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When is an Institution or PI 'Engaged' in Human Subjects Research?

The Office of Human Research Protection (OHRP) has clarified that there are some activities which fall within the "human subjects research" jurisdiction of the IRB, and some which do not. The following summarizes these clarifications, and explains the responsibilities of the PI.

Institutions Engaged in Research: The Bird's Eye View

1. Awardee Institution: Institution receives an award (grant, contract, cooperative agreement) directly from HHS for non-exempt human subjects research, even though all human subjects research activities are executed by employees or agents of another institution.
2. Active Intervention: Institution's employees or agents intervene (invasive or non-invasive procedures) for research purposes with human subjects.
3. Intervention through Manipulation of Subject's Environment: Institution's employees or agents intervene for research purposes by manipulating human subject's environment, for example: controlling environmental light, sound, or temperature; presenting sensory stimuli; or orchestrating environmental events or social interactions.
4. Interaction with Human Subjects: Institution's employees or agents interact with human subjects by engaging in protocol-dictated communication or interpersonal contact (administering questionnaires, collecting specimens, etc.)
5. Obtaining Informed Consent: Institution's employees or agents are responsible for the informed consent process.
6. Obtaining Private Information about Human Subjects: Institution's employees or agents obtain private information or identifiable biological specimens from any source for the research. Does not require direct interaction or intervention with the human subjects.

Institutions NOT Engaged in Research

1. Provision of Services: Institution's employees or agents provide commercial or other services for investigators, provided that **ALL** of following conditions are met:
   a. the services do not merit professional recognition or publication;
   b. the services are typically performed by the institution for non-research purposes; and
   c. the employees or agents do not administer any study intervention being tested or evaluated under the protocol.

2. Provision of Routine Medical Services Dictated by the Protocol: Institution's employees and agents perform medical services required as part of routine clinical monitoring and/or follow-up of subjects, provided that **ALL** of the following conditions are met:
   a. the employees and agents do not administer the study intervention being tested under the protocol;
   b. the clinical-trial related medical services are typically provided by the institution for clinical purposes;
   c. the employees or agents do not enroll or obtain the informed consent of the subjects;
   d. when appropriate, investigators from a different institution which IS engaged in the research retain responsibility for overseeing protocol-related activities and ensuring that protocol-related data is reported to investigators at the ENGAGED institution.
3. One-time or Short-term Administration of Study Intervention: Institutions not initially selected as a research site for study intervention administer the study intervention on a one-time or short-term basis when a study investigator determines that it is in the subject's best interest to have the intervention administered by the non-engaged institution; the institution does not enroll subjects or obtain the informed consent for the research; oversight for the intervention is performed by investigators from the engaged institution; AND
   a. An IRB designated on the engaged institution's FWA is informed that the study intervention will be administered at an institution not selected as a research site.
4. Recruitment or Referral: Institution's employees or agents inform prospective subjects about the availability of a study, provide them with information about a study, provide prospective subjects with contact information for the investigators, or seek or obtain permission from prospective subjects for the investigators to contact them.
5. Provision of Access to Institution Facilities: Institution provides access to its facilities to investigators from another institution.
6. Release of Identifiable Information: Institutions whose employees or agents release to investigators at another institution private information or identifiable specimens associated with subjects in the research. (Such release must comply with regulations, institution policies, IRB review requirements, and terms of informed consent documents, if appropriate.)
7. Obtain Coded Private Information Without Access to the Link: Institutions whose employees or agents obtain coded private information or biological specimens but are unable to readily ascertain the identity of the subjects.

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Responsibility of the Principal Investigator: Grassroots View

Every human subjects research protocol must have at least one person associated with an institution that is "Engaged in the Research" who is responsible for "oversight of the intervention." "Oversight of the intervention" includes the oversight of all study activities that involve the human subjects, including: recruitment, consent, and all protocol directed study procedures, including the study intervention or interaction. The Principal Investigator who has oversight responsibility must have the authority to direct the employees and agents of his or her institution, or those of a collaborating institution, as to how to execute the protocol-directed study procedures and to implement all human subjects protections required by the reviewing IRB.

1. Subcontracts: If the PI of a study subcontracts some of the study activities to another institution, the JHSPH IRB retains the human subjects oversight responsibilities. That oversight must include regular on-site supervision of the study activities that involve human subjects.

   Study supervision by the PI at the awardee institution requires an on-site presence by that PI. Some aspects of study oversight may be delegated to co-investigators, or other agents or employees of the PI, so long as the study procedures and standards are clearly recorded in a standard operating manual. However, the PI must monitor adherence to those operations, and on-site monitoring is the only way to make sure that the study is proceeding according to plan.

2. Collaborations Among Research Institutions: When there are multiple institutions engaged in a research project, the research application must be very clear as to what each institution will be contributing to the project, and who will serve as the oversight investigator for the study activities that involve human subjects.