WOMEN'S INTERAGENCY HIV STUDY

SECTION 6: OVERVIEW OF THE BASELINE VISIT FOR NEW RECRUITS

I. 2001/2002 RECRUITS

This section provides an overview of the components of the baseline visit for 2001/2002 new recruits. Before proceeding with the visit, the *Screening Form (SCR)* and the *Eligibility Form (EL)* must be completed (as well as *Retroactive Abstraction (RAB) Form*, if indicated), and the participant must be eligible and enrolled. Additionally, consent must be obtained prior to starting the baseline visit for new recruits.

NOTE: The baseline visit number for 2001/2002 new recruits will be Visit 15 or Visit 16, depending on the actual calendar date that the new recruit is seen for her baseline visit. Refer to **MOO, Section 7**, page 1, for a listing of visit numbers and their corresponding calendar dates.

A. DEFINITION OF BASELINE ENROLLMENT WINDOW

The first WIHS expansion started at the beginning of WIHS visit 15 (October 1, 2001). Recruitment was completed by the end of WIHS visit 16 (September 30, 2002).

B. COMPONENTS OF THE BASELINE VISIT

The WIHS baseline visit for 2001/02 recruits consists of an interview, physical and gynecological exam, oral exam, tuberculin skin test, and laboratory specimen collection including blood, oral, gynecological, and urine specimens.

1. INTERVIEW

The interview should be administered to all participants.

F20: *New Recruit Baseline History Form*

F21: *Sociodemographics*

F22: *Medical and Health History*

DRUG1: *Antiviral Medications* (if applicable)

DRUG2: *Non-antiviral Medications* (if applicable)

F23: *Obstetric, Gynecological and Contraceptive History*

HX: *Family and Personal Medical History*

F24: *Alcohol, Drug Use and Sexual Behavior*

F25: *Health Care Utilization Questionnaire*

F25a: *Additional Health Care Utilization questions*

F26: *Psychosocial Measures*

ATC: *Ascertainment Tracking Checklist* (if applicable)

ACSR ATC: *AIDS and Cancer Specimen Resource ATC* (if applicable)

2. BASELINE MEDICAL EXAM

Urine Collections

F07: *Physical Exam*

F7r: *Physical Exam Addendum for New Recruits*

- Height/Weight/Vital Signs
- Body Habitus (do not do if participant is pregnant)
- Skinfold Measurements (do not do if participant is pregnant)
- Bioelectric Impedance Analysis (do not do if participant is pregnant)
- Skin Exam
- Oral Exam
- Lymph Node Assessment
- Breast Exam

F08: *Gynecological Exam*

- External Exam
- Vaginal Exam
- Cervical Vaginal Lavage
- Cervical Exam
- Uterine exam
- Adnexal exam
- Rectal Exam

L14: *Colposcopy* (if indicated)

L15: *Biopsy* (if indicated)

L16: *Dysplasia Treatment* (if indicated)

3. PPD SKIN TESTING

L08: *Mantoux Skin Test Result 5TU-PPD-Tuberculin*

4. LABORATORY SPECIMEN COLLECTION

Please refer to the *Schedule of Laboratory Evaluations* (**MOO, Section 10**) for a complete list of lab specimens to be collected at the baseline visit for 2001/02 recruits. Individual specimens collected and plasma cell specimens frozen are recorded on the following forms:

F29a: *Antiviral Usage Assessment for Blood Draw*

F29r: *Blood Specimen Collection Form*

F10: *Plasma and Cell Separation and Freezing Form*

F31r: *Specimens Collected During the Physical Exam*

The phlebotomist should administer form *F29a (Antiviral Usage Assessment for Blood Draw)* prior to the blood draw. Information collected on the date and time the participant took her last dose of antiviral medication(s) will allow the WIHS to look at drug levels in blood and urine and

compare with standard pharmacokinetic data to assess absorption and/or adherence. In addition, the date and time the participant last ate will be collected to assess whether glucose, insulin and lipid levels should be measured.

For reporting results, following is a list of lab tests performed at the baseline visit for 2001/02 recruits, the form numbers that correspond to them, and the outcome variable that was determined through the test:

FORM #	OUTCOME VARIABLE	LAB TEST	TYPE OF SPECIMEN
F08		Amine Odor Test (KOH prep)	Slide
F08	**Trichomonas**	Saline Mount	Slide
F08	**Yeast**	Vaginal KOH prep (KOH Mount for Yeast)	Slide
L01	**HIV Serostatus**	HIV Elisa and Western Blot results	Blood
L02	**Hepatitis B + C**	Serum Antibody Tests: Hepatitis	Blood
L03 (a)	**Cell Counts**	CBC and Automated Differential (a: Manual)	Blood
L04	**T-Cell Count**	Flow Cytometry	Blood
L05	**Liver/Renal Functions**	Partial Chemistries	Blood
L06	**Syphillis**	Serum Antibody Tests: Syphilis Screening	Blood
L08	**TB Exposure**	PPD (Mantoux Skin Test Result 5TU-PPD Tuberculin)	N/A
L12	**Pregnancy**	Urine Pregnancy Test	Urine
L14 (if indicated)	**Cervical Abnormalities**	Colposcopy	Procedure
L15 (if indicated)	**Abnormalities / Cancer**	Biopsy	Procedure
L17	**Herpes**	HSV Culture	Swab
L18 (optional)	**Trichomonas**	Trichomonas Culture (optional)	Swab
L19 (optional)		CVL Processing (optional)	CVL
C31	**HIV Typing**	HTLV 1 + 2, HIV - 2	Blood
C45	**Bacterial Vaginosis**	BV Gram Stain	Slide
C50	**Chlamydia**	LCR for Chlamydia	Urine
C52	**HPV**	HPV by PCR	CVL
C53	**HPV**	HPV by Hybrid Capture	CVL
C54 (HIV+ only)	**Viral Load**	HIV RNA Quantification (HIV+ only)	Varies
C60	**Cervical Abnormalities**	PAP Smear	Swab
C65 (if indicated)	**Syphillis**	Syphilis DFA (done only if ulcers present)	Swab
	Candida	Oral Culture Vaginal Culture	Swab Swab
	Glucose (fructosamine)		Blood
	Gonorrhea	LCR for GC	Urine
	Hemoglobin A1c		Blood
	HHV-8	HHV-8	Blood
	Lipid and Insulin Panel		Blood

C. BASELINE VISIT SEQUENCE

Guidelines for the baseline visit sequence for 2001/02 recruits are identical to those listed for core follow-up visits, including recommendations for fasting (see **MOO, Section 7**), except in the case of the PPD procedures:

PPD Procedures: The PPD panel must be read between 48 and 72 hours after placement. The PPD panel may be planted at the screening visit and read 48 to 72 hours later.

D. COMPLETION WINDOW

The completion window for the baseline visit for 2001/02 recruits is identical to the completion window for core follow-up visits. Refer to the **MOO, Section 7** for the full protocol.

II. 2011/2012 RECRUITS

This section provides an overview of the components of the baseline/enrollment visit for 2011/2012 new recruits. (For instructions on completion of the screening visit, see **MOO, Section 4**.) Before proceeding with the visit, the *Screening Form (SCR)* and the *Eligibility Form (EL)* must be completed (as well as the *Retrospective Abstraction (RAB) Form*, if indicated), and the participant must be eligible and enrolled. Additionally, consent must be obtained prior to starting the baseline visit for new recruits.

NOTE: The baseline visit number for 2011/2012 new recruits will be Visit 33, 34, 35, 36, or 37, depending on the actual calendar date that the new recruit is seen for her baseline visit. Refer to **MOO, Section 7**, page 1, for a listing of visit numbers and their corresponding calendar dates.

A. DEFINITION OF BASELINE ENROLLMENT WINDOW

The WIHS expansion started midway through WIHS visit 33 (January 1, 2011). Recruitment is scheduled to be completed by midway through WIHS Visit 37 (December 31, 2012).

B. COMPONENTS OF THE BASELINE VISIT FOR 2011/2012 NEW RECRUITS

The WIHS baseline visit for 2011/12 recruits consists of an interview, physical and gynecological exam, oral exam, and laboratory specimen collection including blood, gynecological, and urine specimens. In addition, the *Consent Tracking Form* (CONS) should be completed for each new recruit at the time of enrollment.

1. INTERVIEW

The interview should be administered to all participants.

F20: *New Recruit Baseline History Form*

F21: *Sociodemographics*

F22HX: *Health History*

F22MED: *Medication Use History*

DSG: *Antiretroviral Dosage Form* (if applicable)

DRUG1: *Antiviral Medications* (if applicable)

DRUG2: *Non-antiviral Medications* (if applicable)

DRUG3: *Hepatitis Medications* (if applicable)

F23: *Obstetric, Gynecological and Contraceptive History*

HX: *Family and Personal Medical History*

MEN01: *Menopausal Symptom Questionnaire*

F24BEH: *Alcohol, Drug Use and Sexual Behavior*

F25: *Health Care Utilization Questionnaire*

F26r: *History of Abuse*

F26: *Psychosocial Measures*

RACE: *Ethnicity and Race Questionnaire*

ATC: *Ascertainment Tracking Checklist* (if applicable)

NOTE: The *NC02a (English Word List), NC02b (Spanish Word List), NC03 (Educational Experience),* and *NC04 (Pronunciation Word List)* forms will be administered at the participant's first follow-up visit. 2011/2012 recruits will **not** be administered the full WIHS Neurocognitive Battery.

2. BASELINE MEDICAL EXAM

Urine Collection

NP01: *Baseline Neuropathy Signs and Symptoms*

- Neuropathy Symptoms (questionnaire)
- Evaluation of perception of vibration
- Evaluation of deep tendon reflexes
- Evaluation of deep tendon reflexes using the Jendrassik maneuver (if necessary)

F07: *Physical Exam*

F7r: *Physical Exam Addendum for New Recruits*

- Height/Weight/Vital Signs
- Body Habitus Measures (do not do if participant is pregnant)
- Bioelectric Impedance Analysis (do not do if participant is pregnant)
- Skin Exam
- Oral Exam
- Breast Exam
- Abdominal Exam

F08a: *Potential CVL Contaminants*

F08: *Gynecological Exam*

- External Exam
- Vaginal Exam
- Cervical Vaginal Lavage
- Cervical Exam
- Uterine exam
- Adnexal exam

L14: *Colposcopy* (if indicated)

L15: *Biopsy* (if indicated)

L16: *Dysplasia Treatment* (if indicated)

3. LABORATORY SPECIMEN COLLECTION

Please refer to the *Schedule of Laboratory Evaluations* **(MOO, Section 10)** for a complete list of lab specimens to be collected at the baseline visit for 2011/12 recruits. Individual specimens collected and plasma cell specimens frozen are recorded on the following forms:

F29a: *Antiviral Usage Assessment for Blood Draw* (if appropriate)

F29r: *Blood Specimen Collection Form*

L20: *Repository Specimen Processing Form*

F31r: *Specimens Collected During the Physical Exam*

F31a: *Hair Color, Texture, and Treatment Questionnaire* (if appropriate)

The phlebotomist should administer form *F29a (Antiviral Usage Assessment for Blood Draw)* prior to the blood draw. Information collected on the date and time the participant took her last dose of antiviral medication(s) will allow the WIHS to look at drug levels in blood and urine and compare with standard pharmacokinetic data to assess absorption and/or adherence. Sites should ensure that any antiretroviral medications reported on forms *F29a*, *F22MED*, *DSG*, and *DRUG1* are consistent. Any inconsistencies should be resolved with the participant at the time of the visit.

For reporting results, following is a list of lab tests performed at the baseline visit for 2011/12 recruits, the form numbers that correspond to them, and the outcome variable that was determined through the test:

FORM #	OUTCOME VARIABLE	LAB TEST	TYPE OF SPECIMEN
F08		Amine Odor Test (KOH prep)	Slide
F08	**Trichomonas**	Saline Mount	Slide
F08	**Yeast**	Vaginal KOH prep (KOH Mount for Yeast)	Slide
L01	**HIV Serostatus**	HIV ELISA and Western Blot results	Blood
L02	**Hepatitis B + C****	Serum Antibody Tests: Hepatitis (HBcAb, HBsAg, HBsAb, HCAb)	Blood
L03 (a)	**Cell Counts**	CBC and Automated Differential (a: Manual)	Blood
L04	**T-Cell Count**	Flow Cytometry	Blood
L05	**Liver/Renal Functions**	Partial Chemistries (AST, ALT, Alk. Phos., albumin, BUN, creatinine, total bilirubin, GGT, total calcium, phosphate	Blood
L06	**Syphilis***	Serum Antibody Tests: Syphilis Screening	Blood
L09	**Chlamydia***	Chlamydia amplified nucleic acid test	Swab
L10	**Urinalysis***	Complete Urinalysis: micro and macro	Urine
L12	**Pregnancy**	Urine Pregnancy Test	Urine
L13	**Gonorrhea***	Gonorrhea amplified nucleic acid test	Swab
L14 (if indicated)	**Cervical Abnormalities**	Colposcopy	Procedure
L15 (if indicated)	**Abnormalities / Cancer**	Biopsy	Procedure
L18 (optional)	**Trichomonas**	Trichomonas Culture (optional)	Swab
C45	**Bacterial Vaginosis**	BV Gram Stain	Slide
C52	**HPV**	HPV by PCR	CVL
C53	**HPV**	HPV by Hybrid Capture	CVL
C54 (HIV+ only)	**Viral Load**	HIV RNA Quantification (HIV+ only)	Varies
C60	**Cervical Abnormalities**	PAP Smear	Swab
Electronic	**Glucose**		Blood
Electronic	**Hemoglobin A1c**		Blood
Electronic	**Metabolic Panel**	Fasting: insulin TC, HDL-C, LDL-C, trig Non: TC, HDL-C, direct LDL-C	Blood
Electronic	**Hepatitis C**	RIBA and HCV viral load if HCV Ab+; HCV genotype, if detectable	Blood
Electronic	**Sex Steroids**	AMH, DHEAS, testosterone, SHBG	Blood
Electronic	**CRP**	High sensitivity C-reactive protein (hsCRP)	Blood

* See table below for more detail.

** Sites should be ordering/transcribing the correct Hep B core TOTAL antibody tests and not the more common practice of running the Hep B IgM core antibody tests.

	Syphilis *(L06)*	Complete urinalysis, micro and macro *(L10)**	Gonorrhea and Chlamydia** (*L09* and *L13*)
BX	RPR screen & titer, FTA-ABS	Siemens Clinitek Atlas using Clinitek 10-test dipsticks (macro)	Becton Dickinson SDA-ProbeTec amplified nucleic acid method 17305X
BK	RPR screen & titer, TPPA	IRIS machine using Action Stick 9EB (Arkay)	Remel microtest M4 Rt transport (DNA by PCR) reported as -/+
DC	RPR screen & titer, FTA-ABS	Siemens Clinitek Atlas using Clinitek 10-test dipsticks (macro)	Becton Dickinson SDA-ProbeTec amplified nucleic acid method 17305X
LA	RPR screen & titer, FTA-ABS	Siemens Clinitek Atlas using Clinitek 10-test dipsticks (macro)	Becton Dickinson SDA-ProbeTec amplified nucleic acid method 17305X
SF	RPR screen & titer, TPPA	Siemens Clinitek Atlas using Clinitek 10-test dipsticks (macro)	Gen Probe by Pace; nucleic acid hybridization technology
CH	RPR screen & titer, FTA-ABS	Siemens Clinitek Atlas using Clinitek 10-test dipsticks (macro)	Becton Dickinson SDA-ProbeTec amplified nucleic acid method 17305X

* Renal investigators prefer to avoid Clinitek

** Should be an AMPLIFIED nucleic acid test

C. BASELINE VISIT SEQUENCE

Guidelines for the baseline visit sequence for 2011/12 recruits are identical to those listed for core follow-up visits, including recommendations for fasting (see **MOO, Section 7**). 2011/12 recruits will **not** be administered the NC Battery.

D. COMPLETION WINDOW

The completion window for the baseline visit for 2011/12 recruits is identical to the completion window for core follow-up visits. Refer to the **MOO, Section 7** for the full protocol.

E. POST-VISIT CONTACT

Sites will contact each enrolled participant by telephone approximately one month subsequent to the baseline visit. This phone call can be used to convey laboratory results, establish the veracity of participant contact information, and debrief the participant regarding her baseline visit. It is hoped that these calls will allow site staff to establish a rapport with participants, thus encouraging participants to return for future follow-up visits.