**Institutional Review Board**

**Engaged in Research Determination Form**

|  |
| --- |
| **Guidance**The purpose of this worksheet is to provide support for making engagement determinations when there is uncertainty regarding whether the organization is engaged in **Human Research**. This worksheet is based on OHRP’s Guidance on Engagement of Institutions in Human Subjects Research, October 16, 2008, <http://www.hhs.gov/ohrp/policy/engage08.html>.If you are unsure if the activity meets the regulatory definition of **Human Research** please review guidance here first: <https://irb.upenn.edu/mission-institutional-review-board-irb/guidance/types-research> under Human Research - Is IRB Review Required? 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 Human Research that does not fall into one of the exempt human research categories outlined in the regulations at <https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/common-rule-subpart-a-46104/index.html>. For the purpose of this worksheet, 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 the IRB for additional information regarding whether an individual is an agent of the organization.This worksheet does not need to be completed or retained.  |

|  |
| --- |
| **Section A: Conditions Under Which an Organization is Engaged** |
| 1. **The organization receives an award through a grant, contract, or cooperative agreement directly from a federal agency** for the Human Research, even where all activities involving Human Subjects are carried out by **employees or agents** of *another* organization.
 | [ ]  **Yes 🡪** Institution is engaged in any Human Research conducted under this grant. Sections B and C do not apply. [ ]  **No 🡪 CONTINUE** |
| 1. The organization’s employees or agents **obtain the informed consent** of Human Subjects for the research.
 | [ ]  **Yes 🡪** Institution is engaged Human Research. Sections B and C do not apply. [ ]  **No 🡪 CONTINUE** |

|  |
| --- |
| **Section B: Conditions Under Which an Organization is Engaged, unless involvement is limited to items in Section C.** |
| The organization’s employees or agents do ANY of the following for research purposes: |
| 1. [ ]  Intervene with any Human Subjects of the research by performing invasive or noninvasive procedures
 | *Review the exceptions outlined in Section C: 1, 2, and 3* |
| 1. [ ]  Intervene with any Human Subject of the research by manipulating the environment
 | *Review the exceptions outlined in Section C: 1 and 3* |
| 1. [ ]  Interact with any Human Subject of the research
 | *Review the exceptions outlined in Section C: 1, 2, 3, 4* |
| 1. [ ]  Obtain identifiable private information or identifiable biological specimens from any source for the research.

*Note: In general, an organization’s employees or agents obtaining identifiable private information or identifiable specimens for Human Research are considered engaged in the research, even if the they do not directly interact or intervene with Human Subjects.* | *Exceptions are activities outlined in Section C: 1, 2, 3, 5, 6, 7, and 8*  |
| If **no** **boxes are checked** in **Section B** **AND** Responses in **Section A** are **both No** 🡪 The Institution is **not** “engaged” in human research.If **any** boxes (1-4) are checked in this section, **complete Section C** per the recommendation to review exceptions above. |

|  |
| --- |
| **Section C: Exceptions to Section B** |
| 1. The organization’s employees or agents perform *commercial* or *other* services for investigators, provided that **ALL** of the following conditions also are met:
	1. [ ]  The services performed *do not merit professional recognition* or publication privileges; and
	2. [ ]  The services performed are *typically performed by those organizations for non-research purposes*; and
	3. [ ]  The organization’s employees or agents *do not administer any study intervention being tested or evaluated* under the protocol.
 | [ ]  **If all conditions are met AND any** boxes in Section B (1-4) are checked **🡪** The institution is not engaged in human research.  |
| 1. 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 **ALL** of the following conditions also are met:
	1. [ ]  The organization’s employees or agents *do not administer the study interventions being tested or evaluated* under the protocol; and
	2. [ ]  The *clinical trial-related medical services are typically provided* by the organization for clinical purposes; and
	3. [ ]  The organization’s employees or agents *do not enroll subjects* nor *obtain the informed consent* of any subject for participation in the research; and
	4. [ ]  When appropriate, investigators from an organization engaged in the research retain responsibility for **ALL** of the following:
		1. [ ]  Overseeing protocol-related activities; and
		2. [ ]  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.
 | [ ]  **If all conditions are met AND** boxes are checked in Section B 1, 3, or 4 **🡪** The institution is not engaged in human research. |
| 1. 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 **ALL** of the following are true:
	1. [ ]  The organization’s employees or agents *do not enroll subjects or obtain the informed consent* of any subject for participation in the research; and
	2. [ ]  *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; and
	3. [ ]  Investigators from the organization engaged in the research retain responsibility for **ALL** of the following:
		1. [ ]  Overseeing protocol-related activities; and
		2. [ ]  Ensuring the study interventions are administered in accordance with the IRB-approved protocol; and
		3. [ ]  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
 | [ ]  **If all conditions are met AND any** boxes in Section B (1-4) are checked **🡪** The institution is not engaged in human research. |
| 1. The organization’s employees or agents 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 for the research nor 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.
 | [ ]  **If any** boxes (a-d) are checked **AND** Section B3 is checked **🡪** The institution is not engaged in human research. |
| 1. The organization’s employees or agents:
	1. [ ]  Obtain coded private information or human biological specimens from another organization involved in the research that retains a link to individually identifying information; AND
	2. [ ]  Are unable to readily ascertain the identity of the subjects to whom the coded information or specimens pertain [i.e., no identifiers are received]
 | [ ]  **If all conditions are met AND** Section B4 is checked **🡪** The institution is not engaged in human research. |
| 1. 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.
 | [ ] Yes **AND** Section B4 is checked **🡪** The institution is not engaged in human research.[ ]  No **🡪 No exception**  |
| 1. The organization’s employees or agents access or review identifiable private information for purposes of study auditing.
 | [ ] Yes **AND** Section B4 is checked **🡪** The institution is not engaged in human research.[ ]  No **🡪 No exception** |
| 1. The organization’s employees or agents receive identifiable private information for purposes of satisfying U.S. Food and Drug Administration reporting requirements.
 | [ ] Yes **AND** Section B4 is checked **🡪** The institution is not engaged in human research.[ ]  No **🡪 No exception** |

|  |
| --- |
| **Section D: Other activities in which an institution would not be considered to be engaged in human subjects’ research.**  |
| 1. The organization is permitting use of its facilities for intervention or interaction with subjects by investigators from another organization.
 |
| 1. 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.
 |
| 1. The organization’s employees or agents author a paper, journal article, or presentation describing a Human Research study.
 |
| **If activities are limited to those listed above in Section D the institution is not engaged in human subjects’ research.**  |