DMID-CROMS ERDG Instructions for Management of Records Transfer

1. PURPOSE

The purpose of this document is to provide instructions for the transfer of site essential regulatory documents and source data documents from an outside organization to the DMID-CROMS ERDG for long-term storage, as directed by the NIAID DMID.

2. RESPONSIBILITY

DMID Staff will notify DMID-CROMS ERDG that a records transfer for long-term storage is planned and provide the following information:

- DMID Protocol number,
- Expected documents – essential regulatory documents and/or source data documents
- Expected timeframe for completion of transfer,
- Expected format – electronic and/or hard copy, and
- Name and contact information for Outside organization/aka 'Sender' point of contact.

Sender will:

- Contact DMID to request prior approval when a transfer of source data documents to DMID-CROMS ERDG is planned
- Verify that all records and cover transmittals contained in the transfer have been checked for completeness and accuracy,
- Prepare and maintain the integrity of the records transfer by following these instructions or equivalent as agreed upon in advance with ERDG, and
- Communicate with the ERDG regarding transfer schedule and status, as necessary.

DMID-CROMS ERDG is responsible for receiving, logging, tracking and securing the records received from the Sender for long-term electronic and/or hard copy storage, as applicable.

3. SOURCE DATA DOCUMENTS TRANSFER PROCEDURE: (Skip this section if transferring only essential regulatory documents and proceed to Section 4, Electronic Record Transfer procedures)

a. Contact DMID to request prior approval to transfer source data documents to DMID-CROMS ERDG. In addition, the DMID-CROMS COR must approve details of the transfer before source documents are moved.

b. DMID will review the request and provide a decision directly to the organization.
c. Protected health information (PHI) must be redacted before any source data documents are shipped to the DMID-CROMS ERDG location. Refer to the DMID Source Documentation Standards guidelines for personal identifiers guidance.

4. ELECTRONIC RECORD TRANSFER PROCEDURE: (general instructions for Sender)

a. If not already in ACROBAT pdf format, convert to ACROBAT pdf format and name using the following file naming convention: Protocol Number_Essential_Regulatory_Documents_Date file is finalized (YYYY-Mon-DD).

b. Send files as email attachments to ERDG@dmidcroms.com with a cover email message that includes a list of all document types e.g., FDA Form 1572 and IRB Approval Letters, included in the attached files.

c. If total file size is too large for sender convert to a compressed WinZip file, then send as an email attachment to ERDG@dmidcroms.com with a cover email message that includes a list of all document types e.g., FDA Form 1572 and IRB Approval Letters, included in the attached WinZip file.

5. HARD COPY RECORD TRANSFER PROCEDURE: (general instructions for Sender)

a. Use only strong Letter or Legal size storage boxes that will not break during shipment, for example, Quill Standard Storage Box model 30815. The dimensions of the box should be 10”H x 12”W x 15”D.

b. Sort records by title of document. Refer to ICH E6 8.0, Essential Documents for the Conduct of a Clinical Trial for recommendations as to appropriate document titles.

c. At your discretion, place records in manila file folders organized by document type. Multiple document types may be combined in one folder. Label each folder/packet with the following information:

   i. Protocol Number, for example – XX-XXXX
   ii. Site Name
   iii. Principal Investigator Name
   iv. Document Type, for example – Curriculum Vitae
   v. Volume Number, for example – Vol. 1 (applicable if the same document types are in more than one folder)

d. When packaging the documents do so in a way that the paper forms do not tear or become dislodged during shipment.

e. Send all essential regulatory documents related to a given protocol in one shipment. Do not divide them among shipments. It is acceptable to send several protocols in one shipment.

f. Include a detailed inventory/transmittal form inside of each box with the following information:

   i. Header information

1. Box number
2. Protocol number(s) for documents packed in the box
3. Sender Organization Name
4. Principal Investigator Name

ii. Inventory list of contents

1. Protocol Number
2. Principal Investigator Name
3. Site Name
4. Document Type
5. Volume Numbers

g. Also, it is recommended to use the attached records shipment inventory transmittal forms to list contents of each box and of contents in all boxes shipped. If different forms or spreadsheets are used, ensure the same information is included to accurately and completely document shipment inventory.

h. Complete the inventory transmittal form using the same information referenced in 4.c. Examples have been added to the form for your reference. Please delete the sample entries before completing the inventory list.

i. Label the boxes for shipment as follows:

Technical Resources International, Inc.
6500 Rock Spring Drive, Suite 650
Bethesda, MD 20817
Attn: DMID-CROMS
Box Number (## of ##)
Total Number of Boxes in the Shipment (##)

j. Each box should be secured in such a way that the documents do not tear or become dislodged during shipment.

k. If a pallet is used to transport the boxes, it is recommended the boxes should be secured to the pallet using shrink wrap in order to ensure the boxes do not become dislodged during shipment.

l. At least 1 week in advance of proposed shipping dates(s), email a notification of the upcoming shipment and details to ERDG@dmidcroms.com.

Include the total number of boxes in the shipment, confirmation number, and the expected arrival date, along with the copy of the inventory master list "Essential Regulatory Documents Inventory List" (Excel spreadsheet) containing a complete inventory of the documents that are to be included in the shipment to CROMS.

m. It is highly recommended that you retain a copy of the inventory for your records. If requested, upon receipt of the shipment, ERDG will send a return email to confirm when the shipment arrived and has been inventoried at the box level only.

6. INQUIRIES

Questions and comments regarding these Instructions may be directed to DMID-CROMS ERDG. Email: ERDG@dmidcroms.com.