Performance Sites

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.

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.

The PI will obtain and submit appropriate documentation of IRB or institutional approval as required and will notify the IRB of site closures as they occur. The IRB Coordinator will verify that the appropriate documentation for performance sites has been submitted to the IRB before final approval is issued. The IRB Coordinator will verify the FWA and IRB registration number for performance sites in category 1.

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

<table>
<thead>
<tr>
<th>Performance Site</th>
<th>Description</th>
<th>FWA required?</th>
<th>Required approval</th>
</tr>
</thead>
<tbody>
<tr>
<td>Category 1</td>
<td>Engaged in research with federal research support or direct award for study</td>
<td>Engaged in research with federal research</td>
<td>Submit copy of site IRB approval or request that ETSU IRB be IRB of Record.</td>
</tr>
<tr>
<td>Category 2</td>
<td>Engaged in research with no federal research support or direct award for study</td>
<td>No</td>
<td>Submit copy of site IRB approval or request that ETSU IRB be IRB of Record.</td>
</tr>
<tr>
<td>Category 3</td>
<td>Performance site not engaged in research with established IRB</td>
<td>No</td>
<td>Submit letter of permission from the appropriate institutional official stating that the research may be conducted at site.</td>
</tr>
<tr>
<td>Category 4</td>
<td>Performance site not engaged in research without established IRB</td>
<td>No</td>
<td></td>
</tr>
</tbody>
</table>

¹Agents include the institutional research official, other researchers, research staff, nurses, graduate students, technicians, data collectors, and other research employees who are not permanent employees of the institution.