

<b>P&amp;P: GA 103</b> <b>Version No: 1.1</b> <b>Effective Date:11/17/2009</b>	<b>MANAGEMENT of the OFFICE</b> <b>FOR THE PROTECTION OF</b> <b>HUMAN SUBJECTS STAFF</b>	<b>Supercedes: CPHS</b> <b>Policies and Procedures</b> <b>7/1/2007</b>
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## 1. POLICY

The Office for the Protection of Human Subjects (OPHS) staff are vital components in the effective operation of the University of California Berkeley's Human Research Protection Program (HRPP). They provide consistency, expertise, and support to the IRBs, as well as serve as a daily link between the IRB, the research community, and other administrative units. The highest level of professionalism and integrity on the part of OPHS staff is expected.

### Specific Policies

#### 1.1 Job Descriptions and Performance Evaluations

Members of the OPHS staff will have a written description of the responsibilities expected of their positions. The performance of staff will be reviewed according to current Office of the Vice Chancellor for Research and University of California Berkeley policy.

#### 1.2 Staff Positions

Staffing levels and function allocation will be determined according to University of California Office of the Vice Chancellor for Research and Assistant Vice Chancellor for Research Administration and Compliance (AVC-RAC), university policy, management assessment of support requirements, and budget constraints.

#### 1.3 Hiring and Terminating OPHS Staff

The Director of the Office for the Protection of Human Subjects is responsible for implementing the human resource policies of the University of California, Berkeley for recruiting, hiring, developing, and terminating staff.

#### 1.4 Delegation of Authority or Responsibility

Delegation of specific functions, authorities, or responsibilities by the IRB Chair to an IRB administrative staff member will be documented in writing. See P&P GA 105 – Signatory Authority for more details.

#### 1.5 Documentation

The policies of the University of California, Berkeley's Human Resource Services and the Vice Chancellor for Research will determine the means of identifying, documenting, and retaining formal staff interactions (e.g., performance reviews, termination procedures).

## 2. SCOPE

These policies and procedures apply to all OPHS staff members.

### **3. RESPONSIBILITY**

The Director of the Office for the Protection of Human Subjects is responsible for establishing personnel requirements and hiring and evaluating the ongoing performance of the IRB Manager and other administrative staff.

The Director works in close cooperation and consultation with the IRB Chair(s) and the AVC-RAC to meet the needs of the IRBs and the institution, while effectively balancing the sometimes competing interests of each entity. However, in any given situation, the Director and administrative staff will give foremost attention to the protection of human subjects in research by supporting the IRB in fulfilling its duties.

### **4. PROCESS OVERVIEW**

Institutional Official will define management policies and procedures to promote the long-term commitment of employees and ensure the efficient and effective administration and enforcement of IRB decisions.

The AVC-RAC will maintain the job description for the Director, Office for the Protection of Human Subjects.

The Director will maintain the job descriptions for the IRB Manager. He/she is responsible for ensuring that the IRB Manager is adequately oriented and trained.

The Director, with the input of the IRB Manager, will establish the requirements for other OPHS administrative staff. The Director will complete personnel recruitment, hiring, and termination as per VCR/HR policy. The IRB Manager will be responsible for ensuring that IRB staff are adequately oriented and trained.

The Director will evaluate the performance of the IRB Manager and the of the OPHS administrative staff.