

WOMEN'S INTERAGENCY HIV STUDY
MALT STUDY
FORM MG03: SCREENING VISIT

SECTION A: GENERAL INFORMATION

- A1. PARTICIPANT ID: ENTER NUMBER HERE ONLY IF ID LABEL IS NOT AVAILABLE |_|_|-|_|_|_|-|_|_|_|_|_|_|-|_|_|
- A2. WIHS STUDY VISIT #: |_|_|_|
- A3. FORM VERSION: **1 0 / 0 1 / 0 9**
- A4. DATE OF INTERVIEW: |_|_|_| / |_|_|_| / |_|_|_|
M D Y
- A5. INTERVIEWER'S INITIALS: |_|_|_|_|
- A6. MALT STUDY ELIGIBILITY LIST DATE |_|_|_| / |_|_|_| / |_|_|_|
M D Y

SECTION B: TO BE COMPLETED BY SITE STUDY COORDINATOR

- B1. To which of the following WDMAC pre-eligibility groups has the participant been assigned?
- a. HIV Uninfected Group 1 **(GO TO i)**
 - i. ASK PARTICIPANT: Was the HIV antibody test at your last core visit negative?
 - YES 1 **(GO TO SECTION C)**
 - NO 2 **(Ineligible. GO TO SECTION D.)**
 - b. Natural Controller Group 2 **(GO TO ii)**
 - ii. ASK PARTICIPANT: Since your last core visit, have you started anti-HIV medications?
 - YES 1 **(Ineligible. GO TO SECTION D.)**
 - NO 2 **(GO TO SECTION C)**
 - c. Good CD4 responder to HAART Group 3 **(GO TO iii)**
 - iii. ASK PARTICIPANT: Since your core visit, have you continued your anti-HIV medications?
 - YES 1 **(GO TO SECTION C)**
 - NO 2 **(Ineligible. GO TO SECTION D.)**
 - d. Poor CD4 responder to HAART Group 4 **(GO TO iv)**
 - iv. ASK PARTICIPANT: Since your core visit, have you continued your anti-HIV medications?
 - YES 1 **(GO TO SECTION C)**
 - NO 2 **(Ineligible. GO TO SECTION D.)**
 - e. Off Treatment Progressor Group 5 **(GO TO v)**
 - v. ASK PARTICIPANT: Since your core visit, have you started antiretrovirals?
 - YES 1 **(Ineligible. GO TO SECTION D.)**
 - NO 2 **(GO TO SECTION C)**

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SECTION C: SCREENING CRITERIA

READ TO PARTICIPANT: I would like to ask you some more questions to see if you are eligible for this study. Please try to remember what we talked about during the consent process and feel free to ask me about anything you do not understand.

INTERVIEWER: CIRCLE ONE ANSWER FOR EACH QUESTION. IF A RESPONSE FALLS IN A SHADED AREA, PARTICIPANT IS INELIGIBLE. GO TO SECTION D.		Yes	No
C1.	Are you pregnant or planning a pregnancy?	1	2
C2.	Are you willing and able to do home urine testing, and to call study staff when testing shows you have had an LH surge, and to come in for your Biopsy Visit 7 to 9 days later?	1	2
C3.	Do you understand what is involved in the Bowel Prep and are you willing and able to perform it?	1	2
C4.	Are you willing to and able to stop using any vaginal products (for example, douches, spermicides, medications, gels, foams, lubes, etc.) for the 10 days before your Biopsy Visit?	1	2
C5.	Are you willing and able to refrain from vaginal intercourse for 72 hours before your Biopsy Visit, OR to use non-lubricated condoms that the study will give you?	1	2
C6.	Since your last core visit, have you used any immune modulating drugs or systemic corticosteroids in the last 12 months? (This includes drugs like Prednisone, Medrol, Plaquenil, Betamethasone, Interferon, Enbrel, etc.) INTERVIEWER: PLEASE REFER TO MALT STUDY QxQs.	1	2
C7.	Since your last core visit, have you used any hormonal contraceptives (for example, birth control pills, the patch or ring) or an IUD?	1	2
C8.	Since your last core visit, has any health care provider told you that you have inflammatory bowel disease (PROBE: Crohn's disease or ulcerative colitis?)	1	2

INTERVIEWER: CIRCLE ONE ANSWER FOR EACH QUESTION. IF A RESPONSE FALLS IN A SHADED AREA, PARTICIPANT SHOULD BE RESCREENED WHEN CONDITION RESOLVES, OR WHEN 14 DAYS HAS PASSED SINCE VACCINATION.		YES	NO
C9.	Do you currently have any cough, cold, flu-like illness, fever, or diarrhea?	1	2
C10.	Do you currently have any UTI (bladder infection), vaginitis, or genital herpes?	1	2
C11.	Are you HIV positive, AND have you received a vaccination in the last 14 days?	1	2

SECTION D: OUTCOME

D1. ELIGIBILITY (*CIRCLE APPROPRIATE RESPONSE*)

- Participant is ineligible..... 1
- Participant appears eligible, pending today's lab results..... 2
- Participant appears eligible, pending resolution of condition,
OR for positive participants, passage of 14 days since vaccination...3

Comments (For site use only, not entered into Apollo):
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