TEXAS A&M UNIVERSITY	WORKSHEET: Engagement		
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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 DHHS or other federal agency that has adopted "The Common Rule" engagement applies only to non-exempt Human Research. This worksheet is to be used. It does not need to be completed or retained. [1]

1 FDA Exception for "Engagement" (Check if "Yes")

☐	**ONLY** FDA regulations apply to this Human Research as indicated in the "Regulatory Oversight" section on HRP-401 - CHECKLIST - Pre-Review/Submit Pre-Review activity (DHHS regulations or any other Federal agency that has adopted the Common Rule are NOT checked in in the "Regulatory Oversight" section on HRP-401 - CHECKLIST - Pre-Review /Submit Pre-Review activity).

If ONLY FDA regulations apply, **STOP**. The FDA does not have a comparable process that aligns with OHRP's engagement guidance since FDA regulations govern sponsors (and parties they contract with), clinical investigators, and IRBs (and do not address institutions/organizations). If an organization is conducting certain activities of FDA (only) regulated Human Research, determining whether an institution/organization requires IRB oversight depends on many details such as:

- What type of activities are being conducted.
- What the protocol requires.
- Who is conducting the activities.
- Where the activities are being conducted.
- For what purpose the activities are being conducted.

FDA recommends referring to FDA Information Sheet "Use of Investigational Products When Subjects Enter a Second Institution, *Guidance for Institutional Review Boards and Clinical Investigators* (January 1998)" for guidance and to contact the sponsor and/or applicable FDA review division for assistance.[2]

The organization is engaged in the research if the first item in section 2 is true regardless of whether the organization's involvement is limited to one or more of the items in section 3.

The organization is engaged in the research if any item other than the first item in section 2 are true except when the organization's involvement is limited to one or more of the items in section 3.

2 Conditions Under Which an Organization is Engaged

☐	The organization 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 organization.
☐	The organization's employees or agents intervene for Research purposes with any Human Subject of the Research by performing invasive or noninvasive procedures
☐	The organization's employees or agents intervene for Research purposes with any Human Subject of the Research by manipulating the environment.
☐	The organization's employees or agents interact for Research purposes with any Human Subject of the Research.
☐	The organization's employees or agents obtain the informed consent of Human Subjects for the Research.
☐	The organization's employees or agents obtain for Research purposes identifiable private information or identifiable biological specimens from any source for the Research. It is important to note that, in general, the organization's employees or agents obtain identifiable private information or identifiable specimens for Human Research are considered engaged in the Research, even if the organization's employees or agents do not directly interact or intervene with Human Subjects.

[1] This document satisfies AAHRPP element I.1.A

[2] Huron email correspondence with FDA GCP Program dated October 13, 2020.

[3] An organization'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 organization.

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3 Conditions Under Which an Organization is Not Engaged Even Though a Condition in Section 2 is Met

- ☐ The organization'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 organizations for non-Research purposes.
  - ☐ The organization's employees or agents do not administer any study intervention being tested or evaluated under the protocol.
- ☐ The organization 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 organization'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 organization for clinical purposes.
  - ☐ 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.
  - ☐ When appropriate, investigators from an organization 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 organization, including the reporting of safety monitoring data and adverse events as required under the IRB-approved protocol.
- ☐ The organization was not initially selected as a Research site but the organization'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 organization 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 organization'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 organization 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 organization, including the reporting of safety monitoring data and adverse events as required under the IRB-approved protocol. and
  - ☐ 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 Research site.
- ☐ The organization'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 organization is permitting use of its facilities for intervention or interaction with Human Subjects by investigators from another organization.
- ☐ The organization's employees or agents release to investigators at another organization identifiable private information or identifiable biological specimens pertaining to the Human Subjects of the Research.
- ☐ The organization's employees or agents:
  - ☐ Obtain coded private information or human biological specimens from another organization 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 organization's 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.
- ☐ The organization's employees or agents access or review identifiable private information for purposes of study auditing.
- ☐ The organization's employees or agents receive identifiable private information for purposes of satisfying U.S. Food and Drug Administration reporting requirements.

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