Policy for the Retention, Storage and Transfer of Human Subjects Research Records

PURPOSE

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

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

In accordance with 45 CFR 46.115(b), records related to research\(^1\) 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\(^2\) at reasonable times and in a reasonable manner. It is the principal investigator’s responsibility to ensure compliance with 45 CFR 46.115(b).

Following the minimum 3-year retention of data, direct or indirect identifiable subject information (including the study code key\(^3\) and demographic information that could reasonably identify a subject) must be destroyed in accordance with the IRB-approved protocol. De-identified data may be retained indefinitely.

Human subject research records of open\(^4\) VT IRB protocols containing direct or indirect identifiable subject information, including the study code key 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, including identifiable subject 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.

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

During the retention period (see Subpart A above), data, signed consent forms, and other documentation related to human subjects must be stored in accordance with the project’s IRB-approved protocol. Access to data, signed consent forms, and other documentation related to human subjects must be limited to those identified on the IRB-approved protocol as having access to study data.

All direct identifiable subject information must be encrypted while stored on a computer or electronic external device. In addition, the computer on which direct identifiable subject information is stored must be password protected.

When use of study codes is specified within a project’s IRB-approved protocol, the following procedures must be adopted to enhance the level of confidentiality provided to subjects:

1. Stored coded data may not include information that could be used to directly identify a subject.
2. Signed consent forms must be stored separately (i.e., separate computer, separate locked filing cabinet) from coded data.
3. Signed consent forms and the study code key must be stored in a secure manner; examples include storing on a password-protected computer, in an encrypted manner, or within a locked filing cabinet.
4. The study code key must be stored separately from coded data. At a minimum, the following standards related to the use of study codes must be implemented, as applicable:

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\(^1\) 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.

\(^2\) Authorized representatives include individuals within the applicable department or agency (as defined by 45 CFR 46.102), and the VT IRB.

\(^3\) Study code key is defined by the VT IRB as any documentation linking each subject to his/her specific and unique study code.

\(^4\) Open includes any protocol wherein data analysis at VT and/or data collection at VT or any involved institution is ongoing.
a. When storing the study code key and coded data electronically, the study code key and coded data **must not** be stored on the same computer.

b. When storing the study code key and coded data as hardcopy documentation, the study code key and coded data **must not** be stored in the same locked filing cabinet.

**SUBPART C: 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.