UC San Diego INSTITUTIONAL REVIEW BOARD ADMINISTRATION	**OIA-311 WORKSHEET:** Engagement Determination		
	NUMBER	DATE	PAGE
	OIA-311	09/06/2023	1 of 2

The purpose of this worksheet is to provide support for designated reviewers making engagement determinations when there is uncertainty regarding whether the institution is engaged in human research. For the purpose of this worksheet, "engagement" means that the institution's human research protection program is responsible for the human research. For the purposes of being subject to requirements of Department of Health and Human Services (DHHS) or other federal agencies that have adopted "The Common Rule," engagement applies only to non-exempt human research. This worksheet, or equivalent, is to be used. It does not need to be completed or retained.

The institution is engaged in the research if the first item in section 1 is true regardless of whether the institution's involvement is limited to one or more of the items in section 2.

The institution is engaged in the research if any item other than the first item in section 1 are true except when the institution's involvement is limited to one or more of the items in section 2.

	1 Conditions Under Which an Institution is Engaged
☐	The institution receives an award through a grant, contract, or cooperative agreement directly from a federal agency for non-exempt human research, even if all activities involving human subjects are carried out by employees or agents[1] of another institution.
☐	The institution's employees or agents intervene for research purposes with any human subject of the research by performing invasive or noninvasive procedures.
☐	The institution's employees or agents intervene for research purposes with any human subject of the research by manipulating the environment.
☐	The institution's employees or agents interact for research purposes with any human subject of the research.
☐	The institution's employees or agents obtain the informed consent of human subjects for the research.
☐	The institution's employees or agents obtain for research purposes identifiable private information or identifiable biospecimens from any source for the research. It is important to note that, in general, if the institution's employees or agents obtain identifiable private information or identifiable biospecimens for human research, they are considered engaged in the research, even if the institution's employees or agents do not directly interact or intervene with human subjects.

[1] 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. Contact legal counsel for additional information regarding whether an individual is an agent of the institution.

2 Conditions Under Which an Institution is Not Engaged Even Though a Condition in Section 1 is Met

- ☐ The institution's employees or agents perform commercial or other services for 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 typically performed by those institutions for non-research purposes.
  - ☐ The institution's employees or agents do not administer any study intervention being tested or evaluated under the protocol.
- ☐ 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:
  - ☐ The institution's employees or agents do not administer the study interventions being tested or evaluated under the protocol.
  - ☐ The clinical trial-related medical services are typically provided by the institution for clinical purposes.
  - ☐ 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.
  - ☐ When appropriate, investigators from an institution engaged in the research retain responsibility for **ALL** of the following:
    - ☐ Overseeing protocol-related activities.
    - ☐ 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.
- ☐ 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:
  - ☐ 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.
  - ☐ Investigators from the institution engaged in the research retain responsibility for **ALL** of the following:
    - ☐ Overseeing protocol-related activities.
    - ☐ Ensuring the study interventions are administered in accordance with the IRB-approved protocol.
    - ☐ 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, and
  - ☐ 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.
- ☐ The institution's employees or agents 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.
- ☐ The institution is permitting use of its facilities for intervention or interaction with human subjects by investigators from another institution.
- ☐ The institution's employees or agents release to investigators at another institution identifiable private information or identifiable biospecimens pertaining to the human subjects of the research.
- ☐ The institution's employees or agents:
  - ☐ Obtain coded private information or human biological specimens from another institution involved in the research that retains a link to individually identifying information and
  - ☐ Are unable to readily ascertain the identity of the human subjects to whom the coded information or specimens pertain.
- ☐ 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.
- ☐ The institution's employees or agents access or review identifiable private information for purposes of study auditing.
- ☐ The institution's employees or agents receive identifiable private information for purposes of satisfying U.S. Food and Drug Administration (FDA) reporting requirements.
- ☐ The institution's employees or agents author a paper, journal article, or presentation describing a human research study.