

**Visit 105 Preview - October 2024**

**Welcome to Visit 105: What's to Come?**

October 1<sup>st</sup>, 2024 is the start of visit wave 105 (V105) and the visit cycle will end on September 30<sup>th</sup>, 2024. During V105, each participant should expect one Core visit and one short visit, approximately 6 months apart. New this year they are referring to visits between October 2024 and March 2025 as V1051, and visits between April 1, 2025, and September 30, 2025 as V1052

When possible, at Core visits, participants will be asked to come in person to collect blood and other specimens, complete physical and frailty assessments, and participate in other in-person procedures such as neuropsychological testing, and liver scans.

The Short visit will usually be conducted over the phone. The Short visit consists of an interview to collect updated health information. The Short visit may be done in-person if combined with other Flex assessments, such as a pulmonary function test (PFT), Echocardiogram, or the longer neuropsychological battery (BRACE+).

If participants are unable to keep their scheduled V105 Core or Short visit, it is extremely important to maintain contact with study staff throughout the wave and provide any contact information changes or health updates, if possible.

**Some changes to expect in V105**

- New DoxyPEP form that informs participants about use of Doxycycline, asks if they ever heard of this as a prophylactic treatment to prevent STIs, and assesses participants likelihood to take Doxycycline if recommended by a physician. This form is administered to cis-men and trans women at sites with men enrolled.
- New Visit Modality form for which is an administrative form for interviewers to document the modalities of how the visit was completed i.e. over the phone, by video, in-person, self-administered (ACASI and MATL) or a hybrid combination of the

various modalities. I'm not sure if this is pertinent to the newsletter as it's an administrative form.

- The Oral questionnaire asking participants about their oral health has been removed for V1051 as it will only be administered during even visits (V104, V106, etc.)
- The IPAQ questionnaire which assesses physical activity has been added to V1051. This form will be administered during odd numbered visits (V105, V107, etc.)
- The net change in interview length is approximately -2 minutes compared to V104
- The Pap Protocol: For women with a cervix. Pap protocol updated to be consistent with current guidelines, i.e., routinely conduct HPV co-testing along with Paps for women ≥30 years old. This is to be consistent and not inferior to current guidelines.
- Colposcopy follow up protocol has been added to ensure proper follow up and care for study participants.

Several continuing sub-studies will be performed during your V105 site visits. Exact sub study depends on your site. These include:

- Fibroskans (liver ultrasound) will be done for selected participants during their V105. This scan is to be repeated in the study every three years; many initial scans were obtained during V101-V103 and the sub-study enrollment end date is V106.
- Echocardiograms will continue for selected participants. These are painless heart exams using sound waves, like Ultrasounds.
- Stool Microbiome – analyzes the microorganisms in your stool to provide information about your gut

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health, this test can help identify imbalances in your gut microbiome, which may be linked to chronic conditions like inflammatory bowel disease, type 2 diabetes, cardiovascular disease, and colorectal cancer. It can also be used to determine your biological age.

- Brace & BRACe+ - This sub-study is part of the Brainbaseline Assessment of Cognition and Everyday Function battery. Both Brace and Brace+ assess cognitive functions using an I-Pad. Brace is quick, approximately 5 – 7 minutes and Brace+ may take 50 minutes.
- CAT-MH – This sub-study is administered on the iPad yearly at the Core visit with the BRACE of BRACE+. This questionnaire examines potential predictors of cognitive impairment. It takes roughly 5-10 minutes for participants to complete.
- CIDI – The purpose of this study is to determine the prevalence of mental disorders in a large group of HIV positive and matched HIV negative adults by administering the Composite International Diagnostic Interview (CIDI). This is a one-time assessment administered by trained research staff and takes approximately 90 minutes to complete.
- PFT – lung disease is a leading cause of morbidity and mortality in people living with HIV (PLWH). All MWCCS participants will complete at least one round of pulmonary function testing (PFT) as part of the study (i.e., pre- and post-bronchodilation spirometry as well as DLCO).
- Sleep – This sub-study continues through V105 at selected sites.
- Brain MRI – This sub-study continues at selected former WIHS sites and examines brain structure and function among HIV- seropositive and seronegative

women in the era of affective ART. It is only administered to women between 40-60 years of age who meet inclusion criteria.

- Stigma - Eligible sexual minority men at some sites may be contacted to participate in a sub-study concerning Stigma. Participants enrolled in this sub-study will complete a questionnaire at home or during their V105 Core visit

If you have any specific questions, contact your site coordinator.