

P&P: GA 101 Version No: 1.2 Effective Date: 01/15/21	POLICIES AND PROCEDURES MAINTENANCE	Supercedes: CPHS Policies and Procedures 10/1/2009
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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 or the Assistant Vice Chancellor for Research Administration and Compliance; or, the Committee for Protection of Human Subjects (CPHS) that provides for interpretation of regulations and may stipulate required practices of the Office for Protection of Human Subjects (OPHS) and its Human Research Protection Program (HRPP), the IRBs (CPHS 1 & 2), 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 conducts protocol reviews, conducts day-to-day operations, and handles 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; and/or they may just reiterate them; or, they are 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 responsible official(s) at intervals established by the OPHS Director.
- 1.2.3 Approval of new or revised policies is required by the CPHS Executive Committee or OPHS Director as appropriate.
- 1.2.4 Approval of new or revised guidelines is required by the IRB Chair and, if deemed necessary, with review and endorsement of IRB members.
- 1.2.5 Approval of new or revised procedures is required by the OPHS Director and may be endorsed by the Institutional Official (IO) (or designee).
- 1.2.6 Approval of new or revised MOUs is required by the IO or his or 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 Assistant Director (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 Assistant Director (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 UCB 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 or her designees.

3. RESPONSIBILITY

The Vice Chancellor for Research (VCR) is responsible for granting final approval (as appropriate) to new and revised IRB (CPHS) policies and MOUs as described.

The OPHS Director is responsible for establishing and periodically reviewing CPHS policies and procedures and recommending modifications of them (as appropriate). The OPHS Director, in consultation with the IRB Assistant Director and other OPHS staff, is responsible for establishing and periodically reviewing and modifying (as appropriate) SOPs.

The CPHS Executive Committee or OPHS Director is responsible for reviewing and granting final approval to new and revised CPHS policies, as appropriate.

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 Assistant Director monitor appropriate sources and contacts for policy updates, note policies that may need revisions, and determine priority. The IRB Assistant Director consults with the OPHS Director regarding changes to OPHS procedures.

The IRB Assistant Director 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 Assistant Director 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 Assistant Director presents documents to the IRB Chair and ad hoc committee members for review and approval (as necessary) and tracks changes.

The IRB Chair and IRB 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 IRB Assistant Director is responsible for ensuring current policies, guidelines, forms etc. are available to the research community. The Assistant Director replaces and destroys public copies of obsolete forms.

Then, the OPHS Director and IRB Assistant Director 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, Compliance Services

<https://compliance.berkeley.edu/>