

IRB OFFICE RECORDKEEPING

Storage of and Access to Record

1. IRB staff secure all active IRB records in the IRB Office and limit access to the IRB Chair, IRB members, IRB staff, and officials of federal and state regulatory agencies, the Office for Human Research Protections (OHRP), the Food and Drug Administration (FDA), and accrediting bodies. IRB staff may grant Franklin University employees with administrative appointments access to the records on an as-needed basis for official Franklin University business. Investigators or their authorized study personnel have reasonable access to files related to their research activities. IRB staff limit all other access to IRB records to those who have legitimate need for them, as determined by the IRB Manager.

2. Administrative requests for access (e.g., 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.

3. When the IRB Office receives a request for IRB records, IRB 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, IRB staff may copy pertinent parts of the record for that person to pick up or may mail or e-mail the record.

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

5. The IRB Office maintains protocol records 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. IRB staff destroy protocol records for studies that have been closed for three years unless the IRB Manager waives the requirement for a specific study.

6. In addition to protocol files, the IRB Office maintains the following information and records:

- Standard operating procedures;
- IRB membership rosters;
- Meeting minutes, which include documentation of convened IRB meetings;
- Federalwide Assurance;
- Research protocol materials;
- 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 IRB staff.

7. IRB 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 IRB Manager.

Protocol Records

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

- Initial IRB application;
- 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 investigator, including initial and, if applicable, IRB continuing review and modification, deviation, exception review;
- Documentation of type of review;
- Documentation of study close-out;
- Specific findings (federal and institutional requirements);
- Continuing/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;
- 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;
- Other committee approvals/correspondence, if applicable; and
- Mandated reports, if applicable.

For expedited and exempt review protocols, all of the items listed above are required along with the following:

- 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;
- OR --

- 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.