



Number:	Date:	Author:	Approved By:	Page(s):
UGAHRP-070-0	09/18/2015	HSO	IRB	Page 1 of 3

1. PURPOSE

- 1.1. The purpose of this **policy** is to describe the record keeping activities and process for retention of University of Georgia Institutional Review Board (UGA IRB) records that comply with federal regulations, University policy, and any sponsor requirements.

2. POLICY

- 2.1. The Human Subjects Office (HSO) maintains written and/or electronic documentation of IRB activities, including the following:
 - 2.1.1. Protocol-specific records during the initial and **continuing review** such as IRB applications, protocols, submitted and final consent forms, proposed **modifications**, continuing review requests and progress reports, reports of **unanticipated problems involving risks to subjects or others** and **adverse events**, relevant review checklists, the specific permissible exempt or expedited category, specific determinations required under the regulations and, where required, protocol-specific findings supporting determinations, correspondence between the IRB and the researchers, and, if applicable, correspondence from sponsoring agencies. These IRB records will be retained for nine years after study closure or expiration.
 - 2.1.2. IRB records including minutes of meetings with information regarding member attendance, actions taken by the IRB, the vote on these actions (including the number of members voting for, against, and abstaining), the basis for requiring changes in or disapproving **research**, and a written summary of the discussion of controverted issues and their resolution; current and previous IRB member rosters; current and previous IRB membership files; and, current and previous policies and procedures. These IRB records will be retained for nine years after the closure or expiration of all studies that were discussed at a meeting or reviewed by the member(s).
- 2.2. IRB records are accessible for inspection and copying at reasonable times and in a reasonable manner by authorized representatives of federal agencies or departments, the sponsor of the research, and other regulatory or accrediting organizations.
- 2.3. After closure or expiration, protocol records are moved to an inactive state: Closed, Closed by IRB, or Lapsed. Subsequently, paper records will be destroyed per University guidelines. Electronic records will be reduced to the following data points and moved to an archive accessible to appropriate roles in the organization (e.g., IRB Staff, IT Staff): **Principal Investigator** name and **affiliation**, list of study team members and affiliations, study name (title), study/project number, review category (Exempt, Expedited, Full Board), first approval date, number of enrolled participants, and final **expiration date**.

Number:	Date:	Author:	Approved By:	Page(s):
UGAHRP-070-0	09/18/2015	HSO	IRB	Page 2 of 3

2.4. Investigators must retain protocol-specific records, while the study is being conducted and after the research is completed, in accordance with Section 3 below. These records include but are not limited to: copy of approved protocol, continuing reviews, modifications, correspondence to and from the IRB, signed consent form(s) for each research participant (if applicable), grant proposal (if funded), and other related documents.

3. PROCEDURES: Investigator

- 3.1. Federal regulations, University System of Georgia Board of Regents, and sponsor retention requirements are different. As a result, researchers must make the determination of the applicable requirement and comply with the longest retention standard.
 - 3.1.1. OHRP (Office for Human Research Protections): 45 CFR 46 requires research records to be retained for at least three (3) years after completion of the study.
 - 3.1.2. **HIPAA** (Health Insurance Portability and Accountability Act): Any protocol that involved collection of private health information is subject to HIPAA requirements. As a result, records must be retained for a minimum of six (6) years after each subject signed an authorization.
 - 3.1.3. University System of Georgia (USG) Records Retention Schedules: See http://www.usg.edu/records_management/schedules/l/.
 - 3.1.4. FDA (Food and Drug Administration): Any research that involve drugs, devices, or biologics being tested in humans must be retained for a period of 2 years following the date a marketing application is approved for the drug for the indication for which it is being investigated; or, if no application is to be filed or if the application is not approved for such indication, until 2 years after the investigation is discontinued and FDA is notified. Note that this length of time can be much greater than 2 years, i.e., researcher must receive written confirmation from the sponsor and/or FDA granting permission to destroy the records.
 - 3.1.5. Sponsor Requirements: Comply with any terms for record retention detailed in the contract with the sponsor.

4. PROCEDURES: Institutional Review Board

- 4.1. All protocol-specific materials created in the Click IRB electronic submission and management system are saved in the electronic submission records and are accessible to IRB Staff and the IRB Chairperson for the timeline described in 3.1.
 - 4.1.1. Committee members may also access records when assigned a reviewer role for the submission.
 - 4.1.2. All users can access protocol records for studies where they are assigned a study team role.

Number:	Date:	Author:	Approved By:	Page(s):
UGAHRP-070-0	09/18/2015	HSO	IRB	Page 3 of 3

- 4.2. IRB Staff attach PDF copies of all review-related correspondence (such as e-mails) to the submission records in relevant locations (e.g., determination activity forms, clarification request activity forms, and/or comments on the submission workspace).
- 4.3. IRB minutes are uploaded to the electronic meeting workspace.
- 4.4. **IRB Rosters** are maintained in the electronic committee module by IRB Staff.
 - 4.4.1. PDF copies of roster updates to OHRP are maintained electronically on a shared network drive accessible to IRB Staff and responsible organizational members (e.g., system administrators).
 - 4.4.2. After update, the replaced PDF roster is moved to an archive network folder.
- 4.5. All protocol materials for studies created before Click IRB was implemented are printed on paper and retained in filing cabinets accessible to IRB staff. Paper records are moved to the University Records Management facility for storage based on time elapsed since closure/expiration and availability of adequate storage space with the oldest files being moved first.

5. MATERIALS

- 5.1. Archive Files Blank Excel Spreadsheet
- 5.2. Archive Labels Template

6. REFERENCES

- 6.1. §46.115 OHRP's IRB records
- 6.2. 21 CFR 312.62.c FDA's Investigator recordkeeping and record retention
- 6.3. UGA Records Management: <http://www.libs.uga.edu/recman/>
- 6.4. USG Records Retention Schedules http://www.usg.edu/records_management/schedules/I/