Is OSU engaged in Research?

A1. Is OSU the primary awardee of funding?
- Yes → OSU is Engaged
- No

A2. Are OSU agents or employees intervening with research participants by performing invasive or noninvasive procedures?
- Yes → OSU is Engaged
- No

A3. Are OSU agents or employees intervening with research participants by manipulating the environment?
(e.g. controlling environmental lighting, sound or temperature; presenting sensory stimuli; and orchestrating environmental events or social interactions)
- Yes → OSU is Engaged
- No

A4. Are OSU agents or employees interacting for research purposes with any human subjects of the research?
(e.g. conducting interviews, administering questionnaires, engaging in protocol-dictated communication or interpersonal contact)
- Yes → OSU is Engaged
- No

A5. Are OSU agents or employees obtaining informed consent from human subjects for the research?
- Yes → OSU is Engaged
- No

A6. Are OSU agents or employees obtaining identifiable private information or identifiable biological specimens from any source for the research?
(e.g. observing or recording private behavior; using, studying or analyzing identifiable private data or specimens provided by another institution; and using, studying, or analyzing identifiable private data or specimens already in possession of the investigators)
- Yes → OSU is Engaged
- No

Exceptions²

B1
B2
B3

OSU NOT Engaged in Research

¹In general, OHRP considers private information or specimens to be individually identifiable when they can be linked to specific individuals by the investigator(s) either directly or indirectly through coding systems.
²The exceptions outline scenarios in which an institution is not engaged in research if the involvement of their employees or agents in that project is limited to one or more of the items listed in B1–B11.

Please contact us for more information:
Human Research Protection Program
Institutional Review Board
Office of Research Integrity
Phone: 541-737-8008
Email: IRB@oregonstate.edu
Website: oregonstate.edu/research/irb
(a) - Are the OSU agents or employees performing commercial or other services that merit professional recognition or publication privileges?

(b) - Are these OSU agents or employees performing commercial or other services which are typically performed by OSU for non-research purposes?

(c) - Are these OSU agents or employees administering any study intervention being tested or evaluated under the protocol?

OSU NOT Engaged in Research

OSU is Engaged

B2

This exception is for institutions (including private practices) not selected as a research site whose employees or agents provide clinical trial-related medical services that are dictated by the protocol and would typically be performed as part of routine clinical monitoring and/or follow-up of subjects enrolled at a study site by clinical investigators (e.g. medical history, physical exam, assessment of adverse events, blood tests, CT scans, etc.)

(a) - Are OSU agents or employees administering the study intervention being tested or evaluated under the protocol?

(b) - Are the clinical trial-related medical services typically provided by OSU for clinical purposes?

(c) - Are OSU agents or employees enrolling subjects or obtaining informed consent of any subject to participate in the research?

(d) - Do the outside investigators (those engaged in research) retain responsibility for overseeing protocol-related activities AND ensuring appropriate arrangements are made for reporting protocol-related data to the engaged investigators, including the reporting of safety monitoring data and adverse events as required by the IRB-approved protocol?

OSU NOT Engaged in Research

OSU is Engaged

B3

This exception is for institutions (including private practices) not initially selected as a research site whose employees or agents administer the study intervention being tested or evaluated under the protocol on a one-time or short-term basis (e.g. an oncologist at an institution administers chemotherapy to research subjects as part of a clinical trial because the subject unexpectedly goes out of town, or is unexpectedly hospitalized)

(a) - Did an investigator from an engaged institution determine that it would be in the subjects best interest to receive the study intervention being tested under the protocol at OSU?

(b) - Are OSU agents or employees enrolling subjects or obtaining informed consent for participation in the research?

(c) - Do investigators from the engaged institution retain responsibility for (1) overseeing protocol-related activities, (2) ensuring the study interventions are administered in accordance with IRB-approved protocol, AND (3) ensuring appropriate arrangements are made for reporting protocol-related data to investigators at the engaged institutions?

(d) - Is an IRB designated on the engaged institution's FWA informed that the study interventions being tested or evaluated under the protocol have been administered at an institution not selected as a research site?

OSU NOT Engaged in Research

OSU is Engaged
For the purposes of this guidance, coded means that:

(a) identifying information (such as name or social security number) that would enable the investigator to readily ascertain the identity of the individual to whom the private information or specimens pertain has been replaced with a number, letter, symbol, and/or combination thereof (i.e., the code); and

(b) a key to decipher the code exists, enabling the linkage of the identifying information to the private information or specimens.