

Memorandum

To: DAIDS Affiliated Operations Centers

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

Date: 06/23/2010

Re: Instructions for Packaging and Shipping of CRF and Pharmacy Records for Storage

- Shipment of CRF and Pharmacy records for storage at the Washington National Records Center (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>). These instructions will emphasize:
 - a. Only CRF and pharmacy records are to be shipped to the RSC for government long term storage. Other documents such as signed informed consent forms, protocols, protocol registration records, source documents, and regulatory files should not be submitted for storage.
 - b. Clinical Research Sites that wish to transfer CRFs and pharmacy records to DAIDS RSC for long term storage 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.

- c. 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.
 - d. The site must provide the date each study ended at the site and the date range (mm/yyyy to mm/yyyy) for the documents sent for each protocol (i.e., 09/2002 to 10/2009 if the date of the first document collected for the protocol is 09/2002 and the date of the last document collected was 10/2009).
- 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 storage.

The packing and shipping instructions and the associated document (Excel spreadsheet “INVENTORY OF CRF AND PHARMACY RECORDS SUBMITTED FOR STORAGE”) are posted on the RSC website (<http://RSC.tech-res.com>).

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.