New York University
University Committee on Activities Involving Human Subjects
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Worksheet on Engagement in Human Subjects Research

Directions

This worksheet is intended to help in determine if an institution is engaged in human subjects[1] research[2]. It is based on OHRP's guidance document *Engagement of Institutions in Human Subjects Research* (2008). It is for informational purposes and does not need to be submitted to the NYU IRB.

Employees or agents are individuals who: (1) act on behalf of the institution; (2) exercise institutional authority or responsibility; or (3) perform institutionally designated activities. They can include staff, students, contractors, and volunteers, among others, regardless of whether the individual is receiving compensation. If an institution is engaged in human subjects research, then an IRB designated under an OHRP-approved Federalwide Assurance must approve the research on behalf of the engaged institution. See OHRP's FWA website for more information.

Section 1: Conditions under which an institution is engaged WITHOUT exception	
☐	(A) The 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 or agents[3] of another institution.
☐	(B) The institution's employees or agents obtain the informed consent of human subjects for the research.
☐	(C) The institution is initially selected as a research site and its employees or agents administer the study intervention(s) being studied or evaluated under the protocol (e.g., a clinic initially identified as a research site whose clinicians administer a mental health treatment being evaluated under the study protocol).
STOP if at least one of the conditions in Section 1 is met. The institution is engaged in human subjects research. Continue to Section 2 if none of the conditions in Section 1 are met.	

Section 2: Conditions under which an institution may be engaged	
☐	(A) The institution's employees or agents intervene for research purposes with any human subject of the research by performing invasive or noninvasive procedures (e.g., drawing blood, collecting buccal mucosa cells using a cotton swab, administering individual or group counseling or psychotherapy, administering drugs or other treatments, surgically implanting medical devices, utilizing physical sensors, and utilizing other measurement procedures).
☐	(B) The institution's employees or agents intervene for research purposes with any human subject of the research by manipulating the environment (e.g., controlling environmental light, sound, or temperature; presenting sensory stimuli; and orchestrating environmental events or social interactions).
☐	(C) The institution's employees or agents interact for research purposes with any human subject of the research (e.g., engaging in protocol dictated communication or interpersonal contact, asking someone to provide a specimen by voiding or spitting into a specimen container, and conducting research interviews or administering questionnaires).
☐	(D) The institution's employees or agents obtain for research purposes identifiable private information or identifiable biological specimens from any source for the research (e.g., observing or recording private behavior and using, studying, or analyzing for research purposes identifiable private information or identifiable specimens provided by another institution or already in the possession of the investigators). It is important to note that, in general, institutions whose employees or agents obtain identifiable private information or identifiable specimens for 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.
STOP if none of the conditions in Sections 1 or 2 are met. The institution is NOT engaged in human subjects research. Continue to Section 3 if one or more of the conditions in Section 2 are met.	

[1] Human subject refers to 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.
[2] Research refers to a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge
[3] An institution's employees or agents refers to 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.

Section 3: Conditions under which an institution is NOT engaged even though a condition in Section 2 is met

☐ (A) The institution's employees or agents perform commercial or other services for investigators provided that all of the following conditions also are met:

- ☐ (i) The services performed do not merit professional recognition or publication privileges
- ☐ (ii) The services performed are typically performed by the institution for non-research purposes.
- ☐ (iii) The institution's employees or agents do not administer any study intervention being tested or evaluated under the protocol.

☐ (B) The institution is not selected as a research site but its employees or agents 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 by clinical trial investigators provided that **ALL** of the following conditions also are met:

- ☐ (i) The institution's employees or agents do not administer the study interventions being tested or evaluated under the protocol.
- ☐ (ii) The clinical trial-related medical services are typically provided by the institution for clinical purposes.
- ☐ (iii) The institution's employees or agents do not enroll human subjects or obtain the informed consent of any human subject for participation in the research.
- ☐ (iv) When appropriate, investigators from an institution engaged in the research retain responsibility for **ALL** of the following:
  - ☐ (a) Overseeing protocol-related activities.
  - ☐ (b) Ensuring appropriate arrangements are made for 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.

☐ (C) The institution was not initially selected as a research site but the institution's 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 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 and **ALL** of the following are true:

- ☐ (i) The institution's employees or agents do not enroll human subjects or obtain the informed consent of any human subject for participation in the research.
- ☐ (ii) Investigators from the institution engaged in the research retain responsibility for **ALL** of the following:
  - ☐ (a) Overseeing protocol-related activities.
  - ☐ (b) Ensuring the study interventions are administered in accordance with the IRB-approved protocol.
  - ☐ (c) Ensuring appropriate arrangements are made for reporting protocol-related data to investigators at the engaged institution, including the reporting of safety monitoring data and adverse events as required under the IRB-approved protocol.
- ☐ (iii) 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.

☐ (D) The institution's employees or agents' activities are limited to any of the following:

- Informing prospective human subjects about the availability of the research.
- Providing 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.
- Providing prospective human subjects with information about contacting investigators for information or enrollment.
- Seeking or obtaining the prospective human subjects' permission for investigators to contact them.

☐ (E) The institution permits use of its facilities for intervention or interaction with human subjects by investigators from another institution. (e.g., a school that permits investigators from another institution to distribute research surveys in the classroom or a business that permits investigators from another institution to recruit its employees for the research).

☐ (F) The institution's employees or agents release to investigators at another institution identifiable private information or identifiable biological specimens pertaining to the human subjects of the research.

Section 3 Continued		
☐	(G) The institution's employees or agents:	
	☐	(i) Obtain coded private information or human biological specimens from another institution involved in the research that retains a link to individually identifying information
	☐	(ii) Are unable to readily ascertain the identity of the human subjects to whom the coded information or specimens pertain.
☐	(H) The institution's employees or agents access or utilize individually identifiable private information only while visiting an institution that is engaged in the research, provided their research activities are overseen by the IRB of the institution that is engaged in the research.	
☐	(I) The institution's employees or agents access or review identifiable private information for purposes of study auditing (e.g., a government agency will have access to individually identifiable study data for auditing purposes).	
☐	(J) The institution's employees or agents receive identifiable private information for purposes of satisfying U.S. Food and Drug Administration reporting requirements.	
☐	(K) The institution's employees or agents author a paper, journal article, or presentation describing a human research study.	

STOP

The institution is engaged in human subjects research if at least one of the conditions in Section 2 is met and NONE of the conditions in Section 3 are met.

The institution is NOT engaged in human subjects research if at least one of the conditions in Section 2 is met and the institutions' activities are limited to one or more of the conditions in Section 3.