**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 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.*

**EXEMPTION 104 (d)(4): Existing Data**

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

Secondary research uses of 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.

**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*

**VERSION NUMBER:**

*Include the version number of this protocol.*

Response:

**DATE:**

*Include the date of submission or revision.*

Response:

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# Objectives

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

Response:

1. **Description of Source of Data, Documents, or Records**
   1. *Describe the source of the data, documents, or records.*

Response:

* 1. *Are the data publicly available?*

Response:

* 1. *How will you obtain the data?*

Response:

* 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”?*
     + 1. *Yes No*
  2. *If yes, please explain.*

Response:

# Data Analysis & Management

* 1. *What data will be collected? 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. *Describe the final form of the data (i.e. excel spreadsheet with codes, de-identified transcripts, video clips) that you plan to maintain and the steps that will be taken to secure the data (e.g., training, authorization of access, password protection, encryption, physical controls, certificates of confidentiality, and separation of identifiers and data) during storage, use, and dissemination.* Response:
  2. *Will participants be identifiable?*

Response:

* 1. *Who will have access to the data?*

Response:

1. **Risks to Participants**
   1. *List the reasonably foreseeable risks, discomforts, hazards, or inconveniences to the participants related the participants’ participation in the research. Include, as may be useful for the HREB’s consideration, a description of the probability, magnitude, duration, and reversibility of the risks. Consider physical, psychological, social, legal, and economic risks. Please note that no study is considered “no risk.” Minimal risk is defined as risk not greater than that encountered in everyday life.*

Response:

# Potential Benefits

# *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 prior to commencing the research, e.g., school or external sites. Note: If this is an external agency or organization, a letter of cooperation from the highest ranking official is necessary to be submitted directly to the H.R.E.B. Office either on letterhead or their work place e-mail; after pending approval of the proposal is received.*

Response: