

<b>P&amp;P: FO 304 Version No: 1.2 Effective Date: July 2024</b>	<b>RECORD RETENTION AND DISPOSITION</b>	<b>Supersedes Document Dated: 12/20/2011</b>
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## **1. POLICY**

It is the policy of the University of California, Berkeley (UCB) Office for Protection of Human Subjects (OPHS) to maintain Institutional Review Board (IRB) office records for research activities under its jurisdiction, consistent with university policies, applicable state and federal laws, and university contracts.

### **Specific Policies**

#### **1.1 Institutional Review Board (IRB) Records**

1.1.1 Protocols are to be retained for the time period required by law, regulation, or policy, whichever is longer.

1.1.2 The same retention requirements apply to protocols for which no subjects were enrolled or no research was conducted.

1.1.3 Protocols which are no longer required to be retained may be destroyed.

1.1.4 All records other than protocols are retained indefinitely or until no longer deemed to be useful by the OPHS Director.

1.1.5 All records for research conducted or funded by a Common Rule department or agency, or records for research subject to Food and Drug Administration (FDA) regulations, are to be accessible for inspection and copying by authorized representatives of those agencies, respectively, at reasonable times and in a reasonable manner.

1.1.6 Records maintained that document compliance or non-compliance with Department of Defense (DOD) regulations shall be made accessible for inspection and copying by representatives of the DOD at reasonable times and in a reasonable manner as determined by the supporting DOD component.

## **2. SCOPE**

These policies and procedures apply to all IRB and HRPP records maintained by CPHS/OPHS.

## **3. RESPONSIBILITY**

OPHS staff carry out these responsibilities under the supervision of the OPHS Director.

#### **4. RECORD STORAGE HISTORY**

Protocols are maintained within the CPHS/OPHS Berkeley online application submission system (“eProtocol”).

All records other than protocols are stored on UC Berkeley administered cloud service providers.

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

45 CFR 46.115

21 CFR 56.115

[University of California RMP Series - Records Management and Privacy](#)

[University of California Administrative Records Related to Research: Retention and Disposition](#)

[Contracts and Grants Manual – Protection of Research Subjects](#)

[UC Berkeley Office of Ethics - Selected Privacy and Confidentiality Regulations](#)