



TITLE: IRB Record Retention
PURPOSE: Outline the process for retaining IRB Human Subjects Records
RESPONSIBILITIES: HSPP Staff
PROCEDURES:

IRB protocol files are to be retained as long as required by law, six (6) years after the study is completed, or six (6) years past the age of majority for studies involving children (whichever is longer) and then destroyed.

Researcher protocol files are to be retained as long as required by law, sponsor, or six (6) years after the study is completed, or six (6) years past the age of majority for studies involving children, whichever is longer, and then destroyed.

IRB records not in protocol files are retained indefinitely. These include:

- Minutes of IRB meetings
- Copies of all correspondence between the IRB and the investigators that is not protocol related
- IRB member rosters
- IRB member files, including a current resume for each IRB member
- Policies and processes, including:
 - Checklists
 - Forms
 - Template letters
 - Template minutes
 - Worksheets

Approved protocols in which there was no subject enrollment or no research conducted are to be retained the same as protocols where research was conducted.

Records for research conducted or funded by a Common Rule agency are to be accessible for inspection and copying by authorized representatives of that agency at reasonable times and in a reasonable manner.

Records for research subject to FDA regulations are to be accessible for inspection and copying by authorized representatives of FDA at reasonable times and in a reasonable manner.

Records for University of Arizona research must be stored in a secure location on the University of Arizona campus.

Copies of IRB records shall be provided to sponsors, federal agencies, or other appropriate entities when requested.



Send to UA Records Management and Archive all other protocol files when the protocol has been closed, withdrawn, or terminated for more than two months.

Destroy all protocol files as required by law and University policy. Destruction must be done in a confidential and permanent manner.

If the research is sponsored, the investigator should receive guidance from the sponsor prior to destroying records.

MATERIALS:

- None

REFERENCES:

- UA Records Management Archive Policy

REVIEW/REVISIONS: From 10/01/10 Version: Removed referenced to the VA; Renumbered to SOP-071.