

**ACTG A5322
(Participant Summary Sheet)**

Long-Term Follow-up of Older HIV-infected Adults in the ACTG: Addressing Issues of Aging, HIV Infection and Inflammation (HAILO)

Brief Description:

You are being asked to take part in this research study because you are infected with HIV, the virus that causes AIDS, and are currently followed in the ALLRT (A5001) study and are 40 years of age or older. This study, A5322 (also known as the HAILO study), is a long-term follow-up study of persons who are HIV infected and received their first antiretroviral medications in selected clinical trials conducted by the AIDS Clinical Trials Group (ACTG).

Purpose of this Study:

The purpose of this study is to look at the relationships between HIV infection, age and the immune system (how your body fights infection), and how these relate to the development of non-infectious illnesses such as kidney disease, cancer, and diabetes. This study will also see if treating people with HIV for non-infectious illnesses works as well as treating people without HIV for the same illness.

Requirements to Enter Study:

- Participants 40 years of age and older who are actively followed in the ALLRT (A5001), or recently completed follow-up in ALLRT, at the time of enrollment in A5322.
- ART naïve at the time of enrollment into their A5001 parent protocol.
- Eligible participants must agree to be followed long-term for clinical, virologic and immune responses, long-term treatment with potent ART, and aging.
- Planned enrollment to include approximately 22% female subjects (corresponding to the proportion of female subjects aged 40 years and older being followed in A5001).
- Ability to commit to adherence of long-term study requirements.

Treatment:

Treatment for HIV-infection must be arranged independently of the A5322 protocol. No treatment is provided through the A5322 protocol.

Special Testing:

-As in ALLRT, the Neuroscreen will be administered at entry into A5322 and every 48 weeks thereafter and includes both Neurocognitive testing (i.e., digit symbol, HVLT-revised) and Neuropathy testing (i.e., tendon reflexes and vibratory). -In addition there will be a frailty assessment which will be performed for **all** participants enrolled in A5322. This consists of a hand grip assessment followed by a 4-meter walk and will be recorded, along with several interviewer-administered questions on weight loss, physical activity and exhaustion.

-Participation in A5322's substudy (A5323s: Inflammation in the Functional Capacity: Trajectory of those Aging with HIV-Infection [FIT Substudy]) is Optional.

Duration of Study:

Subjects will be followed for 366 weeks (7 years).

For more information contact: Your study nurse at Vanderbilt Therapeutic Clinical Research Site. The main phone number is 615-936-2642.