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**
  - **YES**

- Are employees or agents of the institution involved in the research?*
  - **NO**
  - **YES**

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

- Does the research involving human subjects qualify for exemption under the Common Rule [45CFR§46.104]?
  - **NO**
  - **YES**

*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.

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**STEP 2: Determine if institution is engaged in the research**

- **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.

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

**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**
  - **Will the role of the institution’s employees/agents interact for research purposes with any human subjects for the study?**
    - **YES**
      - Will the institution’s employees/agents intervene for research purposes with any human subjects in the study by manipulating the environment?
        - **NO**
          - Will the institution’s employees/agents provide:
            - Clinical trial-related medical services or procedures that are dictated by the research, but performed as part of routine clinical monitoring, care, or follow-up, OR
            - Commercial or other services for investigators typically performed by the institutions for non-research purposes?
              - **NO**
                - Will the institution’s employees/agents obtain identifiable private information and/or identifiable biological specimens for research purposes?
                  - **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?
                      - **NO**
                        - Will 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**
                            - Will the role of the institution’s employees/agents be limited to any of the following activities?
                              - Informing prospective subjects about the availability of the research.
                              - Providing prospective subjects with information about the research (including an informed consent document or other IRB approved materials) but do not obtain subjects’ consent for the research or act as representatives of the investigators.
                              - Providing prospective subjects with information about contacting investigators or enrollment.
                              - Seeking or obtaining prospective subjects’ permission for investigators to contact them.

- **NO**
  - Other institutional requirements may apply; check with HRPP/IRB office or research administration.

**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**
  - Will the institution’s employees/agents obtain identifiable private information and/or identifiable biological specimens for research purposes?
    - **NO**
      - Will the institution’s employees/agents include more than releasing identifiable private information or biological specimens to investigators at another institution for research?
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            - Providing prospective subjects with information about contacting investigators or enrollment.
            - Seeking or obtaining prospective subjects’ permission for investigators to contact them.

- **NO**
  - Other institutional requirements may apply; check with HRPP/IRB office or research administration.