

Policy Number: 39

Title: Research Involving Use of Human Specimens, and Specimen Banking

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I. Introduction

There is great scientific value in the research acquisition and use of human tissues and genetic material. The history of biomedical science includes a long tradition of collecting biological material, including biopsy specimens obtained for diagnostic purposes, and organs and tissues removed during surgery. The collection and distribution of such material for legitimate research leads to increased knowledge about human diseases and the development of better means of preventing, diagnosing, and treating disease and is an invaluable source of information for public health planning and programming, through disease surveillance and studies of disease incidence and prevalence. The value of such research does not minimize the importance of respect for the rights and welfare of the donors of biological samples.

UCLA policy for the research use of human tissue and genetic material abides by The Belmont Report, federal regulations for the protection of human research subjects, and applicable State law. To that end, human tissue and genetic repositories must have IRB approved standard operating procedures (SOPs) for the collection, maintenance, and distribution of material as well as an adequate protocol for ensuring that donor-subjects receive complete informed consent, as required by the IRB, including the following: (a) ownership of the samples, (b) disposition of the remaining samples, (c) information resulting from the sample, (d) the level of confidentiality and limits to confidentiality donor-subjects can expect as a result of donating a sample, and (e) whether the sample may be shared with other investigators.

II. Definitions

A. **Human Tissue Repositories** collect, store, and distribute human tissue materials for research purposes. Repository activities involve three components: (i) the collectors of tissue samples; (ii) the repository storage and data management center; and (iii) the recipient investigators.¹

B. Examples of Human Subjects Specimens for Research:

1. Bodily human materials such as: cells, mucosal and skin tissue; blood; urine; amniotic fluid; excreta and external secretions (including sweat); saliva; sputum;

¹ OHRP Guidance: [Issues to Consider in the Research Use of Stored Data or Tissues](#), November 7, 1997.

placenta tissue; organs; hair; nail clippings; teeth; dental plaque and calculus; if obtained through “intervention or interaction with an individual” or if “identifiable”; and/or

2. Residual diagnostic and surgical human specimens, including specimens obtained for clinical patient care that would otherwise have been discarded if not used for research.

C. The following definitions have been adopted from the National Bioethics Commission’s report: *Research Involving Human Biological Materials: Ethical Issues and Policy Guidance*.

1. **Unidentified samples:** Sometimes termed “anonymous,” these samples are supplied by repositories to investigators from a collection of unidentified human biological specimens.
2. **Unlinked samples:** Sometimes termed “anonymized,” these samples lack identifiers or codes that can link a particular sample to an identified specimen or a particular human being.
3. **Coded samples:** Sometimes termed “linked” or “identifiable,” these samples are supplied by repositories to investigators from identified specimens with a code rather than with personally identifying information, such as a name or Social Security number.
4. **Identified sample:** These samples are supplied by repositories from identified specimens with a personal identifier (such as a name or patient number) that would allow the researcher to link the biological information derived from the research directly to the individual from whom the material was obtained.

III. Unidentified Samples

- A. Research conducted with unidentified samples is not human subjects² research, provided the samples are not being used for FDA-regulated research involving a device.
 1. Since most existing samples have some level of identifiers, links or codes included, investigators should be very cautious when distinguishing between unidentified samples, unlinked samples and coded samples.
 2. Investigators may request - in writing or in the form of an Application for Exemption from IRB Review - OPRS/IRB assistance in evaluating whether a given project involves human subjects.

² For information about what is and is not human subjects research, please see [OPRS/IRB Policy 3: Human Subject Research Determinations](#).

3. For information regarding an exception to FDA informed consent requirements for *in vitro* diagnostic device studies using leftover human specimens that are not individually identifiable, please see Section XI of [OPRS/IRB Policy 29: Informed Consent Process & Documentation](#).

IV. Unlinked Samples

- A. Research conducted with unlinked samples is research on human subjects.
 1. Although these samples are obtained from a bank of identified specimens, they are anonymous upon receipt by the investigator.
 2. Research involving unlinked samples may qualify for exemption from IRB review. This determination is made by the OPRS/IRB in response to an investigator's submission of an Application for Exemption from IRB Review. Please refer to [OPRS/IRB Policy 5: Certification of Exemption from IRB Review](#) for details.

V. Coded or Identified Samples

- A. Research conducted with coded or identified samples is research on human subjects.
 1. Investigators conducting research involving coded or identified samples are required to submit an Application to Involve Human Subjects in Research.
 2. Research involving coded or identified samples undergoes the appropriate level of IRB review. Please refer to applicable policies and procedures for details.³

VI. Establishment and/or Use of Repositories

- A. The UCLA IRB is responsible for overseeing the collection, use, storage, and re-use of all human tissue, blood or genetic material and all data that are generated within, transferred to, or transferred from UCLA for research purposes.
 1. Specimens (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 should be banked in an IRB-approved "research repository."

³ Please see:

- [OPRS/IRB Policy 8: IRB Review Process–Expedited Review](#)
- [OPRS/IRB Policy 9: IRB Review Process–Full Committee Review](#)
- [OPRS/IRB Policy 19: IRB Review Requirements](#)

2. IRB approval is required for the acquisition of existing specimen collections for research use, for deposit into a research repository, and for subsequent use of stored samples.
 3. An investigator must obtain prospective UCLA IRB approval or certification of exemption from IRB review for a specific study protocol prior to obtaining specimens 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 specimens/data from multiple research studies into a single specimen bank or database that could be accessed by the group and others for further use.
 - a. Research repositories may not be created without prior IRB approval.
 2. Examples of extra-mural repositories that a UCLA Investigator may wish to utilize include the NIH, CDC, ECOG, and NSABP laboratories, as well as laboratories managed by colleagues at other academic institutions.
- C. The IRB does not oversee the storage or management of specimens that are collected and stored as part of routine clinical care or hospital procedures. Individuals collecting, storing or managing specimens from routine clinical care or hospital procedures are responsible for following all applicable UCLA Medical Center policies and procedures regarding such activities.
1. IRB approval, however, is required prior to the use of these specimens/data for research purposes by a UCLA Investigator.
- D. The IRB does not oversee the use or management of specimens/data sent to a UCLA Investigator/ employee for specialized analysis as part of a contractual agreement to provide a commercial service. 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.⁴
1. IRB approval, however, is required prior to the use of these specimens/data for research purposes by a UCLA Investigator.

⁴ 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>. See item B(2) of that guidance for the standards regarding commercial services. Please also see [OPRS/IRB Policy 3: Human Subject Research Determinations](#).

VII. Standard Operating Procedures for Tissue Banking

- A. Consistent with OHRP guidelines, the IRBs review and approve protocols specifying the conditions under which data and specimens 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 samples.
 2. The information submitted by investigators for IRB review should include all information requested in the *UCLA IRB Standard Request for Storage and Sharing of Human Biological Material or Genetic Material*.⁵
 3. There is no requirement regarding the manner in which this information is provided to the IRB. The information may be provided as a formal manual of Standard Operating Procedures for the repository, or it may be provided in some other written manner as long as the information is complete according to the IRB guidance listed in (2) above.
- B. Based on OHRP guidance, the IRBs recommend that research repositories operate under a Certificate of Confidentiality, especially for the banking of genetic samples/information.

VIII. Informed Consent & HIPAA Authorization

- A. The IRBs review the consent process and documentation for initial collection of human specimens for repositories as well as the consent process and documentation for subsequent use of these specimens.⁶
1. Legally effective informed consent as described at 45 CFR 46.116 must be obtained prospectively from each donor-subject unless otherwise waived by the IRB.
 2. Standard surgical or medical consent documents are not sufficient for purposes of research informed consent. The IRB considers on a case-by-case basis whether samples collected for clinical purposes under a standard surgical or medical consent document can become part of research or a research repository under a waiver or modification of the informed consent requirements.

⁵ <http://www.oprs.ucla.edu/human/documents/pdf/Tissue-SOPs-2005.pdf>

⁶ For information about consent requirements, including criteria for waivers or alterations of informed consent requirements, see [OPRS/IRB Policy 29: Informed Consent Process & Documentation](#).

- B. Per OHRP guidance, the IRBs require that informed consent forms for collecting, storing and sharing human specimens for research purposes include a clear description of the following:
1. The operation of the repository;
 2. The specific types of research to be conducted;
 3. The conditions under which data and specimens will be released to recipient-investigators; and
 4. The procedures for protecting the privacy of subjects and maintaining the confidentiality of data.
- C. Information describing the nature and purpose of the research provided in the informed consent document should be as specific as possible. As such, IRBs require that the informed consent forms for collection of human specimens for future use include the following:
1. Statement describing future use of specimens; if future use is currently unspecified, the informed consent document should state as much
 2. Likely areas of research to be conducted with collected specimens
 3. Brief description of who will determine future use
 4. Indication of whether subjects may be re-contacted in the future for specific consent, and if so, a request for permission to be re-contacted
 5. IRBs may require the initial collection consent document to include tiered consent. Examples of tiered consent include:
 - a. The option to use the collected specimens for any future research.
 - b. The option to use the collected specimens for future research involving similar conditions only.
 - c. The option to use the collected specimens for future research only using unidentified specimens or samples.
 6. Standard sections and language as put forth in informed consent templates available on the OPRS website.⁷

⁷ <http://www.oprs.ucla.edu/human/forms/biomedical-informed-consent>

- D. When specimens are obtained in the course of providing a treatment service and identifiers are attached to specimens, all requirements of the Health Insurance Portability & Accountability Act apply. Please refer to [OPRS/IRB Policy 49: HIPAA](#) for details.

Regulations:

45 CFR 46.116

References:

National Bioethics Commission's Report: *Research Involving Human Biological Materials: Ethical Issues and Policy Guidance*. Volume I: August 1999.
<http://bioethics.georgetown.edu/nbac/hbm.pdf>

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>

OHRP, *Compliance Oversight Activities: Significant Findings and Concerns of Noncompliance*, October 12, 2005. <http://hhs.gov/ohrp/compliance/findings.pdf>

Attachments:

OPRS-80 UCLA IRB/OPRS Guidance: Standard Operating Procedures for Tissue Banks
<http://www.oprs.ucla.edu/human/documents/pdf/Tissue-SOPs-2005.pdf>