SOP 12.01 - IRB Records and Documentation

1. Objective

This SOP describes procedures related to IRB record keeping and documentation.

2. General Description

In accordance with Health and Human Services regulations 45 CFR §46.115 and 21 CFR §56.115, the ORI shall prepare and maintain adequate documentation of IRB activities, including the following:

(1) Copies of all research proposals reviewed, scientific evaluations, if any, that accompany the proposals, approved sample consent documents, progress reports submitted by investigators, and reports of injuries to subjects.
(2) Minutes of IRB meetings (See SOP 12.02).
(3) Records of continuing review activities.
(4) Copies of all correspondence between the IRB and the investigators of approved studies.
(5) A list of IRB members identified by name; earned degrees; representative capacity; indications of experience such as board certifications, licenses, etc., sufficient to describe each member's chief anticipated contributions to IRB deliberations; and any employment or other relationship between each member and the institution.
(6) Written procedures for the IRB as required by 56.108 (a) and (b).
(7) Statements of significant new findings provided to subjects, as required by 50.25.

(b) The records required by this regulation shall be retained for at least 3 years after completion of the research, and the records shall be accessible for inspection and copying by authorized representatives of the Food and Drug Administration at reasonable times and in a reasonable manner.

(c) The Food and Drug Administration may refuse to consider a clinical investigation in support of an application for a research or marketing permit if the institution or the IRB that reviewed the investigation refuses to allow an inspection under this section.

3. Roles & Responsibilities

Execution of the SOP: ORI Staff, IRB Members, IRB Chairs, ORI Executive Director, Principal Investigator (PI)/Study Personnel. Specific duties are as follows:

ORI-HS
ORI-HS staff shall be responsible for securing records, limiting access to appropriate UNLV administrators and staff, IRB chairs and members, investigators, funding agency officials, accrediting bodies, and officials of federal regulatory and state agencies.

IRB members
IRB members shall be responsible for providing updated curriculum vita upon request of ORI-HS staff, communicating with investigators in a manner that includes ORI-HS staff to ensure documentation, and communicating needs related to the electronic IRB management system to ORI staff.

Principal Investigators (PIs)
PIs shall be responsible for providing the IRB with all required elements of protocols, maintaining data as specified in their IRB protocols, providing all data/study documentation requested for review by ORI-HS staff or IRB Chairs or Members in a timely manner, and communicating needs related to the electronic IRB management system to ORI-HS staff.

4. Procedures

Storage and Access
ORI-HS staff secure all active IRB records in the ORI-HS and limit access to the IRB Chair, IRB members, ORI Director, ORI-HS staff, Vice President for Research. Officials of federal and state regulatory agencies, the Office for Human Research Protections (OHRP), the Food and Drug Administration (FDA), accrediting bodies, sponsors, and collaborating institutions will be granted access as needed and where it has been deemed appropriate as determined by the ORI Director. ORI-HS staff may grant UNLV employees with administrative appointments access to the records on an as-needed basis for official University business. Investigators or their authorized study personnel have reasonable access to files related to their research activities. ORI-HS staff limits all other access to IRB records to those who have legitimate need for them, as determined by the ORI Director, and/or UNLV Legal Counsel when submitted through state open records statutes.

Administrative requests for access (e.g., Dean, Associate Dean, Department Chair,) 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.

When the ORI-HS receives a request for IRB records, ORI-HS 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 a student investigator, co-PI, or study coordinator on the currently approved protocol proposal form, the ORI-HS staff may provide the requested record(s) for that person to pick up in-person, or send the record(s) to an approved contact location (email, fax, address stated in the currently approved protocol proposal form).

The ORI-HS maintains protocol records for a minimum of three years (as determined by the ORI Director) after a study is closed. This storage requirement applies even if the study has not enrolled any subjects. ORI staff destroy protocol records for studies that have been closed for three years unless the ORI Director determines that a longer retention time is necessary.

In addition to protocol files, the ORI-HS maintains the following information and records. ORI-HS 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;
- IRB Full Board meeting minutes;
- ProIRB, or an alternative Computer-based protocol tracking system;
- Protocol relevant IRB correspondence;
- Resumes of currently active IRB members;
- Records documenting completion of IRB training for study personnel, IRB members, and ORI-HS staff.
- UNLV Federal Wide Assurance updates and renewals

ORI-HS staff maintains 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.

Email communications to and from the ORI-HS office (through the main irb email and staff specific email) are generally maintained by the UNLV IT department servers.

Maintenance of Protocol Records
ORI-HS staff maintains a separate record for every research application. The IRB protocol record may include, but is not limited to:

- Initial IRB application;
- For FDA regulated drugs, the investigator's brochure;
- For FDA regulated devices, a report of prior investigations;
- Data Safety and Monitoring Board reports, if any;
- IRB approved informed consent/assent document(s), 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;
- Continuing 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 as may be pertinent to the review of the proposal;
- Applications for funding/sponsorship, if applicable;
- Advertising or recruiting materials, if applicable;
- Protocol amendments or modifications;
- Instrument(s) 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;
- Confirmation of valid training for principal investigators and study personnel;
- Health Insurance Portability and Accountability Act (HIPAA) forms, if applicable;
- Other committee approvals/correspondence, if applicable;
- Criteria for IRB Approval: Reviewer Checklist (Expedited or Full Board);
- If applicable, IRB Continuation Review;
- Reviewer signature page(s.

ORI Access to and Use of Physical Files

Prior to obtaining IRB approval of a protocol, ORI-HS staff may maintain pending initial review physical files in the ORI-HS 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-HS staff. Once the IRB has conducted initial review and approved a protocol, ORI-HS staff files the physical record in central storage (on or off-site).

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

ORI-HS Database

The ORI-HS maintains a computerized tracking system. Examples of data included in the computerized system include the following:

- Current status (active/inactive);
- Protocol type (medical/nonmedical);
- Title of the research project (protocol);
- Protocol review process (full, expedited, exempt);
- Approval stage (pre-approved, approved, suspended, terminated);
- IRB to which the protocol is assigned;
- Risk determination;
- initial approval date;
- Expiration date;
- Names of the PI, co-investigators, study coordinators, and other study personnel as appropriate;
- Age range of subjects if children;

- Enrollment status (open or closed to accrual);
- General Categories of research (e.g., cancer, genetic research);
- Drug information;
- Funding source type;
- Research sites (if other than UNLV campus);
- 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, unanticipated problem review);
- Other information, such as meeting dates;
- Comment section.

5. References

45 CFR 46.115
21 CFR 56.115