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

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

Catherine Yen, Chief, DAIDS OPCRO Protection of Participants, Evaluation & Policy Branch (ProPEP)

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RE: **Lists of IND and non-IND protocols for which Case Report Forms (CRFs) and Pharmacy 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 Studies);
- Non-U.S. regulatory authority requirements (when applicable);
- National, state, and local laws; and
- Institutional policies

When more than one requirement applies, sites must follow the most stringent retention requirement.

Each research institution and/or investigator is responsible for retaining study documents even if funding for the site has been discontinued and/or the site has been closed. However, there may be certain situations where DAIDS may take custody of the clinical research records. For such cases, only case report forms (CRFs) and pharmacy records may be shipped to the DAIDS Regulatory Support Center (RSC) for long-term storage on behalf of DAIDS. Additional information on this process is posted on the DAIDS RSC website on the *CRF Management* page under the *Clinical Research Sites* tab (https://rsc.niaid.nih.gov/clinical-research-sites/case-report-form-management).

Please note that not all protocols are eligible for transfer of CRFs and pharmacy records to the DAIDS RSC. When protocols have met U.S. record retention requirements, as determined by DAIDS, DAIDS no longer needs access to these records; hence, they are not eligible for shipment of CRFs and pharmacy records to the DAIDS RSC for storage. However, these records may still need to be maintained by the research institution and/or investigator depending on local requirements. Please check the DAIDS RSC website *CRF Management* page for the *Lists of IND and non-IND protocols having Case Report Forms (CRFs) and Pharmacy Records that will not be stored by DAIDS* to confirm which studies are not eligible for potential storage at the DAIDS RSC on behalf of DAIDS.

Similarly, for destruction of clinical research records for protocols that are included on these lists, research institutions and/or investigators must follow local regulations and institutional policies before proceeding with any record destruction.

Any questions regarding this topic should be addressed to the DAIDS RSC CRF Coordination Team at crf@tech-res.com.