

WOMEN'S INTERAGENCY HIV STUDY
FOLLOW UP VISIT
QUESTION BY QUESTION SPECIFICATIONS

CRST FORM: CENTRAL REPOSITORY SHIPMENT TRACKING

Guidelines for completing CRST, "Central Repository Shipment Tracking." The handling and data entry of the CRST form is as follows:

- i. A WIHS lab sends a shipment to the central repository and completes sections A and B of the CRST.
- ii. Lab receives the central repository confirmation and completes section C. Completed sections A, B, and C are delivered to the site's data entry staff. Lab files CRST until the central repository has reported information necessary for section D.
- iii. Lab receives the central repository discrepancy report and completes section D. Lab delivers form to data entry staff.

The central repository's batch numbers are used to query the repository's database to determine if shipments have been committed. Upon repository commitment and data entry of section A-D, WDMAC enters section E. WIHS laboratories are responsible for keeping local records that track and document specimens and correspondence related to individual repository shipments. Refer to the WIHS Manual of Operations Sections 10 and 31 for additional information on specimen handling, labeling, and repository information.

SECTION A: GENERAL INFORMATION

Completed by the WIHS laboratory after shipment

- A1. Circle the number to indicate the site/laboratory that sent the shipment to the central repository.
- A2. Record the date of the shipment.
- A3. Record the shipment number for that day. If only one shipment was sent, enter "01." If more than one shipment was sent, complete a separate CRST form for each shipment and sequentially number the shipment number.
- A4. Record the complete shipment tracking number which is A1 – A2 – A3. This shipment tracking number should be reported to the repository in all correspondence.
- A5. Record the initials of the person completing the form. Proceed to Section B.
- A6. The form version is pre-printed. Be sure that you are using a current version and that all unused, outdated versions have been discarded.

SECTION B: INITIAL SHIPPING INFORMATION

Completed by the WIHS laboratory after shipment

- B1. Record the name of the WIHS laboratory staff person responsible for the shipment.
- B2. Record the number of boxes in the shipment.
- B3. Record the numeric range of boxes in the shipment. This information may be valuable to assist in communicating with the repository about specific boxes. It is not entered into Apollo.
- B4. Record the number of vials in the shipment.
- B5. Indicate the container type used for shipment.

- B6. Indicate the refrigerant type used for shipment.
 - B7. Indicate the type(s) of manifests sent (email, disc, or paper).
 - B8. Record the number of manifest files sent to the repository. (number of boxes=manifests)
- Note:** The CRST does not need to be entered into Apollo until the repository has confirmed receipt of the shipment.

SECTION C: REPOSITORY RECEIPT

Completed by the WIHS laboratory upon confirmation of shipment receipt

- C1. Record the date of shipment arrival at the repository.
 - a. Record the repository's incoming shipment batch identification number. This number begins with an "I."
- C2. Indicate if there was a problem with the shipment.
 - a-b. Indicate if the shipment took longer than one day to arrive at its destination or if little to no refrigerant remained upon arrival.
- C3. Indicate if there was a problem with the manifest.
 - a-c. Indicate if the repository reported that the shipment and the manifest did not agree, if the manifest was not sent, or if the manifest file was unreadable.
 - i. If the manifest file was unreadable or was not originally sent, record the date that a new manifest was sent.
- C4. Indicate if Section D can be completed. If yes, then proceed to Section D. If no, then submit the form to data entry. When the repository completes their inventory process and sends confirmation, complete Section D.

SECTION D: REPOSITORY INVENTORY

Completed by the WIHS laboratory upon repository inventory confirmation

- D1. Record the total number of inventory or discrepancy reports received from the repository for this unique shipment.
- D2. The repository previously reported "D" shipment batch numbers. This question was removed when the repository switched to "I" numbers.
- D3. Indicate whether or not the shipment had any discrepancies. If no, then circle 2 and go to D4.
 - a-f. Record information about the number and type of discrepancies reported by the repository.

Questions D3 and D3a-f are a sub-form of the CRST. This functionality was implemented because the LDMS may produce more than one manifest file per shipment and the repository may subsequently report discrepancies for each LDMS manifest file. If only one manifest file was sent to the repository, then only one sub-form needs to be completed. If more than one discrepancy report was received from the repository, please complete additional sub-forms as needed.

- D4. Record the first date that a site received the inventory/discrepancy report from the repository. This will indicate the date that the repository completed their inventory process and the start date of the timeframe when the site became responsible for corrective action.
- D5. Record the last date that a site sent corrective actions to the repository. This will indicate the date that the site completed their corrective action process and the start date of the timeframe when the

repository became responsible for committing the shipment. The site and the repository may correspond repeatedly about discrepancies and corrective actions. Only the first (D4) and last (D5) dates are necessary to report so that it is clear when the repository completed inventory and when the site completed corrective actions. If there were no discrepancies that required a response from the site, record the same date in D5 as in D4.

SECTION E: COMMITMENT

Completed by WDMAC upon shipment commitment

- E1. Record the total number of repository data entry batch numbers associated for this shipment.
- E2a. Record the associated incoming shipment batch number.
- E3. Record the date that this batch was committed according to the BSI.