IRB Application for Existing and Secondary Data

If your project involves the use of non-identifiable data or biospecimens, YOUR PROJECT DOES NOT REQUIRE IRB SUBMISSION OR REVIEW because it does not satisfy the definition of research with human subjects.

You should only complete this form if your project involves the following:

- **Initial access to information contains identifiable private information but the investigator abstracts the data required for research purposes in a way that the information can no longer identify the subjects.**

  Example: Investigator A has access to a coded private information data set from Investigator B. Investigator A records the information needed for the research without the codes. *However, this method of data collection would NOT require IRB review if, Investigator A enters into an agreement with Investigator B, prohibiting the release of the key to Investigator A under any circumstances or until the death of the individuals about whom the data is about is deceased.*

- **Secondary analysis of retrospective or prospective identifiable data may occur under one of the following conditions:**
  - **Identifiable private information or identifiable biospecimens are publically available**
  - **Information is recorded by the investigator in a manner that the identity of human subjects cannot be readily ascertained either directly or indirectly. That is, investigators cannot contact the subjects or re-identify subjects.**
  - **Data are regulated under HIPAA for the purposes of healthcare operations, research or public health (i.e. medical records or charts)**
  - **Research is conducted by or on behalf of a Federal agency using information generated by the government for non-research purposes (e.g. CDC or Census data).**

  Example: An investigator subsequently revisits a data set collected via a survey that recorded identifiable information from subjects two years ago. The investigator seeks to use the same data set applying the same hypothesis but uses a different statistical strategy to analyze the same data set thus, conducting secondary data analysis of existing data.

  Example: An investigator has a dual appointment with CSULB and the Long Beach Community Health Clinic. The investigator seeks to analyze the medical charts of all patients of the clinic from 2015-2017 and filter out for HEP C to determine other risk factors for the diagnosis. The access and use of data provided in the medical charts contains identifiable information but the clinic has authorized the access to the charts for research purposes that will produce public health results. The information contained in the charts is protected and regulated under HIPAA.

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Instructions: Please confirm that the research activities meet the definition of research with human subjects (the data has identifiers or links to identifiers). Fill out the form completely. Any incomplete forms will be returned. Check boxes can be filled by clicking once inside the box. Please include all applicable supporting documents for this submission such as permission letters and faculty supervisor letter.

1. Basic Information

Principal Investigator:	Click or tap here to enter text.
CITI Member ID Number:	Click or tap here to enter text.
Department:	Click or tap here to enter text.
Telephone Number:	Click or tap here to enter text.
Email:	Click or tap here to enter text.
Affiliation:	☐ Student* ☐ Faculty ☐ Staff ☐ External PI
***Complete the information for the Faculty Advisor below:**	
Faculty Advisor:	Click or tap here to enter text.
Email:	Click or tap here to enter text.
Telephone Number:	Click or tap here to enter text.

2. Project Information

Project Title:		
Click or tap here to enter text.		
Describe the purpose of the project:		
Click or tap here to enter text.		
Describe the characteristics of the subject data or samples such as the total number individuals, demographics (gender, age or race), and any other characteristics unique to the data set:		
Click or tap here to enter text.		
What cohort of data collection will be analyzed (Check one):		
☐ Retrospective Data ☐ Prospective Data ☐ Both, retrospective and prospective data		
Estimated Project Dates	Start: Click or tap to enter a date.	End: Click or tap to enter a date.

3. Data Permissions & Storage

What is the original source of data? (Check all that apply):	
☐ Survey/Questionnaire	☐ Previous IRB Approved Study
☐ Department Data	☐ External PI Data
☐ Medical Records/Charts	☐ Institutional Research & Assessment
☐ Student Data	Other (Explain): Click or tap here to enter text.

What permission(s) do you have to access and analyze the data? Describe the investigator, agency or institution granting access and permission for the use of the data for research purposes. *Note: All data collected by someone other than you (except publically available data), requires a permission letter attached to this project in IRBNet.*	
Click or tap here to enter text.	
What type of *identifiable* secondary data will this project analyze? (Select one):	
☐ Publically available identifiable private information ☐ Information recorded in a manner where subject identity cannot be directly known or determined through links to identifiers	☐ Data regulated by HIPAA (i.e. medical record access for the purpose of healthcare operation, research or public health) ☐ Research conducted by or on behalf of a federal agency and uses government information collected for non-research purposes
Will a subject master list be maintained?	☐ Yes ☐ No*
If no, provide justification for recording data elements that may be linked to individuals:	
Click or tap here to enter text.	
Describe the method and procedures of data analysis:	
Click or tap here to enter text.	
List the potential risks to the subjects in the event there is a loss of confidentiality (Please list the risks numerically):	
Click or tap here to enter text.	
List the procedural safeguards to reduce the risks (Please list the safeguards numerically to correspond to the risks listed above):	
Click or tap here to enter text.	
List any potential benefits to the individuals providing the data, to society or other entities expected from the research:	
Click or tap here to enter text.	
Select the method of data storage (Select all that apply):	
☐ Data will be maintained in a secure location for three years then properly destroyed. ☐ Data will be kept beyond the three year minimum (Explain): Click or tap here to enter text. ☐ Other method of data storage and destruction (Explain): Click or tap here to enter text.	
Lis the names, email and CITI Member ID numbers of all individuals, other that the PI that will have access to the data:	
Click or tap here to enter text.	

4. Appendices

Select all relevant appendices included with this submission on IRBNet (Select all that apply):	
☐ Permission Letter(s) ☐ Faculty Advisor Letter*	☐ Other (Explain): Click or tap here to enter text.
*All student investigators are required to submit a Faculty Advisor letter.	

- Please submit this completed application including all appendices via: www.irbnet.org
- If you have any questions and/or need assistance, please contact the CSULB IRB Office via IRB@csulb.edu, or call (562) 985-8147