PURPOSE
To describe policies and procedures for the University of New Mexico Institutional Review Board (IRB) record keeping.

REVISIONS FROM PREVIOUS VERSION
Revise length of document retention to 3 years per NM state law

POLICY
The Office of the IRB (OIRB) maintains IRB records in accord with applicable regulatory and institutional requirements.

RESPONSIBILITIES
Execution of SOP: OIRB Staff, IRB, Researchers

PROCEDURE
Storage of and Access to Records

1. OIRB staff secure all active IRB records in the OIRB and the OIRB database and limit access to the IRB Chair, IRB members, OIRB staff, Vice President for Research, and officials of federal and state regulatory agencies, the Office for Human Research Protections (OHRP) and accrediting bodies. OIRB staff may grant UNM employees with administrative appointments access to the records on an as-needed basis for official UNM business. Researchers or their authorized study personnel have reasonable access to files related to their research activities. OIRB staff limit all other access to IRB records to those who have legitimate need for them, as determined by the OIRB Director, VPR, and/or UNM Legal Counsel when submitted through state open records statutes. Records are accessible for inspection and copying by authorized representatives of federal agencies and department at reasonable times and in a reasonable manner.

2. Administrative requests for access (e.g. Dean, Associate Dean for Research, 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.
3. When the OIRB receives a request for IRB records, OIRB 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 OIRB staff may provide the individual access to the electronic record.

4. If the person requesting the record is not listed as study personnel on the record requested, the OIRB Director or designee 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, OIRB staff inform the PI that OIRB has received a request for access to the applicable protocol.

5. Records are stored in the electronic OIRB database as well as in an electronic file (e-file room) on the UNM network. The OIRB maintains protocol records in the e-file room for a minimum of three years after a study is closed. This storage requirement applies even if the study has not enrolled a single subject. OIRB staff destroy e-file protocol records for studies that have been closed for three years unless the OIRB Director waives the requirement for a specific study.

6. In addition to protocol files, the OIRB maintains the following information and records. OIRB staff organize and store records as 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 and non-committee reviews;
   - Federalwide Assurance;
   - Computerized research protocol tracking system;
   - Other IRB correspondence;
   - Agendas for IRB meetings, which include all items to be reviewed;
   - Alleged noncompliance case records;
   - Mandated reports;
   - Curriculum vitae of currently active IRB members;
   - Electronic records documenting completion of mandatory IRB training for study personnel, IRB members, and OIRB staff.

7. OIRB 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 OIRB Director.

8. The OIRB also maintains communications to and from the IRB and keeps any relevant communication related to a specific research protocol in the electronic protocol record.

Protocol Records

1. OIRB staff maintain a separate record for every project application. The IRE protocol record includes, but is not limited to:
Full Review Protocol

- Signed initial IRB application (or Project Information Form);
- Scientific evaluations of the proposed research (Department Review);
- Data Safety and Monitoring Board reports, if any;
- Results of Quality Improvement Program reviews, if any;
- IRB approved informed consent document and assent document, if applicable;
- Documentation of all IRB review and approval actions, modifications and all relevant correspondence to and from the researcher, including initial and, if applicable, IRB continuation and amendment review;
- Documentation of type of review;
- Documentation of study close-out;
- Specific findings (federal and institutional requirements);
- Continuation/Closure 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 deviations;
- Any reports of complaints;
- All relevant correspondence to and from the researcher 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;
- Data collection tools, if applicable;
- Department of Health and Human Services/National Institutes of Health (NIH) approved sample informed consent form and protocol, if applicable;
- 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 investigator and study personnel;
- Health Insurance Portability and Accountability Act (HIPAA) forms, if applicable;
- Institutional Biosafety Committee correspondence and approval letters, if applicable;
- Other committee approvals/correspondence, if applicable;
- Mandated reports, if applicable;
- IRB Reviewer Checklists.

Expedited and Exempt 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 or exempt review and the applicable expedited or exempt review category;
- Expedited or Exempt Reviewer Checklists.

**OIRB Access to and Use of Physical Files**

1. OIRB maintains physical files for several older closed studies in a locked closet accessible only to OIRB staff which will be confidentially destroyed three (3) years after study closure.
2. OIRB electronically document any physical files that are transferred out of the office or destroyed.
3. OIRB staff may not take files home to work on minutes or reviews without specific approval from the OIRB Director.

**OIRB Database**

1. The OIRB maintains a computerized tracking system. Examples of data included in the computerized system include the following:
   - IRB number; IRB providing review; designated reviewer and OIRB staff managing review;
   - Current status (active/closed);
   - Title of the research project (protocol);
   - Protocol process type (full, expedited, exempt);
   - Approval stage (pending, modifications requested, approved, suspended, terminated);
   - Risk category;
   - Approval period;
   - Names of the PI, co-investigators, study coordinators, and other study personnel as appropriate;
   - Number and age level of subjects;
   - Enrollment status (open or closed to accrual);
   - Other committee approvals (e.g. Conflict of Interest Committee);
   - Funding source type;
   - Research sites (if other than UNM campus);
   - Dates of initial and most recent approvals;
   - Submission and review dates for each protocol event (initial review, continuation review, final review, amendment review, reportable event review);
   - Other information, such as meeting dates or study notes.
2. IRBNNet maintains the OIRB computerized tracking system and performs a backup of this system on a regular basis.

**Records Destruction**

1. The OIRB will retain records for at least three (3) years following closure of the study and for studies closed without participant enrollment. Following the required three-year minimal data retention period, existing e-file room records may be deleted.
2. Electronic versions of all minutes and study records will be maintained indefinitely in the OIRB database (IRBNNet).
3. OIRB will document what was confidentially destroyed, the date it was destroyed and who destroyed the record(s).
REFERENCES

45 CFR 46.115
21 CFR 56.115
1.21.2 NMAC, et seq.