ACTG NETWORK COORDINATING CENTER
Social & Scientific Systems, Inc., a DLH Holdings Company
8757 Georgia Avenue, 12th Floor
Silver Spring, MD 20910-3714
Phone: 301-628-3000

CLARIFICATION MEMO #1

DATE: 22 September 2022

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

FROM: A5377 Protocol Team

SUBJECT: Clarification Memo #1 for Protocol A5377, Version 4.0

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 purposes of this CM are to update the study roster and to clarify that evaluable Arm B Cohort 8 participants are required to have an entry HIV-1 RNA level of at least 5000 copies/mL.

1. The following are updates to the study's title page and roster:
   A. Title page:
   Clinical Trial Specialist: ~~Evelyn Hogg, BA~~ **Chanelle Wimbish, BS, CCRP**

   B. Team Roster:
   Clinical Trials Specialist
   ~~Evelyn Hogg, BA~~
   ~~ACTG Network Coordinating Center~~
   ~~Social & Scientific Systems,~~ **Inc.,** ~~A DLH~~ **Holdings** ~~Company~~
   ~~8757 Georgia Avenue, 12th Floor~~
   ~~Silver Spring, MD 20910-3714~~
   ~~Phone: 301-628-3337~~
   ~~E-mail: evelyn.hogg@dlhcorp.com~~

   Chanelle Wimbish, BS, CCRP
   ACTG Network Coordinating Center
   Social & Scientific Systems, Inc., A DLH Holdings Company

8757 Georgia Avenue, 12th Floor
Silver Spring, MD 20910-3714
Phone: 301-628-3367
E-mail: chanelle.wimbish@dlhcorp.com

Laboratory Data Manager
~~Kacey Matecki, BS~~
~~Frontier Science and Technology Research Foundation~~
~~4033 Maple Road~~
~~Amherst, NY 14226~~
~~Phone: 716-834-0900~~
~~E-mail: Matecki@frontierscience.org~~

Kevin Knowles, PhD
Frontier Science and Technology Research Foundation
4033 Maple Road
Amherst, NY 14226
Phone: 716-834-0900
E-mail: knowles@frontierscience.org

2. The following clarification applies to the third sentence of the second paragraph in section 10.4, Sample Size and Accrual. In that sentence, a typographical error occurs; this sentence should read as shown below, for consistency with eligibility criteria 4.2.10 and 4.2.11.

   "Arm B participants who discontinue the study prior to Day 14 without sufficient virology data (as judged by the CST), or beginning with Version 4.0 of the protocol, who have an entry plasma HIV-1 RNA ~~<50~~ **<5000** copies/mL, will be replaced to ensure enough efficacy data are available for dose de-escalation evaluation."

These clarifications will be included in the next version of the A5377 protocol if it is amended at a future date.