**UNIVERSITY OF CINCINNATI**

**INSTITUTIONAL REVIEW BOARD – SOCIAL AND BEHAVIORAL SCIENCES (IRB-S)**

**PROTOCOL**

**TITLE:**

**1. PURPOSE of the research project AND GENERAL INFORMATION:**

1. PURPOSE

The purpose of this research study is to…..

1. BACKGROUND

1) Prior research

2) Significance

1. FUNDING

1) Sponsor's name and type

2) Sponsor's role

3) Location of funds

4) Status of funding

1. FACILITIES
2. DURATION OF STUDY
3. RESEARCH TEAM

1) Research team and time commitment

|  |  |
| --- | --- |
| Job Title / Responsibility | Time Commitment |
|  |  |
|  |  |
|  |  |
|  |  |

2) Training team members in research ethics

3) Training team members in research activities

(a) Training

(b) Verification

**2. PARTICIPANTS:**

a. RECRUITMENT

1) Number of participants

(a) Minimum and maximum number of participants

(b) Rationale

2) Inclusion and exclusion criteria

3) Vulnerable participants

(a) Vulnerability

(b) Rationale

(c) Confirmation

4) Risks and discomforts from participating

(a) Type and level of risk or discomfort

|  |  |
| --- | --- |
| Risk or Discomfort | Level |
|  |  |
|  |  |
|  |  |
|  |  |

(b) Safety monitoring plan

(c) Reporting

(1) Notification of PI

(2) Notification of IRB

(3) Other notification

(4) Available resources

5) Direct benefits to the participant

6) Recruitment activities

(a) Recruitment materials

List:

(b) Personnel

(c) Recruitment activities

(d) Participant response

b. CONSENT PROCESS

1) Presenting information to potential participants

2) Answering questions from potential participants

3) Indicating consent

4) Legally authorized representative (LAR) for minors or cognitively impaired participants

5) Verification of LAR for cognitively impaired participants

6) Avoiding coercion

7) Recruitment incentives

c. CONSENT DOCUMENTS (ICDs)

List:

**3. RESEARCH-RELATED ACTIVITY:**

a. SECONDARY ANALYSIS of an EXISTING DATASET

1) Person or entity that holds the dataset

2) General description of the data, including when and how the data were obtained

3) List of the fields (or description of the kinds of information) that will be used from the dataset, with specific mention of any individually identifying data

4) Explanation why individually identifying data are needed for your study, how confidentiality of individually identifiable data will be assured, and how soon identifiers will be purged from the dataset

5) Explanation of how the dataset (or portion of the dataset) will be obtained from the current holder

b. REVIEW OF RECORDS that were collected for NON-RESEARCH PURPOSES

1) Person or entity that holds the records

2) General description of the kind of records, including when and how the records were obtained

3) Specific description of the information (i.e., data fields) that will be used from the records, with specific mention of any individually identifying information

4) Explanation why individually identifying information is needed for your study, and how soon identifiers will be purged from the research records

5) Explanation of how the records (or excerpts from the records) will be obtained from the current holder

c. RESEARCH ACTIVITIES

1) Privacy of participation

2) Confidentiality of data

3) Research-related activities

(a) Participant cohorts

(b) Activities and duration

(c) Data collection tools

List:

(d) Payments to participants: reimbursement of expenses or payment for time and effort

**4. DATA ANALYSIS:**

**5. REFERENCES:**

List:

**6. ADDITIONAL DOCUMENTATION:**

List: