

Memo

To: DAIDS Affiliated Operations Centers

From: Cheryl Hultman, Ph.D., RSC Contract Officer Technical Representative (COTR)

Date: 06/23/2010

Re: List of Protocols having CRF/Pharmacy Records that will not be stored by DAIDS for Sites that are Closing

The excel spreadsheet identified on the website as “List of Protocols having CRF/Pharmacy Records that will not be stored by DAIDS” includes those studies for which the Division of AIDS (DAIDS) has determined, from a regulatory standpoint, that the documents no longer require storage and may be destroyed if allowed by the institution. Studies which are not listed can be transferred through the DAIDS Regulatory Support Center (RSC) to the Washington National Records Center (WNRC) for long term storage. Only CRFs and pharmacy records (with the exception of participant prescriptions) may be shipped by phase-out sites to the DAIDS RSC as directed below for long term storage at the WNRC. These sites may alternatively choose to continue to store CRFs and pharmacy records for those studies.

Shipment of CRF and Pharmacy records for storage at the WNRC is an important step in the close out of sites. To facilitate this process, the Regulatory Support Center (RSC) has provided the following guidelines:

- Timing of the shipment of documents will be coordinated to minimize the space requirements at the RSC for receipt of materials. Prior notification and authorization to ship will be essential.
- The RSC currently maintains instructions for the packaging and inventory of the CRF and pharmacy documents on the RSC website ([http://RSC.tech-res.com/DAIDS Regulatory/Program Information](http://RSC.tech-res.com/DAIDS_Regulatory/Program_Information)). These instructions will emphasize:

- Only CRF and pharmacy records are to be shipped to the RSC for government long term storage at the WNRC. Other documents such as signed informed consent forms, protocols, protocol registration records, source documents, and regulatory files should not be submitted for storage at the WNRC.
- Clinical Research Sites that wish to transfer CRFs and pharmacy records to DAIDS RSC for long term storage at the WNRC should consult with their institution's legal counsel to determine whether de-identification of these records would be necessary under HIPAA prior to transferring the records to DAIDS RSC.
- All documents (either CRF or pharmacy records) for a single protocol should be in the same box (es). The CRF and pharmacy records should be separated.
- The site should notify the RSC CRF Coordination Team that the materials are ready for shipment via email. The inventory for the documents contained in the boxes being shipped should be included with the email. The RSC CRF Coordination Team will forward the inventory to the RSC COTR for approval. Once the shipment is approved, the RSC will provide the shipping address.
- The RSC CRF Coordination Team will confirm the receipt of the materials with the site and notify the RSC COTR regarding the number of boxes received.
- The RSC CRF Coordination Team will repackage the CRF and pharmacy records in appropriate WNRC box (es). These boxes will be shipped to the WNRC for long term storage and eventual destruction.

Please feel free to contact RSC CRF Coordination Team (crf@tech-res.com) if you have any questions concerning the packaging or shipment of these materials.