

**Guidance and Procedures #: 39**  
**Research Collection, Use and Secondary Analyses of Human Specimens and/or Data**  
**Date of Last Revision: 04/13/09**

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**I. Introduction**

This document provides guidance to investigators who plan to acquire and/or use human biological specimens and/or data in their research, or have a change in their research plans for use of specimens or data (sometimes reported to as “secondary use”).

**II. Information Associated with Specimens and/or Data**

- ***Types of Identifiers***

There are three major categories of identifiers associated with human biological specimens/data: Protected Health Information (PHI), Personal Identifying Information (PII), and Sensitive Data. These are described in Table 1.

**Table 1: Protected Health Information and Personal Identifying Information**

Protected Health Information (PHI):	Personal Identifying Information (PII):
<p>An individual's personal and health information that is created, received, or maintained by a health care provider or health plan and includes at least one of the 18 personal identifiers listed below in association with the health information:</p> <ul style="list-style-type: none"> <li>○ Name</li> <li>○ Street address</li> <li>○ All elements of dates except year</li> <li>○ Telephone number</li> <li>○ Fax number</li> <li>○ Email address</li> <li>○ URL address</li> <li>○ IP address</li> <li>○ Social security number</li> <li>○ Account numbers</li> <li>○ License numbers</li> <li>○ Medical record number</li> <li>○ Health plan beneficiary #</li> <li>○ Device identifiers and their serial numbers</li> <li>○ Vehicle identifiers and serial number</li> <li>○ Biometric identifiers (finger and voice prints)</li> <li>○ Full face photos and other comparable images</li> <li>○ Any other unique identifying number, code, or characteristic</li> </ul> <p><i>Limited Data Set</i> - a limited data set can include the following identifiers: a unique number code, or characteristic that does not include any of the above listed identifiers, Geographic data (without street address), and/or dates.</p>	<p>Information about an individual which includes any of the identifiers below:</p> <ul style="list-style-type: none"> <li>○ Name</li> <li>○ Street address</li> <li>○ All elements of dates except year</li> <li>○ Telephone number</li> <li>○ Fax number</li> <li>○ Email address</li> <li>○ URL address</li> <li>○ IP address</li> <li>○ Social security number</li> <li>○ Account number, credit or debit card number, in combination with any required security code, access code or password that would permit access to an individual's financial account</li> <li>○ Driver's License numbers or California or other identification card number</li> <li>○ Device identifiers and their serial numbers</li> <li>○ Vehicle identifiers and serial number</li> <li>○ Biometric identifiers (finger and voice prints)</li> <li>○ Full face photos and other comparable images</li> <li>○ Any other unique identifying number, code, or characteristic (e.g., student identification number)</li> </ul>
<b>Sensitive Data</b>	
<p>An individual's first name (or fist initial) and last name in combination with any of the following:</p> <ul style="list-style-type: none"> <li>○ Social Security Number</li> <li>○ Driver's License Number or California ID card number</li> <li>○ Financial account information such as a credit card number</li> <li>○ Medical Information</li> </ul>	

- **Association of Specimens/Data with Identifiers**

Requirements for type of IRB Review, obtaining consent and authorization, and data storage are related to the types of information associated with specimens/data. The following are definitions in common use:

- Specimens/Data with Identifiers

*Identified Specimens/Data* – These specimens/data are labeled with personal identifiers, PHI and/or PII, that would allow the investigator to link the biological information derived from the research directly to the individual from whom the material was obtained.

- Specimens/Data without Identifiers

*De-identified, Unidentified or Unlinked Specimens/Data* – These specimens/data are not associated with PHI and/or PII. Either the PHI or PII was not collected with the specimens, or it was removed and cannot be retrieved.

- Specimens/Data with Codes

*Coded or Linked Specimens/Data* – These specimens/data are labeled with a code (also called indirect identifier) instead of an identifier. A key to the code exists. Thus, the code can be linked back to the individual's identity.

**Important Note:** Coded or linked specimens/data can be considered to be *without identifiers* if provided to the investigator under the following circumstances:

1. Investigator and the holder of the key enter into an agreement prohibiting the release of the key to the investigators under any circumstances, until the individuals are deceased, or
2. There are IRB-approved written policies and procedures prohibiting release of the identifiers, or
3. There are other legal requirements prohibiting the release of the key to the investigators, until the individuals are deceased.

### III. Use and Disclosure of Protected Health Information (PHI) – Special Considerations

When PHI is used in research, there are specific requirements regarding the use and disclosure of data and how data may be de-identified.

- **Use and Disclosure of Data - Limited Data Set and Data Use Agreement**

Use or Disclosure of PHI for research activities requires an authorization or waiver of authorization except when the investigator enters into a data use agreement in conjunction with a limited data set.

- Limited Data Set - PHI that excludes all categories of direct identifiers except for the following: a unique number code, or characteristic that does not include any

of the above listed identifiers, geographic data (without street address), and/or dates.

- Data Use Agreement - An agreement into which the covered entity enters with the intended recipient of a limited data set that establishes the ways in which the information in the limited data set may be used and how it will be protected. (For a copy of the UCLA Healthcare Data Use Agreement – See [Appendix 2](#) of UCLA Policy HS 9440.)
- ***Specimens/Data can be considered to be de-identified (without identifiers) under the following conditions:***
  - Safe-Harbor Method - all of the 18 identifiers listed in Table 1 are removed and there is no reasonable basis to believe that the remaining information could be used to identify a person.
  - Statistical Method - A qualified statistician, using generally accepted statistical and scientific principles, determines that the risk is very small that the information could be used, alone or in combination with other reasonable available information by an anticipated recipient to identify an individual who is a subject of the information, and that person documents the methods and results of the analysis that justify this determination.

#### IV. Requirements for IRB Review, Consent and Authorization

The type of IRB review and the consent and authorization requirements depend on the following:

- Whether the Investigator has direct contact with study participants
  - The risk of harm from procedures used to obtain specimens and/or data
  - Privacy and confidentiality risks due to PII or PHI associated with the specimens and/or data.
- **Table 2: Specimens and/or Data Acquired or Recorded *without* Identifiers**

Study Characteristics		Requirements
Investigator Contact with Study Participants?	No	<b>Note:</b> The requirements for use of these specimens/data vary by whether or not there is access to identifiers, and if the research is FDA regulated as indicated below.
Source of Specimens and/or Data	<ul style="list-style-type: none"> <li>○ <a href="#">Publicly Available</a> or outside source such as specimen bank, data repository, commercial entity, another institution</li> <li>○ Surgical or diagnostic specimens that would otherwise be thrown away</li> </ul>	
Risk	None	
Investigator Access to Identifiers?	No	

Form: [PI Self-Certification for Determining whether Human subjects are involved in Research](#)

	Yes, however, the identifiers are not recorded by the investigator, <u>and</u> specimens/data are pre-existing (if data are not pre-existing, or identifiers are recorded, go to <a href="#">Table 2</a> )	Form: <a href="#">Application For Certification of Exemption from IRB Review for Exemption Category 4</a>
<b>Other</b>	Involves FDA Regulated Research, Prisoners, human embryonic stem cells, or access to UCLA medical records	Form: Applicable <a href="#">IRB Application Form</a>  <u>Consent:</u> Consent or Waiver Required  <u>Authorization:</u> Authorization or Waiver required if access to PHI

- **Table 3: Specimens and/or Data with Codes or Identifiers – No Contact with Study Participants**

Study Characteristics		Requirements
<b>Investigator Contact with Study Participants?</b>	No	Form: Applicable <a href="#">IRB Application Form</a>
<b>Source of Specimens and/or Data</b>	Outside source such as specimen bank, data repository, commercial entity, another institution, " <a href="#">Restricted Use Data</a> " and <a href="#">Data Enclaves</a>	<u>Consent:</u> May need waiver of consent  <u>Authorization:</u>
<b>Risk</b>	<ul style="list-style-type: none"> <li>○ Minimal</li> <li>○ Investigator <a href="#">securely protects private data</a></li> </ul>	<ul style="list-style-type: none"> <li>• May need waiver of authorization if PHI involved.</li> <li>• A waiver is not required when a limited data set is used with a data use agreement.</li> </ul> <i>Likely to qualify for <a href="#">Expedited Review</a></i>

- [Restricted Use Data](#) – A number of federal agencies and research organizations distribute special files to investigators with use restrictions. These files may contain data fields such as social security numbers, names, or extensive life history markers that might enable an unauthorized user to identify a participant. The use restrictions vary, but typically involve required data security provisions and may limit the types of analyses conducted by the investigator.
- [Data Enclaves](#) – Some organizations create secure environments where investigators can conduct analyses on expurgated data. Investigators have to file a research plan and meet strict criteria for what can be printed, saved and removed from a site.

- **Table 4: Specimens and/or Data with Codes or Identifiers – Obtained with Subject Contact**

Study Characteristics		Requirements
Investigator Contact with Study Participants?	Yes	Form: Applicable <a href="#">IRB Application Form</a>
Source of Specimens and/or Data	Prospective Collection through Research Intervention	Consent: Required Authorization: Required if PHI involved.
Risk	<ul style="list-style-type: none"> <li>○ Minimal →</li> <li>○ Greater than Minimal →</li> </ul>	May qualify for <a href="#">Expedited Review</a>  <a href="#">Full Board Review</a> Required

- Future (Secondary) Use - If there is the potential for future (secondary) use of identified data and/or specimens, this information must be included in the informed consent document for the study. Additionally, the study application should include a description of how the identified materials will be stored to protect confidentiality and guard against unauthorized access.

#### V. Secondary Use of an Investigator’s Own Specimens and/or Data

In the course of research, investigators may have a change in plans for use of specimens or data from current or previously approved research. The requirements for IRB review are described below in Table 5.

- **Table 5: Secondary Use of an Investigator’s Own Specimens and/or Data**

Does the Specimen/Data have Identifiers?	Type of Change Proposed	Requirements for IRB Review
No	No requirements for IRB Review	
Yes	Change in data analysis plans for currently approved research	Submit amendment to original study for IRB review of proposed modifications for approval or certification of exemption  <i>Likely to qualify for <a href="#">Expedited Review</a></i>
	Analysis of data from previously approved research (after the study is closed).	Submit a new protocol describing the data analysis plan. Include a copy of the IRB approval and IRB approved consent form for the original specimen/data collection.  <i>Note: If the original IRB approved protocol and consent did not include the new proposed analyses, a request for a waiver of informed consent (and authorization if PHI is involved) or a procedure for</i>

		obtaining consent should be included with the submission.  <i>Likely to qualify for <a href="#">Expedited Review</a></i>
	Share specimens/data with colleague.	If provisions for sharing are not in the current protocol, amend protocol to allow sharing.  The investigator receiving the specimens/data will need to submit a protocol for IRB approval or certification of exemption.  <i>Likely to qualify for <a href="#">Expedited Review</a></i>
	Storage of specimens/data to share with colleagues or students in future.	Submit a protocol for a bank or repository. Please refer to OPRS/IRB Guidance: <a href="#">Research Involving Banks and Repositories</a> for details.