P&P: FO 304 Version No: 1.2 Effective Date: 12/20/2011	RECORD RETENTION AND DISPOSITION	Supercedes Document Dated: n/a

1. POLICY

In keeping with sound business practices and in support of its mission, the University of California creates, gathers, and maintains operational and historical records of its activities. The objective of the University Records Management Program is to ensure that, consistent with other university policies, applicable state and federal laws, and university contracts, administrative records are appropriately managed and preserved, and can be retrieved as needed. The policy as set forth in this document and Records Management and Privacy (RMP) bulletins, in conjunction with other university policies and guidelines is necessarily general due to the decentralized and diverse nature of the University of California. Per UC Policy on the Protection of Human Subjects in Research, "regulations of the Department of Health and Human Services (HHS), set forth in 45 CFR Part 46, are applicable to all research involving human subjects, as defined by these regulations, for which the University is responsible, regardless of the source of funding, or whether the research is funded."

Specific Policies

1.1 Institutional Review Board (IRB) Records

The IRB shall prepare and maintain adequate paper or electronic documentation of the following items for at least three years (all records shall be retained at least three years and records relating to research which is conducted shall be retained for at least 3 years after completion of the research) :

A. Reviewed research proposals and unfinished applications, including correspondence with investigators

B. Approved sample consent documents

C. Progress reports

D. Records of continuing review activities

E. Scientific evaluations

F. Reports of unanticipated problems involving risks to subjects or others and/or reports of noncompliance

G. IRB Rosters

H. IRB and academic research records pertaining to children as subjects

I. IRB and academic research records pertaining to in vitro studies or pregnant women

J. IRB Policies and Procedures

1.2 Exceptions for Record Retention

1.2.1 Exempt and non-exempt protocols and IRB records involving children are retained for a minimum of 25 years.

1.2.2 Exempt and non-exempt protocols and IRB records involving pregnant women or in-vitro studies are retained for a minimum of 25 years.

1.2.3 Protocols not covered by 1.2.1 or 1.2.2. and determined to be exempt are retained for at least three years after the end of the project.

1.2.4 Non-exempt protocols not covered by 1.2.1 or 1.2.2 are retained for at least three years after the end of the project.

1.2.5 All IRB minutes pertaining to exempt and non-exempt protocols are kept for at least 25 years. Other IRB records are kept per specific policy in 1.1.

1.2.6 Other Human Research Protection Program administrative records are retained at least three years or until no longer deemed to be useful by the Director.

1.2.7 The records identified in 1.1 will be accessible for inspection and copying by authorized representative of the FDA, OHRP, or other appropriate federal departments or agencies at reasonable times and in a reasonable manner. All other access to records shall be in accordance with applicable law and university policy.

1.2.8 For IRB applications that use or obtain Protected Health Information (PHI), pursuant to the Health Insurance Protection and Portability Act of 1996 (HIPAA), OPHS must retain all protocol and IRB records regarding that research for at least six years after the completion of the research.

1.3 Record Destruction

1.4.1 Digital or audio recordings of each convened IRB meeting will be retained for 3 months (90 days) after the minutes of that specific meeting are approved. Audio recording on tape will either be erased or the tape destroyed. In general, digital recording files are stored on an encrypted flash drive. Audio recordings may also be stored on the OPHS secure server, but should not be stored on any laptops or other removable media unless in encrypted form. The IRB Administrator is responsible for working with IT to ensure that recordings are permanently deleted after the 90 day waiting period.

1.4.2 Paper records of research protocols, HRPP documents or IRB records will be shredded or recycled depending on the sensitivity of the information contained therein once they have passed their retention period according to the above schedules.

2. SCOPE

These policies and procedures apply to all IRB and HRPP records, files, memos, email correspondence, regardless of the storage format (e.g. hard copy, digital or electronic). In addition this policy applies to all non-personnel documents held in the Office for the Protection of Human Subjects.

3. RESPONSIBILITY

The OPHS Director has primary responsibility in ensuring adequate IRB documentation of compliance for human subject research activities at UCB. Other records supporting the management of the HRRP and institutional policies, guidelines and standard operating procedures are also the responsibility of the Director to review, replace and purge from office systems and storage as indicated.

Training on the policies and procedures set forth in this document will be provided for the existing workforce of the OPHS by the OPHS Director, to the extent applicable to such workforce members. New members of the workforce of the OPHS must receive such training, to the extent applicable to such workforce members, within a reasonable period of time of joining the OPHS, generally no later than sixty (60) days after their hire date or assignment by their supervisor or another authorized by the Director to provide such training.

The OPHS Director is responsible for granting individuals permission to access HRPP electronic records in computer systems and for ensuring that such individuals abide by institutional policies and procedures with appropriate security measures.

OPHS staff are responsible for collection, documentation, management, and safekeeping of all IRB records, protocols files and the appropriate long-term storage of said items per this policy.

4. RECORD STORAGE HISTORY

eProtocol - UC Berkeley now uses a web-based research compliance management system. CPHS began the transition to the new system in March 2009 with the Exempt review process. In December 2009, the system was opened to Non-Exempt applications. Shortly thereafter, researchers with approved protocols that pre-existed the new system were asked to enter them into eProtocol as new applications prior to the expiration of their current approval. As federal regulations permit approval of human subjects research for a period of one year at a time, it was anticipated that it would take just over a year for all pre-existing protocols to be entered into the system. The full transition to eProtocol was completed in February 2011.

Alfresco - Hardcopy records for exempt determinations and findings of not human subjects have been scanned into an electronic archive since 2004. The process of scanning hard copy records of non-exempt IRB protocols that pre-existed the new web-based system began in 2009 and will continue until all of these records have been archived.

Server - Non-protocol related IRB records are a mixture of electronic records that are stored on a password protected secure server; or, as hard copy records that are in the secured OPHS suite, locked in the Director's office or kept in locked file drawers.

Hardcopy Files - Hard copy records of closed protocols and other IRB records prior to January 2005 that have been retained are stored off site in the following locations: (1) 3200 Regatta, Richmond, CA storage, (2) Old Art Gallery (on campus), and (3) California Hall Attic.

5. APPLICABLE REGULATIONS AND GUIDELINES

45 CFR 46.115
21 CFR 56.115

University of California RMP Series - Records Management and Privacy
http://www.ucop.edu/ucophome/policies/bfb/bfbrmp.html

University of California Administrative Records Related to Research: Retention and Disposition
http://www.ucop.edu/research/policies/documents/retention_disposition_reqs.pdf

Contracts and Grants Manual – Protection of Research Subjects
http://www.ucop.edu/raohome/cgmanual/chap18.html#18-200

UC Berkeley Privacy Regulations
http://cio.berkeley.edu/privacy/regulations.html