University of Kentucky Office of Research Integrity and Institutional Review Board Standard Operating Procedures			
Revision #7	**TITLE: IRB/ORI Recordkeeping**		**Page 1 of 6**
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: 05-09-19

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 (VPR), 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 of studies initiated on paper, 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 current study personnel on the protocol, ORI staff may copy pertinent parts of the paper record for that person to pick up or ORI staff may fax, mail, or e-mail the record.

4. If the authorized 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 current study personnel, the ORI Director/RCO or his/her designee makes a determination as to whether the request is from appropriate accreditation bodies, University officials, administrators, or regulatory agencies that should have access before authorizing the release of any records. Unless the individual provides an acceptable reason for not informing the PI of the request, 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/RCO) after a study is closed. This storage requirement applies even if the study never enrolled a single subject. ORI staff destroy protocol records for studies that have been closed for six (6) years unless the ORI Director/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, binders, or electronically as appropriate. Such records 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;
   - 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 that are not part of specific protocol files such as meeting minutes, agendas, standard operating procedures, and membership rosters and periodically, destroy them as appropriate and determined by the ORI Director/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 (when applicable) but is not limited to:

   Full Review Protocol

   - Initial IRB application;
   - Scientific evaluations of the proposed research, if any;
   - Study drug information (i.e., investigator's brochure, monograph, labeling);
   - Study device information (i.e., prior investigation, operations manual, labeling);
   - Data Safety and Monitoring Board reports, if any;
   - Results of Quality Improvement Program (QIP) reviews, if any;
   - Signed Signature Assurance;
   - IRB approved informed consent document and assent document 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, continuation, modification, deviation, and 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;
   - IRB Authorization Agreements;
   - Any existing contractual agreements for off-site research;
   - Applications for funding/sponsorship;
   - Advertising or recruiting materials;
   - Protocol amendments or modifications;

- Instrument to be used for data collection;
- Department of Health and Human Services (HHS)/National Institutes of Health (NIH) approved sample informed consent form and protocol;
- 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;
- Human subject protection training for principal investigators and study personnel;
- Health Insurance Portability and Accountability Act (HIPAA) forms;
- Institutional Biosafety Committee correspondence, provisional approval and/or approval letters;
- Other committee approvals/correspondence;
- Mandated reports;
- Criteria for IRB Approval: Reviewer Checklist;
- IRB Continuation Review: Primary Reviewer Checklist(s);
- Other 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 identification of the applicable expedited review category(ies);
- Description of action taken by the primary expedited reviewer.

Exempt Review Protocol

- Initial application for exempt review;
- Signed Signature Assurance;
- Items listed under full review protocol, as 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(ies);
- Description of action taken by the exempt reviewer.

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 initials of the individual who is working on the file is documented on the sheet.

2. Prior to obtaining IRB approval of a paper protocol, ORI staff may maintain pending 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 other ORI staff. Once the IRB has conducted 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 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, when applicable:
   - IRB number which identifies the protocol as full, expedited, or exempt;
   - The IRB which provides review and ORI staff who manage the review;
   - Current status (active/inactive);
   - QIP status;
   - 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;
   - 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);
- Research attributes (e.g., cancer, genetic research);
- Drug information;
- Other committee approvals (e.g., Institutional Biosafety Committee);
- Funding source and type;
- Research sites (if other than UK campus);
- Date of initial approval;
- Date of most recent approval;
- Date of most recent continuation approval;
- 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. UK 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.

Electronic submission system

1. Beginning in January 2018, the ORI maintains an online database and submission system.

2. For each protocol submission, the system maintains all study documents and information outlined above.

3. UK RIS maintains the electronic system. Only ORI and RIS staff members have administrative access to the system. Access for investigators, research staff, and IRB members is appropriately limited.

REFERENCES

45 CFR 46.115
21 CFR 56.115