

<b>P&amp;P: QA 903</b> <b>Version No: 1.0</b> <b>Effective Date: 9/1/2007</b>	<b>REVIEW FOR PURPOSES OF VERIFICATION</b>	<b>Supercedes: CPHS Policies and Procedures 11/28/2000</b>
---	--	--

## 1. POLICY

The University of California, Berkeley (UCB) IRB acknowledges that they have a responsibility and the authority to audit the operations of investigators and protocols to ensure the health, safety and well-being of subjects as well as to ensure regulatory compliance with federal and state law governing the conduct of human subjects research as well as university policies. UCB supports such monitoring and audits as part of its continuing effort to maintain high standards for human research protections.

### Specific Policies

#### 1.1 Site Visits and Third Party Verification

The IRB has the authority to observe, or have a third party observe, the informed consent process of research it has approved, and to verify that the study is being conducted as required by the IRB and within the Institutional policies and procedures and site-specific procedures, as appropriate. OPHS staff or IRB members may perform site visits, use questionnaires, or other means, either affiliated or not with the institution, to verify information in the protocol application, or in any interim or continuing review submissions.

The criteria for selecting Investigators to be reviewed for verification may include:

- Investigators who conduct studies that involve exceptionally high risk to subjects,
- Projects where allegations of possible changes occurring without IRB approval have been raised based upon information provided in continuing review reports or from other sources, and
- Investigators with a history of noncompliance.

Sponsors may be asked to submit copies of monitoring reports, or may be requested to complete a questionnaire regarding the protocol and/or the investigative site.

Investigators may be asked to submit copies of signed informed consent forms or other documents to ensure their compliance with IRB requirements. The IRB may conduct interviews with screened and/or enrolled subjects as deemed necessary.

## 2. SCOPE

These policies and procedures apply to all IRBs and investigators affiliated with the University of California Berkeley.

### **3. RESPONSIBILITY**

The Institutional Official is responsible for serving as the responsible institutional official in all regulatory agency matters regarding regulatory compliance, participating as needed in regulatory agency audits, and providing support in responding to and correcting audit findings.

The Assistant Vice Chancellor for Research Administration (or designee) is responsible for all formal regulatory agency correspondence and interactions, establishing logistical support during regulatory agency audits, serving as key institution contact during such audits, and drafting responses to regulatory agency correspondence received following such audits.

IRB Chair, Members and OPHS Staff are responsible for participating in regulatory agency audits as determined by the OPHS Director, and in fully cooperating with government officials during their participation in such audits.

The IRB Chair and IRB (as needed) in consultation with the Director determine which investigators and/or protocols warrant additional monitoring, a site visit or third party verification. The OPHS Director is responsible for implementing monitoring as directed by the IRB and supervising any for cause or not for cause monitoring of investigator activities by OPHS staff.

The Assistant Vice Chancellor for Research Administration and Compliance in cooperation with the IRB Chair is responsible for assisting the OPHS Director in formal responses to regulatory agency audits and in implementing policy and procedure changes indicated by such audits.

### **4. PROCESS AND PROCEDURES EMPLOYED TO IMPLEMENT THIS POLICY**

An OPHS staff member contacts the Investigator and/or key site personnel to set a day and time to conduct a site visit. The days prior to the visit, he or she confirms the date and time with the Investigator and/or key personnel.

The site visitor brings a completed copy of the current protocol, informed consent document, and any adverse event reports submitted.

The site visitor confirms that the study is being conducted in compliance with the information provided on these documents by observation if possible, especially: the method of subject recruitment, and in particular, that there are safeguards in place for the recruitment of subjects vulnerable to coercion or undue influence, the process of obtaining informed consent, the consent form being used, the facilities available in an emergency.

If appropriate, he or she obtains information about (1) any adverse events that may have been reported; (2) any adverse events that may not have been reported; and (3) any unanticipated problems.

If project is inactive, suspended, or terminated, the site visitor will obtain information regarding this status. He or she will complete a site visit report and submit it to the Director.

The Director routes the report to the IRB Chair for review.

The IRB Chair will review the report and determine any necessary follow-up action. A discussion of the site visit may be scheduled on the agenda for next IRB meeting.

## **5. APPLICABLE REGULATIONS AND GUIDELINES**

21 CFR 56.115

45 CFR 46.115