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| **Project Title:** | | | | |
| **RAMP IRB Study #:** | | | | |
| **Principal Investigator (PI):** | | | | |
| The purpose of this worksheet is to provide support for making engagement determinations when there is uncertainty regarding whether FSU is Engaged in Human Research. “Engagement” means that the FSU human research protection program (Office for Human Subjects Protection (OHSP) and/or Institutional Review Board (IRB)) is responsible for the Human Research. For the purposes of applicable federal law engagement applies only to non-exempt Human Research. When completed, this worksheet is to be retained in the OHSP record for this study. | | | | |
| 1. FDA Exception for “Engagement” (Check the box below in this section 1 only if the FDA exception applies; if in doubt, DO NOT check this box) | | | | |
|  | **ONLY** FDA regulations apply to this Human Research as no other Federal agency that has adopted the Common Rule has regulatory oversight of the research. | | |
| 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). | | | | |
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| 1. Conditions Under Which FSU is Engaged in Human Research | | | |
|  | FSU 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 another organization’s employees or agents.[[1]](#footnote-2) | | |
|  | FSU employees or agents[[2]](#footnote-3) intervene for Research purposes with any Human Subject of the Research by performing invasive or noninvasive procedures | | |
|  | FSU employees or agents intervene for Research purposes with any Human Subject of the Research by manipulating the environment. | | |
|  | FSU employees or agents interact for Research purposes with any Human Subject of the Research. | | |
|  | FSU employees or agents obtain the informed consent of Human Subjects for the Research. | | |
|  | FSU 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, FSU’s employees or agents obtain identifiable private information or identifiable specimens for Human Research are considered Engaged in the Research, even if FSU employees or agents do not directly interact or intervene with Human Subjects. | | |
| If any item in section 1 is true, then **STOP: FSU in Engaged in Human Research, and the FSU policy 7-IRB-0 applies.** The Principal Investigator for the study for which FSU is engaged as documented above is required to submit the study for OHSP and/or IRB review. Otherwise, if no item above in section 2 is checked, proceed to section 3. | | | |
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| 1. Conditions Under Which FSU is Not Engaged in Human Research.   Important Note: FSU is Engaged in Human Research if the FIRST item in section 2 above is true, regardless of whether FSU’s involvement is otherwise limited to any item in section 3 below. | | | |
|  | FSU 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. | |
|  |  | FSU employees or agents do not administer any study intervention being tested or evaluated under the protocol. | |
|  | FSU 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: | | |
|  |  | FSU 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 FSU for clinical purposes. | |
|  |  | FSU 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. |
|  | FSU was not initially selected as a Research site but FSU 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: | | |
|  |  | FSU 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. | |
|  | FSU 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. | |
|  | FSU is permitting use of its facilities for intervention or interaction with Human Subjects by investigators from another organization. | | |
|  | FSU employees or agents release to investigators at another organization identifiable private information or identifiable biological specimens pertaining to the Human Subjects of the Research. | | |
|  | FSU 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. | |
|  | FSU 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. | | |
|  | FSU employees or agents access or review identifiable private information for purposes of study auditing. | | |
|  | FSU employees or agents receive identifiable private information for purposes of satisfying U.S. Food and Drug Administration reporting requirements. | | |
|  | FSU employees or agents author a paper, journal article, or presentation describing a Human Research study. | | |

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. Thus, FSU “employees and agents” can include FSU faculty, staff, students, contractors, and volunteers, among others, regardless of whether the individual is receiving compensation. [↑](#footnote-ref-2)
2. Note however that FSU students or affiliated College of Medicine residents that work at a non-FSU institution, and who only work under the direct supervision of a non-FSU PI of non-FSU human research for which no other condition in section 2 above is checked, are not considered to engage FSU in the non-FSU human research. [↑](#footnote-ref-3)