

Policy Number: 40

Title: Data Repositories (a.k.a., “Banks”)

Date of Last Revision: July 5, 2007

I. Introduction

There is great potential scientific value in the research acquisition and banking of personally identifiable data about living individuals. The history of biomedical and social science research includes a long tradition of collecting data on health, social, psychological, legal, academic, and other aspects of human interaction and experience. These data help us to better understand and deepen our knowledge of the human condition, develop better means of delivering, preventing, diagnosing, and treating disease, and improve public health planning and programming. The value of such research does not minimize the importance of respect for the rights and welfare of subjects.

UCLA policy for the research use of personally identifiable data abides by The Belmont Report, federal regulations for the protection of human research subjects and federal and state laws and regulations for the protection of personal information. To that end, research repositories of personally identifiable human subject data must have IRB approved standard operating procedures (SOPs) for the collection, maintenance, and distribution of material. Investigators should establish research repositories only with complete informed consent, including information about the following: (a) disposition of the data, (b) information resulting from the data, (c) the level of confidentiality and limits to confidentiality subjects can reasonably expect as a result of providing personal information, and (d) whether the data may be shared with other investigators.

II. Definitions

- A. **Repository:** A storage site or mechanism by which identifiable data are stored or archived for research by multiple Investigators or multiple research projects.
- B. **Prospective:** Research using human subjects’ data that will be collected after the research is approved by the IRB.
- C. **Retrospective:** Research using human subjects’ data that were previously collected (e.g., on the shelf) before the research was approved by the IRB.

D. Examples of Human Subjects Data for Research:

1. Private information such as clinical notes and medical information, academic records, pharmacy records, interviews, and surveys that can be identified with a specific individual, whether or not the information was specifically collected for the research study in question. This also includes private information provided for specific purposes by an individual, which the individual can reasonably expect will not be made public;
2. Data obtained from voice, video, digital or image recordings; and/or
3. Data obtained from surveys, interviews, oral histories, focus groups, program evaluations, quality assurance methodologies, etc.

III. Establishment and/or Use of Repositories

- A. The UCLA IRB is responsible for overseeing the collection, use, storage, and re-use of all personally identifiable data that are generated within, transferred to, or transferred from UCLA for research purposes.
1. Data (whether collected prospectively or previously stored) that will be shared, used again, or stored for research purposes beyond the scope of the Investigator's originally approved IRB application must be banked in an IRB-approved "research repository."
 2. IRB approval is required for the acquisition of existing data collections for research use or for deposit into a research repository.
 3. An investigator must obtain prospective UCLA IRB approval or certification of exemption from IRB review for a specific study protocol prior to obtaining data from a repository.
- B. A repository may be established within or outside UCLA. There is no single "repository" site or mechanism within UCLA.
1. Repositories may be proposed, built, and maintained by individuals (e.g., Investigators), groups, programs, departments, or institutes. A single Investigator or a group of Investigators may wish to pool research data from multiple research studies into a single bank or database that could be accessed by the group and others for further use.
 2. Examples of outside repositories that a UCLA Investigator may wish to utilize include the NIH, CDC, ECOG, and NSABP laboratories, Department of Education, health care facilities, pharmacies, police agencies, and schools, as well

as laboratories and databases managed by colleagues at other academic institutions.

- C. The IRB does not oversee the storage or management of data that are collected and stored as part of routine clinical care, hospital procedures, or other standard non-research institutional data, such as academic records. Individuals collecting, storing or managing such non-research data are responsible for following all applicable UCLA policies and procedures regarding such activities.
 - 1. However, UCLA IRB approval or certification of exemption is required prior to the use of these data for research purposes by a UCLA Investigator.

- D. The IRB does not oversee the use or management of data sent to a UCLA Investigator/employee for specialized analysis as part of a contractual agreement. As part of the process for executing such a contract or service agreement, the UCLA investigator should contact OPRS for a written determination that the activity does not “engage” UCLA in the research.¹
 - 1. However, UCLA IRB approval or certification of exemption is required prior to the use of these data for research purposes by a UCLA Investigator.

IV. Standard Operating Procedures for Data Repositories

- A. Consistent with OHRP guidelines, the IRBs review and approve protocols specifying the conditions under which data may be stored and shared, and ensuring adequate provisions to protect the privacy of subjects and maintain the confidentiality of data.
 - 1. This requirement includes extra-mural repositories to which UCLA investigators wish to send data.
 - 2. The information submitted by investigators for IRB review must include all information requested in the UCLA OPRS [Standard Operating Procedures for Data Banks](#).

- B. OHRP recommends that research repositories operate under a Certificate of Confidentiality, especially for the banking of genetic information.

¹ Engagement is determined by January 1999 guidance from OHRP, *Engagement of Institutions in Research*, available at <http://www.hhs.gov/ohrp/humansubjects/assurance/engage.htm>. Please also see [OPRS/IRB Policy 3: Human Subject Research Determinations](#).

V. **Informed Consent Requirements for the Establishment and Use of a Repository**

- A. The IRBs review the consent process and documentation for initial collection of data for repositories as well as the consent process and documentation for subsequent use of these data.²
1. Legally effective informed consent as described at 45 CFR 46.116 must be obtained prospectively from each subject unless otherwise waived by the IRB.
- B. Per OHRP guidance, the IRBs require that informed consent forms for collecting, storing and sharing data for research purposes include a clear description of the following:
- (a) The operation of the repository;
 - (b) The specific types of research to be conducted;
 - (c) The conditions under which data and specimens will be released to recipient-investigators; and
 - (d) The procedures for protecting the privacy of subjects and maintaining the confidentiality of data.
- C. Where identifiable data are obtained from medical records for placement in a research repository, all requirements of the Health Insurance Portability & Accountability Act apply. Please refer to [OPRS/IRB Policy 49: HIPAA](#) for details.

VI **Additional Requirements**

- A. The Investigator is responsible for complying with all applicable federal and state laws regarding the confidentiality of information (such as the California Information Practices Act- see below).
1. The release of identifiable data held by the University of California (UC) and the receipt of identifiable data from another state agency both fall under the terms of the California Civil Code 1798.24, as amended in 2005. Unless subjects have provided authorization as required by the law, or another exception exists as outlined in the law, the release of identifiable information to or by UC requires review by the Committee for the Protection of Human Subjects of the California Health and Human Services Agency.³

² For information about consent requirements, including criteria for waivers or alterations of informed consent requirements, see [OPRS/IRB Policy 29: Informed Consent Process & Documentation](#).

³ <http://www.oshpd.ca.gov/CPHS/index.htm>

Regulations:

45 CFR 46
California Civil Code §1798.24

References:

OHRP Guidance: Issues to Consider in the Research Use of Stored Data or Tissues, November 7, 1997. <http://www.hhs.gov/ohrp/humansubjects/guidance/reposit.htm>

OHRP Guidance on Research Involving Coded Private Information or Biological Specimens, August 10, 2004. <http://www.hhs.gov/ohrp/humansubjects/guidance/cdebiol.pdf>

California Committee for the Protection of Human Subjects.
<http://www.oshpd.ca.gov/CPHS/index.htm>

Attachment:

OPRS-79 UCLA IRB/OPRS Guidance: Standard Operating Procedures for Data Banks
<http://www.oprs.ucla.edu/human/documents/pdf/Data%20banking%20SOPs%202005>