



Brandeis University

Committee for Protection of Human Subjects

RESEARCH REVIEW FORM - Existing Data Application

APPLICATION FOR: USE OF EXISTING DATA, DOCUMENTS, RECORDS, PATHOLOGIC OR DIAGNOSTIC SPECIMENS

Use this application for research that only involves the use of existing data, documents, records, pathological specimens, or diagnostic specimens. Criteria: The data must be publicly available or the investigator must record the information so that subjects cannot be identified, either directly or through identifiers linked to the subject. Do not use this application if subjects will be recruited for this study.

Project Title: _____

Principal Investigator: _____ Academic Title: _____

Department: _____ Campus Mailing Address/Code: _____

Work Phone: _____ Home Phone: _____ E-mail Address: _____

Home Address: _____ City/State/Zip: _____

Co-Investigators: List the name and campus address of additional investigators. If you are a student, list the faculty responsible for supervision and oversight of this research.

a. _____ b. _____

Funding Status: Funded (or Pending) Yes ___ No ___ Funding Source _____ Brandeis #: 4- _____

1. Data Source: Is the existing data, document, record or specimen publicly available? Yes ___ No ___

1a. If not, attach a letter authorizing your access to the data, document, record or specimen.

2. Subject Identifiers:

2a. Will subject identifying information be recorded? Yes ___ No ___

2b. Will codes be used to link data to the subject's name? Yes ___ No ___

3. Projected Dates of Analysis: Begin Date _____ End Date _____

4. Findings Used For: Publication ___ ; Presentation ___ ; Thesis ___ ; Dissertation ___ ; Other _____

Principal Investigator: _____ Date _____
Signature

Student Initiated Research: The signature of faculty supervising the research or the person designated by the department to conduct a preliminary review of the proposed research is required. This signature verifies the attached protocol meets with department approval and is in compliance with procedures/regulations designed to protect human subjects.

Department Approval: _____ Date _____
Signature

BCPHS REVIEW: Exempt as per 45CFR46.101(b)(4) Yes ___ No ___

BCPHS Authorization: _____ Date: _____

Protocol Outline for use of Existing Data

Provide a written description of your proposed research using the following outline if you are using existing data, documents, records, pathologic or diagnostic specimens and no subjects will be recruited for additional data collection. Focus the content of this protocol on your research and use of the existing data. Refrain from describing the original research from which the data was obtained.

1 - Study Abstract

Provide a brief summary of your research design. Include the purpose, data source, analyses planned, potential benefits, potential risks, and risk management procedures.

2 - Statement of Purpose and Background

a. Provide brief references to the literature that provide background in support of the proposed research.

b. Specify aims of the research:

1. Hypotheses, questions to answer, data to be analyzed.
2. Relevance to and potential for contribution to the field of study.

3- Description of data, documents, records or specimens to be analyzed.

a. Identify the source of the data. Include a letter indicating permission for your access to the data if not available to the public.

b. If known, briefly describe how data were initially obtained.

c. Describe the variables to be analyzed.

4- Methods

Summarize the methods used in the proposed analyses of data.

5- Potential Benefits

a. Benefits to the population from which the subject is drawn.

b. Benefits to science, society, and humanity in general.

Note: Do not include benefits to the subject since you will not recruit nor interact with the subjects originally involved in the data collection.

6- Potential Risks

Describe any physical, psychological, economic, legal or social risks that may occur as a result of this research.

Note: The primary risk when using existing data is violation of confidentiality. Since the data are to be recorded without any identifiers, this risk is minimized because the data will be anonymous.

7- Precautions taken to minimize risk.

a. Describe how you will record the data.

b. If data are coded, describe the coding scheme. To be eligible for an exempt review, the data must be publicly available or the investigator must record the information so that subjects cannot be identified, either directly or through identifiers linked to the subject.

c. State how the data will be stored.

d. Identify who will have access to the data.

8- Academic background and experience of investigator(s).

Provide a brief description of your academic status, training, and research experience. If you are a student, include reference to the faculty supervising your research.