HUMAN RESEARCH PROTECTION

Engagement determination

Number 107 Version date 2008 (OHRP)

Resource type GUIDANCE

This worksheet may be used for determinations when there is uncertainty whether our institution is engaged in Human Research. "Engagement" means that our human research protection program is responsible for the Human Research. As subject to DHHS or other federal agencies that have adopted "The Common Rule," engagement applies only to non- exempt Human Research.

1. Condition in which our organization is **engaged in Research**

1.1 ☐ Our institution receives an award through a grant, contract, or cooperative agreement directly from a federal agency for non-exempt Human Research, even where all activities involving Human Subjects are carried out by employees of another institution.

2. If **ANY** of the following apply, our organization is **conditionally engaged in research**

2.1 ☐ Our employees intervene for Research purposes with any Human Subject of the Research by performing invasive or noninvasive procedures.

2.2 ☐ Our employees intervene for Research purposes with any Human Subject of the Research by manipulating the environment.

2.3 ☐ Our employees interact for Research purposes with any Human Subject of the Research.

2.4 ☐ Our employees obtain the informed consent of Human Subjects for the Research.

2.5 ☐ Our employees obtain for Research purposes identifiable private information or identifiable biological specimens from any source for the Research, even if our organization's employees do not directly interact or intervene with Human Subjects.

3.* If **ANY** of the following apply, our organization is **NOT engaged in research**, even if any of the conditions under 2 are met

3.1 ☐ Our employees perform commercial or other services for Research investigators provided that **ALL** of the following conditions also are met:

- ☐ The services performed do not merit professional recognition or publication privileges.
- ☐ The services performed are routinely performed by our organization for non-Research purposes.
- ☐ Our employees do not administer any study intervention being tested or evaluated under the protocol.

3.2 ☐ Our organization is not selected as a Research site but our employees provide clinical trial-related medical services that are dictated by the protocol that would **typically be performed as part of routine clinical monitoring or follow-up** of Human Subjects enrolled at a study site provided that **ALL** of the following conditions also are met:

- ☐ Our organization's employees do not administer the study interventions being tested or evaluated under the protocol.
- ☐ The clinical trial-related medical services are routinely provided by our organization for clinical purposes.
- ☐ Our organization's employees do not enroll Human Subjects or obtain the informed consent of any Human Subject for participation in the Research.
- ☐ As applicable, investigators from the institution engaged in the Research retain responsibility for **BOTH** of the following:
  - ☐ *Oversight of protocol-related activities.*
  - ☐ *Reporting of protocol-related data to investigators at an engaged institution, including the reporting of safety monitoring data and adverse events as required under the IRB-approved protocol.*

3.3 ☐ Our organization was not initially selected as a Research site but our employees administer study interventions being tested or evaluated under the protocol **limited to a one-time or short-term basis** provided that **ALL** of the following are true:

- ☐ An investigator from an institution engaged in the Research determines that it would be in the Human Subject's best interest to receive the study interventions being tested or evaluated under the protocol;
- ☐ Our employees do not enroll Human Subjects or obtain the informed consent of any Human Subject for participation in the Research;
- ☐ Investigators from the organization engaged in the Research retain responsibility for ***ALL*** of the following:
  - ☐ *Oversight of protocol-related activities*
  - ☐ *Ensuring the study interventions are administered in accordance with the IRB-approved protocol*
  - ☐ *Reporting protocol-related data to investigators at an engaged institution, including the reporting of safety monitoring data and adverse events as required under the IRB-approved protocol;*
- ☐ An IRB designated on the engaged institution's federalwide assurance (FWA) is informed that study interventions being tested or evaluated under the protocol have been administered at an institution not selected as a Research site.

3.4 ☐ Our employees do **ANY** of the following:

- ☐ Inform prospective Human Subjects about the availability of the Research.
- ☐ Provide prospective Human Subjects with information about the Research but do not obtain Human Subjects' consent for the Research or act as representatives of the investigators.
- ☐ Provide prospective Human Subjects with information about contacting investigators for information or enrollment.
- ☐ Seek or obtain the prospective Human Subjects' permission for investigators to contact them.

3.5 ☐ Our institution is permitting use of its facilities for intervention or interaction with Human Subjects by investigators from another institution.

3.6 ☐ Our institution releases to investigators at another institution identifiable private information or identifiable biological specimens pertaining to the Human Subjects of the Research.

3.7 ☐ Our employees obtain coded private information or human biological specimens from another institution involved in the Research AND are unable to readily ascertain the identity of the Human Subjects to whom the coded information or specimens pertain.

3.8 ☐ Our employees access or use individually identifiable private information only while visiting an institution that is engaged in Research, provided their Research activities are overseen by the IRB of the institution that is engaged in the Research.

3.9 ☐ Our employees access or review identifiable private information for purposes of study auditing.

3.10 ☐ Our employees receive identifiable private information for purposes of satisfying U.S. Food and Drug Administration reporting requirements.

3.11 ☐ Our employees author a paper, journal article, or presentation describing a Human Research study.

*NOTE: There may be other applicable regulations, laws, and/or institutional requirements that need to be satisfied even when our organization isn't engaged in research

Definitions

Employees

For the purpose of this worksheet, “Employees” refers to our employees or agents who: (1) act on behalf of our organization; (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. Contact legal counsel for additional information regarding whether an individual is an agent of our organization.

Human Subject is defined in 45 CFR 46.102(f) as follows:

Human subject means a living individual about whom an investigator (whether professional or student) conducting research obtains

1. data through intervention or interaction with the individual, or
2. identifiable private information.

Intervention includes both physical procedures by which data are gathered (for example, venipuncture) and manipulations of the subject or the subject’s environment that are performed for research purposes. Interaction includes communication or interpersonal contact between investigator and subject. *Private information* includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical record). Private information must be individually identifiable (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information) in order for obtaining the information to constitute research involving human subjects.

Research is defined in 45 CFR 46.102(d) as follows:

Research means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Activities which meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program which is considered research for other purposes. For example, some demonstration and service programs may include research activities.

Source:
Engagement of Institutions in Human Subjects Research (2008), OHRP
https://www.hhs.gov/ohrp/regulations-and-policy/guidance/guidance-on-engagement-of-institutions/index.html