1. PURPOSE
1.1. This procedure establishes the process to retain IRB records.
1.2. This procedure ends when all records that are no longer required to be retained are destroyed.

2. POLICY
2.1. Study files designated by legal counsel as being on “legal hold” are not to be destroyed until the legal hold is removed.
2.2. Study files relating to non-exempt research which has not been conducted are retained for at least 6 years.
2.3. Study files relating to non-exempt research which has been conducted are retained for at least 6 years after completion of the research.
2.4. Study files relating to non-exempt research with no subject enrollment are retained for at least 6 years after completion of the research.
2.5. Study files relating to exempt research are retained for at least 6 years.
2.6. All records pertaining to VA research must be retained indefinitely. Any such records may be transferred to the VA 6 years after completion of research.

3. RESPONSIBILITY
3.1. IRB staff members carry out these procedures.

4. PROCEDURE
4.1. Review the study files that can be destroyed.
   4.1.1. Omit destruction of records on a legal hold.
   4.1.2. Previously approved non-exempt studies: Six years after the date on which all research sites overseen by the UF IRB have been completed either through closure, termination of IRB approval, disapproval, or lapse of approval.
   4.1.3. Non-exempt studies never approved and exempt studies: Six years after the last IRB action or after withdrawal by the submitter.
4.2. Destroy study files in accordance with UF’s Records Destruction Policy.

5. REFERENCES
5.1. 21 CFR §56.115
5.2. 45 CFR §46.115