

Human Research Protection Program Policies & Procedures

Engagement in Research



Research Integrity Office
Mail code L106-RI
Portland, Oregon 97239-3098
Phone: 503-494-7887
Fax: 503-494-5081

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Background

Whether an institution is considered “engaged” in a human subjects research activity determines what oversight requirements apply to that research activity. Research activities in which OHSU is engaged are subject to OHSU’s policies and procedures for IRB oversight, as well as DHHS, FDA, and other applicable federal, state, and local laws and regulations. Determining the engagement of other institutions in research is also an initial step in assessing the compliance requirements for collaborative research projects in which OHSU is involved.

Generally, an institution is engaged in research when its employees or agents obtain: (1) data through intervention or interaction with human subjects for research purposes; (2) identifiable private information about a human subject; or (3) informed consent of human subjects for participation in research. An institution may also be considered engaged in research if it receives financial support for the research.

I. Scope

This policy applies to research projects that have been determined to involve human subjects and are not exempt under HHS regulations at 45 CFR 46.101(b).

II. Responsible Parties

- A. ORIO Staff
- B. IRB Chair/Co-Chairs
- C. Investigators

III. Policy

- A. OHSU is engaged in research whenever OHSU’s involvement in a research activity falls within the scope of activities discussed in the applicable guidance from the Office for Human Research Protections (OHRP). Generally, this includes the following (see Appendix A for specific examples from OHRP guidance):
 - 1. OHSU employees or agents intervene or interact with human subjects for purposes of research;
 - 2. OHSU employees or agents obtain individually identifiable private information about human subjects for purposes of research;
 - 3. OHSU employees or agents obtain informed consent of human subjects for participation in research; or
 - 4. OHSU receives financial support for the conduct of a particular research project (even if all activities involving human subjects are conducted elsewhere, including the VA).
- B. OHSU must ensure IRB review in compliance with all applicable federal, state, and local laws, regulations, and policies for each individual research activity in which it is engaged.

- C. For VA studies where the funding for the research is awarded to OHSU and the research is conducted at the VA, OHSU is considered engaged in research and must perform an IRB review.
- D. When multiple institutions are engaged in a single research project, the OHSU IRB must only review the part(s) of the research in which the institution is engaged, but may decide to review the entire research study if it has relevance to the IRB determinations required to approve the OHSU portion of the research.
- E. When OHSU collaborates with other institutions on a research project and OHSU is either the primary recipient of financial support for the research or the coordinating center or lead site for the project, OHSU will assess whether the collaborating institutions are engaged in the research in order to determine whether OHSU oversight requirements apply to those institutions and/or their investigators. See the [Collaborations with Non-OHSU Institutions and Investigators](#) policy for more information.

IV. Procedure

A. Determining whether OHSU is engaged in research

1. Activities involving OHSU investigators, facilities, and/or resources will be examined prospectively to determine whether the activity is considered human subject research and whether OHSU is engaged in the research. The OHSU Research Integrity Office (ORIO) makes these determinations in accordance with the policy on [Initial Evaluation of Submitted Projects \(Administrative and Regulatory Review\)](#).
2. A Request for Determination may be submitted via the eIRB in order to receive an engagement in research determination from the OHSU IRB on any research activity. This is particularly helpful when an OHSU investigator is collaborating on research organized by another institution or when it is unclear whether OHSU is engaged in the research activity.
3. If it is discovered that research is conducted without appropriate assurances and IRB oversight, it should be reported to the IRB as a protocol deviation.

B. Collaboration with other institutions

1. For collaborative research projects, it is recommended that investigators contact the IRB early in the development process for assistance in determining which collaborators are considered engaged in research and what oversight requirements apply as a result.
2. See the [Collaborations with Non-OHSU Institutions and Investigators](#) policy for more information.

V. Authority

OHRP Guidance on [Engagement of Institutions in Human Subjects Research](#) (October 16, 2008)

OHRP Correspondence on ["Non-engaged" Scenarios](#) (September 22, 2011)

VI. Definitions

Research: A systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.

Human Subject: A living individual about whom an investigator (whether professional or student) conducting research obtains (1) data through intervention or interaction with the individual, or (2) identifiable private information.

Institution: Any public or private entity or agency (including federal, state, and other agencies) and agents of that entity.

OHSU Employees or Agents: Individuals who (1) act on behalf of OHSU; (2) exercise institutional authority or responsibility; or (3) perform institutionally designated activities. This may include staff, students, contractors, and volunteers, among others, regardless of whether the individual is receiving compensation.

Intervention: Both physical procedures by which data are gathered (for example, venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes.

Interaction: Communication or interpersonal contact between investigator and subject.

Private information: Information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical record). Private information must be **individually identifiable** (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information) in order for obtaining the information to constitute research involving human subjects (bolding added for emphasis). Coded information is considered individually identifiable if a key to decipher the code exists, enabling linkage of the identifying information to the private information or specimens.

Obtaining identifiable private information: Receiving or accessing identifiable private information or identifiable specimens for research purposes (OHRP interprets *obtain* to include an investigator's use, study, or analysis for research purposes of identifiable private information or identifiable specimens already in the possession of the investigator).

Coordinating Center: A Coordinating Center is responsible for overall data management, monitoring and communication among all sites, and general oversight of conduct of the project.

VII. Additional Resources

OHSU HRPP Policies & Procedures:

- [Federal-Wide Assurance \(FWA\)](#)
- [Initial Evaluation of Submitted Projects \(Administrative and Regulatory Review\)](#)
- [Collaborations with Non-OHSU Institutions and Investigators](#)

Appendix A – Engaged and Non-Engaged Scenarios

A. Institutions Engaged in Human Subjects Research

In general, institutions are considered *engaged* in an HHS-conducted or -supported non-exempt human subjects research project (and, therefore, would need to hold or obtain OHRP-approved FWAs and certify IRB review and approval to HHS) when the involvement of their employees or agents in that project includes any of the following:

1. Institutions that receive an award through a grant, contract, or cooperative agreement directly from HHS for the non-exempt human subjects research (i.e. awardee institutions), even where all activities involving human subjects are carried out by employees or agents of another institution.
2. Institutions whose employees or agents intervene for research purposes with any human subjects of the research by performing invasive or noninvasive procedures.

Examples of invasive or noninvasive procedures include drawing blood; collecting buccal mucosa cells using a cotton swab; administering individual or group counseling or psychotherapy; administering drugs or other treatments; surgically implanting medical devices; utilizing physical sensors; and utilizing other measurement procedures.

[See scenarios B.(1), B.(2), and B.(3) below for limited exceptions.]

3. Institutions whose employees or agents intervene for research purposes with any human subject of the research by manipulating the environment.

Examples of manipulating the environment include controlling environmental light, sound, or temperature; presenting sensory stimuli; and orchestrating environmental events or social interactions.

[See scenarios B.(1) and B.(3) below for limited exceptions.]

4. Institutions whose employees or agents interact for research purposes with any human subject of the research.

Examples of interacting include engaging in protocol dictated communication or interpersonal contact; asking someone to provide a specimen by voiding or spitting into a specimen container; and conducting research interviews or administering questionnaires.

[See scenarios B.(1), B.(2), B.(3), and B.(4) below for limited exceptions.]

5. Institutions whose employees or agents obtain the informed consent of human subjects for the research.
6. Institutions whose 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, institutions whose employees or agents obtain identifiable private information or identifiable specimens for non-exempt human subjects research are considered engaged in the research, even if the institution's employees or agents do not directly interact or intervene with human subjects. In general, obtaining identifiable private information or identifiable specimens includes, but is not limited to:
 - a. observing or recording private behavior;
 - b. using, studying, or analyzing for research purposes identifiable private information or identifiable specimens provided by another institution; and
 - c. using, studying, or analyzing for research purposes identifiable private information or identifiable specimens already in the possession of the investigators.

In general, OHRP considers private information or specimens to be individually identifiable as defined in 45 CFR 46.102(f) when they can be linked to specific individuals by the investigator(s) either directly or indirectly through coding systems.

[See scenarios B.(1), B.(2), B.(3), B.(7), B.(8), B.(9), and B.(10) below for limited exceptions.]

B. Institutions Not Engaged in Human Subjects Research

Institutions would be considered **not** engaged in an HHS-conducted or -supported non-exempt human subjects research project (and, therefore, would not need to hold an OHRP-approved FWA or certify IRB review and approval to HHS) if the involvement of their employees or agents in that project is **limited to one or more** of the following. The following are scenarios describing the types of institutional involvement that would make an institution **not** engaged in human subjects research; there may be additional such scenarios:

1. Institutions whose employees or agents perform commercial or other services for investigators provided that **all** of the following conditions also are met:
 - a. the services performed do not merit professional recognition or publication privileges;
 - b. the services performed are typically performed by those institutions for non-research purposes; and
 - c. the institution's employees or agents do not administer any study intervention being tested or evaluated under the protocol.

The following are some examples, assuming the services described would not merit professional recognition or publication privileges:

- an appropriately qualified laboratory whose employees perform routine serum chemistry analyses of blood samples for investigators as a commercial service.
- a transcription company whose employees transcribes research study interviews as a commercial service.
- a hospital whose employees obtain blood through a blood draw or collect urine and provide such specimens to investigators as a service.
- a radiology clinic whose employees perform chest x-rays and send the results to investigators as a service.

2. 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 trial investigators (e.g., medical history, physical examination, assessment of adverse events, blood test, chest X-ray, or CT scan) provided that all of the following conditions also are met:
 - a. the institution's employees or agents do not administer the study interventions being tested or evaluated under the protocol;
 - b. the clinical trial-related medical services are typically provided by the institution for clinical purposes;
 - c. the institution's employees or agents do not enroll subjects or obtain the informed consent of any subject for participation in the research; and
 - d. when appropriate, investigators from an institution engaged in the research retain responsibility for:
 - i. overseeing protocol-related activities; and
 - ii. ensuring appropriate arrangements are made for reporting protocol-related data to investigators at an engaged institution, including the reporting of safety monitoring data and adverse events as required under the IRB-approved protocol.

Note that institutions (including private practices) not initially selected as research sites whose employees or agents administer the interventions being tested or evaluated in the study—such as administering either of two chemotherapy regimens as part of an oncology clinical trial evaluating the safety and effectiveness of the two regimens—generally would be engaged in human subjects research (see scenario B.(3) below for a limited exception). If such an institution does not have an FWA, its employees or agents may be covered by the FWA of another institution that is engaged in the research through an Individual Investigator Agreement. See <http://www.hhs.gov/ohrp/policy/guidanceonalternativetofwa.pdf>.

3. Institutions (including private practices) not initially selected as a research site whose employees or agents administer the study interventions being tested or evaluated under the protocol limited to a one-time or short-term basis (e.g., an oncologist at the institution administers chemotherapy to a research subject as part of a clinical trial because the subject unexpectedly goes out of town, or is unexpectedly hospitalized), provided that **all** of the following conditions also are met:
 - a. an investigator from an institution 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;
 - b. the institution's employees or agents do not enroll subjects or obtain the informed consent of any subject for participation in the research;
 - c. investigators from the institution engaged in the research retain responsibility for:
 - i. overseeing protocol-related activities;
 - ii. ensuring the study interventions are administered in accordance with the IRB-approved protocol; and
 - iii. ensuring appropriate arrangements are made for reporting protocol-related data to investigators at the engaged institution, including the reporting of safety monitoring data and adverse events as required under the IRB-approved protocol; and
 - d. an IRB designated on the engaged institution's FWA is informed that study interventions being tested or evaluated under the protocol have been administered at an institution not selected as a research site.
4. Institutions whose employees or agents:
 - a. inform prospective subjects about the availability of the research;

- b. provide prospective subjects with information about the research (which may include a copy of the relevant informed consent document and other IRB approved materials) but do not obtain subjects' consent for the research or act as representatives of the investigators;
- c. provide prospective subjects with information about contacting investigators for information or enrollment; and/or
- d. seek or obtain the prospective subjects' permission for investigators to contact them.

An example of this would be a clinician who provides patients with literature about a research study at another institution, including a copy of the informed consent document, and obtains permission from the patient to provide the patient's name and telephone number to investigators.

- 5. Institutions (e.g., schools, nursing homes, businesses) that permit use of their facilities for intervention or interaction with subjects by investigators from another institution.

Examples would be a school that permits investigators from another institution to conduct or distribute a research survey in the classroom; or a business that permits investigators from another institution to recruit research subjects or to draw a blood sample at the work site for research purposes.

- 6. Institutions whose employees or agents **release** to investigators at another institution identifiable private information or identifiable biological specimens pertaining to the subjects of the research.

Note that in some cases the institution releasing identifiable private information or identifiable biological specimens may have institutional requirements that would need to be satisfied before the information or specimens may be released, and/or may need to comply with other applicable regulations or laws. In addition, if the identifiable private information or identifiable biological specimens to be released were collected for another research study covered by 45 CFR part 46, then the institution releasing such information or specimens should:

- a. ensure that the release would not violate the informed consent provided by the subjects to whom the information or biological specimens pertain (under 45 CFR 46.116), or
- b. if informed consent was waived by the IRB, ensure that the release would be consistent with the IRB's determinations that permitted a waiver of informed consent under 45 CFR 46.116 (c) or (d).

Examples of institutions that might release identifiable private information or identifiable biological specimens to investigators at another institution include:

- a. schools that release identifiable student test scores;
- b. an HHS agency that releases identifiable records about its beneficiaries; and
- c. medical centers that release identifiable human biological specimens.

Note that, in general, the institutions whose employees or agents **obtain** the identifiable private information or identifiable biological specimens from the releasing institution would be engaged in human subjects research. [See scenario A.(6) above.]

- 7. Institutions whose employees or agents:
 - a. obtain 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 social security number); and
 - b. are unable to readily ascertain the identity of the subjects to whom the coded information or specimens pertain because, for example:
 - the institution's employees or agents and the holder of the key enter into an agreement prohibiting the release of the key to the those employees or agents under any circumstances;
 - 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 other legal requirements prohibiting the release of the key to the institution's employees or agents.

For purposes of this document, *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 linkage of the identifying information to the private information or specimens.

Although this scenario resembles some of the language in OHRP's Guidance on Research Involving Coded Private Information or Biological Specimens, it is important to note that OHRP's Guidance on Research Involving Coded Private Information or Biological Specimens addresses when research involving coded private information or specimens is or is not research

involving *human subjects*, as defined in 45 CFR 46.102(f) (see <http://www.dhhs.gov/ohrp/policy/cdebiol.pdf>). As stated above in Section II., this Guidance on Engagement of Institutions in Human Subjects Research should only be applied to research projects that have been determined to involve human subjects and that are not exempt under HHS regulations at 45 CFR 46.101(b).

8. Institutions whose employees or agents access or utilize individually identifiable private information **only** while visiting an institution that is engaged in the research, provided their research activities are overseen by the IRB of the institution that is engaged in the research.
9. Institutions whose employees or agents access or review identifiable private information for purposes of study auditing (e.g. a government agency or private company will have access to individually identifiable study data for auditing purposes).
10. Institutions whose employees or agents receive identifiable private information for purposes of satisfying U.S. Food and Drug Administration reporting requirements.
11. Institutions whose employees or agents author a paper, journal article, or presentation describing a human subjects research study.