1. PURPOSE
   1. This procedure establishes the process to retain IRB records.
   2. This procedure begins every year.
   3. This procedure ends when all records that are no longer required to be retained are destroyed.
2. POLICY
   1. Paper protocol files are to be retained as long as required by this policy and then destroyed.
   2. All files maintained in the electronic system (PRIS3M) are retained indefinitely.
   3. All IRB records for human subjects research must be retained for a minimum of six years after the completion of the research.
   4. Records of research studies that are FDA-regulated (drugs, devices, or biologics being tested in humans) shall retain records or 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.
      1. The date of last marketing approval will not be known at the time the research is completed and can be quite long. Investigators are advised to include funds for storage of the case records in their study budget. Records should be retained until there is written confirmation from the sponsor or FDA granting permission to destroy them.

Research records involving pediatric participants, or *both* pediatric and adult participants, must be retained for either six (6) years after all participants have turned 18 years of age or six years after the completion of the research, whichever is longer.

* 1. Not Human Subjects Determinations must be retained for three years after the determination.
  2. Protocols in which there was no subject enrollment or no research procedures were conducted are to be retained the same as protocols where research was conducted.
  3. All records for research conducted or funded by a Common Rule department or agency are to be accessible for inspection and copying by authorized representatives of that agency at reasonable times and in a reasonable manner.
  4. All records for research subject to FDA regulations are to be accessible for inspection and copying by authorized representatives of FDA at reasonable times and in a reasonable manner.
  5. Study files designated by legal counsel as being on “legal hold” are not to be destroyed until the legal hold is removed.
  6. All other records are retained for at least six years after the end of a member’s service on the IRB. These records include, but are not limited to:
     1. IRB Member Curriculum Vitae (CV) or biosketch
     2. Institutional Official letters of appointment for IRB Members
     3. A current confidentiality agreement for IRB members and HRPO staff
     4. Member’s acceptance letter
     5. Indication of the required human participants protection training, and continuing education for IRB members and HRPO staff
  7. The following documents are retained indefinitely:
     1. IRB meeting minutes
     2. Current and previous versions of IRB member rosters
  8. Access to Documents.
     1. The Institutional Official, HRPO staff and members of the Leadership Committee have full access to the IRB Records at all times.
     2. The IRB panel members have full access to the protocol records for items assigned to their committee meeting.
     3. The HRPO must make all records accessible for inspection and copying by authorized representatives of Federal agencies or departments at reasonable times and in a reasonable manner.
     4. IRB paper records are not to be removed from the HRPO. Authorized representatives may make copies of the documents, but may not remove the original documents.
     5. Records are stored safely and confidentially in locked file cabinets.

1. RESPONSIBILITY
   1. HRPP staff members carry out these procedures.
2. PROCEDURE
   1. Review the study files that can be destroyed.
      1. Omit destruction of records on a legal hold.
   2. Maintain all records of IRB Review in PRIS3M indefinitely.
   3. Before any document is destroyed ensure:
      1. The research records meet the requirements for being destroyed.
      2. Document the date of destruction with the following for each study file destroyed:
         1. IRB Number
         2. Study Title
         3. Principal Investigator Name
         4. Date of Initial Approval
         5. Date of Study Closure
         6. Paper, electronic, or both
3. APPROVAL AND REVISIONS
   1. 4/28/21: Human Research Protections Office Director, Carley Emerson, originally created and approved
4. REFERENCES
   1. 21 CFR §56.115
   2. 45 CFR §46.115