DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

National Institutes of Health
Bethesda, Maryland 20892

www.nih.gov

5601 Fishers Lane
Rockville, Maryland 20852

MEMORANDUM

Date: May 7, 2025

From: Mary Anne Luzar, Ph.D., M.S., Chief, Regulatory Affairs Branch, OPCRO, DAIDS, NIAID, NIH

To: Network Leadership and Operations Centers (ACTG, HVTN, HPTN, IMPAACT), Clinical Research Site (CRS) Leaders, CRS Coordinators, Network Laboratory Centers, Clinical Trial Unit (CTU) Principal Investigators, CTU Coordinators, Pharmacists of Records

Subject: Information about the management of clinical research records for Division of AIDS (DAIDS) -sponsored or -supported trials

The purpose of this memorandum is to communicate information on the management of clinical research records for DAIDS-sponsored or -supported trials, including details for trials that have met DAIDS' record retention requirements, and guidance on next steps when DAIDS' record retention requirements have not yet been met.

Each research institution and/or investigator funded by DAIDS is responsible for retaining clinical research records for trials conducted by that institution and/or investigator. For all trials sponsored by DAIDS, and trials which are supported by DAIDS when there is another sponsor, DAIDS will determine that applicable record retention requirements have been met. This means DAIDS will no longer need to have access to these records. Trials that have met DAIDS' record retention requirements are posted on the DAIDS Regulatory Support Center (RSC) Website, DAIDS Records Storage Assessment page: https://rsc.niaid.nih.gov/clinical-research-sites/daids-record-storage-assessment in the excel document titled "Trial List." This list is updated annually by the DAIDS Regulatory Affairs Branch (RAB).

It is important to note that the list referenced above is for trials that have clinical research records which will NOT be stored by DAIDS. Each institution needs to review their own storage policies and confer with the Institutional Review Board (IRB)/Ethics Committee (EC) as well as other institutional leaders to determine how to manage the records that are no longer needed by DAIDS.

For trials that are not listed on "Trial List," DAIDS' record retention requirements have not yet been met. Therefore, the research institution and/or investigator must maintain the clinical research records.

Even if DAIDS' requirements have been met for maintaining clinical research records of a trial, these records may still require storage at the site because of institutional policies, and/or local requirements, and/or national regulations related to storage of clinical research records. When more than one requirement applies, the most stringent retention requirement must be followed. DAIDS will not ask a site or investigator to destroy clinical research records and will not give any type of "permission" related to this activity. Once DAIDS has determined that DAIDS' requirements have been met, and the trial has been added to the "Trial List," each investigator must determine the next steps to be taken for the clinical research records of a trial based on the requirements noted earlier in this paragraph. We advise you to keep written records of the decision(s) made, who made them, and when they were made.

There may be certain situations which require DAIDS to take custody of clinical research records. Situations related to funding, closing of a site, and/or special regulatory circumstances are all possible reasons. These situations need to be reviewed by DAIDS on a case-by-case basis. After this review, DAIDS **may** decide to take custody of the clinical research records for a given trial. This decision will be issued to the site by DAIDS in writing. For those clinical research records we decide to take custody of, specific steps will be discussed with the site, and then taken, to transfer the records to DAIDS. Please refer to the DAIDS RSC Website, DAIDS Records Storage Assessment page: https://rsc.niaid.nih.gov/clinical-research-sites/daids-record-storage-assessment for further information.

Per the DAIDS Policy on Storage and Retention of Clinical Research Records (DAIDS-OPC-A15-POL00015), all DAIDS-sponsored or -supported clinical research falls under the clinical research record retention requirements of the following:

- U.S. Department of Health and Human Services (HHS) regulations for Protection of Human Research Subjects, as described in 45 CFR Part 46.115(b),
- The International Council for Harmonisation (ICH) E6 R3 Guideline for Good Clinical Practice,
- United States (U.S.) FDA regulations, as described in 21 CFR Parts 56.115(b), 312.57(c), and 312.62(c) (IND Trials),
- Pertinent regulations of national regulatory authorities for sites outside the U.S.,
- National, state, and local laws, and
- Institutional policies.

When more than one requirement applies, the most stringent retention requirement must be followed.

Any questions related to the topics covered in this memo should be sent to the DAIDS RSC Record Storage Team (RST) at rst@tech-res.com. The DAIDS RSC RST will consult with RAB about the issue in question before sending a reply.

Sincerely,

Mary A. Luzar -S

Digitally signed by Mary A. Luzar -S
Date: 2025.05.07 13:33:44 -04'00'

Mary Anne Luzar, Ph.D., M.S.
Chief
Regulatory Affairs Branch (RAB)
Office for Policy in Clinical Research Operations (OPCRO)
Division of Acquired Immunodeficiency Syndrome (DAIDS)
National Institute of Allergy and Infectious Diseases (NIAID)
National Institutes of Health (NIH)

CC: Bola Adedeji, R.Ph., M.S., Deputy Director, Office of Clinical Site Oversight (OCSO)
Yetemegnu Asfaw, M.S., Team Lead, Protocol Registration Team (PRT), RAB
Yancy Bodenstein, M.P.H., Public Health Analyst, DAIDS RSC Contracting Officer's Representative (COR), Chief, Clinical Research Resources Branch (CRRB), OPCRO
Cesar Augusto Boggiano, Ph.D., Director, Vaccine Research Program
Thomas Calder, Ph.D., Deputy Chief, Vaccine Clinical Research Branch
Naana Cleland, Ph.D., Health Specialist, Program Officer, DAIDS Clinical Laboratory Oversight Team (DCLOT) Co-Chair
Michelle Conan-Cibotti, Ph.D., RAC (US, EU), Senior Regulatory Scientist, RAB, OPCRO
Ruth Ebiasah, Pharm.D., Chief, Pharmaceutical Affairs Branch (PAB), OCSO
Sindhu Gopalan, M.B.B.S., Safety and Pharmacovigilance Team (SPT), OPCRO, Office of the Director (OD)
Jonathan Green, J.D., Team Leader, Clinical Trials Agreement Team (CTAT), OPCRO OD
Olukayode (Kayode) Koleoso, M.S., Health Specialist, Monitoring Operations Branch (MOB), OCSO
Peter Kim, M.D., Director, Therapeutics Research Program (TRP)
Melissa Kin, M.S., M.B.A., Associate Director, OPCRO, Acting Team Lead, TMF Team
Dhawala Kovuri, M.S., Senior Clinical Data Manager, Data Management Team (DMT), OPCRO OD
Susan Leister, Ph.D., M.B.A., Quality Assurance Officer
Daniella Livnat, B. Sc., Health Specialist, DCLOT, Laboratory and Clinical Sciences Branch, TRP
Mark Mishkin, M.P.H., Deputy Chief, RAB
Akinlolu Ojumu, M.D., M.P.H., AIDS Clinical Trails Group (ACTG) Program Officer, TRP
Manizhe Payton, M.P.H., Director, Office of Clinical Site Oversight, DAIDS
Dara Potter, Dr.P.H., Deputy Director, OPCRO OD
Craig Sturgeon, Ph.D., IND Manager, RAB
Carol Worrell, M.D., Director, OPCRO OD
Catherine Yen, M.D., M.P.H., FAAP, Branch Chief, ProPEP, OPCRO
Sheryl Zwerski, D.N.P., Director, Prevention Sciences
DAIDS Regulatory Support Center