

WOMEN'S INTERAGENCY HIV STUDY

SECTION 5: OVERVIEW OF THE BASELINE VISIT FOR ORIGINAL RECRUITS

This section provides an overview of the components of the baseline visit. Other sections will provide detailed information and protocols for conducting each of the components of the baseline visit.

A. COMPONENTS OF THE BASELINE VISIT

The baseline visit is the first full study visit after screening in which a woman participates for the WIHS. This visit consists of an interview, physical and gynecological exam, oral exam, tuberculin/anergy skin test, and laboratory specimen collection including blood, oral, gynecological, and two urine specimens.

1. INTERVIEW

- Form 1: Sociodemographics (F01)
- Form 2: Medical and Health History (F02)
- Form 3: Obstetric, Gynecological and Contraceptive History (F03)
- Form 4: Alcohol, Drug Use and Sexual Behavior (F04)
- Form 5: Health Care Utilization Questionnaire (F05)
- Mental Alternations Test (MENT)
- Form 6: Psychosocial Measures (F06)
- Form 27: Karnofsky Performance Scale (F27)

2. BASELINE MEDICAL EXAM

Urine Collections

Form 7: Physical Exam (F07)

- Height/Weight/Vital Signs
- Skin Exam
- Oral Exam
- Lymph Node Assessment
- Abdominal Exam
- Breast Exam

Form 8: Gynecological Exam (F08)

- External Exam
- Vaginal Exam
- Cervical Exam
- Cervical Vaginal Lavage
- Bimanual Exam
- Rectal Exam

Colposcopy, if indicated (L14)

Biopsy, if indicated (L15)

Dysplasia Treatment, if indicated (L16)

3. PPD/ANERGY SKIN TESTING

- Mantoux Skin Test Result Anergy Panel (L07)
- Mantoux Skin Test Result 5TU-PPD-Tuberculin (L08)

4. LABORATORY SPECIMEN COLLECTION

Please refer to the Schedule of Laboratory Evaluations (Section 10 of the Manual of Operations) for a complete list of lab specimens to be collected at the baseline visit. Individual specimens collected and plasma cell specimens frozen are recorded on the following forms:

- Blood Specimen Collection Form (F09)
- Plasma and Cell Separation and Freezing Form (F10)
- Specimens Collected During the Physical Exam (F11)

Following is a list of the form numbers for lab tests performed at the baseline visit.

<u>Form #:</u>	<u>Lab Test:</u>
L01	HIV Elisa and Western Blot Results
L02	Serum Antibody Tests: Hepatitis
L03	CBC and Automated Differential
L03a	Manual Differential
L04	Flow Cytometry
L05	Liver and Renal Function Test/ Partial Chemistries
L06	Serum Antibody Tests Syphilis Screening
L09	Chlamydia Gen-Probe
L10	Dipstick Urinalysis
L11	Urine Culture Result
L12	(Urine) Pregnancy Test
L13	Gonorrhea Gen Probe
L14	Colposcopy
L15	Biopsy
L16	Treatment
L17	HSV Culture
L18	Trichomonas (optional)
L19	CVL Processing
C30	Toxoplasma
C31	HTLV 1 and 2
C45	BV Gram Stain
C50	Chlamydia Confirmatory Test (Urine)
C51	Chlamydia Confirm (Swab)
C52	HPV by PCR
C53	HPV by Hybrid Capture
C54	Viral Load
C60	PAP Smear
C65	Syphilis DFA
C66	HSV Serology

Outcome Variables of Baseline Lab Tests

The following chart indicates which outcome variables will be examined and the lab tests that will be used to determine their status:

OUTCOME VARIABLE	FORM #	TEST	TYPE OF SPECIMEN
Anergy	L07	Mantoux Skin Test Result Anergy Panel	N/A
Bacterial Vaginosis	C45	Bacterial Vaginosis Gram Stain	Smear
	F08	KOH Prep	Slide
	F08	Amine Odor Test	Slide
Candida		Oral Culture	Swab
		Vaginal Culture	Swab
Cervical Abnormalities/ Cancer	C60	PAP Smear	Swab
	L14	Colposcopy	Procedure
	L15	Biopsy	Procedure
Chlamydia	L09	Chlamydia Screening Test	Swab
	C51	Chlamydia Confirmatory Test	Smear
	C50	Chlamydia Confirmatory Test	Urine
Gonorrhea	L13	Gonorrhea Gen Probe	Smear
Cell Counts	L03	CBC with Differential and Platelets	Blood
Hepatitis B + C	L02	Serum Antibody Tests Hepatitis	Blood
Herpes	L17	HSV Culture	Swab
	C66	HSV Serology	Blood
HIV Serostatus	L01	Elisa and Western Blot Results	Blood
HIV Typing	C31	HTLV 1 + 2, HIV - 2	Blood
Toxoplasmosis	C30	Toxoplasma Serology	Blood
HPV	C52	HPV by PCR	CVL Sample
	C53	HPV by Hybrid Capture	CVL Sample
Liver Function	L05	Partial Chemistries	Blood
Pregnancy	L12	(Urine) Pregnancy Test	Urine
Syphilis	L06	Serum Antibody Tests Syphilis Screening	Blood
	C65	Syphilis DFA (Done only if ulcers present)	Swab
TB Exposure	L08	Mantoux Skin Test Result 5TU-PPD-Tuberculin	N/A
Trichomonas	F08	Saline Mount	Slide
	L18	Trichomonas Culture (optional)	Swab
T-Cell Count	L04	Flow Cytometry	Blood
	L03	CBC Differential	Blood
Urinary Tract Infection	L10	Urinalysis	Urine
Renal Functions	L11	Urine Culture Result	Urine
	L05	Partial Chemistries	Blood

B. BASELINE VISIT SEQUENCE

The entire baseline visit is to be administered at a single visit. There are a few possible exceptions (See Section C for a description of the extenuating circumstances that allow for deviation from the protocol.) The WIHS Executive Committee decided upon the following sequence deliberately and it should therefore be followed for each participant. In the event that it is impossible to follow this sequence, there is an alternate visit sequence (Section C) which the Executive Committee approved for such circumstances. In addition, Section D outlines absolutely unacceptable variations to the sequence should there be a need to vary the components of the visit. However, sites should make every attempt to follow the order described below, keeping in mind that deviations from the protocol should be kept to the absolute minimum. All exceptions should be fully documented by writing a memo to the Data Manager and Project Director citing the participant's ID number and an explanation of what happened. This memo should be copied and added to the participant's study files.

1. INTERVIEW

The entire interview (Forms F01–F06, F27 & MENT, as listed in Section A) should be administered in that order, at one time, by a single interviewer, at the beginning of the visit before any of the examinations (physical or gynecological).

2. PHYSICAL EXAM

The physical exam should be done at the completion of the interview. It should include the gynecological exam and all parts should be done exactly in the order as they appear in the physical and gynecological exam forms (Forms F07 and F08). If the woman is menstruating, the gynecological exam can be postponed, but it must occur within the two-week completion window. If it is less than eight weeks since the termination of a pregnancy, the gynecological exam must be postponed and it should be scheduled to occur so that eight weeks have passed since the termination of the pregnancy. However, in this case, the blood draw should occur on the same day as the interview and the non-gynecological portion of the physical exam.

3. COLPOSCOPY

According to the colposcopy protocol (see Section 9 of the Manual of Operations), sites will perform colposcopies as clinically indicated after the gynecological exam has been completed. Ideally, the colposcopy should be performed on the same day as the physical exam. If this is not feasible, it is preferred that it be performed within 30 days of the initial study visit, although a maximum of 60 days is allowed.

4. PHLEBOTOMY, URINE COLLECTION, PPD/ANERGY

The following data must be collected during the baseline visit but flexibility is allowed as to when these occur in the baseline visit sequence:

- a. Phlebotomy: Blood tests may be performed at any time during the visit (i.e., before or after the interview or before physical exam). However, if the physical exam is postponed and not done the day the interview is administered (see Sections C and D) blood should be drawn on the same day as the physical exam.
- b. Urine Collection: Two urine specimens must be collected during the baseline visit. It is recommended that collection of both specimens occur prior to the gynecological exam.
- c. PPD/Anergy Procedures: PPD and Anergy panels must be read between 48 and 72 hours after placement. PPD and Anergy panels may be planted at the screening visit and read 48 to 72 hours later.

C. ALTERNATE BASELINE VISIT SEQUENCE

The entire interview (Forms F01-F06, F27, & MENT) must be completed on the same day it is started. The ideal sequence is: 1) administer interview, then 2) perform examinations (physical and gynecological). In the event that the ideal sequence is not possible, a break may occur after the completion of the Obstetrics and Gynecological History Form (Form F03). During this break, the physical exam may be performed. Following the physical exam, the remaining portions of the interview should be administered that same day.

D. BASELINE VISIT SEQUENCE MODIFICATION ALLOWANCE

After the study was fielded, the site Project Directors expressed a need to have more flexibility in the sequence of the visit when clinic or patient limitations make it impossible to complete the visit as listed above in C and D. When necessary, the WIHS Executive Committee was willing to grant more flexibility with the following stipulations:

a. Unacceptable

- Visit components that fall outside the two-week completion window
- Doing the Physical Exam before the Interview Forms F01–F03

b. Highly Undesirable

- To conduct the blood draw on a date separate from the date of the Physical Exam

c. Optimal

- To keep together the entire exam, blood draw, and interview (especially medication history)
- Keep physical and gynecological exams together. NOTE: If participant is menstruating at the time of her study visit, the gynecological exam may be postponed to another time within the two-week completion window. In such a case, the phlebotomy should be performed on the day of the physical exam.

If the participant delivered or terminated a pregnancy within eight weeks prior to the study visit, then the gynecological exam must be rescheduled to take place at least eight weeks after the delivery or termination date. **Post-partum or post-termination is the only circumstance which allows a gynecological exam to be scheduled outside the two-week completion window.**

When the visit needs to be split, it is strongly suggested that the interviewer indicate in the margin of the instrument how the visit sequence fell and why.

E. COMPLETION WINDOW

The entire study visit (interview, physical exam, and specimen collection) should all be done on the first day that the participant comes in for her baseline visit. The entire physical exam should be done at that time including the gynecological exam. However, if the participant is menstruating, the gynecological exam can occur on another day as long as it falls within the two-week completion window. If the participant is within eight weeks of delivery or termination, then the gynecological exam must take place at least eight weeks after the delivery or termination.

F. DUAL ENROLLMENT

Site staff have discovered that a few participants have dually enrolled at another WIHS site or in another study that causes them to be ineligible to participate in WIHS *after* the baseline visit has been conducted. If a participant is dually enrolled in any of the studies listed on the Screening Form, question B2, the

Screening Form and the database should reflect this information. Question B2a, b, c, or d should be re-coded as “1” for YES and the Screening Disposition at question D1 should be changed to INELIGIBLE - code 2. Any data associated with that ID number should then be removed from the database. Each Data Manager should contact WDMAC in order to change the Screening Form codes and delete any records associated with the ineligible ID number. (**NOTE:** If the IRB at your site dictates that all data collected be maintained in a database, special arrangements should be made with WDMAC to copy the data from the “live” database used for analysis to the “stagnant” database – instead of being deleted entirely.) If the site is going to remove a woman from the study because she is dually enrolled in another study, do not complete the Disenrollment Form (DENR).