Document:
Informed Consent Form – Clients living with HIV (Intervention salons)

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Community-based venues for delivery of healthcare services: Proof of concept pilot

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Community-Based Venues for Delivery of Healthcare Services: proof of concept pilot in the salons
Research Participant Consent Form for Intervention Salons – PLWH

Has this participant ever tested positive for HIV?
 YES
 NO

This will be displayed if participant has previously tested positive for HIV
Why is this research study being done?
We are doing a study to test and evaluate a program for offering sexual health care services, specifically HIV prevention, contraceptives, and sexually transmitted infection screening to young women at hair salons in the Umlazi and Berea areas.

We are asking you to take part in this study because you are a female attending a salon in Umlazi or Berea and may be interested in the services offered as part of this study.

This study will help us better understand women's interest in pre-exposure prophylaxis (PrEP) for HIV prevention, contraceptives, and sexually transmitted infection screening, offered in salon settings. PrEP is a one-pill medication that can be taken daily to prevent the transmission of HIV to a person without HIV. Contraceptives are pills taken daily or injections administered by a nurse or doctor once every three months to prevent pregnancy in women. Tests for sexually transmitted infections are done using either a sample of blood, urine, or cultures from swabs of different parts of the body.

We expect that about 200 clients from various hair salons in and around Umlazi or Berea will participate in the section of the study in which these interventions are offered.

How long will I take part in this research study?
If you are willing to participate in this study, you will be asked to spend about 1 hour with our study team today. You will also be asked to return at 3, 6, 9, and 12-month visits at the salon. These follow-up visits should last about 30 minutes each.

What will happen in this research study?
You will be offered contraceptives (pills **or** injectables). You can choose which of these services you'd like to use or select to use none. If you choose to use contraceptives (pills **or** injectables) you will also be offered testing for sexually transmitted infections (STIs). STI testing will be offered at the baseline visit as well as 6 and 12 months after accepting contraceptives and involves a finger-prick blood sample (Syphilis blood test) and a self-administered vaginal swab (testing for gonorrhea, chlamydia, trichomoniasis). After making your selection, a research assistant will ask you questions for a survey with background information about yourself. A professional nurse will then perform a pregnancy test at baseline and all follow-up visits to determine eligibility if you choose to receive contraceptives. If you do not choose to use contraceptives, you will still be provided with the option to take a pregnancy test at each visit.

I understand that I can choose which services to use, this includes choosing to use no services.

Participant initials: _____ *Date:* _____

To protect your privacy, no one outside of the research team (including no one at the salon) will be allowed to see the information we collect in this study. Our reports about the study will not use anyone's name. Deciding to take part in the study program is completely up to you. Even if you join the study, you can drop out at any time. Your experience at the salon will not be affected if you drop out.

Joining this study means that you cannot join any other research study about PrEP or contraception. If you would like to join another research study about PrEP or contraception, you will have to withdraw from this study.

What are the risks and possible discomforts from being in this research study?
There are some possible discomforts from being in this research study dependent on which services you choose to use.

For participants choosing to receive injectable contraceptives, pain or soreness in the arm may be experienced during or after the injection. Additionally, some side-effects associated with hormonal forms of contraceptives, including both pills and injectables, include: headache, abdominal pain, irregular bleeding or "spotting", breast tenderness, decreased sex drive, changes in mood and/or weight gain.

There is a risk that planned study procedures may be interrupted due to unforeseen circumstances which include but are not limited to COVID-19. In this event, we will make every effort to ensure that any services or medication you are receiving through the study are not interrupted.

During the survey interviews you may be uncomfortable talking about your experiences. We have procedures in place to help protect your confidentiality which are described below. You are also not required to share anything you are uncomfortable talking about.

I understand the risks associated with the various services I can choose to use.
Participant initials: _____ *Date:* _____

What are the possible benefits from being in this research study?
If you choose to receive any of the services through this program, you will benefit from free access to effective health care services offered at a more convenient venue.

If I don't take part in the research study or if I stop taking part, will it affect my status as a patron of the salon?
No. Participating in this research study or choosing not to participate will have no effect on your ability to receive services from the salon. Taking part in this research study is up to you. You can decide not to take part or to change your mind and drop out later.

Will I be paid to take part in this research study?
You will be paid 50 South African Rand for your participation in the study at each visit.

What will I have to pay for if I take part in this research study?
There is no extra cost to you for participation.

If I have questions or concerns about this research study, whom can I call?
The coordinator of this study is Sabina Govere. Her office phone number is [redacted]. Her cell phone number is [redacted]. The local physician in charge of this study is Dr. Tasneem Naidoo. Her phone number is [redacted]. They are available at all times during this study. You can call them with your questions or concerns.

In the event of any problems or concerns/questions you may also contact the UKZN Biomedical Research Ethics Committee, contact details as follows:

BIOMEDICAL RESEARCH ETHICS ADMINISTRATION
Research Office, Westville Campus
Govan Mbeki Building
University of KwaZulu-Natal
Private Bag X 54001, Durban, 4000
KwaZulu-Natal, SOUTH AFRICA
Tel: 27 31 2604769 - Fax: 27 31 2604609

Email: BREC@ukzn.ac.za

If I take part in this research study, how will you protect my privacy?
Any information that we collect in connection with this study and that can be identified with you will remain confidential. The research team will not provide information about you or your health to anyone else, including salon staff.

All information collected will be stored in a locked cabinet or on password protected tablets and kept confidential. Your information will be available only to members of study staff. Any information that is used for research purposes will be kept confidential and will not have your name attached to it.

When we write up a report about our research, the information you share will not be associated with your name in any way.

It may be useful for someone from the study staff to contact you by phone. Is it okay for us to contact you by phone call or SMS at a number you will provide?

□ YES
□ NO

_____
Initials of client

____/_____/_____
Date of initials of client

I (print name) _____ have read and/or had this study explained to me, and understand what options are available to me.

I voluntarily choose to enroll and understand that I may decline or withdraw from any part of the study services and surveys, or the entire study, at any time. I have been provided contact details for members of the study. I can speak to them in the clinic or by phone if I have questions.

_____
Signature of client

_____/_____/_____
Date of signature of client

_____
Signature of research staff

_____
Printed name of research staff

_____/_____/_____
Date of signature of research staff