CLINICAL TRIALS TRANSFORMATION INITIATIVE

Single IRB: Determination of Institutional Engagement Overview

In a multicenter study utilizing a single IRB (sIRB) of record, the sIRB will need to review the protocol on behalf of each engaged institution. As such, the Clinical Trials Transformation Initiative (CTTI) has created a set of resources to assist in making the determination if an institution is engaged in research due to employees or agents of that institution conducting human subjects research on the institution's behalf.

These tools—including an Engagement Flowchart, set of Engagement Scenarios, and Engagement Definitions—are meant only as decision aids for IRBs, research administrators, investigators, or others responsible for research review or oversight. Users should consult the Common Rule (45 CFR Part 46) and the Office for Human Research Protections (OHRP) guidance* on Engagement of Institutions in Human Subjects Research for more information.

Who has the authority to make the final decision on engagement?

This is institution specific, but the decision often lies with one or a combination of the following:

- The Institutional Review Board (IRB) or other Human Research Protection Program (HRPP) office
- Legal counsel
- Department chairs
- Institutional official
- OHRP - in cases of disagreement between reviewing IRB and institution

What information is needed to assess engagement? (See examples in Engagement Scenarios document)

1. A description of the research
2. Which institution is directly receiving research funding?
3. Where are research activities being performed?
4. Who is performing research activities?
   a. What is the relationship of those performing activities to the institution?
   b. For which institution is the research being performed?

Why does it matter if your institution is engaged? What are the implications for the engaged institution?

Responsibilities of your institution when engaged in non-exempt human subjects research:

1. Certify that the research has been reviewed and approved by an IRB on your institution's behalf. In multi-site research using a single IRB:
   a. Execute a reliance agreement, or confirm that a reliance agreement is in place, with the single IRB of record
   b. Determine who will submit materials to the sIRB, PI or some other office, and gain approval from the sIRB of record
2. If research is federally funded, confirm that your institution holds a current OHRP-approved Federalwide Assurance (FWA) to cover the research. If a current FWA is not in place, submit a new filing or update expired version.
3. Develop a plan for reporting noncompliance or research misconduct that may occur as a result of the research.
   a. Include how communication will occur between the study team, institution, sIRB, OHRP, and FDA as applicable.
   b. This may be outlined in your reliance agreement or your own policy and procedures.
4. Complete any additional steps required to conduct research at your institution such as institutional reviews, contracts, and data or equipment use agreements. Consult with your human research protection program/IRB office and research administration for requirements.

***Note:** This guidance is considered an important standard frequently applied to research regardless of funding source. It applies specifically to non-exempt research conducted or supported by the U.S. Department of Health and Human Services (HHS).

To learn more about CTTI's sIRB work, please visit https://www.ctti-clinicaltrials.org/projects/single-irb