HRP-072 | 03/01/2024 | Author: T. Bechert | Approver: S. Brooks

**SOP: IRB Records Retention**

1. **PURPOSE**
   1. This procedure establishes the process to retain IRB records.
   2. The process begins each year in June.
   3. The process ends when records that no longer need to be retained are destroyed.
2. **REVISIONS FROM PREVIOUS VERSION**
   1. None
3. **POLICY**
   1. The HRPP will comply with [institutional policy issued by VCU Technology Services](https://vcu.public.doctract.com/doctract/documentportal/08DA32A740D31ACEF3DE09FFC487DA40) which establishes the general responsibilities for management, retention, and disposition of Virginia Commonwealth University records as mandated by the Virginia Public Records Act (VPRA) as related to IRB records retention procedures.
      1. Electronic or paper records maintained by the HRPP will be accessed, handled, and disposed of (where applicable) consistent with institutional policy for Category I, II, and III information/data.
   2. The HRPP will work with the OVPRI designated department records coordinator on matters related to staff training and program procedures to ensure compliance with institutional policy.
   3. Protocol files are maintained electronically and are retained indefinitely.
   4. All records not in protocol files are retained indefinitely.
   5. Records may be maintained in printed form or electronically.
   6. Protocols in which there was no subject enrollment or no research was conducted are to be retained the same as protocols where research was conducted.
   7. 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.
   8. Records maintained that document compliance or non-compliance with Department of Defense DOD) regulations shall be made accessible for inspection and copying by representatives of the DOD at reasonable times and in a reasonable manner as determined by the supporting DOD component.
   9. 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.
   10. All records are to be accessible for inspection and copying by the Veterans Administration (VA) Research and Development Committee at reasonable times and in a reasonable manner.
   11. Veterans Administration (VA) IRB records are retained in accordance with VHA’s Records Control Schedule.
4. **RESPONSIBILITIES**
   1. IRB staff members carry out these procedures.
5. **PROCEDURE**
   1. Destroy protocol files for Veterans Administration (VA) research per Records Control Schedule 10-1 (VHA RCS 10-1).
   2. Destroy protocol files for the Department of Defense (DOD) research when approved by the Department of Defense. The agency may require submitting records to the Department of Defense for archiving.
   3. All other protocol files must be retained indefinitely or at least until the protocol has been closed, withdrawn, or terminated more than indefinitely, or at least 6 years after project completion for projects involving human subjects and 3 years after project completion for projects not involving human subjects, [[1]](#footnote-1) unless otherwise required by law as outlined in [institutional policy issued by VCU Technology Services](https://vcu.public.doctract.com/doctract/documentportal/08DA32A740D31ACEF3DE09FFC487DA40).
      1. In the case of multi-center research “completion” is referenced to the organization’s involvement in the research, not the entire study.
6. **MATERIALS**
   1. None
7. **REFERENCES**
   1. VHA Directive 1200.05 dated January 7, 2019
   2. AAHRPP elements I.1.A, I-9, II.5.A, 11.5B
   3. Code of Virginia § 42.1-76–§ 42.1-91
   4. DoDI 3216.02

1. Library of Virginia publishes GS-111 General Schedule [↑](#footnote-ref-1)