Exempt Form: Secondary Data Research Exemption

# Instructions: Complete Research Protocol

* Depending on the nature of what you are doing, some sections may not be applicable to your research. If so, you must provide the reason the section is not applicable for the response. For example, under the Grant Applicability section, many would answer, “This protocol is not funded by a grant or contract.”
* When you write a protocol, keep an electronic copy. You will need to modify this copy when making changes.
* Do not remove the italics instructions or headings.
* If you are pasting information from other documents, be sure to use the “Merge Formatting” ("Paste & Match Formatting" on a Mac) paste option so that the formatting of the response boxes is not lost. If information is presented outside of the response boxes, it will not be accepted.
* If this study involves multiple participant groups who participate in different research procedures, consent processes, etc., be certain to provide information in each applicable section for each participant group and clearly label each participant group within a section or subsection. It may be easier to submit an application for each participant group if there if the procedures, consent process, etc... vary greatly.

## Exemption 104 (d)(4): Secondary Data

This application should be used only for Secondary Data research that meets the criteria at 45 CFR 46.104 (d)(4):

Secondary research uses identifiable private information or identifiable biospecimens, if at least one of the following criteria are met:

1. The identifiable private information or identifiable biospecimens are publicly available; or
2. Information, which may include information about biospecimens, is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained directly or through identifiers linked to the subjects, the investigator does not contact the subjects, and the investigator will not re-identify subjects; or
3. The research involves only information collection and analysis involving the investigator’s use of identifiable health information when that use is regulated under 45 CFR 160 and 164, Subparts A and E (HIPAA), for the purposes of “health care operations” or “research” as those terms are defined under HIPAA or for “public health activities and purposes” under HIPAA; or
4. The research is conducted by, or on behalf of a Federal department or agency using government-generated or government-collected information obtained for non-research activities. Categories one (1) through seven (7) pertain to both initial and continuing IRB review.

In order to qualify for this exemption, the level of risk to participants may not exceed minimal risk (physical, psychological, social, undue stress and/or invasion of privacy.) Do not use this form if your research involves any activities other than analyzing existing data.

# Full Protocol Title:

Include the full protocol title.

**Response:**

## Principal Investigator:

**Name**

**Department**

**Telephone Number**

**Email Address**

### Faculty Sponsor (for student projects):

**Name**

**Department**

**Telephone Number**

**Email Address**

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### Objectives

* 1. Describe the purpose and specific aims for the research. If applicable, state specific hypotheses to be tested.

**Response:**

#### Description of Source of Data, Documents, or Records

* 1. Describe the source of the data, documents, or records.

**Response:**

* 1. How will you obtain the data?

**Response:**

* 1. Are the data publicly available?

\_\_\_\_\_\_\_\_Yes \_\_\_\_\_\_\_\_No

* + 1. If not publicly available, indicate if the data records you will use contain any personal identifiers:

\_\_\_\_\_\_\_\_Yes \_\_\_\_\_\_\_\_No

* + - 1. If YES, indicate who will remove the personal identifiers and how.

**Response:**

* 1. Indicate if you are required to enter into a “Data Use Agreement”?

 \_\_\_\_\_\_\_\_Yes \_\_\_\_\_\_\_\_No

* + 1. If yes, please explain.

**Response:**

* 1. Are there any limitations on the use of this data (e.g., licensing, limits on sharing to the cloud)?

\_\_\_\_\_\_\_\_Yes \_\_\_\_\_\_\_\_No

* + 1. If yes, please explain.

**Response:**

# Data Analysis & Management

* 1. Describe the data that you will receive and store.
	2. What variables or information will you use from that data (be sure to include any demographic information)?

**Response:**

* 1. Describe the format of the data you will store (e.g., excel spreadsheet, SPSS file, video or audio recordings, transcripts, photographs, etc...). Describe data that will be stored temporarily (e.g., a videotape until it is transcribed). Describe data that will be stored over a longer period of time (codes in an excel spreadsheet).

**Response:**

* 1. Describe the ways in which the data will be analyzed. For example, for a quantitative study, a description of any statistics should be provided. For a qualitative study, a description of the methods of data generation/process of analysis such as coding themes or heuristic engagement with the material, such as journaling and field notes, should be provided.

**Response:**

* 1. Will participants be identifiable? (data with names, numbers or other identifiers/demographics, data with a key to the participant's identity, video and/or audio recordings.)

**Response:** \_\_\_\_\_\_Yes \_\_\_\_\_\_\_No

* + 1. If yes, you must answer each of the following questions:

1) What is the justification for collecting data that identifies the participants? Why are the identifiers necessary to conduct the research?

**Response:**

2) What is the sensitivity of the data being collected? Would disclosure of the data pose a risk to the participants including reputation, employability, legal, financial, health, personal privacy, etc.?

**Response:**

3) What is the retention period for identifiable data? When will the identified data be deleted or destroyed?

**Response:**

4) What security controls do you have in place for the identifiable data (i.e., physical safeguards for paper records or recordings, technical safeguards for electronic records, secure sharing or transfer of data outside the institution, if applicable)?

**Response:**

5) What is the potential risk for harm that would occur if the security of the data was compromised?

**Response:**

* 1. As part of this study, who will share access to the data?

**Response:**

# Risks to Participants

List the reasonably foreseeable risks, discomforts, hazards, or inconveniences to the participants related to using their data in your research. Describe the probability, magnitude, duration, and reversibility of the risks. Consider physical, psychological, social, legal, and economic risks. Keep in mind that loss of confidentiality and privacy are considered risks. Please note that no study is considered to involve “no risk.” Minimal risk is defined as risk that is not greater than that encountered in everyday life.

**Response:**

## Potential Benefits

4.1 Describe the anticipated benefits to participants, society and/or others. (There must be some benefit described)

**Response:**

### External Approvals

# Describe any approvals that will be obtained from the source of the data prior to commencing the research. Submit documentation in PACs prior to beginning analysis of the data.

**Response:**