

Guidance and Procedures Number: 45

Title: Research Involving Multiple Performance Sites or Collaborating Agencies or Institutions

Date of Last Revision: February 11, 2008

I. Overview

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

Please note that this guidance does not apply when UCLA is one of several sites in multi-site research in which the sites do not interact or otherwise share data/samples with each other.

II. Definitions

1. **Assurance:** A contract or agreement that establishes standards for human subjects research as approved by the Office for Human Research Protections (OHRP).

The Federalwide Assurance (FWA) is the only type of assurance of compliance accepted and approved by the Office for Human Research Protections (OHRP) for institutions engaged in non-exempt human subjects research conducted or supported by the Federal Department of Health and Human Services (HHS). Other federal departments and agencies that have adopted the Federal Policy for the Protection of Human Subjects (also known as the Common Rule) may rely on the FWA for the research that they conduct or support. Investigators engaging in research conducted or supported by non-HHS federal departments or agencies should consult with the sponsoring department or agency for guidance regarding whether the FWA is appropriate for the research in question.¹

2. **"Engagement"** in human subjects research is defined in the U.S. Office for Human Research Protections' (OHRP) October 2008 [Guidance on Engagement of Institutions in Human Subjects Research](#).
3. **Institutional Review Board (IRB):** A specially constituted review body established or designated by an entity to protect the rights and welfare of human subjects recruited to participate in biomedical or behavioral/social science research.
4. **Independent Ethics Committee (IEC):** A specially constituted review body whose responsibility is to ensure the protection of the rights, welfare and safety of research participants. An IEC shares the same composition and operations as an Institutional Review Board.

¹ For additional guidance, please refer to: http://www.hhs.gov/ohrp/assurances/assurances_index.html

5. **Letter of compliance:** A letter of compliance must be on letterhead from the agency/institution, and be signed by the institutional official who is authorized to speak on behalf of the agency/institution and provide permission for the conduct of the research at their site. A letter of compliance should indicate that the agency agrees to the performance of the research and *“will abide and comply with the UCLA IRB requirements for the protection of human research subjects.”*
6. **Letter of permission:** A letter of permission should be on letterhead from the agency/institution, and be signed by the institutional official who can speak on behalf of the agency/institution and provide permission for the conduct of the research at their site.
7. **Performance site:** Facility or institution where study subjects are consented (i.e., give informed consent to participate), enrolled, and/or followed.
8. **IRB of Record:** An IRB which agrees to act as an agency/institution/site's designated IRB when that agency/institution/site either does not have an IRB or requests that another IRB review on its behalf for a given study.

III. UCLA IRB review and determination regarding “engagement”

- A. If non-UCLA sites are involved in research, the UCLA IRB must determine whether or not each non-UCLA site is *engaged* in the research.
- B. The UCLA IRB's correspondence to the investigator will identify those sites which the UCLA IRB has determined are “engaged” in the research; the correspondence may request additional information which may be required in order for the IRB to determine whether a site is “engaged.”
- C. UCLA investigators are responsible for notifying the UCLA IRB promptly if a change in research activities alters the performance site's engagement in the research (e.g., performance site previously “not engaged” begins consenting research participants) in order to obtain the UCLA IRB's updated determination regarding engagement.

IV. Performance sites “engaged” in federally funded research

- A. Performance sites which are *engaged* in federally-funded human subjects research must obtain a Federalwide Assurance (FWA) and IRB approval for their participation in the research. Information about how to obtain an FWA, and when an FWA is required is available on the OHRP website at:
http://www.hhs.gov/ohrp/assurances/assurances_index.html
- B. UCLA investigators are responsible for:
 1. identifying each engaged site's FWA# to the UCLA IRB, and
 2. providing written assurance to the UCLA IRB that he/she will retain copies of IRB/IEC Approval and that he/she will not initiate research at a site until he/she has obtained the site's IRB/IEC Approval.

- C. The performance site “engaged” in federally-funded research may have the proposed research reviewed and approved by:
 - 1. Its own Assurance-holding IRB/IEC;
 - 2. Another designated Assurance-holding IRB/IEC; or
 - 3. The UCLA IRB pursuant to an agreement to act as the designated IRB (or “IRB of Record”) for the site and acceptance of the site’s Individual Investigator Agreement. (See Section V for details.)
- D. UCLA IRB approval to conduct federally funded research at an “engaged” performance site is contingent upon the UCLA IRB’s acceptance of the UCLA investigator’s written assurance that he/she will obtain the appropriate documentation of the performance site’s IRB/IEC determination.
- E. All required performance site documentation must be received by the UCLA investigator prior to initiation of the research at the performance site, maintained in the research files, and available at any time for audit by the UCLA IRB.

V. UCLA IRB review on behalf of non-UCLA site “engaged” in *federally funded* research

- A. UCLA’s IRB approval for the research does not constitute IRB approval for the non-UCLA site except in those circumstances where the UCLA IRB has agreed to be the designated IRB for the site.
- B. When the UCLA IRB agrees to act as a site’s designated IRB, the agreement is made on a study-by study basis.
- C. UCLA will only act as the designated IRB for a non-UCLA site if the UCLA investigator is engaged at the site.
- D. UCLA will not act as the designated IRB for a non-UCLA site if:
 - 1. the site has its own IRB;
 - 2. UCLA has no direct involvement at the site; or
 - 3. UCLA only serves as the coordinating center for the study.
- E. If an “engaged” non-UCLA site does not have an IRB, AND wishes to request that the UCLA IRB act as the site’s designated IRB², the investigator should provide the following to the UCLA IRB:
 - 1. A request that the UCLA IRB agree to act as the designated IRB for the site(s);

² Additional information about the process for requesting that the UCLA IRB act as a site’s designated IRB can be obtained by contacting the UCLA OPRS Directors or Assistant Directors at (310) 825-7122 or (310) 825-5344.

2. An explanation of the UCLA investigator's involvement in the research activities conducted at non-UCLA site(s);
 3. A description of the nature of the UCLA investigator's ongoing oversight of the research activities conducted at the non-UCLA site(s); and
 4. Documentation of the non-UCLA site(s)' Federalwide Assurance number(s).
- F. The UCLA IRB will also serve as the designated IRB for sites/institutions with whom UCLA has signed a Memorandum of Understanding (MOU), in accordance with the terms of the MOU.

VI. Performance sites "engaged" in research that is NOT federally-funded

- A. Performance sites *engaged* in human subjects research that are **not** federally funded must obtain **either IRB approval or a letter of compliance**. Investigators should contact the appropriate authority at the participating site to determine whether the site has its own IRB. If the site has its own IRB, the investigator should obtain written approval for the research from the site's IRB.
- B. If the site does not have its own IRB, the investigators should obtain a *letter of compliance*. The letter of compliance must be on letterhead from the agency/institution, and be signed by the institutional official who can speak on behalf of the agency/institution and provide permission for the conduct of the research at their site. A letter of compliance should indicate that the agency agrees to the performance of the research and "will abide and comply with the UCLA IRB requirements for the protection of human research subjects."

The UCLA IRB's requirements for the protection of human research subjects include compliance with the federal regulations for human subjects research (45 CFR 46), federal and state law, and university policies, as well as adherence to the details of the research protocol approved by the UCLA IRB.

- C. When performance sites are "engaged" in research and the "engaged" site does not have an established IRB/IEC, the UCLA investigator must obtain a *letter of permission* demonstrating that the appropriate institutional officials are permitting the research to be conducted at the performance site.
- D. UCLA IRB approval to conduct non-federally funded research at an "engaged" performance site is contingent upon the UCLA IRB's acceptance of the UCLA investigator's written assurance that he/she will obtain the appropriate documentation of the performance site's IRB/IEC determination, or letter of compliance, as applicable.
- D. All required performance site documentation must be received by the UCLA investigator prior to initiation of the research at the performance site, maintained in the research files, and must be available at any time for audit by the UCLA IRB.

VII. Performance Sites “Not Engaged” in Research

- A. When performance sites are "not engaged" in research and have an established IRB/IEC, the UCLA investigator must obtain approval to conduct the research at the "not engaged" site from the site's IRB/IEC or documentation that the site's IRB/IEC has determined that approval is not necessary for UCLA to conduct the proposed research at the site.
- B. When performance sites are "not engaged" in research and the "not engaged" site does not have an established IRB/IEC, the UCLA investigator must obtain a *letter of permission* demonstrating that the appropriate institutional officials are permitting the research to be conducted at the performance site.
- C. UCLA IRB approval to conduct research at a performance site is contingent upon the UCLA IRB's acceptance of the UCLA investigator's written assurance that he/she will obtain the appropriate documentation of the performance site's IRB/IEC determination, or letter of permission, as applicable.
- D. All required performance site documentation must be received by the UCLA investigator prior to initiation of the research at the performance site, maintained in the research files, and must be available at any time for audit by the UCLA IRB.
- E. Example of site involvement where the site is not engaged in human subjects research: site provides space for research activities, but site staff will not recruit, consent, conduct research procedures, have access to identifiable research data, etc.

VIII. Collaborating Agencies or Institutions

- A. UCLA investigators are responsible for ensuring that collaborating agencies or institutions have obtained appropriate IRB approval for their involvement in research activities, and that sites maintain continued communications with their local IRBs.
- B. UCLA investigators are responsible for managing and maintaining documentation associated with research involving collaborating agencies or institutions. Investigators must provide the UCLA IRB with written policies and procedures for the management of this documentation associated with research involving collaborating agencies or institutions.
- C. If a UCLA investigator is the lead investigator of a multi-site study or UCLA is the lead organization for a multi-site study, the investigator must provide the following information in his/her application for UCLA IRB review:
 - 1. Identify each collaborating site;
 - 2. Describe each site's role (e.g., performance site, data coordinating center, collaborating site, agency whose employees are conducting research procedures, etc.);
 - 3. Provide written assurance that he/she will maintain in the research files copies of all collaborators' IRB approval notices, IRB-approved consent documents, letters of

compliance, and/or letters of permission, including approval for all protocol modifications.³

4. Provide information about the management and communication of information among sites, particularly information that is relevant to the protection of participants, such as:
 - a. Unanticipated problems involving risks to participants or others
 - b. Interim results
 - c. Protocol modifications
- D. If a UCLA investigator is participating in a multi-site study and UCLA is not the lead organization for the multi-site study, the investigator must provide the following information in his/her application for UCLA IRB review:
 1. Identify each collaborating site;
 2. Describe each site's role (e.g., performance site, data coordinating center, collaborating site, agency whose employees are conducting research procedures, etc.);
 3. Identify the lead organization; and
 4. Provide a copy of lead organization's IRB approval notice for the research.

IX. Additional requirements for research conducted in schools

- A. UCLA investigators must obtain *letters of compliance* obtained from all elementary, middle, or high schools at which human subjects research will be conducted, even if the school is not *engaged* in the research.
- B. UCLA investigators must obtain approval from the Los Angeles Unified School District (LAUSD) for any research which is conducted in more than one school in the district.
- C. UCLA investigators must consult other school districts to identify requirements to conduct research in the districts.
- D. UCLA investigators must provide written assurance that he/she will maintain in the research files copies of all letters of compliance for schools at which human subjects research will be conducted.

X. Investigator Responsibilities

- A. UCLA investigators must obtain the UCLA IRB's determination whether sites are "engaged" or "not engaged" in human subjects research.

³ These materials must be received by the UCLA investigator before UCLA personnel may contact, recruit, or enroll subjects at the non-UCLA sites, or access identifiable research data collected at the non-UCLA sites. These materials must be available at any time for audit by the UCLA IRB.

- B. UCLA investigators must provide written assurance that he/she will obtain the appropriate documentation of the performance site's IRB/IEC determination.
- C. When a UCLA investigator is responsible for the overall conduct of the study among collaborating sites (e.g., if serving as the lead investigator), the investigator must provide the IRB with information about plans for the management and communication of information among the sites, particularly information that is relevant to the protection of participants.
- D. UCLA investigators are responsible for maintaining in the research files copies of all performance site(s)' IRB approval notice(s), IRB-approved consent document(s), letter(s) of compliance, and/or letter(s) of permission, including approval for all protocol modifications.
- E. UCLA investigator are responsible for maintaining in the research files copies of all collaborators' IRB approval notices, IRB-approved consent documents, letters of compliance, and/or letters of permission, including approval for all protocol modifications.
- F. The materials required in C and D above must be:
 1. received by the UCLA investigator before UCLA personnel may contact, recruit, or enroll subjects at the non-UCLA sites, or access identifiable research data collected at the non-UCLA sites; and
 2. available at any time for audit by the UCLA IRB.
- G. UCLA investigators are responsible for submitting an amendment and the appropriate supporting documents to obtain UCLA IRB review and approval of the addition of performance sites and/or collaborating agencies/institutions to the research study prior to beginning research activities at the new performance site.
- H. UCLA investigators are responsible for notifying the UCLA IRB of closures of performance sites and/or the cessation of involvement of collaborating agencies/institutions.

XI. IRB/OPRS Responsibilities

- A. The UCLA IRB will verify the investigator's determination of "engaged" versus "not engaged" in research.
- B. The UCLA IRB will review all related documentation for performance sites and collaborators, as specified in this guidance, as part of the conduct of initial and continuing review, for all studies reviewed by Expedited review or Full Committee review procedures.
 1. Documentation related to performance sites and collaborators shall include contact information for those entities.
- C. For studies for which the UCLA investigator is responsible for the overall conduct of the study at multiple sites, the UCLA IRB will review the adequacy of the UCLA

investigator's plans for management and communication of information among sites, particularly information that is relevant to the protection of participants.

- C. The UCLA IRB will review and approve all additions or closures of study sites for studies for which a UCLA investigator is the lead investigator of a multi-site study or UCLA is the lead organization for a multi-site study.
- D. The UCLA OPRS staff will verify that the appropriate documentation for performance sites and collaborators, as specified in this guidance, has been submitted to the UCLA IRB for approval. If omissions in documentation are found, the UCLA IRB staff will contact the investigator specifying the required documentation needed from the performance site(s).
- E. For all federally-funded research where UCLA is the lead investigator or organization, the UCLA OPRS staff will verify the institution's OHRP Assurance number and IRB registration number for performance sites "engaged" in research. Documentation of this verification will be entered into the UCLA IRB database and study file.
- F. For all federally-funded research where UCLA is not the lead investigator or organization, the UCLA OPRS staff will verify the lead institution's OHRP Assurance number and IRB registration number. Documentation of this verification will be entered into the UCLA IRB database and study file.
- G. The UCLA OPRS will maintain copies of Individual Investigator Agreements complied by those performance sites "engaged" in research where UCLA has agreed to serve as the IRB of Record.
- H. The UCLA OPRS staff will document in the UCLA IRB database and study file those instances where UCLA has agreed to serve as the IRB of Record for performance sites "engaged" in research.

Regulations:

45 CFR 46
21 CFR 50 and 56

References:

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

Memorandum of Understanding (MOU) for IRB Review of Multicampus UC Research, Letter of Transmittal from University of California Vice Provost for Research Lawrence B. Coleman, March 28, 2006.

Memorandum of Understanding (MOU) for IRB Review of Multicampus UC Research

Multicampus UC Research Notice of Intent to Rely Form

Multicampus UC Research Model Consent Form