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 non-exempt research which has not been conducted are retained for at least 3 years.
   3. Study files relating to non-exempt research which has been conducted are retained for at least 3 years after completion of the research.
   4. Study files relating to non-exempt research with no subject enrollment are retained for at least 3 years after completion of the research.
   5. Study files relating to exempt research are retained for at least 3 years.
   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 non-exempt studies: 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. Non-exempt studies never approved and exempt studies: 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 your name and the date of destruction with the following for each study file destroyed:
      1. Study title
      2. IRB ID
      3. Date of completion
      4. Paper, electronic, or both
5. REFERENCES
   1. 21 CFR §56.115
   2. 45 CFR §46.115