University of Kentucky Office of Research Integrity and Institutional Review Board Standard Operating Procedures			
SOP #4-5 **Revision #5**	**TITLE: IRB/ORI Recordkeeping**		**Page 1 of 7**
Approved By: ORI Director	Signature	Date	Date First Effective: 07-12-05
Approved By: Nonmedical IRB Chair	Signature	Date	
Approved By: Medical IRB Chair	Signature	Date	Revision Date: 11-06-09

OBJECTIVE

To describe policies and procedures for the University of Kentucky (UK) Institutional Review Board (IRB)/Office of Research Integrity (ORI) record keeping

GENERAL DESCRIPTION

The ORI maintains IRB records in accord with applicable regulatory and institutional requirements.

RESPONSIBILITY

Execution of the SOP: ORI Staff, IRB Members, IRB Chair, ORI Research Compliance Officer (RCO), ORI Director, ORI Associate Director, Principal Investigator (PI)/Study Personnel

PROCEDURES

Storage of and Access to Records

1. ORI staff secure all active IRB records in the ORI and limit access to the IRB Chair, IRB members, ORI Director, ORI staff, Vice President for Research, authorized Veterans Affairs Medical Center (VAMC) representatives including the VA Research and Development Committee, and officials of federal and state regulatory agencies, the Office for Human Research Protections (OHRP), the Food and Drug Administration (FDA), and accrediting bodies. ORI staff may grant UK employees with administrative appointments access to the records on an as-needed basis for official UK business. Investigators or their authorized study personnel have reasonable access to files related to their research activities. ORI staff limit all other access to IRB records to those who have legitimate need for them, as determined by the ORI Director, RCO, and/or UK Legal Counsel when submitted through state open records statutes.

2. Administrative requests for access (e.g., Dean, Associate Dean, Department Chair, Corporate Compliance Officer) must be in writing and contain the following information:
    - The name of the person requesting the information;
    - The information requested;
    - The reason for the request;
    - Assurance of confidentiality.

3. When the ORI receives a request for IRB records, ORI staff check to see whether the request is from a PI or his/her authorized personnel. If the person requesting the record is listed as study personnel on the record requested, the ORI staff may copy pertinent parts of the record for that person to pick up or may fax, mail, or e-mail the record.

4. If the individual requests a substantial amount of material, ORI staff allow access to the record and a copy machine in the ORI for use by the person requesting the material.

5. If the person requesting the record is not listed as study personnel on the record requested, the ORI Director or the RCO makes a determination before releasing any records as to whether the request is from appropriate accreditation bodies, University officials, administrators, or regulatory agencies that should have access. Unless the individual states an acceptable reason for not informing the PI of the request for a record, ORI staff inform the PI that ORI has received a request for access to the applicable protocol.

6. The ORI maintains protocol records for a minimum of six years (as determined by the ORI Director or RCO) after a study is closed. This storage requirement applies even if the study has not enrolled a single subject. ORI staff destroy protocol records for studies that have been closed for six years unless the ORI Director or RCO waives the requirement for a specific study.

7. In addition to protocol files, the ORI maintains the following information and records. ORI staff organize and store records in files or binders or in electronic documents as appropriate which include, but are not limited to, the following categories:
    - Standard operating procedures;
    - IRB membership rosters;
    - Meeting minutes, which include documentation of convened IRB meetings;
    - Federalwide Assurance;
    - Memorandum of Understanding with the VAMC;
    - Computerized research protocol tracking system;
    - Other IRB correspondence;
    - Agendas for IRB meetings, which include all items to be reviewed and documentation of expedited and exempt reviews;
    - Alleged noncompliance case records;
    - Mandated reports;

- Resumes of currently active IRB members;
- Electronic records documenting completion of mandatory IRB training for study personnel, IRB members, and ORI staff.

8. ORI staff maintain records indefinitely that are not part of specific protocol files, such as meeting minutes, agendas, standard operating procedures, membership rosters, or periodically destroy them, as determined by the ORI Director or RCO.

9. The ORI also maintains communications to and from the IRB in the ORI office and keeps any relevant communication related to a specific research protocol in the protocol record.

Protocol Records

1. ORI staff maintain a separate record for every research application. The IRB protocol record includes, but is not limited to:

   <u>Full Review Protocol</u>
   - Initial IRB application;
   - Scientific evaluations of the proposed research if any;
   - For drugs, the investigator's brochure;
   - For devices, a report of prior investigations;
   - Data Safety and Monitoring Board reports, if any;
   - Results of Quality Improvement Program (QIP) reviews, if any;
   - Signed Signature Assurance Sheet;
   - IRB approved informed consent document and assent document, if applicable, with the approval date stamp;
   - Documentation of all IRB review and approval actions, modifications and all relevant correspondence to and from the investigator, including initial and, if applicable, IRB continuation review and modification, deviation, exception review;
   - Documentation of type of review;
   - Documentation of study close-out;
   - Specific findings (federal and institutional requirements);
   - Continuation/final review materials;
   - Significant new findings provided to human subjects, if any;
   - Reports of unanticipated problems/adverse events involving risks to subjects or others;
   - Reports of protocol violations;
   - All relevant correspondence to and from the investigator and any other correspondence related to the protocol either hard copy or e-mail;
   - IRB Authorization Agreements;
   - Any existing contractual agreements for off-site research;
   - Applications for funding/sponsorship, if applicable;

- Advertising or recruiting materials, if applicable;
- Protocol amendments or modifications;
- Instrument to be used for data collection, if applicable;
- Department of Health and Human Services/National Institutes of Health (NIH) approved sample informed consent form and protocol, if applicable;
- Copy of the package insert, drug monograph, or FDA approved label for drug or device studies using the FDA approved medication/device for approved medical indication;
- Sponsor's grant, contract, or device proposal if the protocol does not involve the administration of drugs, if applicable;
- Human subject protection training for principal investigators and study personnel;
- Health Insurance Portability and Accountability Act (HIPAA) forms, if applicable;
- Institutional Biosafety Committee correspondence and approval letters, if applicable;
- Results of Quality Improvement Review, if any;
- Other committee approvals/correspondence, if applicable;
- Mandated reports, if applicable;
- Criteria for IRB Approval: Reviewer Checklist;
- If applicable, IRB Continuation Review: Primary Reviewer Checklist(s);
- If applicable, reviewer signature page(s) (e.g., Prisoner Advocate Reviewer Signature Page, Consultant Signature Page).

Expedited Review Protocol

- All of the items listed above under full review protocol, as applicable to individual studies;
- Documentation and determinations required by the regulations and protocol-specific findings justifying those determinations, including that the study is eligible for expedited review and the applicable expedited review category;
- Description of action taken by the expedited reviewer.

Exempt Review Protocol

- Initial application for exempt review;
- Signed Signature Assurance Sheet;
- All items listed under full review protocol, if applicable to individual studies;
- Documentation and determinations required by the regulations and protocol specific findings justifying the determinations, including documentation of exempt eligibility and specifying appropriate exemption category;
- Description of action taken by exempt reviewer.

Veterans Affairs Medical Center Research Protocol

- All of the items listed in this SOP for full, expedited, or exempt protocols, if applicable to an individual study;

- All relevant protocol specific correspondence between the IRB and the VA Research and Development Committee or VA Research Compliance Officer;
- Problems or adverse events submitted to the IRB that are related to VA research;
- Protocol violations submitted to the IRB that are related to VA research;
- VA Research: Reviewer Checklist(s).

See the Minutes of IRB Meetings SOP for additional examples of VAMC recordkeeping requirements.

ORI Access to and Use of Physical Files

1. ORI staff initial and date the centralized storage check in/out sheet whenever a staff member accesses a physical file or returns a file to central file storage. The initial of the individual who is working on the file must be on the check out sheet.

2. Prior to obtaining IRB approval of a protocol, ORI staff may maintain pending initial review physical files in the ORI staff offices, provided that: a) the location of the pending files is clearly labeled; b) each file is labeled; and c) the file is accessible to the other ORI staff. Once the IRB has conducted initial review and approved a protocol, ORI staff file the physical record in central storage.

3. ORI staff return protocol records for active or inactive studies to central storage within 30 calendar days after checking out the file.

4. ORI staff modify the centralized storage sign in/out sheet when transferring files from one staff person to another. The staff member transferring the file adds the initials of the staff person to whom the file is transferred to the sign in/out sheet.

5. ORI staff may not take files home to work on minutes or reviews without specific approval from the ORI Associate Director or RCO.

ORI Database

1. The ORI maintains a computerized tracking system. Examples of data included in the computerized system include the following:
   - IRB number which identifies the protocol as full, expedited, or exempt; IRB providing review, and ORI staff managing review;
   - Current status (active/inactive);
   - QIP status if applicable;
   - Protocol type (medical/nonmedical);
   - Title of the research project (protocol);
   - Protocol process type (full, expedited, exempt);

- Approval stage (pre-approved, approved, suspended, terminated);
- IRB to which the protocol is assigned;
- Designation as a Subject Use and Research Ethics Committee protocol, if applicable;
- Risk category;
- Dates of research period (initial approval date and anticipated ending date);
- Approval period;
- Names of the PI, co-investigators, study coordinators, and other study personnel as appropriate;
- Number and age level of subjects;
- Subject demographics;
- Enrollment status (open or closed to accrual);
- Categories of research (e.g., cancer, genetic research);
- Drug information;
- Other committee approvals (e.g., Institutional Biosafety Committee);
- Funding source type;
- Research sites (if other than UK campus);
- Date of initial approval;
- Date of most recent approval;
- Date of most recent continuation approval;
- If applicable, prior notice of end of current approval period;
- Submission and review dates for each protocol event (initial review, continuation review, final review, modification review, extension review, unanticipated problem review);
- Other information, such as meeting dates;
- Comment section.

2. Research Information Services (RIS) maintains the ORI computerized tracking system and performs a backup of this system on a regular basis. Only ORI staff members and RIS staff have passwords for the ORI system. RIS maintains documentation of backups and passwords.

REFERENCES

45 CFR 46.115
21 CFR 56.115

Examples of Materials Maintained in IRB Protocol File

University of Kentucky

1. IRB Application/Forms
2. PI Appointment Notice
3. Requested Revisions from IRB
4. PI's Response to Requested Revisions
5. Initial Review Approval Letter
6. Criteria for IRB Approval: Reviewer Checklist
7. Revised, Highlighted Consent Form (Highlighted and IRB Stamped/Dated once approved)
8. Internal Unanticipated Problem/ Adverse Event (AE) and Approval Letter Copy
9. External Unanticipated Problem/AE and Approval Letter Copy
10. Data Safety and Monitoring summary reports
11. Modification Approval Letter Copy, Modification Request/Materials (may include deviation/exception)
12. Protocol Violation Review Letter and Attachments
13. Continuation Review (CR) Notification Letter
14. CR Review Request for Protocol
15. CR Response from PI
16. CR Approval Letter
17. General Correspondence between Investigator and Sponsor
18. Subsequent Revised Versions of Investigator Brochures and other amendments and/or Adverse Event Reports
19. Complaints, if applicable
20. Quality Improvement Review materials, if applicable
21. *CR/FR Lapse of Approval Letters
22. HIPPA Authorization (forms/information/revisions)
23. HIPPA Waiver of Authorization