Investigational Drug Pharmacy

Investigational Drug Record Retention Standard Operating Procedure

Purpose:

- To establish a process for the appropriate storage of essential Investigational Drug Pharmacy-related records following study closure at Froedtert and the Medical College of Wisconsin as required by federal and state regulations and study sponsors.

Federal Requirements:

- For Investigational New Drug (IND) research, the FDA requires that sponsors and investigators retain "records and reports required by this part for 2 years after a marketing application is approved for the drug; or if an application is not approved for drug, until 2 years after shipment and delivery of the drug for investigational use is discontinued and the FDA so notified."

State Requirements:

- According to Wisconsin Administrative Code Rules of the Pharmacy Examining Board, Chapter 450.11 section (2), Every prescription order shall be filed in a suitable book or file and preserved for at least 5 years. Prescription orders transmitted electronically may be filed and preserved in electronic format.

Industry Sponsor Requirements:

- For research sponsored by corporations or private foundations, the investigator should maintain the records for either the length of time required by the corporate sponsor, or the time required by FDA Regulations, or institutional policy, whichever is longer.

MCW Policy/IRB Requirements:

- Per Policy # RS.HS.020, All medical and other records of human research subjects who participate in a clinical research study conducted at the Medical College of Wisconsin, or at another site by a Medical College investigator, must be retained for a period of at least 10 years from the date of the last entry in the record of the last subject enrolled in the study. This retention period applies to all human research subjects regardless of their age.

Policy:

- All records must be stored in a manner that protects patient confidentiality and privacy in accordance with applicable law and institutional standards, for a period not less than 10 years.
- If records are required to be maintained for a longer period of time, by a research sponsor, or a federal agency (e.g. the FDA), they will be retained for the specified amount of time, then destroyed.

Procedure:

- Upon closure of the study, investigational drug pharmacy will scan all pertinent pharmacy records to be kept, i.e. accountability, shipping, and miscellaneous communication records, and save electronic records on the secure Froedtert network within the investigational pharmacy study folder. Access to the investigational pharmacy study folder is limited to investigational drug pharmacy staff.

- All paper pharmacy study records will be sealed in appropriate size containers with tamper evident tape and a sign posted on the container stating, "Do Not Open without IDS Pharmacy Present."
- Transfer of pharmacy study records will be documented and saved in the investigational pharmacy study folder at the time of transfer.
- The sealed box will be given to the appropriate study coordinator or study staff who managed the study. The study staff will then place the pharmacy records with the Trial Master File.
    - It is the responsibility of the study staff to ensure the paper records are stored securely and for the appropriate time period according to applicable laws or sponsor requirements.
    - It is the responsibility of the study staff to dispose of the records at the end of this time period in a secure manner, outlined by privacy laws (i.e. shredding).
    - At the time of notification to investigational pharmacy by study staff of paper record destruction, electronic records will be removed from the secure Froedtert network.

Sources:

Policy and Procedure was adapted from the following:

John's Hopkins University, Policy on Access and Retention of Research Data and Materials.

University of Michigan Hospitals and Health Centers, Research Pharmacy Policy on Essential Document Handling and Retention

Medical College of Wisconsin, Policy # RS.HS.020, RECORD RETENTION GUIDELINES FOR MEDICAL RECORDS OF HUMAN RESEARCH SUBJECTS

Authorization:

KMSMA
Title

10/30/14
Date