

**Procedures to Implement the Reliance Memorandum of Understanding  
Among the University of California Campuses, UC Division of Agriculture and Natural  
Resources, and Lawrence Berkeley National Laboratory for IRB Review of Multi-UC  
Campus Human Subject Research**  
*July 2016*

These procedures and processes have been agreed upon by the Directors of the Human Subjects Protections Program (HRPPs) of the UC campuses, UC Division of Agriculture and Natural Resources (ANR), and the Lawrence Berkeley National Laboratory (hereinafter referred to as “UC Campuses”) as authorized under the above-referenced Reliance Memorandum of Understanding (Reliance MOU). These procedures and processes are intended to implement the Reliance MOU.

**1. DEFINITIONS**

- a. Continuing Noncompliance** – A pattern of noncompliance that indicates an inability or unwillingness to comply with applicable laws, regulations, or institutional policies pertaining to the protection of human subjects and/or with the requirements or determinations of an IRB.
  
- b. Exempt Human Subject Research** – The definition of exempt human subject research is that set forth in the following:
  - i. 45 CFR §46.101(b); and
  - ii. Appendix A to these Procedures to Implement the Reliance Memorandum of Understanding Between Human Research Protection Programs at University of California Campuses, UC Division of Agriculture and Natural Resources, and Lawrence Berkeley National Laboratory for IRB Review of Multi-Campus Human Subjects Research, “Exempt Category 7 for the UC System”.
  
- c. Expedited Human Subject Research** – The definition of expedited human subject research is that set forth in the following:
  - i. 45 CFR §46.110; and
  - ii. 21 CFR §56.110.
  
- d. Human Subject Research** – The definition of human subject research is that set forth in federal regulations describing humans, research, clinical investigation and other closely related terms promulgated by the Office of Human Subject Protections for Human Subject Research at 45 CFR §46.102, and the Food & Drug Administration regulations of Clinical Investigations at 21 CFR §50.3, §312.3 and §812.3, and as required by California law.
  
- e. Human Research Protections Program** – The program operated by the Institution for the protection of Human Subjects in research, which may include IRB oversight, conflict of interest identification and management, radiation safety, biosafety, investigational drug compounding and manufacturing, information privacy and security, and similar activities.
  
- f. Institutional Official** – The Institutional Official is the Signatory Official on the Federalwide Assurance (FWA) filed with OHRP to assure compliance with regulations governing protection of human subjects. OHRP requires the Institutional Official to be a high-level official who has authority to represent the institution named in the FWA.

- g. Institutional Review Board (IRB)** – A specifically 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 or social science research.
  - h. Minimal Risk Research** – The definition of Minimal Risk Research is that set forth in federal regulations promulgated by the Office of Human Subject Protections for Human Subject Research at 45 CFR 46.102, and the Food & Drug Administration regulations at §§ § 56 CFR 50.3(l) and 56.102(i).
  - i. Noncompliance** - Failure to comply with applicable laws, regulations, or institutional policies pertaining to the protection of human subjects, and/or with the requirements or determinations of an IRB.
  - j. UC IRB Reliance Registry** – A web-based electronic tool to facilitate communication among the Reviewing and Relying IRBS.
  - k. Reviewing IRB** – The “IRB of record” that assumes IRB responsibilities for another UC campus or Institution under the MOU.
  - l. Relying IRB** – The IRB that cedes IRB review to a Reviewing IRB for an instance of research under the MOU.
  - m. Serious Noncompliance** – Failure to comply with applicable laws, regulations, or institutional policies pertaining to the protection of human subjects and/or with the requirements or determinations of an IRB that has a significant adverse impact either on the rights or welfare of participants or on the integrity of the data.
  - n. Unanticipated Problem** – An incident, experience, or outcome that meets all of the following criteria:

    - (1) Is unexpected (in terms of nature, severity or frequency) given (a) the research procedures that are described in the protocol-related documents, such as the IRB-approved research protocol and informed consent document; and (b) the characteristics of the subject population being studied;
    - (2) Is related or possibly related to participation in the research (possibly related means there is a reasonable possibility that the incident, experience, or outcome may have been caused by the procedures involved in the research); and
    - (3) Suggests that the research places subjects or others at a greater risk of harm (including physical, psychological, economic, or social harm) than was previously known or recognized.
- 2. DETERMINING THE REVIEWING IRB** – The criteria for determining the Reviewing IRB shall be:
- a.** The campus that is the prime recipient of the research award (or, in the case where the research is not funded by an external award, the campus with which the PI is primarily affiliated);

- b. The UC location where subject contact, recruitment, and/or interactions or interventions shall entirely, or substantively take place; or
- c. Mutually agreed upon by the UC campuses participating in the multi-site study.

### 3. DUTIES AND RESPONSIBILITIES OF BOTH THE REVIEWING AND RELYING IRBS

- a. **Cooperation** – The Reviewing and Relying IRBs will cooperate fully concerning these agreed upon processes and procedures. Relevant documentation to support review, compliance and oversight by the respective IRBs will be made available to the reciprocal IRBs upon request. Each IRB will make available records applicable to the regulatory and accrediting agency activity if and when the reciprocal IRB requires such records. The MOU and these implementing procedures and processes must be kept on file at the IRBs that are party to this agreement and must be provided to the requesting IRB.
- b. **Local Ancillary Review Committees** – The Reviewing and Relying IRBs will ensure that their respective PI(s) have completed required local ancillary reviews and Relying IRBs shall communicate relevant ancillary review committee determinations to the Reviewing IRB. These reviews include, but are not limited to, institutional biosafety review, radiation safety review, review and management of conflict of interest, and others as required.
- c. **Reporting Unanticipated Problems and/or any Serious and/or Continuing Noncompliance** – The Reviewing and Relying IRBs will immediately report to each other in a given study any unanticipated problems involving risks to subjects or others or any incidents of serious and/or continuing noncompliance. This reporting duty is in addition to and does not replace the investigator's duty to report unanticipated problems or serious and/or continuing noncompliance, as required by government regulations and institutional policies and procedures. The Reviewing IRB is the institution responsible for reporting as required by government regulations. The Relying institution shall be provided with an opportunity to review and comment on regulatory-required reporting prior to submission by the Reviewing IRB.
- d. **Human Subjects Training** –The Reviewing and Relying IRBs agree to require initial and continuing education in order for all Reviewing and Relying Investigators to retain their credentials to participate studies under this MOU. All participating campuses agree to accept one another's trainings.

### 4. DUTIES AND RESPONSIBILITIES OF THE REVIEWING IRB

- a. **Review and Oversight** – The Reviewing IRB will conduct initial and continuing reviews and will review amendments to approved protocols and reports of unanticipated problems and serious and/or continuing non-compliance. The Reviewing IRB shall have the authority to suspend or terminate the research.
- b. **Notification of IRB Decision**– Consistent with 45 CFR 46, the Reviewing IRB will notify the Relying IRB(s) of its determination or review decision. Reviewing Principal Investigators are responsible for informing all study investigators about changes after initial approve unless other arrangements have been made with Reviewing IRB.

- c. **Compliance and Oversight** – The Reviewing IRB will notify the Relying IRB(s) of related incidents of noncompliance or unanticipated problems of which it becomes aware including, but not limited to, violations of human research protection regulations. Notification responsibilities of both the Reviewing and Relying IRBs are set forth at section 3, above.
- d. **Approval Letter** – The Reviewing IRB shall make a copy of its Approval Letter available to the Relying IRB(s). This Approval Letter shall be uploaded to the UC IRB Reliance Registry.
- e. **UC IRB Reliance Registry** – The Reviewing IRB shall use the UC IRB Reliance Registry as a communication tool between the Reviewing and Relying IRBs that a determination has been made in its review of a study subject to the MOU.
- e. **Record Keeping** – The Reviewing IRB will keep records of studies subject to the MOU. The records will include, at a minimum, the date the application is submitted, review determinations, dates of approval, location of research activity, and oversight actions.
- f. **Review Rates** – Standard rates for cost of IRB review shall apply to both Reviewing and Relying IRBs on each study.
- g. **Local Administrative Review** – The Reviewing IRB will review as appropriate federally-funded grant applications or proposals to ensure that the protocol covers the human subjects research activities described in the grant proposal(s) supporting the research and that any such activities that are not covered have been/will be covered by an IRB approved protocol. Discrepancies between IRB protocols and grant proposals must be resolved before any funds are released to the investigator in support of human subject research. Consistent with agency policies, this review may be part of the “just-in-time” (JIT) process used in making awards.





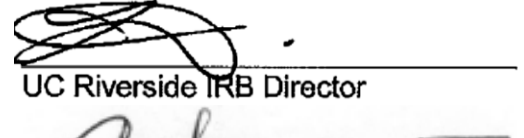
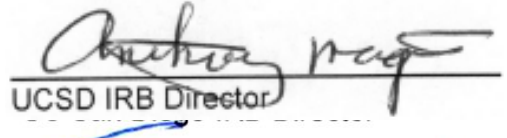

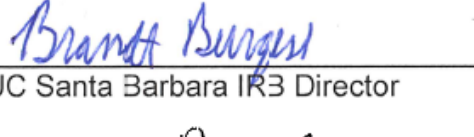


## 5. DUTIES AND RESPONSIBILITIES OF THE RELYING IRB(S)

- a. **Right to Decline to Rely** – A campus IRB may decline, on a case-by-case basis, to rely on an IRB review conducted by another campus. If this occurs, the Relying IRB will notify the PI seeking to rely and the reviewing campus of its decision not to rely.
- b. **UC IRB Reliance Registry** – The Relying IRB shall use the UC IRB Reliance Registry as a communication tool to notify Reviewing IRB of its decision to rely on another campus’ review of a study subject to the MOU.
- c. **Compliance and Oversight** – The Relying IRB will notify the Reviewing IRB of related incidents of noncompliance or unanticipated problems of which it becomes aware including, but not limited to, violations of human research protection regulations. Notification responsibilities of both the Reviewing and Relying IRBs are set forth at section 3, above.

## 6. DUTIES AND RESPONSIBILITIES OF THE PRINCIPAL INVESTIGATORS

- a. The Reviewing Campus Principal Investigator** – The Reviewing Campus Principal Investigator (Reviewing PI), or the Reviewing PI's designee, shall:
- i. Notify his or her IRB that the study will be involve one or more UC campuses;
  - ii. Ensure that the Reviewing PI personnel performing the study are qualified, meet education/training requirements of the reviewing IRB site, and adhere to the provisions of the IRB-approved protocol;
  - iii. Obtain any ancillary approvals required for this project at the Reviewing PI's campus (for example, conflict of interest, stem cells, cancer center, biosafety, radiation, or pharmacy);
  - iv. Submit an amendment to the Reviewing IRB for review and approval of any amendments to the approved protocol and communicate such changes to all study investigators;
  - v. Accept responsibility for the conduct of the study at Reviewing PI's site, the ethical performance of the project, and the protection of the rights and welfare of the human subjects who are directly involved at the Reviewing PI's site;
  - vi. Actively communicate with all study investigators at all relying campus sites to make sure that the necessary and required coordination of any research activities including notification of post-approval events takes place; and
  - vii. Upon the occurrence of a post-approval event requiring notification, the Reviewing PI shall report to the Reviewing IRB, pursuant to local standard procedures.
- b. The Relying Campus Principal Investigator** – The Relying Campus Principal Investigator (Relying PI), or the Relying PI's designee, shall:
- i. Notify his or her IRB that the study will be involve one or more UC campuses;
  - ii. Forward relevant information to the Reviewing PI before the study is submitted to the Reviewing IRB for initial review, amendment, and/or continuing review;
  - iii. Ensure that the Relying PI personnel performing the study are qualified, meet education/training requirements of the relying IRB site, and adhere to the provisions of the IRB-approved protocol;
  - iv. Obtain any ancillary approvals required for this project at the Relying PI's campus (for example, conflict of interest, stem cells, cancer center, biosafety, radiation, or pharmacy);
  - v. Not modify the IRB-approved protocol or any attached materials without first obtaining review and approval from the Reviewing IRB;
  - vi. Be permitted, without prior approval by the Reviewing Campus, to make minor changes in the consent form to reflect local administrative requirements, such as changing the contact phone number and letterhead. However, if the protocol requires a watermarked consent, this must be submitted as an amendment to the reviewing IRB;
  - vii. Accept responsibility for the conduct of the study at Relying PI's site, the ethical performance of the project, and the protection of the rights and welfare of the human subjects who are directly involved at the Relying PI's site;
  - viii. Follow the standards and guidelines of the HRPP of the Reviewing IRB for the reporting of any post-approval events, including adverse events, other safety information, and/or protocol violations or incidents; and
  - ix. Upon the occurrence of a post-approval event requiring notification, the Relying PI shall report to his/her local campus IRB, pursuant to local standard procedures.

7. **Execution** – The undersigned UC Campus IRB Directors have read and agreed to the above procedures and processes, which shall remain in effect until revoked or superseded by revised procedures and policies.

 _____ UC Berkeley IRB Director	<u>8/18/2016</u> Date
<small>Cynthia Gates JD RN CIP</small> <small>Digitally signed by Cynthia Gates JD RN CIP Date: 2016.08.19 15:34:54 -0700</small> _____ UC Davis IRB Director	_____ Date
 _____ UC Irvine IRB Director	<u>09.09.16</u> Date
 _____ UC Los Angeles IRB Director	<u>10/5/16</u> Date
 _____ UC Merced IRB Director	<u>8-25-16</u> Date
 _____ UC Riverside IRB Director	<u>Aug 19/16</u> Date
 _____ UCSD IRB Director	<u>8/29/2016</u> Date
 _____ UC San Francisco IRB Director	<u>8/22/16</u> Date
 _____ UC Santa Barbara IRB Director	<u>8/26/2016</u> Date
 _____ UC Santa Cruz IRB Director	<u>9/9/16</u> Date
 _____ Lawrence Berkeley National Laboratory HSPM Manager	<u>29 Aug 16</u> Date
<small>Cynthia Gates JD RN CIP</small> <small>Digitally signed by Cynthia Gates JD RN CIP Date: 2016.10.04 08:14:58 -0700</small> _____ UC Division of Agriculture and Natural Resources	<u>October 4, 2016</u> Date

## APPENDIX A

### New Exempt Category 7 for UC System

*There are six federal categories of research activities involving human subjects that may be exempt from the requirements of the Policy for the Protection of Human Subjects (45 CFR 46). A seventh category of exempt research activities has been defined by UC using flexibility permitted by the Federalwide Assurance of each UC campus. This category does not exist in the federal regulations and is used solely by the University of California and its system of campuses as per the terms of collective and individual Federalwide Assurances with the government.*

**UC Category 7:** Research that involves no greater than minimal risk to subjects, but does not conform to a specific exempt category under 45 CFR 46.101(b), and does not fall within the exclusions listed under 7.2 below.

- 7.1** Category 7 minimal risk exempt research examples may include non-physically invasive interventions or performance of tasks (but are not limited to):
- a. Reading/writing/drawing tasks;
  - b. Physical activities such as walking, sitting, or manipulating an object;
  - c. Computer tasks and/or doing internet searches;
  - d. Talking and/or listening to words, then making selections; or “think-aloud” exercises;
  - e. Viewing media;
  - f. Role playing;
  - g. Asking subjects to complete a specific physical or mental action (“imagine”);
  - h. Passive monitoring of space (environment) with sensors;
  - i. Playing a game;
  - j. Height/weight measurements.
- 7.2** Such research is NOT exempt if it includes any of the following:
- a. Federal funding or personnel supported by federal training or center or program grants;
  - b. Procedures, devices or drugs subject to FDA oversight;
  - c. Biomedical procedures;
  - d. Sponsor or other contractual restrictions;
  - e. Clinical interventions;
  - f. Prisoners as subjects;
  - g. Children as subjects;
  - h. An NIH-issued Certificate of Confidentiality to protect identifiable research data;
  - i. Deception or lack of full disclosure to subjects;
  - j. Federal personnel or the Department of Veterans Affairs;
  - k. Identifiable, private existing data;
  - l. The information obtained is recorded in such a manner that subjects can be identified, directly or through identifiers linked to the subjects, **and** any disclosure of the subject’s responses outside of the research could reasonably place the subject at risk of criminal or civil liability, be stigmatizing, or be damaging to the subject’s financial standing, employability, insurability or reputation.
- 7.3** If the research is determined to qualify for Category 7 Exempt status and later becomes federally funded, supported, or regulated, the researcher must immediately cease research activities until IRB approval is obtained.
- 7.4** For Expedited Research that meets the terms of 7.2 above, Relying campuses agree to accept the approval period set by the Reviewing campus’s IRB, unless otherwise agreed by the participating campuses.