

IRB Policy 36: Performance Sites

Creation Date January 2, 2008, revised January 24, 2019

I. Pertinent Definitions:

A. Engaged: An institution becomes "engaged" in human subjects research when its employees or agents¹ (i) intervene or interact with living individuals for research purposes; or (ii) obtain individually identifiable private information for research purposes [\[45 CFR 46.102\(d\),\(f\)\]](#).

An institution is automatically considered to be "engaged" in human subjects research whenever it receives a direct HHS award to support such research. In such cases, the awardee institution bears ultimate responsibility for protecting human subjects under the award.

II. Summary Policy

It is the policy of both 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) that appropriate approvals for "engaged" and "non-engaged" performance sites are obtained and documented.

III. Requirements

Performance Site Category	Description	FWA required?	Required approval
Category 1	<ul style="list-style-type: none"> engaged in research with federal research support or direct award for study 	Yes	Submit copy of site IRB approval or request that ETSU IRB be IRB of Record.
Category 2	<ul style="list-style-type: none"> engaged in research with no federal research support or direct award for study 	No	Submit copy of site IRB approval or request that ETSU IRB be IRB of Record.
Category 3	<ul style="list-style-type: none"> Performance site not engaged in research with established IRB 	No	Submit copy of site IRB approval or request that ETSU IRB be IRB of Record.

Category 4	<ul style="list-style-type: none"> • Performance site not engaged in research • without established IRB 	No	Submit letter of permission from the appropriate institutional official stating that the research may be conducted at site.
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For VA studies, if the investigator contracts with a firm (e.g., a survey research firm) to obtain consent from subjects, collect private individually identifiable information from human subjects, or be involved in activities that would institutionally engage the firm in human subjects research, the firm must have its own IRB oversight of the activity. In addition, the Privacy Officer (PO) must determine that there is appropriate authority to allow the disclosure of individual names and other information to the contracted firm.

IV. VA Collaborative Research

Research collaborations between VA and non-VA institutions:

Collaboration is encouraged when VA investigators have a substantive role in the design, conduct, and/or analysis of the research. VA may also serve as a Coordinating Center for collaborative studies.

a. IRB of Record Approval. Each institution is responsible for safeguarding the rights and welfare of human subjects and providing oversight of the research activities conducted by that institution.

(1) Each collaborating institution engaged in human subjects research must obtain approval from its IRB of Record and hold an FWA or another assurance acceptable to VA (e.g. DoD assurance).

(2) VA investigators must submit a protocol or other documentation to their VA IRB of Record that clearly delineates which research activities will be conducted as the VA portion of the overall Collaborative Research study (e.g., by VA investigators on VA time or VA property).

(3) Each institution engaged in the Collaborative Research must use the informed consent document and HIPAA authorization required by its respective institutional policies for subjects recruited from that institution, or procedures requiring participation of the subjects at that institution. The informed consent document may contain information on the project as a whole as long as the document clearly describes which procedures will be performed under VA's auspices and which will be performed under a non-VA institution's auspices

(a) The VA informed consent document must clearly state when procedures conducted at other non-VA institutions are part of the VA's portion of the study.

(b) The informed consent document and HIPAA authorization (for the VA portion of the collaborative study) must not contain inconsistent provisions.

b. Research Data. The protocol, addendum, and/or IRB of Record application must describe the data to be disclosed to collaborators, the entities to which the data are to be disclosed, how the data are to be transmitted, and how the transmitted data will be stored, retained, destroyed, and/or further disclosed and to whom. This includes data from individual subjects as well as other data developed during the research such as the analytic data and the aggregate data.

(1) Each VA facility must retain a complete record of all data obtained during the VA portion of the research in accordance with privacy requirements, the Federal Records Act, and VHA RCS10-1.

(2) All disclosures and data transmission must meet privacy and security requirements per VA Directive 6500, Managing Information Security Risk: VA Information Security Program, dated September 20, 2012; VA Handbook 6500, Risk Management Framework for VA Information Systems – Tier 3: VA Information Security Program, dated March 10, 2015; and VHA Directive 1605.01, any superseding policies.

3) Agreements regarding data use and transmission must be executed as required as applicable in VHA Handbook 1200.12, Use of Data and Data Repositories in VHA Research, dated March 9, 2009, or any superseding policies revising or replacing it. NOTE: VA Directive 1200.05 does not preclude other applicable agreements required for the Collaborative Research (e.g., data use agreement).

V. Responsibilities

A. IRB Administration Responsibilities

1. The IRB Coordinator will verify that the appropriate documentation for performance sites has been submitted to the IRB before final approval is issued.
2. The IRB Coordinator will verify the FWA and IRB registration number for performance sites in category 1.

B. Principal Investigator Responsibilities

1. The PI will obtain and submit appropriate documentation of IRB or institutional approval as required.
2. The PI will notify the IRB of site closures as they occur.

B. IRB Committee Responsibilities

1. IRB reviewers verify the determination of “engaged” versus “non-engaged.”