Amendment to Memorandum of Understanding
Between UCLA and the RAND Corporation
Dated: May 26, 2006

In accordance with section I. part 6. of the Memorandum of Understanding (MOU) between the RAND Corporation ("RAND") and the University of California, Los Angeles ("UCLA"), dated September 2, 2002, this amendment provides details of the coordinated process for reviewing collaborative UCLA/RAND research in the health services (hereinafter "Health Services Research") that involves human research subjects.

This amendment will go into effect as of June 7, 2006 and remain in effect until such time as the Memorandum of Understanding is terminated or further amended.

The parties therefore agree as follows:

1. Health Services Research shall be reviewed under a simplified Institutional Review Board ("IRB") process where only one institution, UCLA or RAND, will serve as the IRB for both institutions utilizing a deferral mechanism ("Deferral").

2. The procedures for Deferral shall be consistent with each party's Federalwide Assurance ("FWA"). In a Deferral, the deferring institution agrees to accept the IRB review performed at the reviewing institution, and the reviewing institution concurrently agrees to the delegation. The reviewing institution agrees to use reasonable efforts to review projects deferred to them in accordance with applicable regulations. Each party, as required per 45 CFR Section 46.114, remains responsible for safeguarding the rights and welfare of human subjects.

3. Health Services Research and research related activities governed by the MOU will be deferred to the RAND IRB. Notwithstanding the foregoing, the following categories of research shall be deferred to the UCLA IRB:
   
   - Research that is subject to regulation by the Food and Drug Administration ("FDA");
   - Research requiring UCLA Health Insurance Portability and Accountability Act (HIPAA) board review, e.g., research involving UCLA medical records or research that generates data to be entered into UCLA medical records; and
   - Research involving the collection or use of human tissue and specimens.

4. RAND retains the right to decline to provide RAND IRB review and to defer back to UCLA. In that event, UCLA will assume the role of the single IRB responsible for reviewing the research to be conducted at both institutions.

5. The Deferral responsibilities for each institution extend to all types of IRB reviews including exempt, expedited, and full committee. Once deferred, IRB review responsibilities remain with the reviewing institution throughout the life of the project.
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6. The deferring institution agrees that there shall be no routine oversight or review of the IRB procedures of the reviewing institution by the other institution. However, in extraordinary cases, by written agreement between the UCLA Vice Chancellor for Research and the RAND Executive Vice President, or their designees, special reviews or oversight activities can be undertaken. Upon request, each party will provide the other with documentation of their procedures. Requests for documentation will be made by the UCLA Vice Chancellor for Research or the RAND Executive Vice President or their designees.

7. In cases where a UCLA IRB reviews research administered by RAND, UCLA shall submit to the RAND IRB administrator a copy of the IRB approval notice for RAND’s records. In cases where the RAND IRB reviews UCLA administered research, RAND shall submit to the UCLA IRB administrator a copy of the IRB approval notice for UCLA’s records. Similarly, records shall be submitted to the other institution following approval of any amendment applications and continuing reviews of ongoing Health Services Research.

8. Adverse events occurring either at RAND or UCLA will be reported to the IRB that reviewed the research protocol.

9. Each party shall be responsible for notifying the other of any instances of non-compliance that are reportable to the federal Office of Human Research Protection (“OHRP”) or the FDA. Any such notices shall be sent to the other party’s IRB Administrator.

10. Mutual Indemnification:

UCLA shall defend, indemnify and hold harmless RAND, its officers, employees and agents from and against and all liability, loss, injury, damages, or expense (including reasonable attorney's fees) (hereinafter collectively referred to as “Liability”) arising out of UCLA’s performance under this Amendment, but only in proportion to and to the extent such liability is caused by or results from the negligent or intentional acts or omissions of UCLA, its officers, employees or agents.

RAND shall defend, indemnify and hold harmless UCLA, its officers, employees and agents from and against and all Liability arising out of RAND’s performance under this Amendment, but only in proportion to and to the extent such liability is caused by or results from the negligent or intentional acts or omissions of RAND, its officers, employees or agents.

The party seeking indemnification shall provide the indemnifying party with prompt written notice of any claims or threats of claims.
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11. The individuals responsible for implementation of this Amendment are:

For RAND:

Michael Rich
Executive Vice President

For UCLA:

Roberto Peccei
Vice Chancellor – Research

12. Each party shall be responsible for amending its Federalwide Assurance in accordance with the terms of this Amendment. Each party agrees to file appropriate paperwork with OHRP immediately after the execution of this Amendment. Each party will notify the other when its respective FWA amendments have been approved. Implementation of the Deferral program will begin immediately thereafter.

13. Review of the Deferral mechanism will be incorporated into the review of the status of the MOU that is to take place every two years in accordance with Section IV. part 3. of the MOU.

14. This Amendment and the September 2002 MOU contain the entire agreement between the parties hereto with respect to Deferral and constitute the complete, final and exclusive embodiment of their agreement with respect to the subject matter hereof. The terms of this Amendment are contractual and not a mere recital. This Amendment is executed without reliance upon any promise, warranty or representation by any party or any representative of any party other than those expressly contained herein, and each party has carefully read this Amendment, and signs the same of his or its own free will.

This Amendment shall be deemed to have been entered into and shall be construed and enforced in accordance with the laws of the State of California. In all other respects, the MOU shall remain in full force and effect.

AGREED TO:

On behalf of RAND Corporation:  
On behalf of UCLA:

James A. Thomson  
President and CEO  

Albert Carnesale  
Chancellor