To: DAIDS-sponsored and/or supported Clinical Research Sites and Operations Centers

From: Mary Anne Luzar, Chief, DAIDS OPCRO Regulatory Affairs Branch (RAB)

Date: September 20, 2024

RE: **Lists of trials for which Clinical Research Records will not be stored by DAIDS**

Per the Division of AIDS (DAIDS) Policy on Storage and Retention of Clinical Research Records (DAIDS-OPC-A15-POL00015), all DAIDS-supported clinical research, including DAIDS-sponsored 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 Guideline for Good Clinical Practice;
- U.S. FDA regulations, as described in 21 CFR Parts 56.115(b), 312.57(c), and 312.62(c) (IND Trials);
- Non-U.S. regulatory authority requirements (when applicable);
- National, state, and local laws; and,
- Institutional policies.

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

Each research institution and/or investigator is responsible for retaining clinical research records for a trial even if funding for the clinical research site (CRS) has been discontinued and/or the CRS has been closed. However, there may be certain situations where DAIDS may take custody of the clinical research records. Please refer to the DAIDS Regulatory Support Center (RSC) Website DAIDS Record Storage Assessment page for further information.

When DAIDS has determined that applicable record retention requirements have been met for a trial, DAIDS will no longer need access to the clinical research records, so the trial's clinical research records will not be eligible for transfer to the DAIDS RSC for storage. Please check the DAIDS RSC Website DAIDS Record Storage Assessment page for the "List of trials for which clinical research records will NOT be stored by DAIDS" via the DAIDS RSC to determine if a trial is eligible for storage.

The "List of trials for which clinical research records will NOT be stored by DAIDS" is updated annually by the DAIDS RSC and reviewed by DAIDS RAB to ensure accuracy and completeness with applicable regulations and guidelines.

Please note, clinical research records for which applicable DAIDS requirements have been met may still need to be maintained by the research institution and/or investigator depending on local and other requirements. Neither DAIDS nor the DAIDS RSC grants permission to destroy clinical research records. Even if a trial is included in the "List of trials for which clinical research records will NOT be stored by DAIDS", the institution and/or investigator must follow local, national regulations and institutional policies before proceeding with any record destruction. When more than one requirement applies, the most stringent retention requirement must be followed.

Any questions regarding this topic should be addressed to the DAIDS RSC Record Storage Team at rst@tech-res.com.