

SOP: 305
FILING AND FILE SYSTEM

1. POLICY

Following a set system of file organization is critical in the daily activities of the IRB office. An organized system facilitates adherence to the regulations of DHHS, FDA, and maintenance of the rights and welfare of the human participants of such research. Standardized procedures for maintaining appropriate documentation of IRB activities must be in place to facilitate the highest quality of review and oversight of research involving human participants.

Specific Policies

1.1 Filing

The IRB Staff maintains separate sections for active and inactive files in the file room. At the HSC campus, all files are filed in numeric order according to the assigned IRB Number. An out-card is used to designate when a file is removed from the file room or file cabinets. At the Norman campus, all files are filed in alphabetical order by the last name of the investigator.

Only authorized IRB Staff, HRPP Staff, IRB Chairs and Vice Chairs, and Institutional Officials have access to the IRB file room.

Archived files are stored in an appropriate facility.

1.2 File System

The IRB Staff uses sectioned file folders to separate the different types of IRB activities. Documents are filed in the appropriate sections of each file folder. The IRB maintains color-coded tags for each type of item.

2. SCOPE

These policies and procedures apply to the file system in the Office of Human Research Participant Protection for each campus.

3. RESPONSIBILITY

The IRB staff is responsible for creating and maintaining the file system in an organized and functional manner.

The IRB Administrator promptly transfers all documents or files ready for filing to the production room. IRB staff is responsible to file the documents or files.

4. APPLICABLE REGULATIONS AND GUIDELINES

45 CFR 46

21 CFR 56

OHRP Guidance Document, IRB Guidebook

5. REFERENCES TO OTHER APPLICABLE SOPS

None.

6. ATTACHMENTS

- 305-A File Folder Set-up
- 305-B Yellow Note Sheet
- 305-C New Study Approval Checklist

7. PROCESS OVERVIEW

The following overview describes the systematic approach used to create and maintain an organized filing system for documentation of IRB activities.

- 7.1 The study is received in the IRB office, is assigned a unique IRB number, and is assigned to an appropriate IRB. The IRB staff reviews the submission for completeness and creates the IRB file.
 - a. The IRB staff affixes the appropriate labels to the outside of the file.
 - b. The IRB staff inserts the yellow note sheet in the file. The staff writes the IRB number and the investigator's name on the yellow note sheet. The yellow note sheet is used by HRPP staff, IRB staff, IRB Chair, and Institutional Officials to record notes and comments about the study.
- 7.2 The Study file is composed of sections and each section is individually designated for a particular IRB activity.
 - a. The first section is reserved for the consent form(s) and HIPAA forms(s).
 - b. The second section is reserved for Protocol Modification Forms (Amendments).
 - c. The third section is reserved for official correspondence between the investigator, Sponsor, regulatory bodies, and/or the IRB Office. A letter from the FDA is an example of official correspondence.
 - d. The fourth section is reserved for the Continuing Reviews.
 - e. The fifth section is reserved for the yellow note sheet and any correspondence between the investigator and the IRB office.
 - f. The sixth section is reserved for the original submission, which may include the following:
 - 1) Application for New Research Project
 - 2) Protocol
 - 3) Advertisements
 - 4) Grant application

The New Study Approval Checklist is filed on top of all of these items. Once the approval letter is signed by the IRB Chair, copy of the approval letter is placed on top of the New Study Approval Checklist.

If applicable, the IRB staff creates a separate folder for the investigator Brochure and prints and affixes the file labels.

- 7.3 Each item in the file is tagged with a colored tag, when appropriate. For example:

- a. The protocol is tagged with a pink tag.
 - b. The original Application for New Research Project is tagged with a yellow tag.
 - c. The Continuing Review form is tagged with a yellow tag.
 - d. The Protocol Modification form is tagged with a blue tag.
 - e. The advertisements are tagged with a green tag.
 - f. All other items are tagged with a purple or green tag.
- 7.4 The IRB staff manages and maintains the individual files. Active and inactive study files shall be maintained in the appropriate section of the file room or file cabinet. An IRB staff member files on a daily basis, assuring that all documents are filed accurately and in a timely manner.
- 7.5 Whenever a file is removed from the file room or a file cabinet, an out-card is used to notate the number of the file removed, the name of the person who removed the file, and the date the file was removed.
- 7.6 The IRB files are available for use only by IRB Staff, HRPP Staff, IRB Chairs, Vice Chairs, and Institutional Officials. The IRB files are not accessible to other individuals without approval from the HRPP Director or Director of Compliance or their designee.

APPROVED BY: _____ **DATE:** 09/01/2009

NEXT ESTABLISHED REVIEW DATE: MAY 2012