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CLARIFICATION MEMO

DATE: January 22, 2024

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

FROM: A5403 Protocol Team

SUBJECT: Clarification Memo #2 for Protocol A5403, Version 2.0, 30Jun2023, Entitled, "Giving Standardized Estradiol Therapy In Transgender Women to Research Interactions with HIV Therapy: the GET IT RIgHT 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 CMs 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 clarifications contained in this memo should be implemented immediately.

Sex/Gender for Laboratory Reference Ranges

For participants completing screening/entry evaluations, sites should use sex assigned at birth for reference laboratory ranges and CrCl estimation. For post-entry evaluations, sites should use female reference laboratory ranges and CrCl estimation for adverse event grading.

Transdermal Estrogen

For participants receiving transdermal estrogen prior to entry, the protocol team suggests that the sites follow the guidance associated with oral estrogen, and that participants should be off transdermal estrogen for at least 14 days prior to entry. There is no change to exclusion criterion 4.2.6 as the participant will not be receiving either oral or injectable estrogens.