University of La Verne Institutional Review Board
Policy and Procedure on Projects Using Secondary Data
Approved February 10, 2017

The Institutional Review Board (IRB) at the University of La Verne (La Verne) realizes that some research involving existing data sets and archives may not meet the definition of Human Subjects Research and therefore would not require La Verne IRB review; however, some may meet definitions of research and may require La Verne IRB review and approval. This policy seeks to clarify what data would be considered Human Subjects Research and which would be Not Human Subjects Research (NHSR)

1. Analysis of De-Identified, Publicly Available Data

The La Verne IRB recognizes that the analysis of de-identified, publicly available data does not constitute human subjects research as defined at 45 CFR 46.102 and that it does not require La Verne IRB review. Many studies utilize data made available through large data consolidation bureaus and consortiums. To reduce burdens on investigators, the La Verne IRB maintains a list of data holders (some shown below) whose archives include publicly available, de-identified data**.**

If you request access to data from these studies that includes identifiers, your study will be subject to the protocol described in 3 (Analysis of publicly available data with private identifiable information or of non-publicly available data where researchers will not record individual identifiers), below.

- Agency for Health Care Research and Quality (AHCRQ)
  - Healthcare Cost and Utilization Project (HCUP)
  - Medical Expenditure Panel Survey (MEPS)
- American Changing Lives
- Autism Brain Imaging Data Exchange (ABIDE)
- Better Access to Data for Global Interdisciplinary Research (BADGIR)
- California Department of Education
- California Health Interview Survey (CHIS)
- Center for AIDS Prevention Studies (CAPS)
- Center for Disease Control and Prevention (CDC)
  - National Behavioral Risk Factor Surveillance System (BRFSS)
  - National Health and Nutrition Examination Survey (NHANES)
  - National Health Interview Survey (NHIS)
  - National Youth Risk Behavior Survey (NYRBS)
- Center for Medicare and Medicaid Services (CMS)
- Demographic and Health Surveys
- Health and Retirement Study
  - Survey of Health, Ageing, and Retirement in Europe (SHARE)
- Health Reform Monitoring Survey (HRMS)
- Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) Survey
- Integrated Public Use Microdata Series (IPUMS-International)

- Integrated Public Use Microdata Series (IPUMS-USA)
- Integrated Public Use Microdata Series (IPUMS-CPS)
- Inter-University Consortium for Political and Social Research (ICPSR)[1]
- Luxembourg Income Study (LIS)
- Medical Expenditure Panel Survey (MEPS)
- Medicare Hospital Value-Base Purchasing (HVBP) program
- Midlife in the United States (MIDUS)
- Monitoring the Future
- National Center for Education Statistics
- National Center for Health Statistics
- National Election Studies
- National Hospital Ambulatory Medical Care Survey (NHAMCS)
- National Longitudinal Surveys
- National Nursing Assistant Survey (NNAS)
- National Nursing Home Survey
- National Survey on Drug Use and Health (NSDUH)
- New Immigrant Survey
- Panel Study of Income Dynamics (PSID)
    - Child Development Supplement (CSD)
    - Transition into Adulthood Supplement (TAS)
- Roper Center for Public Opinion Research
- Surveillance Epidemiology and End Results Cancer Registry (SEER)
- Treatment Episode Data Set-Admissions (TEDS-A)
- University of Wisconsin-Madison Data and Information Services Center (DISC)
- U.S. Bureau of the Census
- Vaccine Adverse Event Reporting System (VAERS)

Procedures

The La Verne IRB does not require a review for studies involving the analysis of data held by these organizations unless a project merges multiple data sets and in so doing enables the identification of individuals whose data is analyzed.

If a researcher requires a letter from the La Verne IRB that states the research does not fall under the purview of the IRB (usually required by granting agencies and some journals), the researcher can apply for such letter in IRBManager using the Not Human Subjects Research Application. The turnaround time on these letters are extremely quick.

2. Analysis of Non-Publicly Available Data with Restricted Access to Participant Identifiers (Coded Private Information)

The La Verne IRB recognizes that increasing numbers of studies involve the analysis of non-publicly available datasets that include coded private information or that are provided to researchers after the removal of identifying information. Further, a number of data holding organizations (e.g., Bureau of Labor Statistics, Centers for Disease Control, etc.) provide statistical analysis services for

[1] All data that is stored in this database.

investigators that generate aggregated data from data sets with private identifying information. Many of these studies do not involve human subjects. Data use permissions vary widely across data sets and holders; as such, the IRB requests that investigators conducting studies using coded private information or contracting data holders for statistical analyses of data sets involving private information seek a determination from the La Verne IRB as to whether the study constitutes human subjects research. This request is made in accordance with guidance from the Office of Human Research Protections (OHRP) concerning research involving coded private information.

Procedures

For studies involving the analysis of coded private information or the analysis of private information by a third party on behalf of a research team, the La Verne IRB requests that investigators submit the following information in the Not Human Subjects Research Application in IRBManager:

- Title and brief description of the research study
- Name of data set/archive that will be used
- Description of the data access or security plan to be implemented
- Variables used
- Sample size
- Link to website (if applicable)
- Agreements/permissions by data holder

If the La Verne IRB determines that the project does not constitute human subjects research, a letter stating this determination will be sent to the investigator. If the La Verne IRB determines that the project does involve human subjects research the investigator will be asked to submit an Initial Application in IRBManager for review by the La Verne IRB. Turnaround time for an NHSR letter is very quick.

3. Analysis of publicly available data with private identifiable information or of non-publicly available data where researchers will not record individual identifiers

Research involving the analysis of publicly available data containing private identifiable information or the analysis of non-publicly available data that will not be recorded by the investigator in a manner that allows the direct or indirect identification of individuals may qualify for Exempt review (45 CFR 46.101(b)4). Research involving these analyses requires the submission of an Initial Application.

Procedures

Investigators submitting protocols involving these research procedures are asked to provide the following minimum information in their submitted Initial Application in IRBManager to aid the La Verne IRB in making a determination of exemption (or the need for a higher review).

- Description of data set and availability
- Description of data to be accessed for analysis
- Copies of data use agreements/permissions by data holder
- Other Initial Application required information

4. Analysis of Non-Publicly Available Data Containing Private Identifiable Information

Research involving the analysis of non-publicly available data that contains private identifiable information about living individuals is considered by the La Verne IRB to constitute human subjects research that is possibly not exempt from 45 CFR 46 and La Verne IRB review requirements.

Procedures

Studies involving analysis of this form of data require review by the La Verne IRB. This review is conducted usually under expedited or standard review procedures in accordance with the La Verne IRB's review policies. Research involving these analyses requires the submission of an expedited/standard review La Verne IRB Initial Application.

Investigators submitting protocols involving these research procedures are asked to include the following minimum information in their submitted application to aid the La Verne IRB in its review.

- Description of data set(s) to be analyzed
- Copies of data use or security agreements/permissions
- Description of data security and access procedures