

Policy Number: 3

Title: Research Involving Performance Sites

Date of Last Revision: 08/10/05, 11/06/10, 4/20/12, 05/01/16

Policy:

It is the policy of the UC Irvine (UCI) Institutional Review Board to assure that appropriate approvals and/or written agreements are in place when human subjects research involves performance sites. In general, an institution is considered *engaged* in a particular non-exempt human subjects research project when its employees or agents for the purposes of the research project obtain: (1) data about the subjects of the research through intervention or interaction with them; (2) identifiable private information about the subjects of the research; or (3) the informed consent of human subjects for the research.

I. Performance Sites "Engaged" in Research

- A. Regardless of financial support or funding, UCI's IRB must assure that all performance sites "engaged" in research have approval from the IRB of Record for the proposed research to be conducted at the site.
- B. The performance site "engaged" in research may have the proposed research reviewed and approved by:
 - 1. its own assurance holding IRB;
 - 2. another designated assurance holding IRB; or
 - 3. UCI IRB providing an approved MOU is on file.
- C. Initiation of research conducted at a performance site "engaged" in research is contingent upon UCI's IRB receipt and review of the IRB approval from the "engaged" performance site.
- D. It is the responsibility of the IRB of Record and the Assurance holding institution to assure that the resources and facilities are appropriate for the nature of the research under its jurisdiction.

II. Performance Sites "Not engaged" in Research

- A. When performance sites are "not engaged" in research and have an established IRB, the Lead Researcher must obtain documentation to conduct the research at the "not engaged" site from the site's IRB (e.g., evidence that IRB approval is not needed for that activity).
- B. When performance sites are "not engaged" in research and the "not engaged" site does not have an established IRB, a letter of cooperation/permission must be obtained demonstrating that the appropriate institutional officials/representatives are permitting the research to be conducted at the performance site.
- C. It is the responsibility of the UCI LR and the performance site "not engaged" in research to assure that the resources and facilities are appropriate for the nature of the research.

- D. It is the responsibility of the UCI LR and/or the performance site “not engaged” in research to notify the UCI IRB promptly if a change in research activities alters the performance site’s engagement in the research (e.g., performance site “not engaged” begins consenting research participants, etc.)
- E. The IRB reserves the right to require a copy of the cooperation/permission letter before initial IRB approval, require a copy of the letter once available, at the time of continuing review, or as part of a routine quality improvement review.

References:

45 CFR 46

21 CFR 50 and 56

OHRP Guidance Document: Assurance of Performance Sites, September 1998

OHRP Guidance Document: Engagement of Institutions in Research, October 2008

Procedure Number: 3.A

Title: Procedure for Research Involving Performance Sites

Procedure:

This procedure outlines the process for assuring approval for "engaged" and "not engaged" performance sites associated with UCI human subject research.

I. Lead Researcher (LR) Responsibilities

- A. The LR will obtain documentation of IRB approval or letter of cooperation / permission for sites "engaged" and "not engaged" in human subjects research with UCI.
- B. The LR will include any IRB approval documentation for "engaged" sites in the initial submission to the IRB. The LR may begin research activities at each site as it is approved by UCI's IRB.
- C. The LR will obtain the IRB approval letters or letters of cooperation/permission for each performance site. It is the responsibility of the LR to maintain current IRB documentation, (e.g. approvals, continuing reviews, updated assurance, investigator qualifications, etc.), throughout the course of the research.
- D. It is the LR's responsibility to assist performance sites that do not have an IRB and are "engaged" in research in securing the appropriate Assurance and IRB approvals.

II. IRB Committee Responsibilities

- A. The Committee needs to determine whether the site is "engaged" versus "not engaged" in research. See Policy 3.
- B. Additions of study sites may be reviewed and approved in an expedited manner by the Chairperson or his/her designee, when appropriate documentation (e.g. IRB approval, Letter of Cooperation, etc.) is provided by the LR.
- C. For performance sites "engaged" in research where UCI has agreed to serve as the IRB of Record through a Memorandum of Understanding (MOU), the HRP will maintain a current MOU binder in the office of the Executive Director of Research Protections.
- D. As noted above, the IRB reserves the right to require a copy of the cooperation/permission letter before initial IRB approval, require a copy of the letter once available, at the time of continuing review, or as part of a routine quality improvement review.

III. The Human Research Protections (HRP) Team Responsibilities

- A. The HRP team (Administrator, Sr. Analyst, and Analyst) under the direction of the Administrator will verify that the appropriate documentation for performance sites has been submitted to the IRB for approval. If omissions in documentation are found, a team member will contact the LR specifying the required documentation needed from the performance site(s).
- B. The HRP team will verify the institution's OHRP Assurance number and IRB registration number with both OHRP and the FDA as applicable for performance sites "engaged" in research. These numbers are located on the

OHRP website. For those performance sites "engaged" in research where UCI has agreed to serve as the IRB of Record through an executed MOU, UCI HRP staff will verify and enter the information the Human Protocol System (HPS) database.

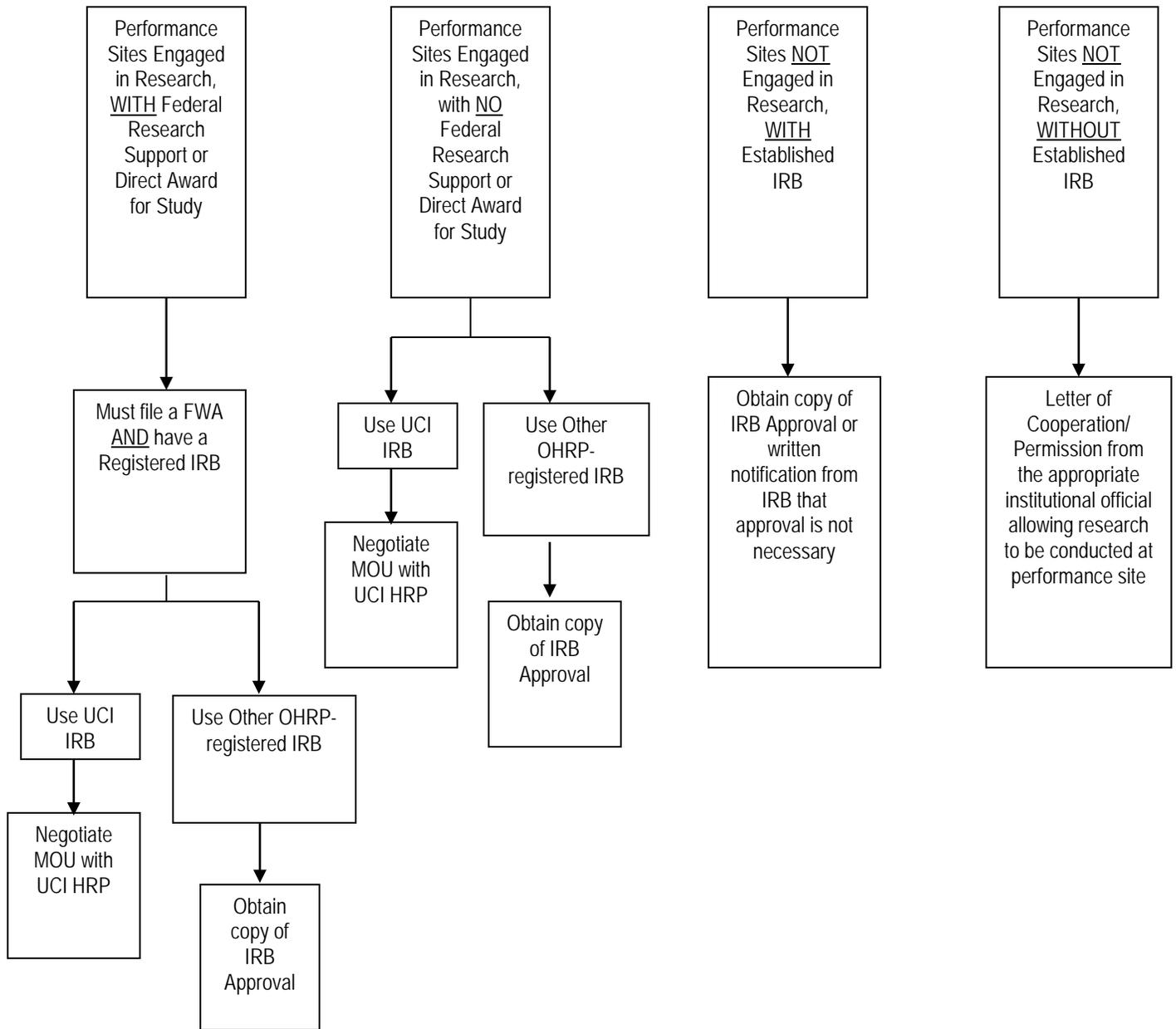
- C. The Administrator will provide Committee reviewers with a copy of the performance site's IRB approval letter(s) and as necessary, letter(s) of cooperation/permission demonstrating performance site agreement that UCI may conduct research at each site.

Attachment:

Collaborating Institution and Performance Site Flow Chart

Examples of Research Activities Meeting Requirements for "Engaged" vs. "Not Engaged."

PERFORMANCE SITES *ENGAGED IN RESEARCH AND NOT ENGAGED IN RESEARCH



***Engaged in Research.** A performance site becomes “engaged” in human subject research when its employees or agents (i) intervene or interact with living individuals for research purposes; or (ii) obtain individually identifiable private information for research purposes. Further, an institution is automatically considered to be “engaged” in human subject research whenever it receives a direct federal award to support such research. In this case, the awardee institution bears ultimate responsibility for protecting human subjects under the award. See OHRP [Guidance on Engagement of Institutions in Human Subjects Research](#) for more information.

Social/Behavioral
Examples of Research Meeting Requirements for "Engaged" vs. "Not Engaged"

EXAMPLE	IRB DECISIONS BASED ON REGULATIONS
<p>UCI Investigators are allowed to come into the elementary school classroom to observe, audio/video tape, or distribute surveys/questionnaires for research purposes. The students and teachers of the school are consented by UCI Investigators to participate.</p>	<p>The school would be considered "not engaged" in research. The students and teachers of the school are participants in a study for which they have been consented.</p>
<p>A teacher is administering a standardized test at his elementary school as part of an educational requirement. The UCI Investigator is collecting the test scores as part of a UC Irvine research project. The teacher is not administering the informed consent or performing data analysis.</p>	<p>The school would be considered "not engaged" in research. The teacher is performing a task as part of his professional responsibility. The school will release data to the UCI Investigator with parental permission.</p>
<p>An organization performs its own research, which is completed by its own personnel. Investigators at UCI will analyze the data. The data will not have identifiers. However, the UCI Investigator will be included in the publication.</p>	<p>The organization would be "engaged" in research. UCI would be considered "not engaged." The investigator will not analyze data that includes identifiable private information and co-authoring a paper, journal article or presentation does not constitute engagement.</p>
<p>High School teachers and UCI Investigators are paired together to develop a novel math curriculum that will be evaluated in the classroom. The teachers will administer the curriculum while the UCI Investigators will interview the students throughout the process.</p>	<p>Both the schools and UCI would be "engaged in research" as both would be collecting data and involved in the publication of the results.</p>
<p>UCI receives an award and obtains a letter of cooperation from Garden Grove School District to perform research, which involves students. The teachers do not obtain consent from the students but will be administering surveys to the students as part of the research. UCI Investigators obtain informed consent; the teacher is not involved in the planning of the study, the analysis of data, or the publication of results.</p>	<p>UCI would be considered "engaged in research" as UCI received funding to conduct the research. The school is "not engaged" in research as the teacher is not obtaining consent, etc., but is functioning as a contract provider and is performing a task that he/she is trained and qualified to perform. Teachers may also be research subjects, which may require informed consent.</p>

Biomedical
Examples of Research Meeting Requirements for "Engaged" vs. "Not Engaged"

EXAMPLE	IRB DECISIONS BASED ON REGULATIONS
<p>A UCI Investigator is conducting research and consenting subjects for research. Subjects may get their blood and tissue samples taken from a local clinic instead of the UCI site, because of convenience.</p>	<p>The local clinic is "not engaged" in research as they are considered to be a "contract" provider and the participant requested use of the local clinic. A contract provider may only perform commercial services in which they are appropriately qualified (e.g., an appropriately qualified laboratory performs analyses of blood samples for Investigators solely on a commercial basis) or perform other genuinely non-collaborative services meriting neither professional recognition nor publication privileges. UCI is "engaged" in research.</p>
<p>A UCI Investigator has a 5-year research study, which requires a hearing evaluation as part of follow-up. A subject chooses to see his/her local doctor to obtain the hearing evaluation.</p>	<p>The local doctor would be considered "not engaged" in research as they are providing a service, which is considered standard practice. UCI is "engaged" in research.</p>
<p>A UCI Investigator will contract with an independent MRI center to conduct MRI procedures for research purposes. The MRI center will then send all reports to the Investigator.</p>	<p>The independent MRI center is considered "not engaged" in research. The MRI center is considered a contract provider and providing a service for which they are qualified to perform outside of the research context. UCI is "engaged" in research.</p>
<p>An external clinic (outside UCI) has written permission from the participants to disclose Protected Health Information to a UCI Investigator for research purposes. The data was collected at the external clinic solely for the purpose of routine clinical care.</p>	<p>The external site is "not engaged" in research because they have obtained explicit written permission from the participants to release PHI. UCI is "engaged" in research.</p>
<p>A UCI Investigator receives grant funding from the Federal government. The research is conducted at the OC Health Department with the assistance of OC Health Department employees.</p>	<p>OC Health department would be considered "engaged" in research. UCI is "engaged" in research as the recipient of the funding and as such the UCI IRB must also approve the research. The OC Health Department IRB must also review and approve the research study.</p>
<p>A UCI Investigator is conducting an oncology study in which additional non-UCI sites would follow the protocol and administer the chemotherapy.</p>	<p>Both UCI and non-UCI sites would be considered "engaged" in research as they will be obtaining consent and performing research procedures. All sites require IRB approval from each site's IRB.</p>