DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health
National Institute of Allergy
and Infectious Diseases
Bethesda, Maryland 20892

MEMORANDUM

TO: Laboratories Performing Testing for DAIDS-Supported and/or Sponsored Clinical Trials and Partners

FROM: DAIDS Clinical Laboratory Oversight Team (DCLOT)

SUBJECT: Good Clinical Laboratory Practice (GCLP) Training Requirement for Study Nurses and other Non-Laboratory Personnel

DATE: November 10, 2021

Per the DAIDS GCLP Guidelines Version 4.1, effective 16-Aug-2021, documentation of GCLP training is required for all study nurses and other non-laboratory personnel performing specimen processing and/or rapid testing in the clinic or clinical laboratory. As an alternative to completing all of the required online GCLP training modules, DCLOT is proposing three options to address fulfilment of GCLP training requirements for these staff.

- Documentation of training on a set of abbreviated GCLP modules (approximately 1.5-2 hrs). These modules are being developed and will be available on the DAIDS Learning Portal by March 31st, 2022.
- Documentation of participation in a DAIDS-sponsored instructor-led (on-site or remote) focused-GCLP training session. Prior approval will be required from DCLOT to participate in the training.
- Documentation of review and training on the GCLP Guidelines Version 4.1.

Training records must be documented and maintained, and readily accessible upon request. At minimum, training records should include the title and date of the training, and name and signature of the trainee.

Please contact DCLOT if there are any questions (NIAIDDCLOT@niaid.nih.gov).

Dr. Patricia D'Souza Marie P. D Souza -S Digitally signed by Marie P. D Souza -S Date: 2021.11.10 09:42:28 -05'00'

DCLOT Co-Chair

Dr. Naana Cleland Naana G. Cleland -S Digitally signed by Naana G. Cleland -S Date: 2021.11.10 10:02:16 -05'00'

DCLOT Co-Chair