

VIRGINIA TECH INSTITUTIONAL REVIEW BOARD

Policy for the Storage and Transfer of Human Subjects Research Records

PURPOSE

The purpose of this policy is to establish requirements for the storage (Subpart A below) and transfer (Subpart B below) of human subjects research records (hardcopy and electronic) related to **non-exempt** IRB protocols.

SUBPART A: REQUIREMENTS FOR THE STORAGE OF HUMAN SUBJECTS RESEARCH RECORDS

Human subject research records of open* VT IRB protocols containing direct or indirect identifiable participant information, including study codes and demographic information that could reasonably identify a subject, must remain at VT or at the institution/facility specified on the approved IRB research protocol. Requests to move the data must be approved by the VT IRB via a formal amendment.

Human subject research records of closed VT IRB protocols containing identifiable participant information may be removed from the VT premises without VT IRB approval; however, must be retained in a manner that will preserve the level of confidentiality promised to subjects.

In accordance with 45 CFR 46.115(b), records related to research** shall be retained for at least 3 years after completion of the research. All records shall be accessible for inspection and copying by authorized representatives*** at reasonable times and in a reasonable manner. It is the principal investigator's responsibility to ensure compliance with 45 CFR 46.115(b).

The Policy for Online Research Data Collection Activities and the Storage of Electronic Data Involving Human Subjects (Subpart C) contains more information related to the record retention requirements for electronic data, and may be found at the following link: <http://www.irb.vt.edu/documents/onlinepolicy.pdf>.

SUBPART B: TRANSFER OF HUMAN SUBJECTS RESEARCH RECORDS

If a VT IRB-approved research project (whether open or closed with the VT IRB) is to be fully transferred to another institution or facility, the principal investigator is responsible for (1) complying with the new institution's policies and procedures; (2) complying with the researcher's VT departmental requirements; (3) retaining research records consistent with human subjects protection regulations; and (4) properly closing the research protocol with the VT IRB.

*Open includes any protocol wherein data analysis at VT and/or data collection at VT or any involved institution is ongoing.

**Records related to research include but are not limited to consent forms, questionnaires, audiotapes/videotapes, photographs, and health records – regardless of whether the data are de-identified.

***Authorized representatives include individuals within the applicable department or agency (as defined by 45 CFR 46.102), and the VT IRB.