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Australian models of care for HIV Negative patients receiving antiretrovirals as Pre-exposure Prophylaxis (PrEP)

PARTICIPANT INFORMATION STATEMENT

(1) What is this study about?

You are invited to take part in a research study about the evolving services of delivering pre-exposure prophylaxis (PrEP) to people at risk of HIV infection in Australia. This is a study of knowledge, experiences and opinions of health professionals engaged or interested in provision of HIV prevention to patients at risk for HIV infection.

You have been invited to participate because as a professional you may be involved in PrEP delivery, now or in the future.

This Participant Information Statement tells you about the research study and may help you decide if you want to take part in the research. Your participation is voluntary. By taking part, you are telling us that you:

- ✓ Understand what you have read.
- ✓ Agree to take part in the research study.
- ✓ Agree to the use of your personal information as described.

(2) Who is running the study?

The study is being carried out by researchers at the Sydney Medical School - Westmead, The University of Sydney Associate Professor Iryna Zablotska-Manos*, Professor David Lewis and Doctor Shailendra Sawleshwarkar.

*A/Prof Iryna Zablotska is a recipient of previous research support from Gilead Sciences, specifically a research grant for the study of PrEP acceptability among gay men and an in-kind supply of medication for PrEP implementation studies in Australia.

(3) What will the study involve for me?

You have received an email invitation which contains a link to the online survey. We ask you to follow that link and complete the survey. It is focused on your knowledge about PrEP, willingness to provide PrEP and yur opinion about PrEP services. It includes questions about yourself and your workplace without revealing your identity.

The survey takes place in May-June 2018. You will also receive two reminders, spaced by two weeks. Please ignore them if you have already completed the survey. Your professional association will not have access to the study database, and thus will not be able to identify you as a participant.

To enable a follow-up survey in 12-24 months, at the end of the survey we will ask you whether you are willing to be contacted once again and, if so, to provide your email address. The entry of contact email into the study database will be taken as consent to be contacted for a follow-up survey about PrEP services.

Upon completion of the survey, a summary of the research findings (in aggregated form) will be provided to the professional organisations participating in the research, and they will share this summary with their membership using standard organisational communication means (e.g., membership emails, newsletters organizational website, as appropriate). Individual participants will not be identifiable in this summary or in any publication of the results.

(4) How much of my time will the study take?

The entire survey should take you no more than 15-25 minutes to complete.

(5) Who can take part in the study?

Eligible to participate in this study are members of the following professional health workers associations: Australasian Society for HIV Medicine (ASHM), Pharmaceutical Society of Australia (PSA), The Australasian Sexual Health and HIV Nurses Association (ASHHNA) and Royal Australian College of General Practitioners (RACGP).

(6) Do I have to be in the study? Can I withdraw from the study once I've started?

Being in this study is completely voluntary. Submitting your completed questionnaire is an indication of your consent to participate. Your decision whether to participate will not affect your current or future relationship with the researchers or anyone else at the University of Sydney, your professional organisation or your workplace.

If you decide to take part and then change your mind later, you are free to withdraw at any time, with no consequences. You can do this by simply terminating the survey. If you decide to withdraw, we will not collect any more information from you. Any information that we have already collected, however, will be kept in our study records and may be included in the study results.

If you choose to stop and return to the survey later, this opportunity is also available. At the bottom of each survey page, there is a “Save and Return Later” button. Once this button is triggered, you will receive a Return Code with instructions on how to return to the survey (to the same place where you stopped).

(7) Are there any risks or costs associated with being in the study?

Aside from giving up your time, we do not expect any risks or costs associated with taking part in this study.

(8) Are there any benefits associated with being in the study?

There are no direct benefits and/or reimbursement of your time for participation in this study. However, you and all members of your professional association will have some professional benefits from your participation in this project, as a summary of findings about PrEP services in Australia will be shares with all members of the professional associations participating in this research.

(9) What will happen to information about me that is collected during the study?

This survey collects information including but not limited to: characteristics of clinical services: type of service, number of doctors, nurses, pharmacists accredited laboratory services); proportion of staff involved in providing PrEP, pathways of patient assessments; time and resources allocated to PrEP services; cost of services; pay for services; number of patients serviced; record keeping about PrEP; attitudes and willingness to provide PrEP; knowledge about PrEP; perceptions of challenges, education needs, etc.

If you choose to provide your contact details as consent to be contacted in follow-up research, this information will be stored securely and separately from the survey responses.

Data collection is set-up online. Questionnaires are designed in REDCap (a mature, secure web application for building and managing online surveys and databases. The University of Sydney is a member of Australian Access Federation. REDCap ensures a password-protected access to data to only pre-approved project investigators.

Data collected by this study will belong to the University of Sydney. Upon study completion, all study materials will be stored by the University of Sydney in its Research Data Store for a mandatory period of 5 (five) years and then securely disposed of under the requirements of the University's Data Management Policy.

After you complete the survey, you will not be able to access your responses. The results of this research project will be disseminated via peer-reviewed journal publications, book chapters, conference presentations, and students learning projects. The summary of the results will also be provided to your professional organisation, so that it can share this summary with the entire membership using standard organisational communication means (e.g., membership emails, newsletters organizational website, as appropriate).

Your information will only be used for the purposes outlined in this Participant Information Statement. Your information will be stored securely and strictly confidential, except as required by law. Study findings may be published, but you will not be individually identifiable in these publications.

(10) Can I tell other people about the study?

Yes, you are welcome to tell other people about the study.

(11) What if I would like further information about the study?

If you would like to know more at any stage during the study, please feel free to contact A/Prof Iryna Zablotska-Manos, Sydney Medical School - Westmead, University of Sydney, by email to *Iryna.zabltoska@sydney.edu.au* or calling to +61 (2) 9762 5382.

(12) Will I be told the results of the study?

You have a right to receive feedback about the overall results of this study. All study participants will receive feedback after the study is finished. A summary of the research findings will be circulated by the professional organisations participating in this research to their membership using standard organisational communication means (membership emails and newsletters posted on the organizational websites, as appropriate).

(13) What if I have a complaint or any concerns about the study?

Research involving humans in Australia is reviewed by an independent group of people called a Human Research Ethics Committee (HREC). The ethical aspects of this study have been approved by the HREC of the University of Sydney (protocol number 2018/347). As part of this process, we have agreed to carry out the study according to the *National Statement on Ethical Conduct in Human Research (2007).* This statement has been developed to protect people who agree to take part in research studies.

If you are concerned about the way this study is being conducted or you wish to make a complaint to someone independent from the study, please contact the university using the details outlined below. Please quote the study title and protocol number.

The Manager, Ethics Administration, University of Sydney:

- **Telephone:** +61 2 8627 8176
- **Email:** ro.humanethics@sydney.edu.au
- **Fax:** +61 2 8627 8177 (Facsimile)

This information sheet is for you to keep