sIRB Flowchart: Determining Engagement of Institutions in Research

**PURPOSE:** Assist in determining if activities an institution’s employees or agents perform constitute human subjects research as outlined by the Office for Human Research Protections (OHRP)* and thus engage the institution in that research. When multiple institutions are involved, review flowchart separately for each institution.

**EXPERTISE NEEDED:** Ability to assess -
- who is performing activities,
- where the activities are being performed, and
- the relationship of those performing activities with the institution

**LIMITATIONS:** Intended only as a tool. Contact IRB/other human research protection program (HRPP) office or research administration for final determination. Consult OHRP resources for additional information.

**STEP 1:** Confirm the activity constitutes non-exempt human subjects research and that employees or agents of institution are involved.

Does the activity meet the definition of human subjects research under the Common Rule [45CFR§46.102(l)]?

- **NO**

Are employees or agents of the institution involved in the research?*

- **NO**
- **YES OR MAYBE**

Does the research involving human subjects qualify for exemption under the Common Rule [45CFR§46.104]?

- **NO**
- **YES**

**ENGAGEMENT DOES NOT APPLY. STOP HERE.**

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*Employee/agent defined as individuals who: (1) act on behalf of the institution; (2) exercise institutional authority or responsibility; or (3) perform institutionally designated activities.

"Employees and agents" can include staff, students, contractors, and volunteers, among others, regardless of whether the individual is receiving compensation.
STEP 2: Determine if institution is engaged in the research

Will/has the institution received an award through a grant, contract or cooperative agreement directly from the Department of Health & Human Services for the non-exempt human subjects research?

YES

ENGAGED in non-exempt human subjects research. For multi-site research using a single IRB, ensure engaged institution(s) sign a reliance agreement. Check with institution’s IRB/HRPP for other requirements.

NO

Will the role of the institution be limited EXCLUSIVELY to permitting the use of their facilities for intervention or interaction with subjects by investigators from another institution?

YES

NOT ENGAGED. Other institutional requirements may apply; check with HRPP/IRB office or research administration.

NO

Will the institution’s employees/agents interact for research purposes with any human subjects for the study?

YES

NO

Will the institution’s employees/agents intervene for research purposes with any human subjects in the study by manipulating the environment?

YES

NO

Will the institution’s employees/agents intervene for research purposes in any of the following ways:
- Provide services or procedures, that are dictated by the protocol, and are NOT typically performed by the institution for non-research clinical or commercial purposes?
- Request professional recognition or publication privileges based on services provided for their participation?
- Obtain informed consent from human subjects?
- Administer study intervention being tested or evaluated in the protocol?

YES

NO

Will the institution’s employees/agents obtain identifiable private information and/or identifiable biological specimens for research purposes?

YES

NO

Will the role of the institution’s employees/agents include more than releasing identifiable private information or biological specimens to investigators at another institution for research?