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CLARIFICATION MEMO

DATE: March 21, 2024

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

FROM: A5403 Protocol Team

SUBJECT: Clarification Memo #3 for Protocol A5403, Version 2.0, 30Jun2023, titled “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 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 contained in this memo should be implemented immediately.

The A5403 study team would like to clarify the inclusion of potential participants who have a history of gall bladder disease but have had their gall bladder removed.

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

1. Exclusion Criterion Section 4.2.10 is being revised as shown below.

Known or a history of gall bladder disease.

NOTE: Persons who have a history of gall bladder disease and have had their gallbladder surgically removed are not excluded.