**Why will we record the discussion?**

The focus group discussion will be recorded to help us analyse the data and to make sure we don’t forget or miss important information that you tell us. The audio-recorded file will be safely kept at Glasgow Caledonian University (GCU) and/or University College London (UCL) premises.

**How will we keep the recording safe and make sure you are not identified from it?**

The audio-recording will be written up (transcribed) for analysis purposes but identifiable information, such as your name, will be removed. The audio-recording will be destroyed as soon as we have the written transcript. Identifiable information is not revealed and only members of the research team will have access to these documents. Quotations (exact words) from documents may be used in publications, reports and/or presentations provided that anonymity is preserved. For the purpose of the analysis, fictitious names and/or codes might be used.

**What are the possible advantages of taking part?**

Participation in the study will not necessarily help you personally. However, we want your participation to be a beneficial experience to you as well. We will give you relevant information about how to follow the progress and findings of this study. We hope that you will find participating in our study an interesting experience and that you will benefit from sharing your opinions on Accelerated Partner Therapy.

**What are the possible disadvantages of taking part?**

We do not anticipate that there will be any risks or disadvantages of you taking part in this study. However, during the discussion if you feel uncomfortable due to any topics raised, you must let the researcher know that you do not wish to discuss this issue or that you wish to leave the discussion altogether.

**Will taking part in this study be kept confidential?**

Yes. We will follow good clinical practice guidelines, and all of your information will be handled in confidence. Your name and any identifiable information will be stored safely, and only members of the research team will have access to them. Your personal data will be kept for the duration of the study (which is due to end in March 2021) and will then be destroyed. Your demographic information will be grouped with other participants’ so that we are able to ensure we have a good balance and mix of participants, and so that we can give an overall report about the sample’s characteristics, without sharing any details that could identify you as an individual. Your rights are protected under the Data Protection Act 1998 and any information that might identify you will not be shared outside of the research team.

If we believe you or someone else to be in danger or at risk of significant harm, this will be reported directly to [name], [Lead for Safeguarding] and Professor Claudia Estcourt, Chief Investigator on the study. Any allegations of poor practice discovered during the course of the study will be reported directly to [name], Head of Service for GU/HIV medicine and [name], Service Manager.

**What will happen to the results of the study?**

The results will be analysed and presented in a form that does not allow any individual to be identified. They will be shared with healthcare services, academics, professionals and practitioners, community based organisations and service users. We will also publish the findings from this study in academic journals. Quotations (exact words) from documents may be used in publications, reports and/or presentations with fictitious names and/or codes and broad terms, such as ‘Health Advisor London’, ‘Nurse Glasgow’, without any further descriptive details, thus ensuring anonymity. We aim to use our findings to improve sexual health services and help in decision making about further service development. We will share updates of the research programme and its progress through the project website ([www.lustrum.org.uk](http://www.lustrum.org.uk/)) and through the project twitter account ‘@LUSTRUM\_5’

**What if I have concerns or there is a problem?**

If you have any concerns about any aspect of this research, or the way you have been approached or treated by members of staff due to your participation in the research, or wish to complain about your participation in the research itself, please speak to a member of the research team who will do their best to address the issue. If you remain unhappy and wish to complain formally your National Health Service complaints mechanisms are available to you. Please ask your [Site Principal Investigator] 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.

**What if something goes wrong?**

In the event that something does go wrong and you are harmed during the research and this is due to how the research has been designed or someone's negligence then you may have grounds for a legal action for compensation against Glasgow Caledonian University and/or the clinic/hospital [delete as appropriate] but you may have to pay your legal costs. The normal National Health Service complaints mechanisms will still be available to you (if appropriate).

**What if I want more information?**

If you have any requests or you want to get more information on the study please contact:

Dr Maria Pothoulaki Professor Paul Flowers

(email: Maria.Pothoulaki@gcu.ac.uk) (email:p.flowers@gcu.ac.uk)

(te.0141 331 3701) (tel.0141 331 8617)

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

**Your Information, NHS Research, and the General Data Protection Regulation (GDPR)**

Central and North West London (CNWL) NHS Foundation Trust is the Sponsor for this study and Glasgow Caledonian University is a collaborator that is organising this research, both organisations are based in the United Kingdom. CNWL NHS Foundation Trust and Glasgow Caledonian University will be using information from you in order to undertake this study. CNWL NHS Foundation Trust will act as the data controller for this study, this means that we are responsible for looking after your information and using it properly. Glasgow Caledonian Universitywill keep identifiable information about you until the study has finished (March 2021).

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. If you withdraw from the study, we will keep the information about you that we have already obtained. To safeguard your rights, we will use the minimum personally-identifiable information possible. You can find out more about how we use your information by contacting Dr Maria Pothoulaki or Professor Paul Flowers.

[NHS site], Glasgow Caledonian University and University College London will keep your name and contact details confidential and will not pass this information to CNWL NHS Foundation Trust. [NHS site], Glasgow Caledonian University and University College London will use this information as needed, to contact you about the research study and to oversee the quality of the study. Certain individuals from CNWL NHS Foundation Trust and regulatory organisations may look at your research records to check the accuracy of the research study. CNWL NHS Foundation Trust will only receive information without any identifying information.

[NHS site], Glasgow Caledonian University and University College London will keep identifiable information about you until the study has finished (March 2021).