TITLE:	**IRB Records**
PURPOSE:	Maintain IRB Records as required by law or policy
RESPONSIBILTIES:	HSPP Staff
PROCEDURES:	

IRB records include:
- Protocol files;
- Minutes of IRB meetings;
- Copies of all correspondence between the IRB and the investigators.
- IRB member rosters;
- RB member files, including a current resume for each IRB member; and
- Policies and processes, which include:
- Policies and processes include:
  - Checklists;
  - Databases;
  - Forms;
  - Templates;
  - Worksheets; and
  - Manuals.

Protocol Files:
- Are maintained in chronological order. Print a copy of the current protocol action, place it on top of all other materials to be filed, place it on top of previous materials.
- Include:
  - All submitted materials;
  - Protocols;
  - Scientific evaluations;
  - DHHS-approved sample consent document and protocol, if applicable;
  - Progress reports submitted by investigators;
  - Reports of injuries to subjects;
  - Records of continuing review activities;
  - Correspondence between the IRB and investigator related to the protocol;
  - Statements of significant new findings provided to subjects;
  - For exemption determinations the specific category of exemption;
  - For initial and continuing review of research by the expedited procedure:
    - The specific permissible category;
    - Description of action taken by the reviewer; and
    - Any findings required under the regulations.
  - Unless documented in the IRB minutes, determinations required by the regulations and protocol-specific findings supporting those determinations for:
    - Waiver or alteration of the consent process;

- Research involving pregnant women, fetuses, and neonates;
- Research involving prisoners;
- Research involving children; and/or
- Significant/non-significant device determinations.

o For each protocol's initial and continuing review, the frequency for the next continuing review.

o Correspondence between the IRB and other appropriate entities (such as the Veterans Administration (VA) Research and Development Committee).

o Problems submitted to the IRB, including unanticipated problems and protocol violations that require prompt reporting to the IRB.

Paper records:
- As of April 2013, all paper IRB records for active IRB projects were scanned into the HSPP electronic drive.
- Any paper record recalled from UA Records Management and Archive should be scanned and filed electronically before being returned.
- See Operations Manual for instructions on how to recall records from long-term storage.

Electronic Records:
- The electronic File Cabinet, located on the HSPP server, is the storage location for electronic records prior to December 16, 2013.
- After December 16, 2013, electronic protocol records are stored in UAR.
- Projects stored in UAR are to be archived as required by policy or law.
- Electronic IRB records that are not protocol files are stored on the HSPP server.

UA Records Management and Archive
If IRB records are kept with UA Records Management and Archive, Records Management and Archive will confirm destruction with the HSPP.

IRB Records Copy Availability
Copies of IRB records are available to sponsors, federal agencies, or other appropriate entities when requested and as outlined in the Operations Manual.

MATERIALS:
- Operations Manual

REFERENCES:
- UA Records Retention Policy

REVIEW/REVISIONS: From 10/01/2010 version: Updated according to paper and electronic records.

From 01/2014 version: Renumbered from P&P-070.