TITLE: IRB Records

PURPOSE: Maintain IRB Records as required by law or policy

RESPONSIBILITIES: 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.

- For each protocol’s initial and continuing review, the frequency for the next continuing review.
- Correspondence between the IRB and other appropriate entities (such as the Veterans Administration (VA) Research and Development Committee).
- 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.