INSTRUCTIONS FOR TRANSFER OF CLINICAL RESEARCH RECORDS TO THE DAIDS REGULATORY SUPPORT CENTER (DAIDS RSC)

Effective Date: September 20, 2024

1. PURPOSE

The purpose of this document is to provide guidance to current DAIDS-sponsored and/or supported clinical research sites (CRS), on the process for transferring clinical research records of trials that DAIDS has determined it will store. These instructions apply to Principal Investigators (PIs)/Investigators of Record, Site Coordinators and Pharmacists who are responsible for clinical research records at DAIDS-funded and/or supported CRSs.

2. BACKGROUND

U.S. Code of Federal Regulations, Title 45, Part 46.115 (b) requires that records be stored for a minimum of 3 years after completion of the research. However, this period of time may be longer if the trial involved an investigational product that was subject to U.S. Food and Drug Administration (FDA) regulations or if DAIDS as the regulatory sponsor has determined that a longer period of time is required.

The DAIDS Regulatory Support Center (RSC) website provides a "List of trials for which clinical research records will NOT be stored by DAIDS". DAIDS has determined that the clinical research records associated with these trials no longer require storage and may be destroyed in accordance with the CRS's local laws/regulations and institutional policies. Clinical research records from trials that are not included in this list, or from CRSs that are defunded or closing, must be stored in accordance with local institutional policy and may be transferred to the DAIDS RSC for storage, upon authorization by DAIDS, if requested by the Principal Investigator or their designee. To determine if your CRS's circumstances warrant a transfer of clinical research records to DAIDS via the DAIDS RSC for storage, please contact your CRS's DAIDS Office of Clinical Site Oversight (OCSO) Program Officer to discuss.

Note: Only specific types of clinical research records may be shipped to the DAIDS RSC for storage. Alternatively, a CRS may choose to continue to store clinical research records for these trials.

Note: For Pharmacy records, refer to the Pharmacy Guidelines and Instructions for DAIDS Clinical Trials Networks.

3. DEFINITIONS

Division of AIDS (DAIDS) sponsored: DAIDS is responsible for the management (including submission of the Investigational New Drug Application (IND) to FDA and initiation of the trial) and oversight for the trial. (DAIDS)

Division of AIDS (DAIDS) supported: DAIDS is providing financial support for the clinical trial. For more information see DAIDS Glossary. (DAIDS)

Investigator of Record (IoR): The individual at the CRS responsible for ensuring that a clinical trial is conducted in accordance with the protocol, applicable U.S. federal regulations, in-country regulations and any provisions imposed by the reviewing IRB/EC/other regulatory entity. This person is the signatory for the Form FDA 1572 for studies conducted under an IND or the DAIDS Investigator of Record Agreement for non-IND studies. (DAIDS)

Principal Investigator (PI): The qualified person designated by the applicant institution to direct the research. PIs oversee the scientific and technical aspects of a grant and the day-to-day management of the research. (DAIDS)

Pharmacist of Record: A licensed/registered pharmacist who performs the day-to- day pharmacy activities and study product management including but not limited to the procurement, storage, preparation, dispensing and final disposition of study products for DAIDS-funded and/or supported clinical research trial(s), who must be identified as the Pharmacist of Record. (DAIDS)

Site Coordinator: Person responsible for the day-to-day conduct of the research activities and oversight or performance of actual duties surrounding conduct of research activities at an individual clinical research site. (DAIDS)

For additional definitions see the Glossary of Division of AIDS Clinical Research Policy Terms.

4. RESPONSIBILITIES

The Principal Investigators/Investigators of Record, Site Coordinators and Pharmacists at the clinical research sites are the responsible parties for implementing these instructions at their CRS. The Principal Investigator/Investigator of Record is responsible for submitting the request for authorization to transfer clinical research records to the DAIDS RSC as described in Section 5.

The DAIDS RSC is responsible for receiving and repacking clinical research records from DAIDS-funded and/or supported clinical trials, for which DAIDS has an interest, for transfer to storage.

5. PROCEDURE

5.1. As stated in Section 2, the DAIDS RSC website provides a list of trials for which DAIDS has no regulatory obligation to retain clinical research records. DAIDS will not store clinical research records for trials on this list. For trials not included on this list, please contact your DAIDS OCSO PO to discuss if your CRS's circumstances warrant a transfer of clinical research records to DAIDS via the DAIDS RSC.

5.1.1. Before destroying any clinical research records check the list on the DAIDS RSC website

5.1.2. If the trial is on the list you must then check with your institution to determine whether your institution requires the records be kept for a longer period of time.

5.1.3. Clinical research records are to be destroyed in accordance with institutional policy.

5.2. Requests for Authorization to Ship Clinical Research Records

5.2.1. To request authorization to ship clinical research records to the DAIDS RSC please email the DAIDS RSC Record Storage Team using the contact information provided below:

DAIDS RSC Record Storage
Team Email: rst@tech-res.com with "cc" to: protocol@tech-res.com
Direct Line: 1-301-897-1706
Main Line: 1-301-564-6400
Fax: 1-301-897-7400

5.2.2. Do not ship any boxes without e-mail authorization from the DAIDS RSC.

5.3. Procedure for Shipping Clinical Research Records upon Authorization.
Once authorization is received the following actions can be taken:

5.3.1. Use strong boxes that will not break during shipment. Do not send any clinical research records other than those approved for storage.

5.3.2. As applicable, remove paper records from notebook bindings.

5.3.3. Separate clinical research records by type and remove any record types that are not approved for storage.

5.3.4. Place each clinical research record type into a manila folder or package them in such a way that the records do not tear or become dislodged during shipment and label each folder/packet with the clinical research record type, trial number, and date range of records.

5.3.5. Send all clinical research records in one shipment. Do not divide them among shipments. It is acceptable to send several trials in one shipment.

5.3.6. Include the following information in each box:

Name and number of the site.
Name of the current Principal Investigator (PI)/Investigator of Record for the trial.
Trial number(s) for clinical research records packed in the box
Complete list of clinical research record types by trial.
Date when each trial ended at the CRS.
Date range for the clinical research records for each trial (mm/yyyy to mm/yyyy).
Copy of the inventory master list. We would recommend using an Excel spreadsheet to prepare the master list. A sample spreadsheet titled, "Clinical Research Records Master Inventory List Template", can be found on the DAIDS RSC website.

5.3.7. Email the "Clinical Research Records Master Inventory List Template" (or Excel spreadsheet) containing a complete inventory of the clinical research records that are to be included in the shipment to the DAIDS RSC Record Storage Team at rst@tech-res.com and copy (cc) protocol@tech-res.com Retain a copy of the inventory for your files. The DAIDS RSC will respond with confirmation of receipt.

5.3.8. Upon receipt of the email confirmation from the DAIDS RSC for shipment, schedule the shipments so that the DAIDS RSC receives the shipment on a workday. The DAIDS RSC will provide the shipping address in the email confirmation for shipment. DO NOT SHIP ANY BOXES WITHOUT EMAIL APPROVAL.

5.3.9. Using the sides of the box, number each box according to the order of packing and indicate the total number of boxes in the shipment.

5.3.10. Label the boxes as follows:

Technical Resources International, Inc.
[Address to be provided at the time of the request for shipment]
Attn: DAIDS RSC Record Storage Team
Box Number
Total Number of Boxes in the Shipment

5.3.11. Notify the DAIDS RSC Record Storage Team of the expected arrival date of the shipment and the number of boxes.

5.3.12. The DAIDS RSC Record Storage Team will send a confirmation email to the CRS when the shipment arrives.

5.3.13. Contact the DAIDS RSC Record Storage Team at rst@tech-res.com if you have any questions concerning the packaging or shipment of these materials.

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6. REFERENCES

6.1. U.S. Code of Federal Regulations, Title 21, Parts 50, 56, and 312
6.2. U.S. Code of Federal Regulations, Title 45, Part 46.115
6.3. DAIDS Storage and Retention of Clinical Research Records Policy

7. INQUIRIES

Questions and comments regarding these instructions may be directed to the DAIDS RSC Record Storage Team: Email: rst@tech-res.com which will contact the appropriate DAIDS Office and/or Branch.