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?
   - Yes: OSU is Engaged
   - No

A4. Are OSU agents or employees interacting for research purposes with any human subjects of the research?
   - 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?
   - Yes: OSU is Engaged
   - No

Exceptions:

B1. If the involvement of OSU’s employees or agents in that project is limited to one or more of the items listed in B1-B11.

B2. If the involvement is limited to the environment manipulation discussed in A3.

B3. If the involvement is limited to the interaction with human subjects discussed in A4.

B4. If the involvement is limited to obtaining informed consent discussed in A5.

B5. If the involvement is limited to obtaining identifiable private information or biological specimens discussed in A6.

1 In 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.

2 The 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:
Institutional Review Board Office
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

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 subject's 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 is Engaged
(a) Are OSU agents or employees activities limited to informing prospective subjects about the availability of research?

-OR-

(b) Are they providing prospective subjects with information about the research (which may include a copy of the relevant informed consent document and other IRB-approved materials)?

-OR-

Yes

Are they obtaining the subject’s consent to participate?

Yes

OSU is Engaged

No

Are they acting as a representative of the investigators?

Yes

OSU is Engaged

No

OSU NOT Engaged in Research

(c) Are they providing subjects with information about contacting investigators for information or enrollment?

-OR-

(d) Are they seeking or obtaining the prospective subjects’ permission for investigators to contact them.

OSU NOT Engaged in Research

B5

This exception is for institutions (e.g., schools, nursing homes, businesses) that permit use of their facilities for intervention or interaction with subjects by investigators from another institution.

(e.g., a school that permits investigators from another institution to conduct or distribute a survey in a classroom; or a business that permits investigators from another institution to recruit research participants)

Are OSU facilities being used for an intervention or interaction with subjects by investigators from another institution?

Is OSU Engaged by items A1-A6? (See 1st page)

Yes

OSU is Engaged

No

OSU NOT Engaged in Research

B6

This exception is for institutions whose employees or agents release to investigators at another institution identifiable private information or identifiable biological specimens pertaining to the subjects of research.

Although this will not affect the engagement determination, consider if the release of the information or specimens meets all OSU requirements?

Yes

OSU NOT Engaged in Research

No

Contact the EHS/OCCD

Was the individually identifiable private information or biological specimen collected for another human subjects research study at OSU?

Yes

OSU NOT Engaged in Research

No

Does the release of that information violate the informed consent provided by the subjects to whom the information or biological specimens pertain?

Yes

OSU NOT Engaged in Research

No

Contact the IRB Office for Guidance

Was the informed consent waived by the IRB?

Yes

OSU NOT Engaged in Research

No

Is the release of the information or specimens consistent with the IRB’s determination that permitted the waiver of informed consent?

Yes

OSU NOT Engaged in Research

No

Contact the EHS/OCCD

Please contact us for more information:
Institutional Review Board Office
Office of Research Integrity
Phone: 541-737-8008
Email: IRB@oregonstate.edu
Website: oregonstate.edu/research/irb
Are OSU employees or agents obtaining coded private information or human biological specimens from another institution involved in the research that retains a link to individually identifying information (such as name or SSN)?

Yes

Are the OSU employees or agents able to readily ascertain the identity of the subjects to whom the coded information or specimens pertain?

Yes

Is there a mechanism in place to prevent the sharing of the link to OSU employees or agents? (See examples below)

Examples:
- the institution’s employees or agents and the holder of the key enter into an agreement prohibiting the release of the key to those employees or agents under any circumstance
- the releasing institution has IRB-approved written policies and operating procedures applicable to the research project that prohibit the release of the key to the institution’s employees or agents under any circumstances, or
- there are legal requirements prohibiting the release of the key to the institution’s employees or agents

Yes

OSU NOT Engaged in Research

OSU is Engaged

Are OSU agents or employees accessing or utilizing individually identifiable private information while visiting an institution that is engaged in research?

Yes

Are these employees or agents accessing or utilizing this information only while visiting the other institution?

No

OSU is Engaged

OSU NOT Engaged in Research

Are the OSU employees or agents research activities overseen by the IRB of the institution that is engaged in the research?

No

OSU is Engaged

OSU NOT Engaged in Research

Are OSU agents or employees accessing or reviewing identifiable private information only for the purposes of study auditing?

Yes

OSU NOT Engaged in Research

Are OSU employees or agents receiving identifiable private information only for purposes of satisfying U.S. Food and Drug Administration reporting requirements?

Yes

OSU NOT Engaged in Research

Are OSU employees or agents authoring a paper, journal article, or presentation describing a human subjects research study?

Yes

OSU is Engaged

Is OSU otherwise engaged via A1-A6? (see 1st page)

Yes

OSU is Engaged

No

OSU NOT Engaged in Research

*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.