

UCLA/RAND Memorandum of Understanding and Affiliated IRB Procedures
QUESTIONS AND ANSWERS

SUMMARY OF QUESTIONS

1. What is the UCLA/RAND Memorandum of Understanding?
2. What is the scope of research covered by the MOU?
3. What is the IRB deferral mechanism?
4. When does this deferral mechanism begin?
5. Do I need to be affiliated with UCLA to submit an application to the UCLA IRB? Do I need to be affiliated with RAND to submit an application to the RAND IRB?
6. What happens if my research qualifies for review by a single IRB under the MOU, but I don't submit a *Request to Defer Review of Human Subjects Research*?
7. What constitutes "collaborative research" conducted by UCLA and RAND?
8. When can I submit a *Request to Defer Review of Human Subjects Research*?
9. How do I submit a *Request to Defer Review of Human Subjects Research* for a new project to a single IRB?
10. Which IRB will review the Robert Wood Johnson Clinical Scholars' research?
11. If my research involves UCLA, RAND, and additional collaborating institutions, which IRBs do I need to submit to?
12. What if my project involves collaborating community partners for whom the UCLA or RAND IRB has agreed to act as the partners' designated IRB, but in accordance with the MOU, the research will now be reviewed by the other IRB?
13. What if my project was previously reviewed by both IRBs, but in accordance with the MOU an amendment or continuation application should now be reviewed by one IRB?
14. What if my project was previously reviewed by one IRB, but in accordance with the MOU an amendment or continuation application should now be reviewed by the other IRB?
15. Who do I contact if I have questions?

UCLA/RAND Memorandum of Understanding and Affiliated IRB Procedures QUESTIONS AND ANSWERS

1. What is the UCLA/RAND Memorandum of Understanding? (MOU)

The "Memorandum of Understanding Between RAND and UCLA" (MOU), in place since September 2002, promotes collaboration in health services research conducted by UCLA and RAND. It celebrates the joint research of the institutions, supports joint recruitment and appointments, and through an amendment, facilitates human subjects research review through a deferral mechanism that allows one of the two institutions to take responsibility for IRB review on behalf of both institutions. See the MOU at: <http://www.research.ucla.edu/ocga/memos/ucla-rand-mou-9-02.pdf>, or <http://intranet.rand.org/groups/hspc/MOU/ucla-rand-mou-9-02.pdf>.

2. What is the scope of research covered by the MOU?

UCLA and RAND programs are jointly involved in research to document and improve health care services, quality of care, health policy, community health, and health-related outcomes (including societal, environmental, and individual determinants of health), and also in other health-related research. Research within these broad fields, conducted jointly by UCLA and RAND or jointly supported by the infrastructures of these institutions, falls under the scope of the MOU.

3. What is the IRB deferral mechanism?

For research that falls within the scope of the MOU, only one institution – either UCLA or RAND – will be the sole IRB.

There are three categories of studies for which UCLA will be the sole IRB:

- Research involving the collection and/or use of human tissue and specimens;
- Research that is subject to regulation by the Food and Drug Administration (FDA); and
- Research requiring UCLA Health Insurance Portability Accountability Act (HIPAA) privacy board review, e.g., research involving UCLA medical records or research that generates data to be entered into UCLA medical records.

All other research will be reviewed with RAND as the sole IRB. However, RAND has the right to defer any review back to UCLA, in which case UCLA will be the sole IRB.

The IRB that conducts the initial review will remain the IRB throughout a project's life, except in certain circumstances, such as when a project initially reviewed by RAND subsequently is revised so it meets the criteria for review by UCLA, e.g., by addition of procedures for collecting blood samples.

The Deferral Request Form is available at:

RAND: <http://intranet.rand.org/groups/hspc/MOU/DeferralRequestForm.doc>

UCLA: <http://www.oprs.ucla.edu/human/forms/checklists>

UCLA/RAND Memorandum of Understanding and Affiliated IRB Procedures
QUESTIONS AND ANSWERS

4. When does this deferral mechanism begin?

The deferral mechanism will begin on September 1, 2006 and be in effect until any change in mechanisms or processes are jointly agreed upon by UCLA and RAND, either through amendment or cancellation. Updates will be posted on the human subjects protection websites of each institution.

**5. Do I need to be affiliated with UCLA to submit an application to the UCLA IRB?
Do I need to be affiliated with RAND to submit an application to the RAND IRB?**

No, but a member of the research team who is affiliated with the reviewing institution should be identified as the "Lead Investigator at the Reviewing Institution" on the *Request to Defer Review of Human Subjects Research*.

A UCLA-affiliated member of the research team should be identified as "Lead Investigator at the Reviewing Institution" on an application for UCLA IRB review or Certification of Exemption from IRB review, and a RAND-affiliated member of the research team should be identified as "PI at the Reviewing Institution" on an application for RAND IRB review or exemption from IRB review.

NOTE: The Lead Investigator must be affiliated with the Reviewing Institution and need not be the Principal Investigator for the research, nor the Principal Investigator on the grant or contract. The Principal Investigator for the research and/or the grant or contract may be affiliated with the institution that is not performing the IRB review.

6. What happens if my research qualifies for review by a single IRB under the MOU, but I don't submit a *Request to Defer Review of Human Subjects Research*?

The project will undergo review by both IRBs. It is an investigator's responsibility to identify applications that fall under the MOU, and to request deferral of review to a single IRB. Due to the large volume of research handled by the RAND and UCLA IRBs, they cannot proactively identify all research that may qualify for review by a single IRB under the MOU.

7. What constitutes "collaborative research" conducted by UCLA and RAND?

"Collaborative" is not defined by or restricted to financial arrangements involving both UCLA and RAND, but instead pertains to the persons and property involved in the conduct of the research, as described in the IRB application and supporting materials. Both institutions must be "engaged" in the research. [<http://www.hhs.gov/ohrp/humansubjects/assurance/engage.htm>]

In the event that either UCLA or RAND receives an application that is not collaborative and does not fall under the MOU, the UCLA or RAND IRB will communicate this determination to the investigator, and the investigator will be required to submit to the IRB at the institution with which he/she is affiliated. If one of the institutions is not engaged, as defined by the regulations, the research must be reviewed at the institution that *is* engaged in the research.

**UCLA/RAND Memorandum of Understanding and Affiliated IRB Procedures
QUESTIONS AND ANSWERS**

8. When can I submit a *Request to Defer Review of Human Subjects Research*?

Requests to defer review of a study to a single IRB may be submitted at the time of submission of:

- a new application,
- an amendment to a previously-reviewed application, or
- an annual continuing review application.

Requests to defer review of a study to a single IRB will be accepted for previously approved projects only when an amendment or annual continuing review is required. Requests to defer review of a previously certified exempt study to a single IRB will be accepted when an amendment is required.

9. How do I submit a *Request to Defer Review of Human Subjects Research* for a new project to a single IRB?

Please refer to the institution-specific directions below.

<u>For review by the UCLA IRB</u> , please provide the following materials to the UCLA OPRS/IRB office:	<u>For review by the RAND IRB</u> , please provide the following materials to the RAND HSPC office:
<ol style="list-style-type: none">1. Completed <i>Request to Defer Review of Human Subjects Research</i>;2. Completed UCLA Form HS-1, HS-7, or HS-9, and all supporting documentation, including copies of all recruitment and consent materials, measures/instruments, etc., and a copy of grant proposal/funding application, if applicable.	<ol style="list-style-type: none">1. Completed <i>Request to Defer Review of Human Subjects Research</i>;2. Completed HSPC Form A (Human Subjects Research Screening) at http://intranet.rand.org/groups.hspc/formA.html; <p>The RAND IRB will let you know if and what additional information is needed.</p>

NOTE: The Request to Defer Review of Human Subjects Research ("Deferral Form") and accompanying application for IRB/HSPC review should be submitted solely to the reviewing institution as determined by the conditions of the MOU. The reviewing institution must be the same institution that the Lead Investigator identified on the Deferral Form is affiliated with, but need not be the institution with which the Principal Investigator of the research and/or contract or grant is affiliated.

UCLA/RAND Memorandum of Understanding and Affiliated IRB Procedures
QUESTIONS AND ANSWERS

10. Which IRB will review the Robert Wood Johnson Clinical Scholars' research?

The Robert Wood Johnson (RWJ) Clinical Scholars program is considered a joint UCLA/RAND program. Research conducted by RWJ Clinical Scholars should be submitted to the RAND IRB, unless it:

- (1) involves the collection and/or use of human tissue and specimens,
- (2) is subject to regulation by the Food and Drug Administration (FDA), and/or
- (3) involves UCLA medical records or generates data to be entered into UCLA medical records.

Please contact Cristina Punzalan (Email: punzalan@ucla.edu) for additional guidance regarding the IRB review of research conducted by RWJ Clinical Scholars.

11. If my research involves UCLA, RAND, and additional collaborating institutions, which IRBs do I need to submit to?

The UCLA/RAND MOU does not eliminate the requirement to obtain IRB approval from collaborating institutions outside UCLA and RAND. If your research involves additional collaborating institutions, you will be required to obtain (1) UCLA OR RAND IRB approval, as determined by the UCLA/RAND MOU, and (2) IRB approval from the additional collaborating institutions.

12. What if my project involves collaborating community partners for whom the UCLA or RAND IRB has agreed to act as the partners' designated IRB, but in accordance with the MOU, the research will now be reviewed by the other IRB?

Agreements for the UCLA IRB or the RAND IRB to act as the designated IRB for collaborating community partners who do not have their own IRB are made on a study-by-study basis.

Continuations and amendments to previously-approved research: If the UCLA or RAND IRB previously agreed to act as the designated IRB for a community partner for a study which will now be reviewed by the other IRB in accordance with the MOU, the community partner will need to request that the reviewing IRB act as its designated IRB at this time.

New proposals: New proposals involving community partners for which the UCLA or RAND IRB has previously agreed to act as their designated IRB will need to follow the same procedures they do now to formalize an agreement that the UCLA or RAND IRB act as their designated IRB.

Please contact the UCLA or RAND IRB staff to discuss individual requests for the UCLA or RAND IRB to act as the designated IRB for a collaborating community partner.

**UCLA/RAND Memorandum of Understanding and Affiliated IRB Procedures
QUESTIONS AND ANSWERS**

13. What if my project was previously reviewed by both IRBs, but in accordance with the MOU an amendment or continuation application should now be reviewed by one IRB?

Please refer to the institution-specific directions below.

<p>For projects reviewed previously by both IRBs but <u>now to be reviewed only by the UCLA IRB</u>, please provide the following materials:</p>	<p>For projects previously reviewed by both IRBs but <u>now to be reviewed only by the RAND IRB</u>, please provide the following materials:</p>
<ol style="list-style-type: none"> 1. Completed <i>Request to Defer Review of Human Subjects Research</i>; 2. Materials required for the continuation or addendum application, as described in the "Continuation Submission Checklist" or "Addendum Checklist." http://www.oprs.ucla.edu/human/forms/checklists 	<ol style="list-style-type: none"> 1. Completed <i>Request to Defer Review of Human Subjects Research</i>; 2. For an amendment, a Request for HSPC Approval of Changes to Research Affecting Human Subjects, available at http://intranet.rand.org/groups/hspc/change.html; 3. For a continuation, an HSPC Form C (Annual Review), which the HSPC will email to the RAND Lead Investigator.

14. What if my project was previously reviewed by one IRB, but in accordance with the MOU an amendment or continuation application should now be reviewed by the other IRB?

Please refer to the institution-specific directions below.

<p>For projects previously reviewed only by the RAND IRB but <u>now to be reviewed for the first time by the UCLA IRB</u>, please provide the following:</p>	<p>For projects previously reviewed only by the UCLA IRB but <u>now to be reviewed for the first time by the RAND IRB</u>, please provide the following:</p>
<ol style="list-style-type: none"> 1. Completed <i>Request to Defer Review of Human Subjects Research</i>; 2. A copy of the previous RAND IRB approval or Certification of Exemption; 3. A copy of the RAND IRB-approved recruitment and consent materials; 4. Cover letter including a progress report and outlining proposed addendum changes (if applicable); 	<ol style="list-style-type: none"> 1. Completed <i>Request to Defer Review of Human Subjects Research</i>; 2. A chronology of UCLA IRB review(s); 3. A copy of the previous UCLA approval or exemption notification(s); 4. A copy of all recruitment and consent materials; 5. Completed HSPC Form B, which the HSPC will email to the RAND Lead Investigator;

**UCLA/RAND Memorandum of Understanding and Affiliated IRB Procedures
QUESTIONS AND ANSWERS**

14. (continued) Institution-specific directions for submitting an amendment or continuation application to the other IRB when a project was previously reviewed by the other IRB

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| <ul style="list-style-type: none">5. Completed HS-1 or HS-7 application for IRB review or Certification of Exemption;6. Copies of all recruitment and consent materials which are still to be used;7. Copies of all relevant measures/instruments, etc.; and8. Copy of grant proposal/funding application, if applicable. | <ul style="list-style-type: none">6. For an amendment, a Request for HSPC Approval of Changes to Research Affecting Human Subjects, available at http://intranet.rand.org/groups/hspc/change.html;7. For a continuation, an HSPC Form C (Annual Review), which the HSPC will email to the RAND Lead Investigator;8. Copy of the grant proposal/funding application(s), if applicable. |
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Investigators are encouraged to refer to UCLA's "New Submission Checklist - General" or the UCLA HS-7 Guidelines for a complete listing of materials required for new applications for UCLA IRB review or Certification of Exemption.

<http://www.oprs.ucla.edu/human/forms/checklists>

Investigators are encouraged to refer to the RAND HSPC website at

<http://intranet.rand.org/groups/hspc/>.

NOTE: For security purposes, access to the RAND intranet is restricted to RAND staff. Therefore only the Lead Investigator who is affiliated with RAND and/or his/her RAND staff will have access to the RAND HSPC forms.

Researchers may also have RAND HSPC forms emailed to them by sending a message to hspcadmin@rand.org or by calling (310) 393-0411, x7522.

15. Who do I contact if I have questions?

Please contact the staff at the RAND and UCLA human subjects protections/Institutional Review Board (IRB) offices if you have any questions.

For projects being reviewed at UCLA:

UCLA Office for Protection of Research Subjects (OPRS)

gcirb@oprs.ucla.edu

(310) 825-7122

For projects being reviewed at RAND:

RAND HSPC Administrative Office

hspcadmin@rand.org

OR

(310) 393-0411 x7522