Table of Contents

I. OHRP Guidance on Engagement of Institutions in Human Subjects Research

This guidance should only be applied to activities that have been determined to be research involving human subjects that are not exempt under the Department of Health and Human Services (HHS) regulations at 45 CFR 46.101(b). When an activity is determined to involve non-exempt human subjects research, this guidance should be used to determine whether an *institution* involved in some aspect of the research is *engaged* in that human subjects research, because if it is, certain regulatory requirements apply.

Specifically, institutions that are engaged in non-exempt human subjects research are required by the Office of Human Research Protections (OHRP) to:

1. Hold or obtain an applicable OHRP-approved FWA [45 CFR 46.103(a)]; and

2. Certify to the HHS agency conducting or supporting the research that the research has been reviewed and approved by an *[OHRP registered*]* IRB *[obtaining an*]* FWA, and will be subject to continuing review by an IRB [45 CFR 46.103(b)].

   **language added to reflect OHRP's stance on cooperative research of multiple, engaged institutions.*

If two or more institutions are engaged in the same non-exempt human subject research project, they can enter an agreement according to 45 CFR 46.114.

II. External Investigators: The institution in question is *not engaged*

OHRP notes that multiple institutions may be *involved* in the same non-exempt human subjects research project, but does not *engage* all institutions involved.[1] If an institution in a research project is considered "not engaged in research" according to OHRP guidance, then there is no requirement for that institution to provide certification of IRB review or approval for the research activity.

- This example is relevant to off-site investigators involving an institution in the research for use of data, students/faculty/staff as subjects, or use of facilities. Because the institution is not engaged, IRB approval from the non-engaged institution is not required. However, the study must have IRB approval from the investigator's home institution.

Please see B. Institutions Not Engaged in Human Subjects Research for guidance and examples of institutions which are not engaged in research and do not require IRB review or approval from the non-engaged institution.

Procedure

IRB Administration will request certification of IRB approval from the investigator's institution if the investigator notifies the involved institution(s). Administration will verify approval and then notify the investigator whom to contact for applicable authorizations to utilize facilities or access data. Other offices or personnel granting access to facilities, data, or subjects may be the requestors of the home institution's IRB approval. Please see External Investigator Procedures for further guidance.

It is recognized that institutions not engaged in the research need not review and approve the study and may not be contacted by the investigator. However, it is strongly encouraged that the investigator provides certification of IRB approval to involved institution's IRB Administration prior to conducting research out of courtesy and best practices.

---

[1] Guidance on Engagement, http://www.hhs.gov/ohrp/policy/engage08.html

III. Cooperative Research: The institution in question *is engaged*

When an institution is *engaged* in non-exempt cooperative research along the lines of scenarios A.(0), A.(2), A.(0), A.(0), or A.(0) in A. Institutions Engaged in Human Subjects Research,[2] the institution may rely upon an *OHRP registered IRB* operated by another institution or organization for review of research. Similarly, the institution may be the sole reviewing institution for multi-site cooperative research if they have an FWA and OHRP registered IRB. This arrangement must be documented by a written agreement between the relying and reviewing institutions outlining their relationship and including a commitment that the reviewing IRB will adhere to the requirements of the relying institution's FWA. [3]

The Federalwide Assurance Instructions state in item #6, Designation of Institutional Review Boards [*on an FWA*], that the "Institution assures that it will rely upon only Institutional Review Boards (IRBs) registered with OHRP to review the research to which this FWA applies, and notes that "Institutions designating internal IRBs do not need to designate any of the external IRBs upon which it relies."[4]

The written agreement must be kept on file at both institutions and made available upon request to OHRP or any US federal department or agency conducting or supporting research to which the FWA applies.[5]

Procedure

Institutions which are both engaged in non-exempt research can enter an agreement in which one IRB reviews for both institutions when the reviewing institution's IRB is registered with OHRP and agrees to follow the terms of the relying institution's FWA. Review and approval should begin with the lead institution, or an institution deemed "lead" by participating investigators. Once approval is received from the lead institution, a Cooperative Research Agreement form must be submitted with the approved IRB application and approval letter to the Relying Institution. The Relying Institution may accept the Agreement and depend upon the reviewing institution to monitor the project in its entirety.

IV. Definitions

The following definitions are relevant for determining whether an institution's activities are covered by the HHS protection of human subjects regulations (45 CFR part 46), and whether the institution is engaged in human subjects research. These definitions are taken directly from the regulations or directly from OHRP's *Guidance on Engagement of Institutions in Human Subjects Research* (October 16, 2008).

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;

---

[2] Guidance on Engagement, http://www.hhs.gov/ohrp/policy/engage08.html
[3] FWA Terms of Assurance, http://www.hhs.gov/ohrp/assurances/assurances/filasurt.html
[4] Federalwide Assurance Instructions, http://www.hhs.gov/ohrp/assurances/forms/fwainstructions.html
[5] FWA Terms of Assurance, http://www.hhs.gov/ohrp/assurances/assurances/filasurt.html

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.

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.(0) 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.

C. Research is defined in 45 CFR 46.102(d) as follows:
Research means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Activities which meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program which is considered research for other purposes. For example, some demonstration and service programs may include research activities.

D. Human Subject is defined in 45 CFR 46.102(f) as follows:
Human subject means 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.

Intervention includes 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 includes communication or interpersonal contact between investigator and subject. *Private information* includes 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.

E. Institution is defined in 45 CFR 46.102(b) as any public or private entity or agency (including federal, state, and other agencies).
For purposes of this document, an institution'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.

V. External Investigator Procedures

These procedures are for the use of external investigators, or investigators not associated with Sacramento State, who would like to recruit on campus, conduct research on campus, or otherwise involve the institution in research. Sacramento State affiliates may not collect informed consent from subjects, collect data, or analyze data in order to be considered *not engaged*. See B. Institutions Not Engaged in Human Subjects Research for guidance.

Submission

To notify Sacramento State of your intent to involve the campus in your research, please email the following to irb@csus.edu before commencing:

1. IRB approval letter from your home institution
2. Informed consent form(s)
3. Flyer(s) or other recruitment materials

Verification

The verification process involves administrative review of the home institution's IRB status with OHRP and documents supplied from the investigator. Once the review is complete, administration will contact the external investigator of verification and will direct them to other offices or personnel granting access to facilities, data, or participants.

Scope of IRB Review

It is recognized that institutions not engaged in the research need not review and approve the study and may not be contacted by the investigator. However, it is strongly encouraged that the investigator provides certification of IRB approval to involved institution's IRB Administration prior to conducting research out of courtesy and best practices.

Contact Information

Sacramento State
Office of Research Affairs
Research Integrity & Compliance
Phone: (916) 278-5674
Email: irb@csus.edu
Website: http://www.csus.edu/research/irb/

Cooperative Research Agreement for Human Subjects Research

Instructions

1. This form is to be used when Sacramento State is *engaged* in research with another institution through collaborative research.
2. Submit this form and required attachments to the Office of Research Affairs electronically to leah.vargas@csus.edu. If you have any questions, please call Leah Vargas, (916) 278-5674 or email.

External Institution Information	
External Investigator's Name:	Email Address:
Phone Number: (including area code)**:**	Other: (if needed)**:**

Name of External Investigator's Institution or Agency:
FWA# (required):
Administration Contact Information for External IRB (if applicable):

Project / Research Title:

Describe the relationship between your institution and CSUS in this research (required):

Sacramento State Information	
Sacramento Sate will be the: ☐ Reviewing IRB for both institutions engaged in research. ☐ Relying IRB for both institutions engaged in research.	
Sac State Investigator's Name:	Email Address:
Phone Number: (including area code)**:**	Other: (if needed)**:**

Required Attachments
Required Attachments if Sacramento State is **relying**: 1. ☐ Approved protocol from external investigator's home IRB 2. ☐ Approval letter/ Exemption letter from the external investigator's home IRB 3. ☐ Certification of training in human subject research protections for all personnel involved
Required Attachments if Sacramento State is **reviewing**: 1. ☐ Protocol Review Form 2. ☐ Data collection instruments and recruitment materials, consent forms, etc. 3. ☐ Certification of training in human subject research protections for all personnel involved

The review performed by the designated IRB will meet the human subjects protection requirements of the relying IRB's OHRP-approved FWA. The Reviewing Institution will follow written procedures for reporting its findings and actions to appropriate officials at the Relying Institution. Relevant minutes of IRB meetings will be made available to the Relying Institution upon request. The Reviewing Institution remains responsible for ensuring compliance with the IRB's determinations and with the Terms of its OHRP-approved FWA. This document must be kept on file by both parties and provided to OHRP upon request.

External Institution Authorization
Signature of External Institutional Official or IRB Chair: _____ Date: _____ Print Full Name: _____Institutional Title: _____
Sacramento State Authorization
Signature of Sacramento State's Institutional Official or IRB Chair: _____ Date: _____ Print Full Name: _____Institutional Title: _____