

Visit 49
Training
Document

Visit 49 Training Document

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🌀 Visit Sequence for Visit 49 🌀

Standard Follow-up Sequence:

- 1) Phlebotomy (*HIV-positive only; if participant is fasting*)
- 2) Core interview
- 3) Site-specific substudy forms, if applicable
- 4) Phlebotomy (*HIV-positive only; 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 ≥ 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 ≥ 40 years old and if not administered at visit 48*)
 - e) Electrocardiogram (ECG/EKG) (*administer at core visit if not done at visit 47 or 48*)
 - f) Lung Function Test (PFT or DLCO) (*administer to all participants at core or separate visit if not done at visit 48*)

Preferred Follow-up Sequence with Neurocognitive Battery:

- 1) Phlebotomy (*HIV-positive only; if participant is fasting*)
- 2) Neurocognitive Battery
- 3) Phlebotomy (*HIV-positive only; 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 ≥ 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 ≥ 40 years old and if not administered at visit 48*)
 - e) Electrocardiogram (ECG/EKG) (*administer at core visit if not done at visit 47 or 48*)
 - f) Lung Function Test (PFT or DLCO) (*administer to all participants at core or separate visit if not done at visit 48*)
- 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** 🌀

(For ALL participants with at least one prior follow-up visit)

- **Sociodemographics** (F21, 10/01/18)
- **Follow-up Health History** (F22HX, 10/01/18)
- **Hospitalization Form** (HOSP, 04/01/18)
- **Biopsy Report Form** (BX, English & QxQs 04/01/18; Spanish 04/01/18a)
- **Medication Use History** (F22MED, 04/02/17f; 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, 04/02/18)
- **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
- **Healthcare Trust** (TRUST2, 10/01/18)
- **Women's Adherence and visit Engagement Study** (WAVE, 10/01/17)
 - Administer to all women; follow skip patterns on form
- **Genetics Research Participation Survey** (GENE, 10/01/18)
 - Administer to women at UAB/Mississippi and Atlanta sites only
- **Educational Experience Form** (NC03, 10/01/04a) (if not administered at a prior visit)
- Site-specific substudy data collection forms (if applicable)

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🌀 Changes to Visit 49 Interview and Administrative Forms 🌀

Sociodemographics (F21) – 10/01/18

- 1) Add **Question B3b**: “How long have you lived at this address?”
- 2) Add **Question B3c**: “How long have you lived in the same zip code that you currently live in?”
This question will be asked of women who report living less than 20 years at the same address.

Follow-up Health History Form (F22HX) – 10/01/18

- 3) **Questions C52a through C52j**: “Ever” questions regarding pulmonary disease will be retained for visit 49 to ensure women who missed visit 48 will be asked these questions.
- 4) Add **Question C51k**: A new question will be added to the form so that women who answered Questions C52a through C52j at visit 48 will skip them for visit 49.

Medication History (F22MED) – 04/02/17f

- 1) **Question B2b**: Add newly-approved ARV “Symtuza (darunavir 200 mg, cobicistat 150 mg, emtricitabine 200 mg, and tenofovir alafenamide 10 mg)” to list of combination medications. Drug code will be 322.
- 2) **Question B2b**: Add newly-approved ARV “Delstrigo (100 mg doravirine, 300 mg lamivudine, and 300 mg TDF)” to list of combination medications. Drug code will be 323.
- 3) **Question B2b**: Add newly-approved ARV “Pifeltro (100 mg doravirine)” to list of combination medications. Drug code will be 313.
- 4) **Question D1a**: Add new Hepatitis C medication “Mavyret” to list of HCV medications. Drug code will be 725.

OB/GYN and Contraceptive Use (F23) – English form and QxQs 10/01/16b; Spanish form 10/01/16c

- 1) **Question B6**: Add note to form and QxQs, “If VCS indicates participant has previously reported having a hysterectomy, please probe to confirm correct hysterectomy status.”

Health Care Utilization (F25) – 04/01/17a

- 1) **Questions D1 through D8**: Add “neither agree nor disagree” as an option listed in Introduction to Participant.
- 2) **Questions E1 through E3**: Add new response card for three response options.

Carotid Ultrasound Tracking Form (CV01) – 10/01/04g

- 1) **Question A4**: Change “videotape” to “videotape or CD/DVD.”
- 2) **Question A5**: Update to add response options for new site equipment in Chicago.

🌀 New Forms 🌀

Healthcare Trust (TRUST2) – 10/01/18

- 1) New form to be administered to **all participants at all sites** for visit 49 only.

Genetics Review Participation Survey (GENE) – 10/01/18

- 1) New form to be administered to **all participants at UAB/Mississippi and Atlanta sites** for visit 49 only.

🌀 Discontinued Forms 🌀

Stigma and Discrimination Questionnaire (DISC)

Pittsburgh Sleep Quality Index (PSQI)

Personal Progress Scale Revised (PPSR)

Stanford Presenteeism Scale Revised (SPSR)

🌀 Neurocognitive Battery Forms 🌀

Form administration order for the NC Battery is as follows:

- **Neurocognitive Study Introduction** (MOO, Appendix B, 04/01/17)
- **Lawton Instrumental Activities of Daily Living**
 - **Long Form** (IADL-LF, 04/02/15a, QxQs 04/02/15) (if not previously administered)
 - **Short Form** (IADL-SF, 04/02/15a, QxQs 04/02/15) (if IADL-LF has already been administered)
- **Hopkins Verbal Learning Test – Revised Form 6, Section B** (NC06, 04/01/17) Immediate Recall Trials 1 through 3
- **Stroop** (NC07, 04/01/15a; QxQs 04/01/15)
- **Trail Making Test** (NC01a, Sections B1 and B2, 04/01/15b; QxQs 04/01/15a)
- **Symbol Digit Modalities Task** (NC01a, Section C, 04/01/15b; QxQs 04/01/15a)
- **HVLT-R Form 6, Section C** (NC06, 04/01/17), Delayed Recall and Recognition Trials
- **Verbal Fluency** (NC08, 10/01/09e; QxQs 10/01/09c)
- **Letter Number Sequencing Task** (NC09, 10/01/09b; QxQs 10/01/09c)
- **Grooved Pegboard** (NC10, 04/01/09; QxQs 04/01/09c)
- **English Word List (WRAT-3)** (NC02a, 04/01/09b; QxQs 04/01/09d) (if not previously administered)
- **Spanish Word List (WAT)** (NC02b, 04/01/09a; QxQs 04/01/09) (if not previously administered)
- **Pronunciation Word List (WTAR)** (NC04, 04/01/09b; QxQs 04/01/09c) (if not previously administered)
- **Stress Assessment Questionnaires** (PTSD, 10/01/08e)
- **Neurocognitive Study Closing Statement** (MOO, Appendix C, 04/01/17)
- **Interviewer Feedback** (NC05, 10/01/11a) – completed by interviewer if **entire** NC Battery is not administered.

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NC Battery Notes:

- ❖ **Visit 49** encompasses the fifth wave of NC Battery testing for those women who completed their baseline NC Battery during **visit 33**. The target window for Wave 5 NC Batteries is two years after the Wave 4 NC Battery completion date, +/- three months. (Or, if Wave 4 was missed, then eight years after the Wave 1 NC Battery completion date.)
- ❖ If a woman did not complete the NC Battery during any of Waves 1, 2, 3, or 4, she should still be invited to participate during Wave 5. Those completing the NC Battery for the first time during Wave 5 should use current versions of the forms, not those used for prior waves.
- ❖ *NC02a* (WRAT-3), *NC02b* (WAT), *NC03* (Educational Experience), and *NC04* (WTAR) should be administered to all women who have not yet completed these forms (as indicated on the VCS). *NC03* should be administered as part of the core interview. *NC02a*, *NC02b*, and *NC04* should be administered as part of the NC Battery.
- ❖ If no NC visits are scheduled for a period of three months, interviewers should perform mock interviews with each other. Each interviewer should conduct one mock interview per month during an expected lull in NC Battery Wave 5 administrations.
- ❖ NC forms **may not** be administered via direct data entry (DDE).
- ❖ Please **DO** perform NC Battery if participant has experienced a prior stroke or transient ischemic attack (TIA).

How to determine WAVE 5 NC visits:

If WAVE 1 at visit	<u>OR</u> If WAVE 2 at visit	<u>OR</u> If WAVE 3 at visit	<u>OR</u> if Wave 4 at visit	Then Wave 5 at visit
30	34	38	42	46
31	35	39	43	47
32	36	40	44	48
33	37	41	45	49
Not completed	Not completed	Not completed	Not completed	1 st of visits 46-49 that participant attends

🌀 Changes to Visit 49 NC Battery Forms 🌀

NO CHANGES

🌀 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, 04/01/18) (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
- **Gynecological Exam** (F08, 10/02/16)
- **Electrocardiogram (ECG/EKG)** (ECGNOTI, 10/02/17) **(if not done at visit 47 or 48)**
- **Echocardiogram (ECHO)** (ECHOTW, 02/22/18) (ECHONYHA, 10/01/17a) (ECHOROSE, 10/01/17a) **(if not done at visit 47 or 48)**
 - To be administered at a visit separate from the core visit. ECHO does not need to be performed within a specific timeframe related to the core visit. It can be performed at any time.
- **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)**
- **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 49:

- 1) **Collect blood specimens from HIV-positive women only at visit 49. For HIV-negative participants, do an HIV test, but do not collect blood specimens for other testing or for the repository.**
- 2) 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**).
- 3) Collect specimen for *CBC/diff* (**F29, Question C19**) from **HIV-positive women only** during visit 49 follow-up visits.
- 4) Collect specimen for *T-cell subsets* (**F29, Question C20**) from **HIV-positive participants only** during visit 49 follow-up visits.

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- 5) Collect *urine for pregnancy testing (F31, Question A2)* from **all participants**, where applicable, during visit 49 *follow-up* visits. For visit 49 **follow-up visits**, the urine specimen should be processed and aliquoted as follows:
 - a) Pregnancy test, if applicable
- 5) When calling to schedule or remind participants of their visits during visit 49, please remind them to *drink water in the morning before their visits* to improve hydration for the blood draw and urine collection.

- 6) **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 49:

- 1) **Frailty Assessment** should be performed at visit 49 for all eligible women (≥ 40 years old) who did not complete it at visit 48.

🌀 Changes to Visit 49 Laboratory, Specimen Collection and Exam Forms 🌀

Drug Usage Assessment for Blood Draw (F29a) – 10/01/09m

- 1) **Question 1a:** Add newly-approved ARV “*Symtuza (darunavir 200 mg, cobicistat 150 mg, emtricitabine 200 mg, and tenofovir alafenamide 10 mg)*” to list of combination medications. Drug code will be 322.
- 2) **Question 1a:** Add newly-approved ARV “*Delstrigo (100 mg doravirine, 300 mg lamivudine, and 300 mg TDF)*” to list of combination medications. Drug code will be 323.
- 3) **Question 1a:** Add newly-approved ARV “*Pifeltro (100 mg doravirine)*” to list of combination medications. Drug code will be 313.

Specimens Collected During the Physical Exam (F31) – 10/01/16c

- 1) **Question A2:** Change footnote to add instructions for urine collection for visits 48 and 50.
- 2) **Question B1:** Change note to indicate that newly-approved ARV *Symtuza* (drug code 322) is a tenofovir-containing regimen, and participants taking it should thus have 100 strands of hair collected.
- 3) **Question B1:** Change note to indicate that newly-approved ARV *Delstrigo* (drug code 323) is a tenofovir-containing regimen, and participants taking it should thus have 100 strands of hair collected.

🌀 Protocol Revisions 🌀

Section 7: Follow-up Visits – 10/01/18

- 1) Update *list of follow-up forms* to be administered at visit 49.

Section 10: Laboratory Protocol – 10/01/18

- 1) Include indication that L20 form should be completed when processing EDTA plasma for central repository (p 39).

Section 40: Geocoding – 10/01/18

- 1) Update section heading to include correct section number.

Section 41: LIVRA Protocol – 10/01/18

- 1) Add 18-month scan interval to assessment post-HCV treatment.
- 2) Add indication that women with baseline median LS values ≥ 9.5 kPa should have an annual scan obtained.
- 3) Clarify that women of any age should have scans post-HCV treatment.