IRB Policy 36: Performance Sites  
Creation Date January 2, 2008

I. Pertinent Definitions:

A. Engaged: An institution becomes "engaged" in human subjects research when its employees or agents\(^1\) (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

<table>
<thead>
<tr>
<th>Performance Site Category</th>
<th>Description</th>
<th>FWA required?</th>
<th>Required approval</th>
</tr>
</thead>
</table>
| Category 1                | • 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                | • 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                | • 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. |
IV. 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.

C. IRB Committee Responsibilities

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