DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

National Institutes of Health,
Bethesda, Maryland 20892

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Rockville, Maryland 20852

MEMORANDUM

September 22nd, 2026

To: NIAID/DAIDS HIV/AIDS Network Leadership and Operations Centers (ACTG and IMPAACT), Clinical Trial Unit (CTU) Principal Investigators, Clinical Research Site (CRS) Leaders, CTU Coordinators, CRS Coordinators

From: DAIDS Clinical Laboratory Oversight Team (DCLOT); Office of Clinical Site Oversight (OCSO)

Subject: FDA form 1572: Completion of section 4

Background:
FDA regulations require that sites "Identify clinical laboratories or testing facilities directly contributing to or supporting the clinical study (for example, diagnostic labs performing blood work, imaging centers, cardiology labs, etc.). This may include analytical labs that provide pharmacokinetic analysis, and laboratories supplying efficacy data for clinical investigations conducted under an Investigational New Drug Application (IND)."

According to U.S. regulations, DAIDS study monitors expect a site to have a certificate for each testing laboratory, captured on the 1572 form, attesting to the quality of such testing. Additionally, DAIDS, as Sponsor, must be able to confirm that laboratories listed on the 1572 forms submitted to DAIDS are indeed being used for a particular study.

Issues:
- The 1572 form is submitted at protocol registration, before a site has a final, Laboratory Center/DCLOT-approved Protocol Analyte List (PAL) and Laboratory Approval Checklist (LAC), which capture the study-supporting laboratories.
- FDA regulations are silent on whether the form needs to be revised when testing laboratories change. As a result, Section 4 of the FDA Form 1572 that DAIDS receives is sometimes incomplete or inaccurate.
- We have noted entities captured on the 1572 that do not map to the LAC, and vice versa, as well as laboratories on the LAC that do not appear on the 1572. The BRI repository should not be listed as it is not a testing laboratory.
- Monitors have sometimes requested CLIA certificates for laboratories that do not need them (e.g., endpoint labs) and have been advised that CLIA does not apply to sites outside the United States.

Guidance to Sites Going Forward:

- The laboratories listed on the LAC for a protocol and site should be listed on the 1572 form.
- As per the Instructions for Filling out Form FDA 1572, the full names and addresses must be provided for the listed testing laboratories. The LAC does not provide addresses for the laboratories. However, a site-specific record should have addresses for its clinical testing laboratories. Addresses for LAC-listed endpoint laboratories are available on the study-specific Laboratory Processing Chart (LPC).
- The LAC often uses abbreviated names for listed laboratories and includes Laboratory Data Management System (LDMS) and/or High-Identity (HID) numbers to identify them. For easy data mapping, sites should include the abbreviated names and identifying numbers for each testing laboratory on the 1572 form.
- Monitors will be expecting to see CLIA certificates for laboratories, as applicable, from US sites. For non-US sites and/or endpoint laboratories, the LAC, approved by the Network Laboratory Center and DCLOT, will serve as attestation of approval for Form 1572-listed laboratories to support a study.
- Importantly, sites should upload an updated 1572 form in the protocol registration module at DAIDS once they receive a signed study LAC.

If you have any questions, please do not hesitate to reach out to your DAIDS Program Officer (PO).

Many thanks for your continued participation in and support of DAIDS clinical trials.

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Cc: DAIDS Staff