

**IRB AUTHORIZATION AGREEMENT (IAA)
AND
MEMORANDUM OF UNDERSTANDING (MOU)
BETWEEN
NATIONAL BUREAU OF ECONOMIC RESEARCH
AND
UNIVERSITY OF CALIFORNIA LOS ANGELES**

1) PURPOSE:

This IRB Authorization Agreement (IAA) and Memorandum of Understanding (MOU) sets forth the express agreement between:

National Bureau of Economic Research (hereinafter NBER)
1050 Massachusetts Avenue
Cambridge, MA 02138 and

University of Southern California Los Angeles (hereinafter UCLA)
10889 Wilshire Blvd, Suite 830
Los Angeles, CA 90095-1406

concerning the utilization of NBER's Institutional Review Board (IRB).

2) SCOPE:

The signatory official agrees that University of California Los Angeles may rely on the NBER IRB for review and continuing oversight of research described below: (check one)

X	Limited to the following subset of research:
	<i>Any Human Subjects Research which is funded by NBER</i>

3) AUTHORITY:

- A. 45 CFR Part 46 Subparts A (Common rule), B, C & D
- B. 21 CFR Parts 50, 56, 312, and 812
- C. 45 CFR Part 160 and Subparts A and E of Part 164 (HIPAA Privacy Rule)

4) BACKGROUND:

NBER and the University of California Los Angeles maintain separate, active Federalwide Assurances (FWA) from the Office for Human Research Protections (OHRP) under the U.S. Department of Health and Human Services (HHS). Both institutions use OHRP's current policy

guidance on defining when an institution is engaged in research covered by the Common Rule and each institution's assurance.

This MOU will allow the University of California Los Angeles to rely on the NBER's IRBs for review and continuing oversight of its human subject research described above.

Institution Providing IRB Review (NBER):

IRB Registration #: IRB00002946

Federalwide Assurance #: 00003692

Institution Relying on the Designated IRB (UCLA)

IRB Registration #'s: IRB00000172, IRB00000173, IRB00000174, IRB00004473, IRB00004474

Federalwide Assurance #: 00004642

The review and continuing oversight performed by the designated NBER IRB will meet the human subject protection requirements of UCLA's OHRP-approved FWA. The IRB at NBER will follow written procedures for reporting its findings and actions to appropriate officials at UCLA. Relevant minutes of IRB meetings will be made available to UCLA upon request. UCLA remains responsible for ensuring compliance with the IRB's determinations and with the terms of its OHRP-approved Assurance. This document must be kept on file at both institutions and provided to OHRP upon request.

5) RIGHTS, DUTIES, AND RESPONSIBILITIES OF THE NBER IRB:

- a) The NBER IRB will perform all of the functions required under 45 CFR Part 46, 21 CFR Parts 50, 56, and 312 and 812 (where applicable), 45 CFR Part 160 and Subparts A and E of Part 164 (where applicable), and the human subjects protection requirements of UCLA's OHRP-approved FWA for the review and continuing oversight of human subjects research conducted under the auspices of the research outlined in Section 2.
- b) The NBER IRB will have the authority to suspend the research for failure to comply with conditions of approval or regulatory requirements.
- c) The NBER IRB will consider conflicts of interest and confirm, where appropriate, that the application or proposal for human subjects research submitted to the funding agency matches the protocol submitted for IRB approval.
- d) The NBER IRB will notify UCLA's of any unanticipated problems, termination, or suspension of research, as detailed in Section 7.
- e) NBER IRB shall establish written procedures for:
 - i) IRB membership;
 - ii) IRB quorum and review procedures;
 - iii) The requirements for full Board and expedited review of new research;
 - iv) The requirements for obtainment of informed consent/assent;
 - v) The requirements for documentation of informed consent/assent;
 - vi) The requirements for reporting the IRB findings and actions to the Principal Investigator and Institution;
 - vii) Determining which projects require review more often than annually;

- viii) Determining which projects need verification from sources other than the investigators that no material changes have occurred since the previous IRB review;
 - ix) Ensuring prompt reporting to the IRB of proposed changes in a research activity;
 - x) Ensuring that changes in approved research, during the period for which IRB approval has already been given, are not initiated without IRB review and approval; except when necessary to eliminate apparent immediate hazards to the subject;
 - xi) Ensuring prompt reporting of any unanticipated problems involving risks to subjects or others;
 - xii) Ensuring prompt reporting of any serious or continuing noncompliance;
 - xiii) Observation of the consent process by a NBER IRB designee; Observation of the conduct of the research by a NBER IRB designee
- f) The NBER IRB, or its authorized representatives, including its cultural consultant, the FDA, and HHS to the extent permitted by law, will be permitted to conduct the following:
- i) Examine and inspect the UCLA's facilities used for the performance of the studies, including storage and use of any investigational products;
 - ii) Observe the conduct of the studies;
 - iii) Inspect and copy all documents relating to the studies, including research records, informed consent documents, investigational logs, and other study specific data.
 - iv) Interview, as necessary, all personnel involved in human subject interaction for the studies.
- g) The NBER IRB shall maintain all documents reviewed in connection with UCLA's research, including any relevant communication with investigators. The NBER IRB will make its records for studies approved under this agreement available upon written request to appropriate officials at UCLA's. NBER IRB records shall be maintained for six years following project termination. Prior to destruction, UCLA may request transfer of records maintained at the NBER IRB scheduled for routine destruction.
- h) The NBER IRB will cooperate fully with UCLA and make appropriate records available to regulatory and accrediting entities at such time as UCLA's Human Research Protections Program (HRPP) is under review (including making appropriate records available to the reviewers).
- 6) RIGHTS, DUTIES, AND RESPONSIBILITIES OF THE INSTITUTION RELYING ON THE NBER IRB (UCLA):**
- a) UCLA is ultimately responsible and bears full responsibility for all research covered under its FWA.
 - b) UCLA is responsible for maintaining a HRPP to include a formal process to monitor, evaluate, and continually improve the protection of human research participants, dedicating resources sufficient to do so; exercising oversight of research protection; educating investigators and research staff about their ethical responsibility to protect research participants; and, when appropriate, providing a mechanism to intervene in research and responding directly to concerns of research participants. The HRPP will also monitor compliance with the terms and conditions of NBER IRB's approval.
 - c) UCLA assures and warrants that all investigators participating in research specified in Section 2 above are and will remain members of its staff in good standing and are credentialed and privileged to perform the procedures outlined in the studies.

- d) UCLA will notify, within three business days, the NBER IRB Research Compliance Manager (RCM) of the termination, suspension, or modification of any research privileges of members of its Staff who are participating in the study authorized by the NBER IRB.
- e) UCLA will notify, within three business days, the NBER IRB RCM of any: 1) unanticipated problems involving risks to subjects or others; or 2) any serious or continuing noncompliance with the federal regulations or the requirements or determinations of the NBER IRB.
- f) UCLA will inform the NBER IRB of any contact by the HHS, or any other persons or entities regarding any of the research specified in Section 2 above within three business days of contact. UCLA will also notify the NBER IRB within three business days, in the event that any governmental agency issues a "Notice of Inspectional Observations," "Warning Letters," or other communications citing improper or inadequate research practices with respect to the research specified in Section 2 above.
- g) UCLA will maintain this Agreement as part of the institution's HRPP records.
- h) UCLA is responsible for ensuring compliance with the terms of its OHRP approved FWA.
- i) UCLA investigators will comply with the NBER investigator ethics education requirement and other human research related policies. UCLA may require additional training and education for its research personnel in addition to the NBER requirements.
- j) Following the NBER IRB approval, UCLA may require additional review as determined by the UCLA's Authorized Institutional Official (IO) and may be subject to additional administrative requirements as determined by UCLA policy.

7) REPORTING

- a) The NBER IRB Office will provide the UCLA's HRPP point of contact with the data listed in Appendix A - Data Provided to UCLA that is applicable to UCLA research.
- b) The NBER IRB Office will report to the UCLA's HRPP point of contact the following:
 - i) Reports of serious or continuing non-compliance
 - ii) Reports of unanticipated problems involving risks to subjects or others
 - iii) Suspension of IRB approval
 - iv) Terminations of IRB approval
 - v) Allegations of scientific misconduct
 - vi) Disclosure of significant conflicts of interest by UCLA investigators engaged in research
 - vii) Oversight agency or other organization initiates any action (including audits, compliance monitoring, and reporting)
 - viii) Any modification to the FWA or changes to the status of the FWA documents
 - ix) Changes in the IRB point of contact information.
- c) The UCLA will promptly report to the NBER IRB Office the following:
 - i) Reports of serious or continuing non-compliance
 - ii) Reports of unanticipated problems involving risks to subjects or others
 - iii) Suspension of UCLA IO approval
 - iv) Terminations of UCLA IO approval
 - v) Allegations of scientific misconduct
 - vi) Disclosure of significant conflicts of interest by UCLA investigators engaged in research
 - vii) Oversight agency or other organization initiates any action (including audits, compliance monitoring, and reporting)
 - viii) Any modification to the FWA or changes to the status of the FWA documents
 - ix) Changes in the HRPP Office Point of Contact information

- d) The NBER IRB will promptly report to OHRP and HHS: (i) unanticipated problems involving risks to subjects or others; (ii) serious or continuing noncompliance; and (iii) suspensions or terminations of previously approved research related to the UCLA FWA

8) MODIFICATIONS

Any modifications to this agreement must also be in writing and with the concurrence of all parties to the agreement.

9) CONFIDENTIALITY

Each party shall hold in confidence any information obtained from the other party during the course of this agreement. The recipient party's obligation shall not apply to information that:

- a) is already in the recipient party's possession at the time of disclosure;
- b) is or later becomes part of the public domain through no fault of the recipient party;
- c) is received from a third party having no obligations of confidentiality to the disclosing party;
- d) is independently developed by the recipient party;
- e) is ethically required to be disclosed to participants because of any unforeseen risk identified by either party during or after completion of the Study;
- f) or is required by law or regulation to be disclosed.

In the event that information is required to be disclosed pursuant to subsection (f), the party required to make disclosure shall notify the other to allow that party to assert whatever exclusions or exemptions may be available to it under such law or regulation.

10) TERM AND TERMINATION

This agreement remains in effect as long as UCLA is engaged in the research for which UCLA required the services of NBER's IRB.

Either party may terminate this agreement without cause upon 30-days written notice to the other party.

Each party's duty of confidentiality will continue after the termination of this agreement.

11) NOTICES

Any party giving or making any notice, request, demand, or other communication (each, a "notice") pursuant to this agreement must give the notice in writing.

Notices are effective upon the date of receipt.

Written notice must be delivered by one of the following means: registered or certified mail (in each case, return receipt requested); nationally recognized overnight courier; electronic mail; or facsimile. Any party giving notice must address the notice to the appropriate person at the receiving party at the address listed below:

NBER: Research Compliance Manager (Kristen Kenny)

National Bureau of Economic Research
1050 Massachusetts Avenue
Cambridge, MA 02138, USA
Email: kennyk@nber.org

Alterra Milone
Director, Research and Grants Management
National Bureau of Economic Research
1050 Massachusetts Avenue
Cambridge, MA 02138, USA
Email: alterra@nber.org

University of California Los Angeles:
C/O Dr Roger Wakimoto
Box 951405
2248 Murphy Hall
Los Angeles, CA 90095

Kristin Craun
Director, Office of the Human Research Protections Program
10889 Wilshire Blvd, Suite 830
Los Angeles, CA 90095

The undersigned have read and agreed to all of the terms above, and have the authority to bind their respective institutions. Written concurrence is required for this MOU to have legal effect, as memorialized by signature below.

FOR

FOR


NBER

UCLA



Date

Alterra Milone
Director of Research and
Grants Management
Authorized Institutional Official



Date

Roger Wakimoto, PhD
Vice Chancellor for Research
Authorized Institutional Official

