IRB Application for Existing and Secondary Data

Please refer to CSULB IRB Guidance and Procedure: Collection, Use, Sharing and Secondary Analyses of Human Subject Data or Specimens for Research Purposes version 04-08-2022.

You are highly recommended to contact IRB@csulb.edu, to seek advice on whether your project meets the definition of Human Subject Research.

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 individuals whom the data is about are deceased.*

- **Secondary analysis of retrospective or prospective identifiable data may occur under one of the following conditions:**
  - **Identifiable private information or identifiable biospecimens are publicly 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 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.

PLEASE DELETE THIS PAGE BEFORE SUBMISSION

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Instructions: The Principal Investigator (PI) is responsible for all information in this form. The PI should fill out the form completely; incomplete forms will be returned. Use as much space as necessary to answer each question adequately. **Please upload the completed application and all relevant appendices (e.g., Permission Letter(s), Faculty Advisor Letter, etc.) to IRBNet (www.irbnet.org).**

NOTE: Before submission, confirm that the research activities meet the definition of research with human subjects (the data has identifiers or links to identifiers). If you are unsure, please email IRB@csulb.edu.

1. Basic Information

Principal Investigator:	
CITI Member ID Number:	
Department:	
Telephone Number:	
Email:	
Affiliation:	[ ] Student* [ ] Faculty [ ] Staff [ ] External PI
***If you are a student, please complete the information below for your Faculty Advisor:**	
Faculty Advisor:	
Email:	
CITI Member ID Number:	

2. Project Information

Project Title:		
Describe the purpose of the project:		
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:		
What cohort of data collection will be analyzed (Check one):		
[ ] Retrospective Data [ ] Prospective Data [ ] Both retrospective and prospective data		
Estimated Project Dates	Start:	End:

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):

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 publicly available data), require a permission letter. This letter MUST be included in your submission.**	
What type of *identifiable* secondary data will this project analyze? (Select one):	
[ ] Publicly 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:**	
Describe the method and procedures of data analysis:	
List the potential risks to the subjects in the event there is a loss of confidentiality (Please list the risks numerically):	
List the procedural safeguards to reduce the risks (Please list the safeguards numerically to correspond to the risks listed above):	
List any potential benefits to the individuals providing the data, to society or other entities expected from the research:	
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): [ ] Other method of data storage and destruction (Explain):	
List the name, CITI Member ID #, and email of all individuals, other that the PI (and Faculty Advisor, if applicable) that will have access to the data:	

4. Appendices

Select all relevant appendices included with this submission on IRBNet (Select all that apply):	
[ ] Permission Letter(s) [ ] Faculty Advisor Letter*	[ ] Other (Explain):
*All students are required to submit a Faculty Advisor letter.	

5. Investigator Assurance

As the Principal Investigator (PI) for this project, I certify the following (please check and confirm all):

[ ] All provisions to maintain subject confidentiality and protect subject data will be upheld.
[ ] The CITI online training is complete for me and all personnel listed. Training will remain valid for the duration of research activity.
[ ] Research activities will be conducted as described in the approved version of this application.
[ ] Any modifications, including personnel changes to this project will be submitted, reviewed, and approved by the CSULB IRB prior to implementation.
[ ] I will comply with the CSULB IRB research policies (https://www.csulb.edu/office-of-research-and-economic-development/research-related-policies).
[ ] I will comply with the Department of Health and Human Services (HHS) research policy and regulation (https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html).

Name: Date: MM/DD/YYYY

Please submit the following via IRBNet (www.irbnet.org):

1. This completed application
2. All appendices (combined into a single document)

If you have any questions and/or need assistance, please contact the CSULB IRB Office via IRB@csulb.edu.