

CCS/WIHS

Visit 50

Training

Document

❧ Table of Contents ❧

Section	Page
Visit Sequence for Visit 50	3
Follow-up Interview Form Sequence	4
Changes to Visit 50 Interview and Administrative Forms.....	5
Discontinued Forms	8
Examination, Specimen Collection, and Laboratory (form administration order).....	8
Specimen Collection Notes for Visit 50	8
Exam Performance Notes for Visit 50	9
Changes to Visit 50 Laboratory, Specimen Collection, and Exam Forms	9
Protocol Revisions.....	10

🌸 Visit Sequence for Visit 50 🌸

Standard Follow-up Sequence:

- 1) Phlebotomy (*HIV-positive and HIV-negative; if participant is fasting*)
- 2) Core interview
- 3) Site-specific substudy forms, if applicable
- 4) Phlebotomy (*HIV-positive and HIV-negative; if participant is not fasting*)
- 5) Exams, in any order:
 - a) Physical and Gynecological exams (*including gynecological specimen and urine collection*)
 - b) Arterial Brachial Index Measurement (*women \geq 40 years of age only; if not done before phlebotomy ensure there is at least an hour between phlebotomy and ABI, and that blood draw site has clotted*)
 - c) Fibroscan (*if eligible via protocols W15038/Tien or W15040/French*) (*NOTE: participant must be fasting for 3 hours prior to Fibroscan*)
 - d) Frailty Assessment (*administer if participant \geq 40 years old and if not administered at visit 49*)
 - e) Lung Function Test (PFT or DLCO) (*administer to all participants at core or separate visit if not done at visit 48 or 49*)

Preferred Follow-up Sequence with Neurocognitive Battery:

- 1) Phlebotomy (*HIV-positive and HIV-negative; if participant is fasting*)
- 2) Neurocognitive Battery
- 3) Phlebotomy (*HIV-positive and HIV-negative; if participant is not fasting*)
- 4) *Exams, in any order:
 - a) Physical and Gynecological exams (*including gynecological specimen and urine collection*)
 - b) Arterial Brachial Index Measurement (*women \geq 40 years of age only; if not done before phlebotomy ensure there is at least an hour between phlebotomy and ABI, and that blood draw site has clotted*)
 - c) Fibroscan (*if eligible via protocols W15038/Tien or W15040/French*) (*NOTE: participant must be fasting for 3 hours prior to Fibroscan*)
 - d) Frailty Assessment (*administer if participant \geq 40 years old and if not administered at visit 49*)
 - e) Lung Function Test (PFT or DLCO) (*administer to all participants at core or separate visit if not done at visit 48 or 49*)
- 5) *Core interview
- 6) Site-specific substudy forms, if applicable

* For follow-up sequence with NC Battery, either exams or core interview may be administered first.

NC NOTE: If participant finishes core interview and wants to complete NC Battery because core interview was shorter than anticipated, then NC Battery may be administered after the core interview. However, participant must be alert and willing to do so.

🌀 Follow-up Interview Form Sequence 🌀

- **Sociodemographics** (F21, 10/01/18)
- **Follow-up Health History** (F22HX, 04/01/19)
- **Hospitalization Form** (HOSP, 04/01/18; QxQs 04/01/18a)
- **Biopsy Report Form** (BX, English 04/01/18; Spanish & QxQs 04/01/18a)
- **Medication Use History** (F22MED, 04/02/17g; QxQs 04/02/17a)
- **Obstetric, Gynecological and Contraceptive History** (F23, English & QxQs 10/01/16b; Spanish 10/01/16c)
- **Alcohol, Drug Use and Sexual Behavior** (F24BEH, 04/01/19)
- **Health Care Utilization Questionnaire** (F25, 04/01/17a)
- **Psychosocial Measures** (F26, 10/02/13a; QxQs 10/02/13)
- **San Diego Claudication Questionnaire** (SDCQ, 04/01/14a; QxQs 04/01/14)
 - Administer to women ≥ 40 years of age, once every two years as part of ABI protocol
- **Physical Activity Questionnaire** (PAQ, 04/01/05a)
 - Administer to women ≥ 40 years of age, once every two years as part of ABI protocol
- **Women's Adherence and visit Engagement Study** (WAVE, 10/01/17)
 - Administer to all women; follow skip patterns on form
- Site-specific substudy data collection forms (if applicable)

🦋 Changes to Visit 50 Interview and Administrative Forms 🦋

Follow-up Health History Form (F22HX) – 04/01/19

- 1) Delete **Question C51k**: “Did participant attend visit 48?”
- 2) Delete **Question C52**: “Have you ever been diagnosed with any of the following pulmonary or lung diseases?”
 - a) Delete **Question C52a**: “Chronic obstructive pulmonary disease (COPD) or emphysema?”
 - b) Delete **Question C52b**: “Asthma?”
 - c) Delete **Question C52c**: “Pulmonary fibrosis?”
 - d) Delete **Question C52d**: “Pulmonary hypertension?”
 - e) Delete **Question C52e**: “Pulmonary embolism (PE), blood clot in lung?”
 - f) Delete **Question C52f**: “Deep vein thrombosis?”
 - g) Delete **Question C52g**: “Lung nodule or granuloma?”
 - h) Delete **Question C52h**: “Sleep apnea?”
 - i) Delete **Question C52i**: “Insomnia?”
 - j) Delete **Question C52j**: “Restless leg syndrome?”

Medication History Form (F22MED) – 04/02/17h

- 1) **Question D1a (F22MEDs9)**: Add hepatitis B medication “Vemlidy (tenofovir alafenamide),” drug code 305.

Alcohol, Drug Use, and Sexual Behavior (F24BEH) – 04/01/19

- 1) Revise **Question B5**: Replace question “Since your (MONTH) study visit have you vaped or used an electronic cigarette to smoke nicotine?” with “Since your last visit, have you used e-cigarettes (for example, JUUL) or vaped?”
- 2) Add **Question B5a**: If Question B5 is “yes,” “Are you using them now (as of one month ago)?”
- 3) Add **Question B5b**: If Question B5a is “yes,” “Since your last visit, how often have you used e-cigarettes or vaped?” Potential responses:
 - a) “Less than monthly”
 - b) “Monthly”
 - c) “Weekly”
 - d) “Daily”
- 4) Add **Question B5c**: If Question B5a is “yes,” “What is the reason(s) you use an e-cigarette or vape?” (select all that apply)
 - a) “To quit smoking”
 - b) “To cut down on smoking”
 - c) “To use when I cannot or am not allowed to smoke”

CCS/WIHS Visit 50 Training Document

- d) *"To avoid returning to smoking"*
 - e) *"Because I enjoy it"*
 - f) *"Curiosity/just wanted to try it"*
 - g) *"Some other reason"*
- 5) Add **Question C39**: *"In the last 6 months, have you overdosed by accident (i.e., where you had a negative reaction from using too much drugs, using a drug that was stronger than you thought, or had a bad trip)? This includes a situation where you passed out and couldn't wake up or your lips turned blue, or you were revived by someone else (i.e., they shook you awake, provided oxygen, or gave you naloxone)."*
- 6) Add **Question C39a**: *"How many times in the last 6 months?"*
- 7) Add **Question C40**: *"Have you been given Narcan/naloxone in the last 6 months?"*
- 8) Add **Question C40a**: *"Who administered it? (select all that apply)"*
- a) *"Someone known to me"*
 - b) *"Non-medical staff (front desk attendant, outreach worker, etc.)"*
 - c) *"Medical staff (insite staff, ambulance or hospital employee, street nurse)"*
 - d) *"Someone I didn't know (stranger, passer-by)"*
 - e) *"Self-administered"*
- 9) Add **Question C41**: *"The last time you overdosed, what drug did you intend to take?"*
- a) *"Heroin"*
 - b) *"Cocaine"*
 - c) *"Crystal Meth"*
 - d) *"Speedballs"*
 - e) *"Methadone"*
 - f) *"Suboxone"*
 - g) *"Morphine"*
 - h) *"Ts & Rs"*
 - i) *"Benzos"*
 - j) *"Dilaudid"*
 - k) *"Heroin & Crystal (goofball)"*
 - l) *"Sleeping pills"*
 - m) *"Crack cocaine"*
 - n) *"Alcohol"*
 - o) *"Ketamine (Special K)"*
 - p) *"Fentanyl powder/pills"*

- q) *“Other non-injection”*
- r) *“Other injection”*
- s) *“Don’t know / didn’t care”*

10) Add **Question C42**: *“Were you taking any other drugs?”*

11) Add **Question C42a**: *“What other drugs were you taking?”*

- a) *“Heroin”*
- b) *“Cocaine”*
- c) *“Crystal Meth”*
- d) *“Speedballs”*
- e) *“Methadone”*
- f) *“Suboxone”*
- g) *“Benzos”*
- h) *“Crack cocaine”*
- i) *“Alcohol”*
- j) *“Amitryptiline”*
- k) *“Other”*

Clinical Outcome Reporting Form (CORE) – 04/01/19

- 1) Add **Question D5a**: *“ICD code for admitting diagnosis:”*
 - a) *“Obtained via coding summary”*
 - b) *“Missing”*
 - c) *“Assigned by site (for sites participating in pilot)”*
- 2) Add **Question D6a**: *“ICD code for primary discharge diagnosis:”*
 - a) *“Obtained via coding summary”*
 - b) *“Missing”*
 - c) *“Assigned by site (for sites participating in pilot)”*
- 3) Add **Question D7b**: *“ICD codes for secondary diagnoses:”*
 - a) *“Obtained via coding summary”*
 - b) *“Missing”*
 - c) *“Assigned by site (for sites participating in pilot)”*

These questions are being added as part of a pilot study for UNC and Bronx sites. For other sites, if no ICD code is available in the medical records, enter **“-9”** for ICD code and circle **“2 (Missing)”** for **“ICD code...”** questions.

🌀 Discontinued Forms 🌀

Healthcare Trust (TRUST2)

Genetics Review Participation Survey (GENE)

🌀 Examinations, Specimen Collection and Laboratory 🌀

Follow-up Visit physical exam can be performed in any order, though Phlebotomy should be completed first. Components include:

- **Phlebotomy** (F29, 04/01/19) (F29a, 10/01/09n; QxQs 10/01/09)
- **Arterial Brachial Index Measurement (ABI, 04/01/15)**
 - For women ≥ 40 years of age only, once every two years
- **Physical Exam** (F07, 10/01/16)
- **Urine collection** (F31, 10/01/16d)
 - For pregnancy testing only, if applicable, and for repository
- **Gynecological Exam** (F08, 10/02/16)
- **Echocardiogram (ECHO)** (ECHOTW, 02/22/18) (ECHONYHA, 10/01/17a) (ECHOROSE, 10/01/17a) (if not done at visit 47, 48, or 49)
- **Lung Function Testing (PFT or DLCO)** (PFTSCR, 04/02/18) (PFTNOTI, 04/01/18) (PFTAER, 04/01/18)(MMRC, 04/01/18) (SGRQ, 04/01/18) (if DLCO, then PFT29, 04/01/18) (if DLCO, then PFTLAB, 04/01/18) (if not done at visit 48 or 49)
- **Specimen Collection and Processing** (F08, 10/02/16) (F31, 10/01/16d) (L20, 04/01/18)
- **Colposcopy** (L14, 10/01/16), if indicated
- **Biopsy** (L15, 10/01/07a; QxQs 10/01/07), if indicated
- **Treatment** (L16, 05/01/95; QxQs 09/15/97), if indicated

Specimen Collection Notes for Visit 50:

- 1) **Collect blood specimens from HIV-positive and HIV-negative women at visit 50.**
- 2) Collect specimen for TC, HDL-C, TRIG, LDL-C, insulin (**F29, Question C3**) and specimen for Hemoglobin A1c (HgA1c) (**F29, Question C22**) during visit 50 follow-up visits.
- 3) Check **Visit Control Sheet (VCS)** for indication that participant has completed Hepatitis C treatment at a prior visit. If indicated, then collect SST/red-top tube for *Serum HCV Med tx completed* (**F29, Question C5**).
- 4) Collect specimen for CBC/diff (**F29, Question C19**) from all participants during visit 50 follow-up visits.
- 5) Collect specimen for T-cell subsets (**F29, Question C20**) from HIV-positive participants only during visit 50 follow-up visits.

CCS/WIHS Visit 50 Training Document

- 6) **Do not** collect separate specimen for *glucose* from participants during visit 50 *follow-up* visits. Serum glucose will now be recorded on form L05 when measured as part of the standard chem panel.
- 7) Collect *urine for pregnancy testing (F31, Question A2) and reposting* from **all participants** during visit 50 *follow-up* visits. For visit 50 **follow-up visits**, the urine specimen should be processed and aliquoted as follows:
 - a) Pregnancy test, if applicable
 - b) Urine supernatant for repository: 1 vial x 1 ml; 1 vial x 1.5 ml
 - c) Urine pellet for repository: 1 vial
- 8) When calling to schedule or remind participants of their visits during visit 50, please remind them to *drink water in the morning before their visits* to improve hydration for the blood draw and urine collection.

9) **ALL** participants undergoing phlebotomy should be encouraged to attend **ALL** visits fasting, regardless of whether or not lipid/insulin/glucose testing is scheduled to be performed at that visit. This is because specimens may be withdrawn from the repository at a later date for lipid/insulin/glucose or other testing and not all tests can be performed on non-fasting specimens.

Exam Performance Notes for Visit 50:

- 1) **Bioelectric Impedance Analysis (BIA) and Circumference Measurements WILL be** performed at visit 50.
- 2) **Frailty Assessment** should be performed at visit 50 for all eligible women (≥ 40 years old) who did not complete it at visit 49.

🌀 Changes to Visit 50 Laboratory, Specimen Collection and Exam Forms 🌀

Blood Specimen Collection Form (F29) – 04/01/19

- 1) Delete **Question A0e**: “Participant in Musculoskeletal (MSK) Substudy?”
- 2) Delete **Question C7**: “Serum for MSK SUbstudy.”
- 3) Delete **Questions C16-C18**: “Cells for MSK Substudy.”
- 4) Delete **Question C23**: “Glucose.” Serum glucose will now be measured as part of the standard chem panel and results recorded on the L05 form.

Liver and Renal Function Tests, Partial Chemistries (L05) – 04/01/19

- 1) Add **Question A2k**: “Glucose (if available) (65-125).” Serum glucose as measured as part of the standard chem panel should have results recorded on the L05 form.

🌀 Protocol Revisions 🌀

Section 7: Follow-up Visits – 04/01/19

- 1) Update *list of follow-up forms* to be administered at visit 50.

Section 10: Laboratory Protocol – 04/01/19

- 1) Remove plasma glucose tube collection and processing information. Add note to Schedule of Lab Evaluations that serum glucose will now be measured/recorded as part of the standard chem panel.

Section 46: PFT Protocol – 04/01/19

- 1) Shorten and clarify protocol. No substantive changes to procedures.