

# WORKSHEET: Engagement

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This worksheet is used to determine whether an organization (or organization's site) is engaged in research.

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**1. Unconditional engagement criterion (The organization is engaged if the following criterion is met)**

1.1  The organization receives funding directly from a federal department or agency (other than DOD) for non-exempt research.

**2. Conditional engagement criteria: (The organization is engaged if any of the following are true, unless criterion in Section 3 are met)**

2.1  Employees or agents will obtain data about subjects through interaction for research purposes (see Footnote 1)

2.2  Employees or agents will obtain data about subjects through intervention for research purposes

2.3  Employees or agents will obtain informed consent of subjects to take part in the research

2.4  Employees or agents will obtain identifiable private information about subjects for research purposes

**3. Engagement exclusion criteria: (The organization is not engaged if all Section 2 criteria are situations where one or more of the following are true.)**

3.1  Employees or agents will perform commercial or other services for investigators, where all of the following are true:

- 1) The services performed do not merit professional recognition or publication privileges
- 2) The services performed are typically performed by those organizations for purposes other than research
- 3) Employees or agents do not administer any study intervention being tested or evaluated under the protocol

3.2  The organization was not selected as a research site, but employees or agents will provide clinical trial-related medical services that are dictated by the protocol and are typically performed as part of routine clinical monitoring or follow-up of subjects enrolled at a study site by clinical trial investigators, where all of the following are true:

- 1) Employees or agents do not administer the interventions being tested or evaluated under the protocol
- 2) The clinical trial-related medical services are typically provided by the organization for clinical purposes
- 3) The organization's employees or agents do not enroll subjects or obtain the informed consent of subjects to take part in the research
- 4) When appropriate, investigators from an engaged organization retain responsibility for both:
  - a) Overseeing protocol-related activities
  - b) 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 by the protocol.

3.3  The organization was not initially selected as a site, but employees or agents will administer the interventions being tested or evaluated under the protocol on a one-time or short-term basis, where all of the following are true:

- 1) An investigator from an engaged organization determines that it will be in the subject's best interest to receive the interventions being tested or evaluated
- 2) The organization's employees or agents do not enroll subjects or obtain their informed consent to take part in the research
- 3) Investigators from the organization engaged in the research retain responsibility for all of the following:
  - a) Overseeing protocol-related activities
  - b) Ensuring the interventions are administered in accordance with the protocol
  - c) 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 by the protocol
- 4) The organization's IRB is informed that interventions being tested or evaluated have been administered at the organization's site

3.4  Employees or agents will do any of the following:

- 1) Inform prospective subjects about the availability of the research
- 2) Provide prospective subjects with information about the research but do not obtain subjects' consent to take part in the research or act as representatives of the investigators
- 3) Provide prospective subjects with information about contacting investigators for information or enrollment
- 4) Seek or obtain the prospective subjects' permission for investigators to contact them

3.5  The organization will permit use of its facilities for intervention or interaction with subjects by investigators from another organization

3.6  Employees or agents will release to investigators at another organization identifiable private information about subjects

3.7  The organization's employees or agents both:

- 1) Obtain coded private information from another organization involved in the research that retains a link to identifiable private information
- 2) Are unable to readily ascertain the identity of the subjects to whom the coded information or specimens

3.8  The organization's employees or agents access or use identifiable private information only while visiting an organization that is engaged in the research, provided their activities are overseen by an IRB of the organization that is engaged in the research

3.9  Employees or agents access or review identifiable private information for auditing purposes

3.10  Employees or agents receive identifiable private information for purposes of satisfying FDA reporting requirements

3.11  Employees or agents author a paper, journal article, or presentation describing a research study

**4. Notes**

**5. Footnotes**

5.1 *Employees or agents* refer to individuals who: (1) act on behalf of the organization; (2) exercise organizational authority or responsibility; or (3) perform organizationally designated activities.