CSULB Institutional Review Board (IRB)

Guidance and Procedure: Collection, Use, Sharing and Secondary Analyses of Human Subject Data or Specimens for Research Purposes(last updated 08/01/2024)

I- Overview

This document provides guidance to investigators who plan to collect, use, share and/or conduct existing/secondary analyses of human subject data or biological specimens in their research.

Does the project for the existing/secondary human data/specimen meet the definition of human subject research?

Investigators should not make a self-determination and should contact CSULB IRB via IRB@csulb.edu. A project requires IRB review if it includes both research and human subjects.

I-Does the project meet the definition of research?

Research is defined as a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.

II-Does the research involves human subjects?

a) If the research **only** involves the use of existing/secondary **non-identifiable/de-identified** human data or biospecimens, it does not satisfy the definition of research with human subjects; therefore, it does not require IRB review. CSULB IRB can provide the investigator with certification of non-human subject research.

b) If the research involves the use of identifiable or coded human data or biospecimens of live persons, it does satisfy the definition of research with human subjects; therefore, it does require the submission of an IRB Application for Existing and Secondary Data, along with required appendices such as Permission Letter, Informed Consent form, Authorization Letter for Releasing PHI covered by HIPPA Regulation, etc.

Investigators should consider the provisions for sharing of data early on and up front when preparing an application for IRB review.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.

II - Identifiable Information Associated with Human Data or Specimens

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

Table 1: Types of Identifiers	
Protected Health Information (PHI)	**Personal IdentifyingInformation (PII)**
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: ○ Name ○ Street address ○ All elements of dates except year ○ Telephone number ○ Fax number ○ Email address ○ URL address ○ IP address ○ Social security number ○ Account numbers ○ License numbers ○ Medical record number ○ Health plan beneficiary # ○ Device identifiers and their serial numbers ○ Vehicle identifiers and serial number ○ Biometric identifiers (finger and voice prints) ○ Full face photos and other comparable images ○ 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 identifiersbelow: ○ Name ○ Street address ○ All elements of dates exceptyear ○ Telephone number ○ Fax number ○ Email address ○ URL address ○ IP address ○ Social security number ○ Account number, credit or debitcard number, in combination with any required security code,access code or password that would permit access to an individual's financial account ○ Driver's License number or other identificationcard number ○ Device identifiers and their serialnumbers ○ Vehicle identifiers and serialnumber ○ Biometric identifiers (finger andvoice prints) ○ Full face photos and othercomparable images ○ Any other unique identifying number, code, or characteristic(e.g., student identification number) ○ Protocol Specific Identifying Information (PSII) depending on unique scenarios, such as a combination of gender and ethnicity within a small subject group.

III - Commonly Used Definitions of Human Data/Data/specimens with and Without Identifiers

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

- **Human Data/Data/specimens with Identifiers**: *Identified Data/specimens* – These data/specimens arelabeled with personal identifiers, PHI and/or PII, that would allow the investigator to link theinformation derived from the research directly to the individual from whom the material/information was obtained.

- **Human Data/Data/specimens without Identifiers:** *De-identified, Unidentified or Unlinked Data/specimens* –These data/specimens are not associated with PHI and/or PII. Either the PHI or PII was not collected with the data/specimens, or it was removed and cannot be retrieved.

- **Human Data/Data/specimens Codes or Links:** *Coded or Linked Data/specimens* – These data/specimens 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 theindividual's identity.

> **IMPORTANT NOTE:** Coded or linked data/specimens 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.

IV - Methods to Assure Providing De-identified Human Data/Specimens

Human Data/specimens that involve Protected Health Information (PHI) or PII can be considered to be de-identified (without identifiers) under the following conditions:

- **Safe-Harbor Method:** All of the 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.

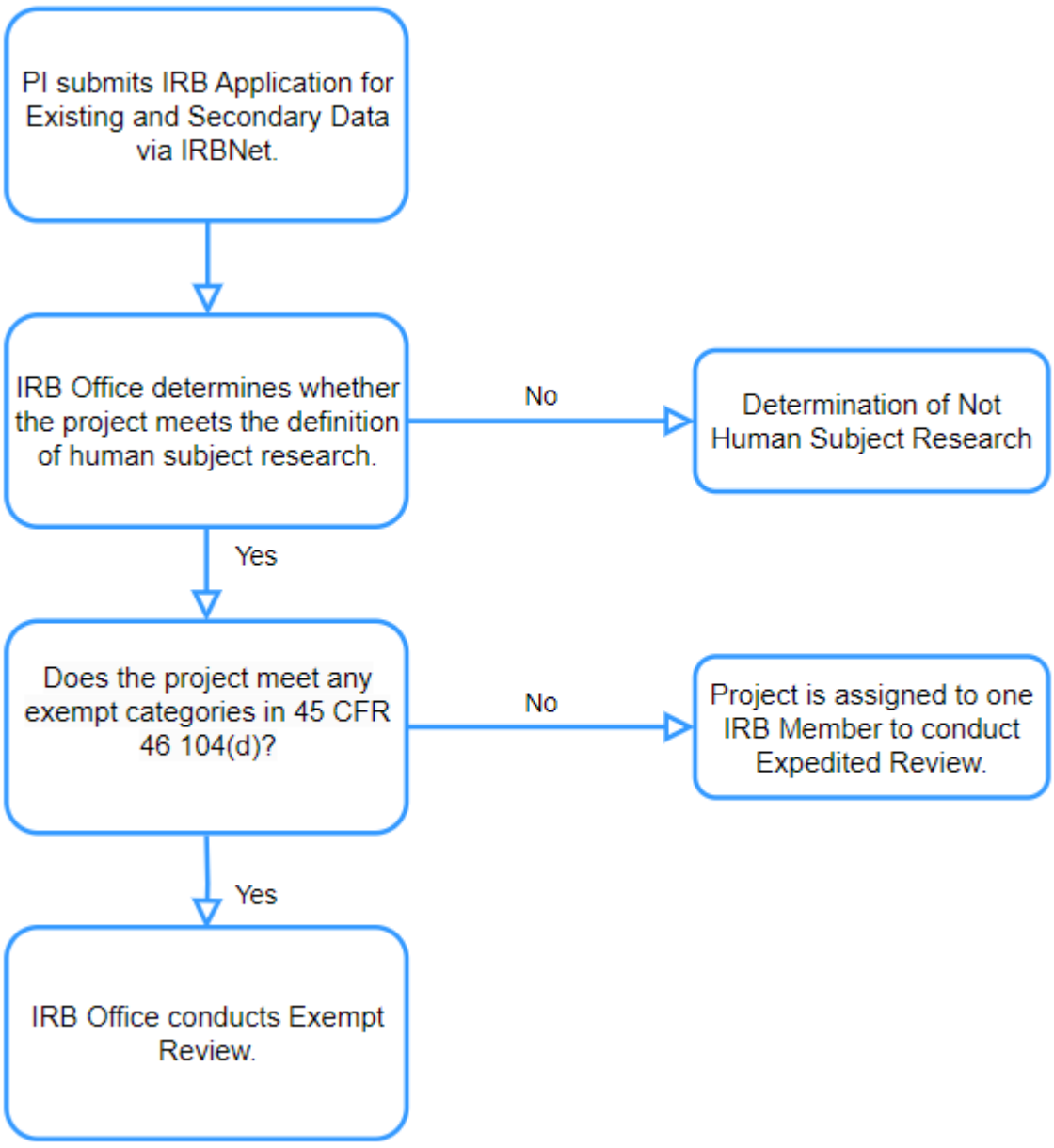
V - Requirements for IRB Review, Consent and Authorization

The type of IRB review and the informed consent and authorization for releasing PHI requirements depend on the following:

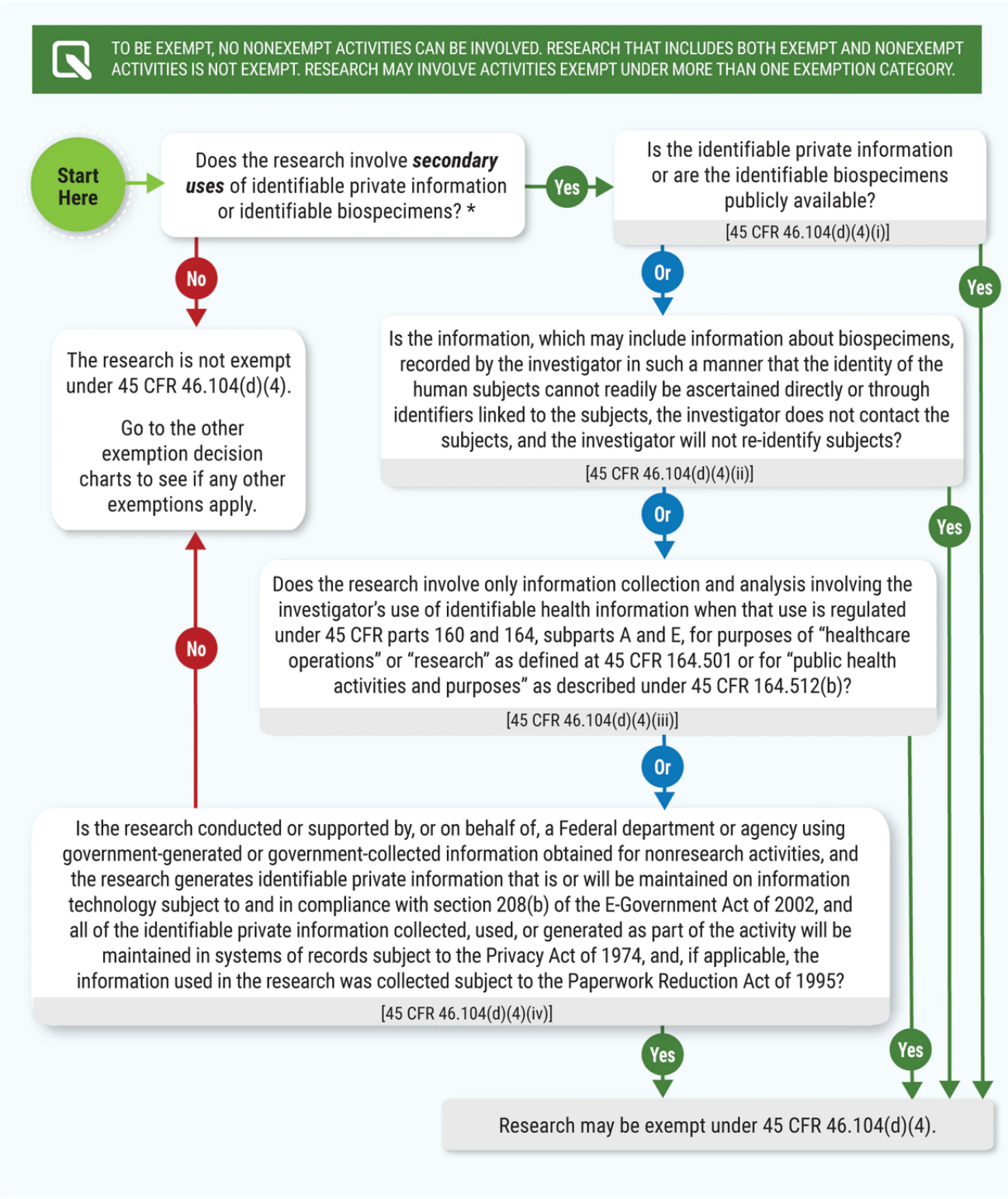
- Whether the Investigator has direct contact with study participants
- The risk of harm from procedures used to obtain specimens and/or data
- Privacy and confidentiality risks due to PII or PHI associated with the specimens and/or data

VI - Project Submission & Review Process

Review Workflow for Project Involving Existing/Secondary Human Data or Biospecimens



VII - DHHS OHRP Chart 06: Does Exemption 45 CFR 46.104(d)(4) for Secondary Research that Does Not Require Consent Apply?



VIII - Regulations and References

DHHS – Office for Human Research Protections (OHRP):

- OHRP Guidance on Coded Private Information or Specimens Use in Research (2008)
- OHRP Guidance Regarding Methods for De-identification of Protected Health Information in Accordance with the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule
- OHRP Human Subject Regulations Decision Charts (2018 Requirements)