

PrEPVacc Registration Cohort Protocol

Eligibility Assessment CRF

Study ID: P 0 1

Visit date:

Visit number:

Check list of risks (To be considered at risk, the volunteer should answer Yes to option 'a' and at least one of the other listed criteria that is considered a risk factor for HIV infection at the site)	Yes	No	N/A	Code
a) Sexually active?	☐	☐		RISK1
b) Sex without a condom in the past 12 months?	☐	☐		RISK2
c) Sex without a condom with two or more partners in the past 3 months?	☐	☐		RISK3
d) Sex without a condom with a new partner in the past 3 months?	☐	☐		RISK4
e) Sex without a condom with an HIV-positive partner in the past 6 months?	☐	☐		RISK5
f) Sex without a condom with a partner who is a long-distance truck driver or miner in the past 6 months?	☐	☐		RISK6
g) If male, anal sex without a condom with other males in the past 3 months?	☐	☐	☐	RISK7
h) Sex in exchange for money/goods without a condom in the past month?	☐	☐		RISK8
i) Sex in exchange for money/goods with a condom in the past month?	☐	☐		RISK9
j) More than one sexual partner, without knowing the HIV status of at least one of them?	☐	☐		RISK10
k) More than one sexual partner at the same point in time in the past 12 months?	☐	☐		RISK11
l) Sex with partner of unknown HIV status in the past 12 months?	☐	☐		RISK12
m) Anonymous or casual sexual partners?	☐	☐		RISK13
n) Sexual partner is older by 10 years or more?	☐	☐		RISK14
o) Sexual partner(s) has/have other partners?	☐	☐		RISK15
p) Current abnormal genital discharge or ulcer or other genital symptoms?	☐	☐		RISK16
q) Abnormal genital discharge or genital ulcers or other genital symptoms in the past 3 months?	☐	☐		RISK17
r) Diagnosed with/treated for a sexually transmitted infection in the past 3 months?	☐	☐		RISK18
s) Sexual partner diagnosed with/treated for a sexually transmitted infection in the past 3 months?	☐	☐		RISK19
t) Used (including via injection) recreational drugs in the past 3 months?	☐	☐		RISK20
u) Sex after consuming alcohol or using recreational drugs in the past 12 months?	☐	☐		RISK21

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Inclusion criteria (All answers must be Yes except where N/A to be eligible)	Yes	No	N/A	Code
1. At least 18 years old and no more than 39 years of age on the day of enrolment?	☐	☐		AGE
2. Able and willing to provide informed consent?	☐	☐		CONS
3. Considered to be at risk of HIV infection in the opinion of the volunteer or investigator.	☐	☐		RISK
4. Willing to undergo HIV testing and counselling, and receive HIV test results?	☐	☐		HIVT
5. If female, willing to undergo regular pregnancy testing?	☐	☐	☐	PREG
6. Available for follow-up and willing to provide adequate locator information for tracking purposes, and willing to be contacted (through home visits or telephone, or via family or neighbours or other site specific procedures) by the study staff?	☐	☐		FUP
7. Willing to complete interviewer administered questionnaires on behavioural and other risk factors for HIV?	☐	☐		QUEST
Exclusion criteria (All answers must be 'No' to be eligible)	Yes	No	N/A	
8. Confirmed HIV-1/2 infection?	☐	☐		HIV
9. Current participation in another HIV prevention study that may reduce HIV incidence?	☐	☐		OSTUD
10. Condition(s) that, in the opinion of the investigator, might make it difficult for an individual to participate in the study or for the study to achieve its objectives?	☐	☐		INV
Individuals who test HIV-positive	Yes	No		
11. Has individual ever tested for HIV?	☐	☐		PHIVT
12. If yes to question 11, has individual ever tested HIV-negative?	☐	☐		
13. If yes to question 12, state date of the last HIV-negative test (please refer to date conventions in the Study Operations Manual)	 			DLHNT
Confirmation of eligibility and enrolment	Yes	No		
14. Individual meets all eligibility criteria for this study?	☐	☐		ELI
15. Individual has been enrolled?	☐	☐		ENR
16. Staff who assessed eligibility	 			SAELI
17. Staff who confirmed eligibility/ineligibility	 			SCELI

Not for data entry

Reviewed by:

Initials

Date

1st data entry performed by:

Initials

Date

2nd data entry performed by:

Initials

Date