IRB Policy 30: Record Keeping

Revision Date: April 16, 2008, revision November 19, 2009, revised January 27, 2011, revised January 17,2012, revised 10/13/2012, revised 5/28/13, revised September 4, 2013, revised February 9, 2015, revised January 12, 2016, revised May 5, 2016, revised April 2, 2018, revised 9.14.18, revised Feb 7, 2019

I. Summary Policy:

It is the policy of the ETSU Office for the Protection of Human Research Subjects to maintain IRB office records that comply with all regulatory requirements for all research activities within its domain.

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, initial submission, including 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. IRB records are retained for at least six (6) years from the end of the calendar year in which the study is closed. All records regarding a proposed study, even if unapproved, must be kept for at least six (6) years from the end of the calendar year of the proposal. For all applications that are approved, the IRB Office must retain all records regarding that research for at least six (6) years from the end of the calendar year after completion of the research. If a protocol is cancelled without participant enrollment, IRB records have to be maintained for at least six 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 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 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 staff must make all records accessible for inspection and copying by all authorized representatives of any regulatory oversight agency at reasonable times and in a reasonable manner. For VAMC research, the VA R&D Committee has access to IRB records.

II. Documents

IRB records will include copies of all correspondence between the IRB and VAMC Research and Development Committee.

A. Study Files

For IRB applications, the IRB Staff must maintain all 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 (on studies subject to the 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).

~~"When the revised Common Rule goes into effect~~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. When the IRB is not required to conduct continuing review, records 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."

In addition, 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.

B. Minutes

The IRB will maintain minutes of all IRB meetings. IRB Coordinator completes meeting minutes so that they are available for review within 3 weeks of the meeting date. Once approved by IRB members at a subsequent IRB meeting, minutes may not be altered by anyone including a higher authority.

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. For VA studies only, the minutes will document the rationale for the study's determination of degree of risk (minimal or more than minimal). For VA studies only, the expedited review eligibility category for initial expedited approvals and continuing review expedited approvals will be documented in the minutes. For VA studies only, approvals issued by an expedited process will be included in the meeting minutes of the *next* convened IRB meeting. Non-VA expedited approvals will be placed on the subsequent agenda (and minutes) if those decisions are made in the period after an agenda has already been generated for an upcoming meeting.
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 (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) Actions taken by the IRB
b) Separate deliberations, actions, and votes for each protocol undergoing initial review by the convened board
c) Separate deliberations, actions, and votes for each protocol undergoing continuing review by the convened board
d) Separate deliberation, actions, and votes for each protocol undergoing review of modification by the convened board
e) Votes on actions including number of members for, against, and abstaining
f) The names of IRB members who abstain from voting
g) On each action, the names of IRB members who absent themselves from the meeting due to a conflicting interest
h) Attendance at the meeting for each action
i) The basis for requiring change in research
j) The basis for disapproving research
k) The rationale for significant or non-significant risk device determinations.
l) 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
m) 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.
n) 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., wavier or research involving children)

IRB IRT forwards the approved minutes of the ETSU IRB to the following institutional officials for signature:

- Vice Provost for Research and Sponsored Programs

- Vice President for Academic Affairs
- Vice President for Health Affairs
- President, East Tennessee State University

IRB IRT forwards the approved minutes of the ETSU/VA IRB to the following institutional officials for signature:

- Vice Provost for Research and Sponsored Programs
- Dean of Medicine
- Vice President for Health Affairs
- Vice President for Academic Affairs
- President, East Tennessee State University
- Director, James H. Quillen VAMC

IRB Secretary IRT forwards the approved minutes of the ETSU/VA IRB to the VA Administrative Officer (AO). The 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. For the ETSU/VA IRB, 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)