UCLA Research Administration
Human Research Protection Program

Guidance and Procedure: Collection, Use, Sharing and Secondary Analyses of Human Specimens and/or Data for Research Purposes

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Overview

This document provides guidance to investigators who plan to collect, use, share and/or conduct secondary analyses of human biological specimens and/or human subject data in their research, or have a change in their research plans for use of specimens or data (sometimes reported as "secondary use").

All data/specimen analysis activities which are determined to constitute research with human subjects require prospective UCLA IRB review and approval or Certification of Exemption from UCLA IRB review. Federal regulations define specific Expedited and Exempt Review categories for research analyses of human subject data and human biological specimens. See UCLA OHRPP Guidance: Determining Which Activities Require UCLA OHRPP/IRB Review for additional assistance in determining if the project in question fits the definition of "human research."

If data/specimen analysis activities do not meet the definition of human subject research, researchers may use the IRB application to assist in determining if the study in question may actually be considered non-human subject research. If so, the IRB will provide the investigator with a self-certification or direct the investigator to apply for IRB review or exempt certification.

Investigators should consider the provisions for sharing of data early on and up front when preparing an application for IRB review and should take care to allow for this important scientific tool. The National Institutes of Health and other sponsoring agencies often encourage or even require that researchers share data. See the NIH Data Sharing Policy and Implementation Guidelines for details about the NIH policy or check with your particular sponsor to see if it has requirements or guidelines for data sharing.

Information Associated with Specimens and/or Data

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

Table 1: Types of Identifiers

Protected Health Information (PHI)	Personal Identifying Information (PII)	Sensitive Information
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: o Name o Street address o All elements of dates except year o Telephone number o Fax number o Email address o URL address o IP address o Social security number o Account numbers o License numbers o Medical record number o Health plan beneficiary # o Device identifiers and their serial numbers o Vehicle identifiers and serial number o Biometric identifiers (finger and voice prints) o Full face photos and other comparable images o Any other unique identifying number, code, or characteristic ***Limited Data Set*** - 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.	Information about an individual which includes any of the identifiers below: o Name o Street address o All elements of dates except year o Telephone number o Fax number o Email address o URL address o IP address o Social security number o 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 o Driver's License numbers or California or other identification card number o Device identifiers and their serial numbers o Vehicle identifiers and serial number o Biometric identifiers (finger and voice prints) o Full face photos and other comparable images o Any other unique identifying number, code, or characteristic (e.g., student identification number)	An individual's first name (or first initial) and last name in combination with any of the following: o Social Security Number o Driver's License Number or California ID card number o Financial account information such as a credit card number o Medical Information

Commonly Used Definitions of Specimens/Data with and Without 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 information derived from the research directly to the individual from whom the material/information 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/data, or it was removed and cannot be retrieved.

- **Specimens/Data with Codes or Links:** *Coded or Linked Specimens/Data* – These specimens/data are labeled with a code (sometimes called "indirect identifier") instead of a direct 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 investigator under any circumstances, until the individuals are deceased, ***or***
>
> ***2.*** There are IRB-approved written policies and procedures prohibiting release the identifiers, ***or***
>
> 3. There are other legal requirements prohibiting the release of the key to the investigator, until the individuals are deceased.

Specimens/Data that involve Protected Health Information (PHI) 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 reasonably available information by an anticipated recipient to identify an individual who is a subject of the information, and the statistician documents the methods and results of the analysis that justify this determination.

Use and Disclosure of Protected Health Information (PHI)

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 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.

See **UCLA OHRPP HIPAA Research Guidelines and Information** for additional information about Limited Data Sets and Data Use Agreements for use or disclosure of PHI.

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	***Note*:** The requirements for use of these specimens/data vary based upon whether or not there is access to identifiers, and if the research is FDA regulated, as indicated below.
Source of Specimens and/or Data	• Publicly available or outside source such as specimen bank, data repository, commercial entity, another institution • Surgical or diagnostic specimens that would otherwise be thrown away	
Investigator Access to Identifiers?	No	• IRB application
	Yes, however, the identifiers are not recorded by the investigator, *and* specimens/data are pre-existing (If data are not pre-existing, or identifiers are recorded, go to Table 3.)	• IRB application
Other Considerations	Research is FDA regulated, federal funding is awarded directly to UCLA, prisoners are involved, or investigator has access to UCLA medical records	• IRB application • Consent: Consent or Waiver Required • Authorization: Authorization or Waiver required if access to PHI
Risk Levels	Varies from none, to low depending on level of contact with subjects and how confidentiality and security of data is managed	

Table 3: Specimens and/or Data with Codes or Identifiers–No Participant Contact		
Study Characteristics		**Requirements**
Investigator Contact with Study Participants?	No	• IRB application • Consent: May need waiver of consent • Authorization: o May need waiver of authorization if PHI involved. o A waiver is not required when a limited data set is used with a data use agreement. • Likely to qualify for Expedited Review
Source of Specimens and/or Data	Outside source such as specimen bank, data repository, commercial entity, another institution, restricted use data, and data enclaves	
Risk Levels	• Minimal • Investigator securely protects private data	

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.

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. An example of this at UCLA is The California Center for Population Research (CCPR) Secure Data Enclave.

Table 4: Specimens/Data with Codes or Identifiers –Obtained with Participant Contact		
Study Characteristics		**Requirements**
Investigator Contact with Study Participants?	Yes	• IRB application • Consent: Required Authorization: Required if PHI involved.
Source of Specimens and/or Data	Prospective Collection through Research Intervention	
Risk Levels	Minimal →	• May qualify for Expedited Review
	Greater than Minimal →	• Full Committee Review Required

Future (Secondary) Use: Since there is often the potential for future (secondary) use of identified data and/or specimens, it is wise to include this fact in the informed consent document--unless you are certain there will be no future use. Additionally, the study application should include a description of how the identified materials will be stored to protect confidentiality and guard against unauthorized access.

Secondary Use of an Investigator's Own Specimens and/or Data

In the course of research, investigators may change or expand plans for the use of specimens or data from current or previously-approved research. It is wise to include a broad description of the planned uses of the specimens and data in the original application so that the researcher does not have to amend the protocol for minor changes. See table below.

Table 5: Secondary Use of an Investigator's Own Specimens and/or Data

Do Specimens / 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 *Likely to qualify for Expedited Review*
	Analysis of data from previously approved research (after the study is closed)	Submit a new protocol describing the data analysis plan. Describe the IRB approval and IRB approved consent form for the original specimen/data collection. *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 obtaining consent should be included with the submission. *Likely to qualify for Expedited Review*
	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. *Likely to qualify for Expedited Review*
	Storage of specimens/data to share with colleagues or students in future	Submit a protocol for a bank or repository. Please refer to OHRPP Guidance: Data and Specimen Repositories for details.

Regulations and References

DHHS – Office for Human Research Protections (OHRP):

- Guidance on Research Involving Coded Private Information or Biological Specimens
- OHRP Human Subject Regulations Decision Charts

FDA

- FDA FAQs on *In Vitro* Diagnostic Device Studies
- FDA Guidance on Informed Consent for *In Vitro* Diagnostic Device Studies Using Leftover Human Specimens that are Not Individually Identifiable
- 21 CFR 50.3 - Definitions
- 21 CFR 56.102 and 56.103 - IRB Responsibilities

UCLA OHRPP Guidance:

- Data and Specimen Repositories
- Determining Which Activities Require OHRPP/UCLA Review
- HIPAA Research Guidelines and Information
- Requesting Waivers and Exceptions to Informed Consent

Change history:
9/7/2023: Updated weblinks and OHRPP guidance references, minor formatting edits, removed references to webIRB.