P&P: GA 101 Version No: 1.1 Effective Date:11/16/2009	POLICIES AND PROCEDURES MAINTENANCE	Supercedes: CPHS Policies and Procedures 7/1/2007

1. POLICY

Written procedures must be in place to ensure the highest quality and integrity of the review and oversight of research involving human subjects and for the adequate documentation of such oversight. The following regulations and guidance of the Office of Human Research Protection (OHRP), Food and Drug Administration (FDA), and the International Conference on Harmonisation (ICH), supported by institutional policies and procedures, ensures that the rights, safety, and welfare of the human subjects of such research will be overseen and protected in a uniform manner, regardless of changes in personnel.

Policies and Procedures and Guidelines provide the framework for the ethical and scientifically sound conduct of human research.

Specific Policies

1.1 Definitions

1.1.1 Policy. A document issued by the University of California Office of the President (UCOP); the University of California Berkeley (UCB), the Vice Chancellor for Research (VCR) or Assistant Vice Chancellor (AVC) for Research Administration and Compliance (RAC); or the Committee for Protection of Human Subjects (CPHS) that provides for interpretation of regulations and may stipulate required practices of the Office for the Protection of Human Subjects (OPHS) and its Human Research Protection Program (HRPP), the IRBs (CPHS I & II), and/or investigators as it pertains to human subjects research.

1.1.2 Procedure. A document issued by the OPHS/HRPP and/or the IRB that identifies the processes and steps by which the IRB and associated OPHS staff conduct protocol reviews, day-to-day operations, and other particular matters.

1.1.3 Guideline. A document issued by the IRB that identifies recommended practices or IRB preferences for investigators. The local guidelines may be based on guidelines issued by the OHRP or they may just reiterate them or they may be local IRB interpretations of regulations or current Committee positions on topics.

1.1.4 Memorandum of Understanding (MOU). A document developed to define specific relationships between the University of California at Berkeley and other institutions with regard to IRB review of collaborative research.

1.2 Review, Revision, and Approval

1.2.1 Changes to regulations, federal guidelines, or research practice as well as the policies and procedures of the UCOP and/or UCB may require that policies, procedures, guidelines, and/or MOUs be created or revised.

1.2.2 Policies, procedures, guidelines, and MOUs will be reviewed by the appropriate institutional official(s) at intervals established by the OPHS Director.

1.2.3 Documentation of review and approval is required by signature of the responsible and authorized individuals.

A. Approval of new or revised policies is required by the Institutional Official (IO) or his/her designee, and the IRB Chair or OPHS Director as appropriate.

B. Approval of new or revised procedures is required by the OPHS Director and may be endorsed by the IO (or designee).

C. Approval of new or revised guidelines is required by the IRB Chair with review and endorsement of IRB members.

D. Approval of new or revised MOUs is required by the IO or his/her designee.

1.3 Dissemination and Training

1.3.1 When new or revised policies, procedures, guidelines, and MOUs are approved, they will be disseminated to the appropriate individuals and departments via a variety of channels, including the Research Advocate newsletter, email, website, university memoranda, and/or training seminars as appropriate.

1.3.2 Training will be provided to all members of the IRB (CPHS) and the OPHS staff on any new or revised policy, guideline, and/or procedure. Provision of training must be documented by the OPHS Director or IRB Manager (or other designee).

1.3.3 Each new IRB member or staff employee must review all applicable policies, procedures, and guidelines prior to undertaking any responsibilities at the IRB or OPHS respectively. Documentation of training must be done by the OPHS Director or IRB Manager (or other designee).

1.4 Forms

Forms are used to: 1) ensure that policies are integrated into the daily operations of research and review throughout UCB, and 2) enable OPHS staff to manage review, tracking, and notification functions consistently. Forms are either *controlled* or *non-controlled*.

1.4.1 Controlled forms are regulatory documents that become part of the permanent record of IRB review and determination. Therefore, they must be reviewed and approved as described in sections 1.1 and 1.2.

1.4.2 Non-controlled forms are management tools that are not subject to the standards of control cited in sections 1.1 and 1.2.

2. SCOPE

These policies and procedures apply to all UC Berkeley Investigators, all IRB members including Chairs, Vice Chairs, Acting Chairs, OPHS Director and staff, and the Vice Chancellor of Research as the Institutional Official or his/her designees.

3. RESPONSIBILITY

The Vice Chancellor for Research (VCR) is responsible for granting final approval (as appropriate) to new and revised VCR policies and procedures. He/she is responsible for endorsing CPHS and/or OPHS policies, procedures and guidelines, that is, officially acknowledging that the documents are consistent with the interests of the human subjects participating in research, the institution, and institutional policy.

The OPHS Director is responsible for establishing and periodically reviewing VCR policies and procedures and recommending modifications of them (as appropriate). The OPHS Director, in consultation with the IRB Manager and other OPHS staff, is responsible for establishing and periodically reviewing and modifying (as appropriate) P&Ps.

Designated ad hoc working groups of IRB members and/or OPHS staff are responsible for guiding, developing, and periodically reviewing and modifying (as appropriate) IRB policies and guidelines, and, in collaboration with the IRB Chair and OPHS Director, establishing procedures.

4. PROCESS OVERVIEW

The OPHS Director and IRB Manager monitor appropriate sources and contacts for policy updates, note policies that may need revisions, and determine priorities. The OPHS Director maintains records of current UCOP, VCR and IRB policies in the OPHS. The IRB Manger consults with the OPHS Director regarding changes to OPHS procedures.

The IRB Manager and OPHS staff members discuss changes and determine if additional procedures are required or if forms need revisions.

The Director in collaboration with the IRB Manager ensures that IRB policies, procedures, guidelines, and forms are drafted and/or revised as necessary to meet regulatory requirements and reflect changes in internal processes. The OPHS Director and/or IRB Manager presents documents to the IRB Chair and ad hoc committee members for review and approval (as necessary) and tracks changes.

The IRB Chair, OPHS Director and IRB Manager collaborate in formulating current IRB policies, regulatory interpretations and positions. IRB members collectively discuss topics where investigators need guidance and OPHS staff assist in drafting and formalizing such guidance.

The Institutional Official (or OPHS Director, as appropriate) has final approval authority for new and revised policies and procedures.

The IRB Manager is responsible for ensuring current policies, guidelines, forms, etc. are available to the research community. He/she replaces and destroys public copies of obsolete forms.

Then, the OPHS Director and IRB Manager collaborate in notifying the research community and distributing new policies, procedures, guidelines, and forms as needed.

5. APPLICABLE REGULATIONS AND GUIDELINES

21 CFR 56.108, 56.109, 56.113

45 CFR 46.103, 46.108

UC Berkeley, Official Campus Policies and Procedures
http://campuspol.chance.berkeley.edu/