WOMEN'S INTERAGENCY HIV STUDY MALT STUDY

FORM MG03: SCREENING VISIT

SECTION A: GENERAL INFORMATION

A1.	WIHS or NON-WIHS PARTICIPANT ID: ENTEI IS NOT AVAILABLE	R NUMBER HERE ONLY IF LABEL
A2.	WIHS STUDY VISIT #:	
A3.	FORM VERSION:	8/24/10
A4.	DATE OF INTERVIEW:	_ / _ / _ M D Y
A5.	INTERVIEWER'S INITIALS:	
	SECTION B: TO BE COMPLETED BY SITE	E STUDY COORDINATOR
B1.	To which of the following pre-eligibility groups ha	as the participant been assigned?
	a. HIV Uninfected Group1	(GO TO i)
	i. ASK PARTICIPANT: Was the HIV ant negative? (Please note: we are not enrolling no	cibody test at your last core or provider visit on-WIHS negative participants.)
	YES	`
	b. Natural Controller Group2	(GO TO ii)
	ii. ASK PARTICIPANT: Have you ever take	n anti-HIV medications?
	YES	
	iii. ASK PARTICIPANT: Was it during pregna	ancy only?
	YES	
	c. Good CD4 Responder to HAART Group3	(GO TO iv)
	iv. ASK PARTICIPANT: Have you been on a	anti-HIV medications for at least 2.5 years?
	YES	· ·
	v. During that 2.5 years, what is the longest co without taking your HIV medications?	- · · · · · · · · · · · · · · · · · · ·
	If over 1 month (30 days)	
	d. Poor CD4 Responder 4	(GO TO vi)
	vi. ASK PARTICIPANT: Have you been on a	nti-HIV medications for at least 2.5 years?
	YES	(GO TO vii) (Ineligible. GO TO SECTION D.)
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	vii. During that 2.5 years, what is the longest continuous period of time you have gone without taking your HIV medications? days
	If over 1 month (30 days)
e.	(,
	vii. ASK PARTICIPANT: Have you taken antiretrovirals in the past year??
	YES

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	N/A
C1.	C1. Are you pregnant or planning a pregnancy?		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	3
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	3
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	3
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.)	1	2	
	INTERVIEWER: PLEASE REFER TO MALT STUDY QxQs.			
C7.	Since your last core visit, have you used any hormonal contraceptives (for example, birth control pills, the patch or ring) or hormone replacement therapy or an IUD?			
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		YES	NO
IN A SHADED AREA, PARTICIPANT SHOULD BE RESCREENED WHEN CONDITION			
RESOLVES, OR WHEN 14 DAYS HAS PASSED SINCE VACCINATION.			
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

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	SECTION D: OUTCOME		
D1.	ELIGIBILITY (CIRCLE APPROPRIATE RESPONSE)		
	Participant is ineligible1		
	Participant appears eligible, pending today's lab results		
	OR for positive participants, passage of 14 days since vaccination3		
	Participant appears eligible, pending approval of enrollment exception		
	by Dr. Greenblatt (Describe below)4		