

## **IRB Policy 30: Record Keeping**

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### **I. Summary Policy**

It is the policy of the East Tennessee State University Campus Institutional Review Board (ETSU IRB) and the East Tennessee State University/ Veterans Affairs Institutional Review Board (ETSU/VA IRB) to maintain IRB records that comply with all regulatory requirements for all research activities within its domain. The administrative office that supports the IRB will be responsible for maintaining records of IRB actions as described in this policy.

#### **A. Complete History of IRB Actions**

The IRB files must be maintained so that each study file contains a complete history of all IRB actions related to review and approval of a protocol, including initial submission, continuing reviews, amendments and adverse event reports. IRB files should be organized to allow a reconstruction of the history of all IRB actions related to review and approval of the study. Records must clearly indicate what the IRB approved.

#### **B. Retention**

##### For non-VA files

All IRB records regarding a proposed study, even if disapproved, must be kept for at least six (6) years from the end of the calendar year in which the study is closed. If an IRB-approved protocol is cancelled without participant enrollment, IRB records will be maintained for at least six (6) years from the end of the calendar year after cancellation.

##### For VA files

Required records, including the researcher's research records, must be retained for six (6) years from the end of the calendar year in which the study is closed, and polices must follow *Guidance on ORD's New Record Control Schedule*; August 2015 ORD Records Schedule: DAA-0015-2015-0004; and the VA Handbook 6500. Researcher records include codes/keys linking subject data to identifiers; these must be kept as part of the research record for six (6) years (rather than being destroyed at the earliest opportunity as can be the practice in private sector or with academic affiliates).

### **C. Inspection and Copying**

The IRB Office will make all records accessible for inspection and copying by authorized representatives of any regulatory oversight agency at reasonable times and in a reasonable manner. For VA research, the VA R&D Committee has access to IRB records.

## **II. Documents**

### **A. Study Files**

For IRB applications, the IRB Office will maintain the following documents: copies of all research applications reviewed, including scientific and scholarly evaluations, if any; protocol or research plans; investigator brochure, if any; recruitment materials; consent documents; HIPAA Authorizations or documentation of HIPAA waiver (for studies subject to HIPAA rules); amendments; data safety monitoring board/committee reports; progress reports submitted by the Investigators; reports of any adverse events and unanticipated problems to participants or others; documentation of non-compliance; all correspondence between the IRB and the investigators; records of continuing review activities; and statements of significant new findings provided to participants; reports of injuries to participants; internal serious adverse events; subject complaints; and protocol violations submitted to the IRBs. IRB records will also include for each protocol's initial and continuing review the frequency for the next continuing review (if continuing review is required).

For studies subject to the 2018 Common Rule:

When the IRB is not required to conduct continuing review, records will document the rationale for any decisions to conduct continuing review of research and will contain documentation of other oversight procedures (i.e., administrative check in). Records will also contain documentation of any limited IRB reviews for exempt studies. Additionally, IRB records will contain documentation of the rationale for a reviewer determination that research appearing on the expedited review list is greater than minimal risk, as well as the rationale for review by the convened IRB.

For collaborative research, IRB records will maintain the Institutional Authorization Agreements documenting the responsibilities of each entity when ETSU serves as the IRB of record or defers review to another IRB.

IRB records will include copies of all correspondence between the IRB and VA R&D Committee.

### **B. Minutes**

The IRB will maintain minutes of all IRB meetings. The IRB Coordinator completes meeting minutes so that they are available for review within 3 weeks of the meeting date.

Minutes will include the following:

- a) Summarization of the discussion of any controverted issues and their resolution
- b) Clearness about the actions of the IRB and exactly what the IRB approved
- c) Clear specification of any modifications required to obtain approval
- d) Documentation of required determinations (i.e., for waiver of informed consent, waiver of documentation of informed consent; or research with children, prisoners, pregnant women, fetuses, neonates, or cognitively impaired participants) along with protocol specific findings that justify the determination. Minutes must document that the IRB judged each one of the regulatory criteria and the IRB's justification for each of the criteria based on protocol-specific findings
- e) Documentation of the members present at the meeting ("Members present" is defined as members present at any time during the meeting) including each member's full name, representative capacity (i.e., scientist, non-scientist, member who represents the general perspective of research participants, unaffiliated)
- f) If a consultant is present at the convened meeting, the name of the consultant, and a brief description of the consultant's expertise, and documentation that the consultant did not vote with the IRB on the study
- g) The names of non-members and guests, such as IRB support staff, researchers, and study coordinators
- h) The names of IRB members who leave the meeting because of a conflict of interest along with the fact that a conflict of interest is the reason for the absence
- i) Information about members entering or leaving the room
- j) Each vote will list all members from the "members present" list who are not present for that vote
- k) Documentation of alternate members attending the meeting and for whom they are substituting
- l) Determination of degree of risk (minimal or more than minimal)
- m) For studies approved by the IRB, that the IRB determined that all the criteria for approval of the research were satisfied

IRB minutes additionally document:

- a) Separate deliberations, actions, and votes for each protocol undergoing initial review by the convened board
- b) Separate deliberations, actions, and votes for each protocol undergoing continuing review by the convened board
- c) Separate deliberation, actions, and votes for each protocol undergoing review of modification by the convened board
- d) Votes on actions including number of members for, against, and abstaining
- e) The names of IRB members who abstain from voting
- f) The basis for requiring change in research
- g) The basis for disapproving research
- h) The rationale for significant or non-significant risk device determinations
- i) For DHHS studies, a justification of any deletion or substantive modification

- of information concerning risks or alternative procedures contained in the DHHS-approved sample informed consent
- j) For initial and continuing reviews, documentation of the degree of risk, and the approval period to reflect the determination of which protocols require continuing review more often than annually, as appropriate to the degree of risk
  - k) Approval of research contingent on specific minor conditions by an IRB Chair or designee must be documented in the minutes of the first IRB meeting after the date of the approval

IRB minutes will not:

- a) Contain information that does not reflect the IRB's deliberation, such as protocol summary information
- b) List only regulatory criteria or say study met regulatory criteria when documentation of certain determinations is required (i.e., waiver or research involving children)

Once approved by the IRB at a subsequent IRB meeting, minutes may not be altered by anyone including a higher authority. The IRB Chair signs the IRB-approved minutes, and the administrative office that supports the IRB retains a copy of the final minutes.

For the ETSU/VA IRB, the IRB Coordinator forwards a copy of the IRB-approved minutes to the VA in a timely manner. The Administrative Officer (AO) distributes the ETSU/VA IRB minutes to members of the VA R&D Committee.

### **C. Committee Rosters**

A list of IRB members and their qualifications and affiliations will be maintained. IRB records will also include a resume or curriculum vitae for each IRB member. All previous rosters will be retained.

### **D. IRB Policies and Procedures**

The IRB will maintain written policies and procedures as described in the Introductory Policy.

### **References:**

45 CFR 46.115  
VHA Record's Control Schedule (RCS 10-1)