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CLARIFICATION MEMO

DATE: January 17, 2024

TO: ACTG CTU Principal Investigators, CRS Leaders, and CTU/CRS Coordinators

FROM: A5403 Protocol Team

SUBJECT: Clarification Memo #1 for Protocol A5403, Version 2.0, 30Jun2023, Entitled "Giving Standardized Estradiol Therapy In Transgender Women to Research Interactions with HIV Therapy: the GET IT Rlght Study"

This clarification memo (CM) does not result in a change in the protocol informed consent document. The Division of AIDS does not require you to forward it to your institutional review board (IRB); however, you must follow your IRB's policies and procedures. If IRB review of clarification memos is required at your site, please submit this document for review.

Each site should file a copy of this CM with the protocol for reference.

The protocol clarification(s) contained in this memo should be implemented immediately.

The A5403 study team would like to correct a typo in the protocol inclusion criteria for Prolactin.

The following clarification (noted in bold or strikethrough) to Protocol A5403, Version 2.0, 30Jun2023, titled, "Giving Standardized Estradiol Therapy In Transgender Women to Research Interactions with HIV Therapy: the GET IT Rlght Study." These clarifications will be included in the next version of the A5403 protocol if it is amended at a future date.

1. In section 4.1.9, Inclusion Criteria, the last bullet point is being revised as shown below.

The following laboratory values obtained within 60 days prior to study entry by any US laboratory that has a CLIA certification or its equivalent, or at any network-approved non-US laboratory that operates in accordance with GCLP and participates in appropriate external quality assurance programs.

- Hemoglobin ≥ 9.0 g/dL
- Platelet count $\geq 75,000/\text{mm}^3$
- Estimated Glomerular Filtration Rate (eGFR) ≥ 30 mL/min/1.73m² if on or switching to TAF, ≥ 50 mL/min/1.73m² if on or switching to TDF without cobicistat, or ≥ 70 mL/min/1.73m² if on or switching to TDF in combination with cobicistat, calculated using

the CKD-Epi equation (a calculator is available at:
https://qxmd.com/calculate/calculator_251/egfr-using-ckd-epi).

- Aspartate aminotransferase (AST) (SGOT), alanine aminotransferase (ALT) (SGPT), and alkaline phosphatase are within normal range per local laboratory range
- Prolactin <25 ng/dmL