Date: November 25, 2013

From: Robert Coombs, M.D., Ph.D., ACTG Network Laboratory Principal Investigator
ACTG Laboratory Science Group

To: ACTG Laboratories, CTU/CRS PIs

Re: Patient Identification Numbers (PID), Changes to ACTG Protocol Specimen Labels

The purpose of this memo is to outline the expectations the ACTG has with regard to use of PIDs and changes to ACTG protocol specimen labels.

Overview of Patient Identification Numbers

The Patient Identification Number (PID) is an alpha-numeric code that is used to uniquely identify a protocol participant. The PID is used for the duration of a protocol participant's affiliation with the ACTG, whether in a single protocol or over the course of multiple protocols. The PID allows for:

- Coordination of orders for testing, procedures or medications, and reporting study participant results.
- Monitoring study participant progress through the pre-analytical, analytical and post analytical stages of a protocol
- Maintenance of clear study participant records
- Storage and access to historical study participant information such as past medical history, diagnosis, participation in other protocols and all test results

Requirements from the ACTG

We have recently received reports of ACTG specimens from processing laboratories being relabeled with new PIDs after shipment to testing laboratories and/or to the Repository. These specimens have in the past been handled in a variety of ways according to the specific specimen management policy of the processing/testing laboratory or Repository:

- CLIA certified laboratories cannot make PID changes to specimens for any reason
- Research laboratories have made PID changes depending on their individual policies
- The ACTG Repository, BRI, cannot make PID changes; processing labs must create corrected labels and send them to BRI to correct mis-labeled specimens.

When PID change requests are received by the DMC, instructions are sent to the ACTG sites asking them to notify the processing laboratories and/or Repository in writing that they have received mislabeled specimens. Laboratories are instructed to reference the Guidelines for Data Entry Changes in the LDMS for addition details (Attachment 1).

Although DMC guidelines do allow for changes to PIDs and specimen labels, in accordance with 42 CFR 493.1232[i] the ACTG prohibits changes in the PID labeling for specimens that have already been collected and sent to either the BRI Repository or an outside testing lab. If mislabeling is identified then the sites are asked to immediately notify the data manager for the protocol at the DMC. The Performance Evaluation Committee (PEC) will monitor mislabeling errors and an incident follow-up report will be required.

[i] 42 CFR 493.1232 Standard**: Specimen identification and integrity**. The laboratory must establish and follow written policies and procedures that ensure positive identification and optimum integrity of a patient's specimen from the time of collection or receipt of the specimen through completion of testing and reporting of results. Available at: http://www.gpo.gov/fdsys/

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