



## Non-Engagement Determination

The purpose of this checklist is to provide support for Designated Reviewers making engagement determinations when there is uncertainty regarding whether the organization 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. 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 checklist is to be completed by the Designated Reviewer, signed, dated, and retained.

**The organization is engaged in the research if any item in section 1 are true except when the organization’s involvement is limited to one or more of the items in section 2**

### 1 Conditions Under Which an Organization is Engaged

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|--------------------------|--|
| <input type="checkbox"/> | The organization receives an award through a grant, contract, or cooperative agreement directly from a federal agency for the <u>Human Research</u> , even where all activities involving Human Subjects are carried out by employees or agents <sup>1</sup> of another organization.  |
| <input type="checkbox"/> | The organization’s employees or agents intervene for research purposes with any <u>Human Subjects</u> of the research by performing invasive or noninvasive procedures   |
| <input type="checkbox"/> | The organization’s employees or agents intervene for research purposes with any <u>Human Subject</u> of the research by manipulating the environment.  |
| <input type="checkbox"/> | The organization’s employees or agents interact for research purposes with any <u>Human Subject</u> of the research.   |
| <input type="checkbox"/> | The organization’s employees or agents obtain the informed consent of <u>Human Subjects</u> for the research.  |
| <input type="checkbox"/> | 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 <u>Human Research</u> are considered engaged in the research, even if the organization’s employees or agents do not directly interact or intervene with <u>Human Subjects</u> . |

<sup>1</sup> 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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| <b>2 Conditions Under Which an Organization is Not Engaged Even Though a Condition in Section 1 is Met</b> |   |
|--|---|
| <input type="checkbox"/>   | The organization's employees or agents perform commercial or other services for investigators provided that <b>ALL</b> of the following conditions also are met:  |
| <input type="checkbox"/>   | The services performed do not merit professional recognition or publication privileges.   |
| <input type="checkbox"/>   | The services performed are typically performed by those organizations for non-research purposes.  |
| <input type="checkbox"/>   | The organization's employees or agents do not administer any study intervention being tested or evaluated under the protocol.   |
| <input type="checkbox"/>   | 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 subjects enrolled at a study site by clinical trial investigators provided that <b>ALL</b> of the following conditions also are met:   |
| <input type="checkbox"/>   | The organization's employees or agents do not administer the study interventions being tested or evaluated under the protocol.  |
| <input type="checkbox"/>   | The clinical trial-related medical services are typically provided by the organization for clinical purposes.   |
| <input type="checkbox"/>   | The organization's employees or agents do not enroll subjects or obtain the informed consent of any subject for participation in the research.  |
| <input type="checkbox"/>   | When appropriate, investigators from an organization engaged in the research retain responsibility for <b>ALL</b> of the following:   |
| <input type="checkbox"/>   | Overseeing protocol-related activities.   |
| <input type="checkbox"/>   | 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.   |
| <input type="checkbox"/>   | 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 subject's best interest to receive the study interventions being tested or evaluated under the protocol and <b>ALL</b> of the following are true: |
| <input type="checkbox"/>   | The organization's employees or agents do not enroll subjects or obtain the informed consent of any subject for participation in the research.  |
| <input type="checkbox"/>   | Investigators from the organization engaged in the research retain responsibility for <b>ALL</b> of the following:  |
| <input type="checkbox"/>   | Overseeing protocol-related activities.   |
| <input type="checkbox"/>   | Ensuring the study interventions are administered in accordance with the IRB-approved protocol.   |
| <input type="checkbox"/>   | 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  |
| <input type="checkbox"/>   | An IRB designated on the engaged organization's 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.  |
| <input type="checkbox"/>   | The organization's employees or agents do <b>ANY</b> of the following:  |
| <input type="checkbox"/>   | Inform prospective subjects about the availability of the research.   |
| <input type="checkbox"/>   | Provide prospective subjects with information about the research but do not obtain subjects' consent for the research or act as representatives of the investigators.   |
| <input type="checkbox"/>   | Provide prospective subjects with information about contacting investigators for information or enrollment.   |
| <input type="checkbox"/>   | Seek or obtain the prospective subjects' permission for investigators to contact them.  |
| <input type="checkbox"/>   | The organization is permitting use of its facilities for intervention or interaction with subjects by investigators from another organization.  |
| <input type="checkbox"/>   | The organization's employees or agents release to investigators at another organization identifiable private information or identifiable biological specimens pertaining to the subjects of the research.   |
| <input type="checkbox"/>   | The organization's employees or agents:   |
| <input type="checkbox"/>   | Obtain coded private information or human biological specimens from another organization involved in the research that retains a link to individually identifying information. and  |
| <input type="checkbox"/>   | Are unable to readily ascertain the identity of the subjects to whom the coded information or specimens pertain.  |
| <input type="checkbox"/>   | 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.   |
| <input type="checkbox"/>   | The organization's employees or agents access or review identifiable private information for purposes of study auditing .   |
| <input type="checkbox"/>   | The organization's employees or agents receive identifiable private information for purposes of satisfying U.S. Food and Drug Administration reporting requirements.  |
| <input type="checkbox"/>   | The organization's employees or agents author a paper, journal article, or presentation describing a <u>Human Research</u> study.   |

**Attach completed checklists that need to be filed and documentation of protocol-specific findings justifying regulatory determinations.**



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|---------------------|--|-------|--|
| Reviewer Signature: |  | Date: |  |
|---------------------|--|-------|--|