1. PURPOSE
   1. This procedure establishes the process to retain IRB records.
   2. This procedure begins every three months.
   3. This procedure ends when all records that are no longer required to be retained are destroyed.
2. POLICY
   1. Study files designated by legal counsel as being on “legal hold” are not to be destroyed until the legal hold is removed.
   2. Study files relating to research requiring continuing review which has not been conducted are retained for at least 3 years after the last IRB action.
   3. Study files relating to research requiring continuing review which has been conducted are retained for at least 3 years after completion of the research, regardless of whether there was subject enrollment.
   4. Study files relating to research not requiring continuing review are retained for at least 3 years after the last IRB action.
   5. Incomplete study files that were never finalized and sent to <Committee Review> or <Non-Committee Review> are retained for at least 3 years after the last IRB action.
   6. The following documents are retained indefinitely:
      1. IRB meeting minutes
      2. A resume or curriculum vitae for each IRB member
      3. Current and previous versions of IRB member rosters
      4. Current and previous versions of controlled documents
3. RESPONSIBILITY
   1. HRPP staff members carry out these procedures.
4. PROCEDURE
   1. Review the study files that can be destroyed.
      1. Omit destruction of records on a legal hold.
      2. Previously approved studies requiring continuing review: Three years after the date on which all research sites overseen by the [Organization]’s IRB have been completed either through closure, <Termination of IRB Approval>, disapproval, or lapse of approval
      3. Research never approved and research not requiring continuing review: Three years after the last IRB action or after withdrawal by the submitter
   2. Shred paper documents and dispose the shredded materials securely.
   3. Notify information technology to destroy electronic documents by either deleting the files or replacing the files with stub files documenting the date of deletion.
   4. Document the date of destruction with the following for each study file destroyed:
      1. IRB ID
      2. Protocol ID
      3. Date of completion
      4. Paper, electronic, or both
5. REFERENCES
   1. 21 CFR §56.115
   2. 45 CFR §46.115