INSTRUCTIONS FOR TRANSFER OF CASE REPORT FORMS (CRF) AND PHARMACY RECORDS TO THE DAIDS REGULATORY SUPPORT CENTER

Effective Date: June 14, 2013

1.0 PURPOSE

The purpose of this document is to provide guidance to current DAIDS-sponsored and/or supported sites, on the process for transferring case report forms (CRFs) and pharmacy records of studies that DAIDS determines it will store long-term. It also provides guidance to defunded sites on what they need to do for documents that are required by the study and sponsor to be stored. These Instructions apply to Principal Investigators (PIs), Site Coordinators and Pharmacists who are responsible for clinical research records at DAIDS-funded and/or supported clinical research sites.

2.0 BACKGROUND

HHS 45 CFR §46 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 study involved an investigational product that was subject to U.S. Food and Drug Administration (FDA) regulations.

The DAIDS Regulatory Support Center (RSC) website provides "Lists of IND and non-IND Protocols Having CRF/Pharmacy Records that will not be stored by DAIDS". DAIDS has determined that the documents associated with these studies no longer require storage and may be destroyed **in accordance with investigator's institutional policies**. Documents from studies that are not included in these lists must be stored in accordance with local institutional policy or if defunded, may be transferred to the DAIDS RSC for long-term storage, **upon authorization by DAIDS**, if requested by the Principal Investigator or their designee. Note that only CRFs and pharmacy records (except for participant prescriptions) may be shipped to the DAIDS RSC for long-term storage. Alternatively, sites may choose to continue to store CRFs and pharmacy records for these studies.

Note: For Pharmacy records, refer to the Pharmacy Guidelines and Instructions for DAIDS Clinical Trials Networks of July 2008.

3.0 DEFINITIONS

Case Report Form (CRF): A printed, optical, or electronic document designed to record all of the protocol required information to be reported to the sponsor on each trial subject. (ICH E6 1.11)

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 study) 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)

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 DAIDS glossary.

4.0 RESPONSIBILITIES

The Principal Investigators, Site Coordinators and Pharmacists at the clinical research sites are the responsible parties for implementing these instructions at their sites. The Principal Investigator is responsible for submitting the request for authorization to ship CRFs and pharmacy records to the DAIDS RSC as described in section 6.0.

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

5.0 PROCEDURE

6.1 As stated in section 2.0, the DAIDS RSC website provides lists of protocols for which DAIDS has no regulatory obligation to retain CRFs and pharmacy records. DAIDS will not store records for protocols on these lists.

6.1.1 Before destroying any research records check the Lists on the DAIDS RSC website to determine if the protocol is listed. These Lists can be found on the DAIDS RSC website under the case report form management tab: https://rsc.niaid.nih.gov/clinical-research-sites/case-report-form-management

6.1.2 If the protocol 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.

6.1.3 Records are to be destroyed in accordance with institutional policy.

6.2 Requests for Authorization to ship CRFs and pharmacy records.

6.2.1 To request authorization to ship CRFs and pharmacy records to the DAIDS RSC please email the DAIDS RSC CRF Coordination Team using the contact information provided below:

DAIDS RSC CRF Coordination Team
Email: crf@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

6.2.2 Do not ship any boxes without e-mail authorization from DAIDS.

6.3 Procedure for Shipping CRFs and Pharmacy Records upon Authorization. Once authorization is received the following actions can be taken:

6.3.1 Use strong boxes that will not break during shipment. Do not send any documents other than the CRFs and the Pharmacy records.

6.3.2 Remove each participant's CRFs from the notebook binder.

6.3.3 Separate CRFs and pharmacy records (except participant prescriptions) from all other clinical trial associated documents. Remove any source documents from the CRFs and pharmacy records.

6.3.4 Place the CRFs in a manila folder or package them in such a way that the forms do not tear or become dislodged during shipment and label each folder/packet with the Patient Identification (PID) number.

6.3.5 Pack the pharmacy records (except participant prescriptions) in a manila folder or package them in such a way that the documents do

not tear or become dislodged during shipment and label each folder/packet with the PID number.

6.3.6 Organize the CRFs and the corresponding Pharmacy folder by PID number for each protocol.

6.3.7 Using strong boxes that will not break during shipment send all CRFs and pharmacy records for a protocol in one shipment. Do not divide them among shipments. It is acceptable to send several protocols in one shipment.

6.3.8 DO NOT SEND ANY DOCUMENTS OTHER THAN CRFs AND PHARMACY RECORDS.

6.3.9 Include the following information in each box:

1. Name and number of the site.
2. Name of the current Principal Investigator (PI).
3. Protocol number(s) for documents packed in the box
4. Complete list of PIDs in numerical order by protocol.
5. Date when each study ended at the site (i.e., date when the last CRF for the study was collected).
6. Date range for the documents for each protocol (mm/yyyy to mm/yyyy).
7. Copy of the inventory master list. We would recommend using an Excel spreadsheet to prepare the master list. A sample spreadsheet titled, "Inventory of CRF and Pharmacy Records Submitted for Storage", can be found on the DAIDS RSC website: https://rsc.niaid.nih.gov/clinical-research-sites/case-report-form-management

6.3.10 Email a request for authorization to ship records along with the "INVENTORY OF CRF AND PHARMACY RECORDS SUBMITTED FOR STORAGE" (Excel spreadsheet) containing a complete inventory of the documents that are to be included in the shipment to the DAIDS RSC CRF Coordination Team at crf@tech-res.com and copy (cc) protocol@tech-res.com Retain a copy of the inventory for your files.

6.3.11 Upon receipt of the email approval for shipment from the DAIDS RSC, 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 approval for shipment. DO NOT SHIP ANY BOXES WITHOUT EMAIL AUTHORIZATION

6.3.12 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.

6.3.13 Label the boxes as follows:

1. Technical Resources International, Inc.
2. [Address to be provided at the time of the request for shipment]
3. Attn: DAIDS RSC CRF Coordination Team
4. Box Number
5. Total Number of Boxes in the Shipment

6.3.14 Notify the DAIDS RSC CRF Coordination Team of the expected arrival date of the shipment and the number of boxes.

6.3.15 The DAIDS RSC CRF Coordination Team will send a confirmation email to the site when the shipment arrives.

6.3.16 Contact the DAIDS RSC CRF Coordination Team at crf@tech-res.com if you have any questions concerning the packaging or shipment of these materials.

6.0 REFERENCES

45 CFR Part 46 http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html

21 CFR Part 50
http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=50

21 CFR Part 56
http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=56

21 CFR Part 312
http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=312

DAIDS Policy on Record Retention
https://www.niaid.nih.gov/sites/default/files/Record_Retention_policyVersion2%20Final.pdf

7.0 INQUIRIES

Questions and comments regarding these Instructions may be directed to the DAIDS RSC CRF Coordination Team: Email: crf@tech-res.com which will contact the appropriate DAIDS Office and/or Branch.