

P&P: GA 105 Version No: 1.1 Effective Date:11/16/2009	SIGNATORY AUTHORITY	Supercedes: CPHS Policies and Procedures 7/1/2007
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1. POLICY

The IRB Chair and his/her designee(s) are authorized to sign any and all documents on behalf of the IRB in connection with the review and approval (or a determination of exemption) of research projects involving the use of humans as subjects, which have been reviewed and approved pursuant to University of California Berkeley and IRB policies and procedures. Individuals must sign their own name and no other, indicate their title under their signature, and date their signature.

Specific Policies

1.1 Definitions

- 1.1.1 Handwritten signature means the scripted name or legal mark of an individual handwritten by that individual and executed or adopted with the present intention to authenticate writing in permanent form. The act of signing with a writing or marking instrument such as a pen or stylus is preserved. The scripted name or legal mark is conventionally applied to paper.
- 1.1.2 Electronic signature means a computer data compilation of any symbol or series of symbols executed, adopted, or authorized by an individual to be the legally binding equivalent of the individual's handwritten signature.
- 1.1.3 Digital signature means an electronic signature based upon cryptographic methods of originator authentication, computed by using a set of rules and a set of parameters such that the identity of the signer and the integrity of the data can be verified. Digital signatures may be accepted in lieu of handwritten signatures.
- 1.1.4 Initials. The first letter of each word in a person's name written in ink with his or her own hand.
- 1.1.5 Scanned Signature. A person's handwritten signature that is electronically scanned and reproduced in a pdf format to match the appearance of his or her signature. Scanned signatures may be used by the IRB or the OPHS Director in lieu of handwritten signatures only if approved and documented by the Institutional Official (or his/her designee).
- 1.1.6 Signature block. A person's name (usually accompanied by his or her title and contact information) that is appended to the end of email messages and other electronic communication when an electronic or digital signature as defined above is not applicable.

1.2 Authorization for Signatory Authority

Requests for authorization to sign documents not described in this policy may be made in writing to the OPHS Director.

1.3 Results of Reviews, Actions, and Decisions

The IRB Chair(s) or designee(s) are authorized and required to sign results of expedited reviews. IRB Committee decisions (e.g. deferrals, conditional approvals, approvals) are communicated to investigators in correspondence that comes out under the IRB Chair's signature.

OPHS staff are authorized to add the scanned signature of the above IRB member who approved the research on the official approval letter notifying the investigator of the approval date and the date on which the protocol approval will expire. Likewise, OPHS staff are authorized to affix the Chair's signature on behalf of the Committee in communications with the investigator.

The OPHS Director (or his/her designee) is authorized and required to sign results of reviews and actions taken that notify investigators of a determination of exemption or a finding that the project the investigator proposed is found to be not human subjects research. OPHS staff are authorized to add the Director's scanned signature to correspondence affirming a determination of exemption or a finding of not human subjects research.

1.4 Routine Internal Correspondence

Designated OPHS staff members are authorized to sign any actions, letters, memos, or emails between and on behalf of the IRB and/or members of the faculty and staff of UC Berkeley or other investigators submitting to the UC Berkeley IRB that provide information concerning the review of research protocols and do not imply or appear to imply approval of the protocols.

1.5 Correspondence with External Agencies

The OPHS Director and Institutional Official (or his/her designee) are authorized to sign any assurances, formal notification letters, memos, or emails sent to agencies of the federal government or state, funding agencies (whether private or public), or their agents.

The Assistant Vice Chancellor for Research Administration and Compliance, IRB Chair and members, and OPHS staff members may correspond informally with agencies of the federal government and funding agencies (whether private or public) to seek guidance, clarification, and other general information.

1.6 Private Health Information

At UCB, the IRB has been designated as the Privacy Board under the Health Insurance Portability and Accountability Act (HIPAA) and therefore, the IRB Chair (or his/her designee) is authorized to sign IRB reviewed and approved documents for a Request for Waiver, Partial Waiver or Modification of Individual Authorization for Disclosure of Protected Health Information forms as required by the Privacy Rule.

2. SCOPE

These policies and procedures apply to all persons associated with the review of human subjects research at UC Berkeley.

3. RESPONSIBILITY

The Institutional Official is responsible for establishing the overall procedure for delegating signatory authority. The IO is responsible for committing UC Berkeley to serve as the IRB of record for other institutions or investigators and authorizing such commitments.

The OPHS Director is responsible for implementing and controlling signatory authority delegations.

The IRB Chair, IRB members, and OPHS staff are responsible for adhering to institutional signatory authority policies.

4. PROCESS OVERVIEW

The Institutional Official will establish signature authority delegation based on the nature of documents being signed and may designate signature authority in his/her absence.

The OPHS Director routinely signs all documents related to the review and determination of exemption for research projects and correspondence with external agencies (e.g., updating IRB registration and FWA documentation).

The IRB Chair, in consultation with the OPHS Director and IRB Manager, decides what (if any) signatory authority the IRB Manager, Administrator or other OPHS staff members will be designated to undertake on his/her behalf.

5. APPLICABLE REGULATIONS AND GUIDELINES

45 CFR 46.103

45 CFR 46.115

45 CFR 160, 162 and 164 (HIPAA)