Participant Information Sheet (PIS)

INTERACT: Indonesia Intervention Study to Test & Treat people with Acute HIV infection

1. What is the purpose of this study?

HIV (human immunodeficiency virus) is a virus that attacks the body's immune system. If HIV is not treated, it can lead to AIDS (acquired immunodeficiency syndrome). There is currently no effective cure. But with effective HIV treatment, HIV can be controlled, and people with HIV can live long, healthy lives and protect their partners.

To know if you have HIV, you need to get tested, on a blood sample drawn from a vein. However, standard antigen/antibody HIV tests, offered by the clinic, cannot always detect HIV immediately after infection, so-called "acute HIV". The purpose of this study is to implement an additional very sensitive HIV test, called "HIV-RNA" (in addition to the standard antigen/antibody HIV test), which will allow to diagnose more people during acute HIV infection, get them started on HIV treatment immediately, and, in doing so, keep them healthier. We will use the study data to find out if this intervention, if rolled out at scale, could curb the growing HIV epidemic in Indonesia. We are doing this study in sexual health clinics in Jakarta and Bali, in a collaboration between the Atma Jaya Catholic University, University of Oxford in the UK, and other partners. The funding comes from the UK Medical Research Council.

2. Why have I been invited to take part?

You have been taking a risk of getting HIV, and you have come to this clinic to take an HIV test. We are offering an additional, very sensitive test to detect if you have "acute HIV" to all clinic attendees.

3. What's involved for me?

We will first check if you are eligible to be included in the study and ask your digital consent. You will then be asked to answer some questions regarding your risk of having acute HIV (so-called "Risk Checker"). The study team will also extract some basic information on your health from your medical record at the clinic. We will use the remnant of the blood sample taken for your standard HIV test, to perform the extra test for acute HIV. No additional blood sample will be taken for this study. This procedure will be done every time you decide to come to the clinic to take a standard HIV test (recommended every 3 months, or any time sooner if you have symptoms that may suggest you have acute HIV) for the duration of the study (maximum one year). Should you be newly diagnosed with HIV, the study will also extract data on your health and HIV treatment during the first six months of your treatment from your medical record.

4. What will happen to my data?

Data about you will be collected in an electronic study database, using password protected tablets/laptops. Your name or identify will not be identified in the study database. We will collect personal data (your clinic identification number, gender and date of birth) only to correctly match you to your laboratory test results. Only the study team will be able to access the study database. The de-identified study data will be aggregated for analysis and the findings will be published in scientific journals, reports to policy makers and possibly as part of student theses. Your name or identify will not be identified in any report. Research ethical committees or representatives from the study sponsor may also have access to study documents to make sure that the study is properly conducted. This data will be deleted no later than five year after the end of the study.

5. Are there any risks in taking part?

The only risk of taking part in this study is loss of confidentiality, but we have processes in place to ensure that does not happen. As described above, personal data, i.e. things that could possibly identify you, will be removed before data is moved outside of the clinic.

6. What are the benefits of taking part?

You will receive, free of charge, an additional test for acute HIV (called "HIV-RNA") and screening for other sexually transmitted infections every time you come to the clinic for an HIV test during the study period. There are no other direct benefits to you if you take part in this study. However, participating in the study will help improve the diagnosis and treatment of HIV for future patients. Use of de-identified routine medical data to better understand the risks, prevention, diagnosis, and treatment of acute HIV is a major benefit to society. There are no extra costs and you will not receive any payment for study participation, but you will receive a reasonable compensation (up to Rp 70,000/visit) to compensate for your time and travel expenses.

7. Do I have to take part?

Whether or not you agree for you take part is entirely your choice and this choice will not affect your clinical care. If you do agree to take part, you may withdraw yourself from the study without penalty at any time. If you decide to withdraw yourself, the reason for withdrawal will be entered into a logbook. However, you do not need to give a reason for withdrawal. We will use any data collected up to the time of withdrawal, unless you decide that you don't want us to use data collected earlier.

8. Has the study been approved by an ethics committee?

This study has been approved by research ethics committee of the Faculty of Medicine Atma Jaya Catholic University, and the Oxford Tropical Research Ethics Committee in the UK.

9. Cofidentiality

The University of Oxford and Atma Jaya Catholic University are responsible for ensuring safe and proper use of any personal information you provide, solely for research purposes.

10. What if I have any questions or want to raise a concern?

If you have any questions about the study, please ask a member of the study team or your doctor.

If you have any questions later, you can contact the site lead researcher **Nurhayati, SS., M.Epid. (Mobilee:** +62 812-8739-6154**)** in Jakarta or **dr. Hendry Luis** (Mobile:e +62 812-4664-5739) in Bali, or the study Principal Investigator **Prof. Irwanto, Ph.D.** Atma Jaya Catholic University (Email: irwanto_i@yahoo.com ; Mobile: +62 896-5693-1279). If you remain unhappy or wish to make a formal complaint, please contact the Chair of the Research Ethics Committee of the Atma Jaya Catholic University (Email: ppe@atmajaya.ac.id ; Phone: (+62-21) 572 7615 ext. 159).