TEXAS A&M UNIVERSITY CORPUS CHRISTI

Engagement Determination			
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The purpose of this checklist is to provide support for making engagement determinations when there is uncertainty regarding whether the organization or employee is engaged in Human Research. For the purpose of this worksheet, "Engagement" means that the organization's human research protection program is responsible for the Human Research. This worksheet is to be used. It does not need to be completed or retained.

An organiza**tion is engaged in research if any item in section 1 is true** and an exception in section 2 does not apply

1 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[1] 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. NOTE: 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] 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.

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

- ☐ Performs commercial or services for investigators. **ALL** of the following conditions must be met:
  - ☐ Services performed do not merit professional recognition or publication privileges.
  - ☐ Services performed are typically performed by those organizations for non-Research purposes.
  - ☐ Organization's employees/agents do not administer any study intervention being tested or evaluated.
- ☐ Organization is not selected as a research site but its employees/agents provide clinical trial-related medical services that would typically be performed as part of routine clinical monitoring or follow-up. **ALL** must be met:
  - ☐ Organization's employees/agents do not administer the study interventions being tested under the protocol.
  - ☐ Clinical trial-related medical services are typically provided by the organization for clinical purposes.
  - ☐ Organization's employees/agents do not enroll Human Subjects or obtain the informed consent from subjects.
  - ☐ Investigators from an organization engaged in the Research retain responsibility for **ALL** of the following:
    - ☐ Overseeing protocol-related activities.
    - ☐ 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.
- ☐ Organization is not selected as a research site but organization's employees/agents administers study interventions on a limited to a one-time or short-term basis where an investigator from an engaged organization determines it is in the Human Subject's best interest to receive the study interventions being tested. **ALL** of the following are true:
  - ☐ Organization's employees/agents do not enroll Human Subjects or obtain the informed consent of subjects.
  - ☐ 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 safety monitoring data and adverse events
  - ☐ IRB is informed study interventions have been administered at an organization not selected as a Research site.
- ☐ The organization's employees or agents interactions are limited only to 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.
  - ☐ Seek or obtain the prospective Human Subjects' permission for investigators to contact them.
- ☐ Organization is permitting use of its facilities for research by investigators from another organization.
- ☐ Organization's employees/agents releases 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 identity of the Human Subjects to whom coded information/specimens pertain.
- ☐ Organization's employees/agents access/utilize individually identifiable private information while visiting an engaged organization, provided their Research activities is overseen by the IRB of the engaged organization.
- ☐ Organization's employees/agents access or review identifiable private information for purposes of study auditing.
- ☐ The organization's employees/agents receive identifiable private information for purposes of satisfying FDA.
- ☐ Organization's employees/agents author journal article or presentation describing a Human Research study.