Individual and Institutional Engagement in Research

This guidance assists investigators in determining whether the role of an individual on a research study constitutes engagement in human subjects research. Engagement determinations allow investigators to decide which individuals to list as study team member in OnCore or what institutions to list as participating sites in the research. Investigators should review the Engagement Determination worksheet available on the Office for Human Research Studies (OHRS) website when considering whether or not their role on a project constitutes engagement in research.

In 2008 the Office of Human Research Protections (OHRP) issued guidance on the Engagement of Institutions in Research and provides examples of when an institution is considered engaged. In all cases, if an investigator receives federal funds to conduct human subjects research, the institution receiving the award is considered engaged even if the investigator does not participate in the conduct of the research.

When are Institutions considered Engaged in research?

Institutions are considered engaged in human subjects research if their agents or employees:

1. Receive an award through a grant, contract, or cooperative agreement directly from a federal agency for the non-exempt human subjects research (i.e. awardee institutions), even where all activities involving human subjects are carried out by employees or agents of another institution.
2. Intervene for research purposes with any human subjects of the research by performing invasive or noninvasive procedures.
3. Intervene for research purposes with any human subject of the research by manipulating the environment.
4. Interact for research purposes with any human subject of the research.
5. Obtain the informed consent of human subjects for the research.
6. Obtain, for research purposes, identifiable private information[i] or identifiable biological specimens from any source for the research.
    - In general, institutions whose employees or agents obtain identifiable private information or identifiable specimens for non-exempt human subjects research are considered engaged in the research, even if the institution's employees or agents do not directly interact or intervene with human subjects.
    - In general, obtaining identifiable private information or identifiable specimens includes, but is not limited to:
        a. observing or recording private behavior;
        b. using, studying, or analyzing for research purposes identifiable private information or identifiable specimens provided by another institution; and

c. using, studying, or analyzing for research purposes identifiable private information or identifiable specimens already in the possession of the investigators.

When are Institutions <u>not</u> considered to be Engaged in research?

The following scenarios describe the types of institutional involvement that make an institution not engaged in human subjects research, even if a condition in Section 1 above is met:

1. Institutions whose employees or agents perform commercial or other services for investigators provided that all of the following conditions also are met:
    a. the services performed do not merit professional recognition or publication privileges;
    b. the services performed are typically performed by those institutions for non-research purposes; and
    c. the institution's employees or agents do not administer any study intervention being tested or evaluated under the protocol.
2. Institutions whose employees or agents provide clinical trial-related medical services that are dictated by the protocol and would typically be performed as part of routine clinical monitoring and/or follow-up of subjects enrolled at a study site by clinical trial investigators, provided that all of the following conditions are also met:
    a. The organization's employees or agents do not administer the study interventions being tested or evaluated under the protocol.
    b. The clinical trial-related medical services are typically provided by the organization for clinical purposes.
    c. The organization's employees or agents do not enroll <u>Human Subjects</u> or obtain the informed consent of any <u>Human Subject</u> for participation in the <u>Research</u>.
    d. When appropriate, investigators from an organization engaged in the <u>Research</u> retain responsibility for **ALL** of the following:
        i. Overseeing protocol-related activities.
        ii. Ensuring appropriate arrangements are made for reporting protocol-related data to investigators at an engaged organization, including the reporting of safety monitoring data and adverse events as required under the IRB-approved protocol.
        iii.
3. Institutions whose employees or agents administer the study interventions being tested or evaluated under the protocol limited to a one-time or short-term basis where an investigator from an organization engaged in the <u>Research</u> determines that it would be in the <u>Human Subject</u>'s best interest to receive the study interventions being tested or evaluated under the protocol and **ALL** of the following are true:

   a. The organization's employees or agents do not enroll Human Subjects or obtain the informed consent of any Human Subject for participation in the Research
   b. Investigators from the organization engaged in the Research retain responsibility for **ALL** of the following:
      i. Overseeing protocol-related activities
      ii. Ensuring the study interventions are administered in accordance with the IRB-approved protocol.
      iii. Ensuring appropriate arrangements are made for reporting protocol-related data to investigators at the engaged organization, including the reporting of safety monitoring data and adverse events as required under the IRB-approved protocol. and
   c. An IRB designated on the engaged organization's federalwide assurance (FWA) is informed that study interventions being tested or evaluated under the protocol have been administered at an organization not selected as a researh site.
4. Institutions whose employees or agents:
   a. inform prospective subjects about the availability of the research,
   b. provide prospective subjects with information about the research but do not obtain consent or act as representatives of the investigators,
   c. provide prospective subjects with information about contacting investigators for information or enrollment; and/or
   d. seek or obtain the prospective subjects' permission for investigators to contact them.
5. Institutions that permit use of their facilities for intervention or interaction with subjects by investigators from another institution.
6. Institutions whose employees or agents release to investigators at another institution identifiable private information or identifiable biological specimens pertaining to the subjects of the research[ii].
7. Institutions whose employees or agents:
   a. obtain coded private information or human biological specimens from another institution involved in the research that retains a link to individually identifying information (such as name or social security number); and
   b. are unable to readily ascertain the identity of the subjects to whom the coded information or specimens pertain.
8. Institutions whose employees or agents author a paper, journal article, or presentation describing a human subjects research study
9. Institutions whose employees or agents access or utilize individually identifiable private information only while visiting an organization that is engaged in the Research, provided their Research activities are overseen by the IRB of the organization that is engaged in the Research
10. Institutions whose employees or agents access or review identifiable private information for purposes of study auditing.

11. Institutions whose employees or agents receive identifiable private information for purposes of satisfying U.S. Food and Drug Administration reporting requirements.

Resources

Office of Human Research Protections Guidance on Engagement of Institutions in Human Subjects Research (2008)

[i] In general, OHRP considers private information or specimens to be individually identifiable as defined in 45 CFR 46.102(f) when they can be linked to specific individuals by the investigator(s) either directly or indirectly through coding systems.

[ii] Note that in some cases the institution releasing identifiable private information or identifiable biological specimens may have institutional requirements that would need to be satisfied before the information or specimens may be released, and/or may need to comply with other applicable regulations or laws. In addition, if the identifiable private information or identifiable biological specimens to be released were collected for another research study covered by 45 CFR part 46, then the institution releasing such information or specimens should: a).ensure that the release would not violate the informed consent provided by the subjects to whom the information or biological specimens pertain (under 45 CFR 46.116), or b) if informed consent was waived by the IRB, ensure that the release would be consistent with the IRB's determinations that permitted a waiver of informed consent under 45 CFR 46.116 (c) or (d).