**BUTLER UNIVERSITY**

**Institutional Review Board**

**Application for Expedited Approval or Full Approval**

**You must complete ALL sections of the application and answer every question** (i.e., your response to a question cannot refer to an attached document, such as a research proposal, that provides the answer)**.** Please download this application and type the requested information into the form. **Submission instructions: once the application is complete, including all of the required signatures, submit it to the Butler Office of Sponsored Programs by scanning the entire application package into one PDF file and sending an electronic version to** **IRB@butler.edu****. If instead submitting as hard copy brought to the Butler Office of Sponsored Programs, format copies as one-sided pages only, no staples.**

**You must submit a separate application for each project.**

Federal regulations limit IRB approval to one year (365 days) or less. At the end of this time, the PI must submit a written closure report or initiate a continuing review to extend the study beyond one year. **Please note that data collection may not begin until you have received an official letter of IRB approval from the Butler Office of Sponsored Programs.**

**Once the project is completed, the protocol must be closed and a statement of closure sent to the Butler Office of Sponsored Programs.**

To ensure that all required materials, besides the application, are included with the protocol when it is submitted, please review the checklist provided below. If any of these elements are being used in your research, be sure to include a copy of the item with your protocol. Your protocol will not be reviewed until all required materials are submitted.

|  |  |  |
| --- | --- | --- |
|  | **Used in Research** | **Included with Application** |
|  | Yes | No | Yes | No |
| 1. Copy of any questionnaires and/or measures to be completed by participants | [ ]  | [ ]  | [ ]  | [ ]  |
| 2. List of interview questions | [ ]  | [ ]  | [ ]  | [ ]  |
| 3. Copy of data collection table and/or data coding schemes | [ ]  | [ ]  | [ ]  | [ ]  |
| 4. Informed consent statement | [ ]  | [ ]  | [ ]  | [ ]  |
| 5. Assent statement for research involving children who are capable of providing assent | [ ]  | [ ]  | [ ]  | [ ]  |
| 6. Debriefing script for research involving deception | [ ]  | [ ]  | [ ]  | [ ]  |

**Completion of the appropriate modules of the CITI training by the Principal Investigator, the Student Researcher and all Key Personnel is required before submitting your IRB application. Your application will not be reviewed until the Butler office of Sponsored Programs has been notified by CITI that all investigators listed on the application have completed this training. Have all investigators associated with the research (PI, student researcher and people listed as key personnel) completed the appropriate modules of the CITI training?**

 Yes [ ]  No [ ]

**A. INVESTIGATOR INFORMATION**

**Principal Investigator:**

Name:        Phone:       Date:
(must be faculty, staff, or the sponsor of student research)

Campus Address:       E-mail:       Department/College:
Select: [ ]  Faculty [ ]  Staff

**Student Researcher (if applicable):**

Name:       Phone:       Department/College:

Local Address:       City:       State:       Zip Code:

E-mail:

**B. BASIC PROTOCOL INFORMATION**

Project Title:

Anticipated dates of data collection: date of IRB approval to       (Note: If your actual data collection will extend beyond the end date specified on your application, you must submit a request for an extension of your IRB approval.)

Anticipated dates of data analysis:       to

Length of time for data storage:       (note: health-related and medical data is required by law to be kept for 7 years)

Does the Research require approvals from other organizations or IRBs?

 [ ]  Yes [ ] No

If YES, state where:

Status: [ ]  Pending [ ]  Approval received (copy attached)

Is this project being performed away from the main Butler University campus? (Note: If data is being collected using an online survey, such as survey monkey, choose NO)

[ ]  Yes [ ] No

If YES, what other sites:

Is this project being funded?

[ ]  Yes [ ] No If YES, please indicate funding source:

The IRB is responsible for reviewing all research involving the use of human participants. The IRB determines which type of review your protocol will receive. Please consult the guidelines and then check the type of review you believe applies.

[ ]  Full [ ]  Expedited

**C. KEY PERSONNEL**

List all additional investigators involved in this project. This includes all personnel involved in collecting and analyzing data.

Name:

Department:

Position:

Phone:

Mailing Address (if not at Butler):

E-mail:

**D. OTHER CONSIDERATIONS**

1. Is participation in this research required by reason of a participant's employment?

[ ]  Yes [ ] No

2. Is participation in this research required to receive a particular service?

[ ]  Yes [ ] No

3. Does this research involve the evaluation of a program or service?

[ ]  Yes [ ] No

**E. SUMMARY OF PROJECT**

Provide a brief summary (3 to 5 sentences) in lay terms of the purpose of your study.

**F. BACKGROUND**

Describe the Purpose of the study. It should include: a) a brief description of prior, relevant research findings; b) the hypotheses to be tested or research questions to be addressed; and c) the potential knowledge to be gained. Please limit to 1 page.

**G. PROCEDURES**

Describe the procedures participants in your study will undergo. Describe specifically what participants will be asked to do and the approximate time involvement for each participant. Also describe all types of data that will be collected from (or about) participants and where or how the data will be collected.

**H. PARTICIPANTS**

Check whether you anticipate having participants in your research that fit into any of the categories below:

[ ]  Children (<18years) [ ]  Cognitively Impaired

[ ]  Prisoners [ ]  Agency Administrators/Staff

[ ]  Clients/Patients [ ]  Pregnant women

[ ]  People who live overseas [ ]  Non-English speakers

[ ]  Students

1. Anticipated number of participants:

2. Age range(s):

3. Sex: [ ]  Male [ ]  Female [ ]  Both

4. Describe the anticipated race/ethnicity of your participants:

5. Will you be selecting participants based upon health-related criteria?

[ ]  Yes [ ]  No

 If yes, describe the criteria you will use.

6. Will any of your participants be from vulnerable populations either because they might possess limited or diminished mental capacity (e.g. children, people with dementia) or because they might be subject to undue influence (e.g. subjects in hierarchical social structures, such as employees or students, subjects who are economically or educationally disadvantaged, subjects who are marginalized in society, subjects with fatal or incurable diseases, subjects in emergency situations)?

[ ]  Yes [ ]  No

If yes, describe the nature of their vulnerability and the procedures you will use to ensure that these individuals are not subject to coercion or undue influence from others.

7. Describe the procedures for participant recruitment. Attach proposed announcements, fliers, advertisements, etc., if applicable.

8. Will participants be paid for their participation or offered an incentive to participate?

 [ ]  Yes [ ]  No

 If YES, describe.

**I. RISK/BENEFIT ASSESSMENT**

1. Does this study involve any of the following elements?

YES NO

[ ]  [ ]  Deception (If **yes**, you must submit your debriefing script.)

[ ]  [ ]  Punishment

[ ]  [ ]  Use of drugs

[ ]  [ ]  Biomedical procedures

[ ]  [ ]  Procedures which might cause physical harm to participant

[ ]  [ ]  Covert and/or participant observation

[ ]  [ ]  Induction of mental and/or physical stress

 [ ]  [ ]  Materials and behaviors commonly regarded as

 socially unacceptable

[ ]  [ ]  Procedures that might be regarded as an invasion of

privacy

 [ ]  [ ]  Collection of information that, if disclosed, could place the participant at risk for criminal or civil liability or be harmful to participant’s financial standing, employability, insurability or reputation

 If you answered “yes” to any of the above, describe specifically how it will be incorporated into the study procedures, provide the rationale for using it and discuss any potential risks associated with its use. Describe also the procedures you will use to mitigate these risks as well as any provisions for ensuring necessary professional intervention in the event of a distressed participant.

2. Describe any other potential risks to the participants in the study besides those above. You should consider potential physical, psychological, social, legal or other risks. For all potential risks, assess the likelihood of their occurring and their seriousness, even if you think these risks will be avoided. Describe the procedures you will use to mitigate these risks as well as any provisions for ensuring necessary professional intervention in the event of a distressed participant.

3. Describe the potential benefits of your research to the participants and/or to society in general.

**J. CONFIDENTIALITY ISSUES**

1. Will data be collected anonymously (i.e. so that no one, *not even the researchers or any research assistants involved in data collection*, can determine which participant provided which data)?

 [ ]  Yes [ ]  No

 If you answered **YES**, explain the procedures used to ensure anonymity.

 If you answered **NO** to #1, describe procedures for keeping data confidential (i.e., for ensuring that even though the researchers could determine which participant provided which data, no third party could gain access to the data and determine who provided the data). Be sure to explain where and how the data will be stored both *during* the data collection process *and after* the study is concluded since this will affect the confidentiality of the data.

2. Will data from each participant be collected at more than one point in time or from more than one setting?

 [ ]  Yes [ ]  No

 If YES, explain the procedures you will use to connect the various pieces of data from each participant and how these procedures will protect the confidentiality of participant data.

3. Will you be audio/video taping participants or photographing them?

 [ ]  Yes [ ]  No

 If YES, provide the rationale for video/audio-taping or photographing participants. Describe how the recordings/photographs will be used (e.g. shown at scientific meetings, transcribed and/or coded etc.) and how they will be stored to ensure confidentiality of participant data. Finally, describe what you will do with the recordings/photographs when the study is concluded (i.e., will they be destroyed/erased or archived?).

**K. INFORMED CONSENT**

Please describe the process that will be used to obtain informed consent. If your research involves the use of minors, you must get informed consent from the participant’s parent or legal guardian. If the minors are of an age where it would be appropriate to get their agreement to participate in the research, you should also describe the procedures for getting participant assent. Make sure your informed consent statement is free from grammatical errors, and that it is written clearly and at a level that will be understandable to your participants. If the first language of your participants is not English, it may be necessary to have your consent/assent form translated into the primary language of your participants to ensure their understanding.

1. Who will obtain consent (and assent, if applicable)?

2. How will consent (and assent, if applicable) be obtained?

3. When will consent (and assent, if applicable) be obtained?

4. How will you verify that the participant fully understands the consent (and assent, if applicable)?

5. Do you wish to waive the requirement of documenting informed consent? (i.e., participants will receive a statement of consent, but will not be asked to sign the form and no written record of the consent will be kept by the researchers)?

 [ ]  Yes [ ]  No

 If YES, explain why (see 45 CFR 46.117 (c) for the conditions which must be met for this waiver to be approved).

6. Do you wish to alter any of the elements of informed consent or waive the requirement of getting informed consent from participants prior to their participating in your research?

 [ ]  Yes [ ]  No

 If YES, explain why (see 45 CFR 46.116. (c) or (d) for the conditions which must be met for this waiver to be approved).

**L. CERTIFICATION**

I certify that the protocol and the method of obtaining Informed Consent as approved by the IRB will be followed during the period of this research project. Any changes of protocol, investigator, consent, or recruiting of participants will be submitted for IRB review and approval before implementation. Any adverse reactions or participant complaints will be promptly reported to

Butler Office of Sponsored Programs (irb@butler.edu). This research will be conducted only with the approved faculty investigator and, if any, student investigator(s). All records of this research will be maintained as required by the Butler office of Sponsored Programs (see: http://www.butler.edu/osp)

Principal Investigator Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date:

(faculty or staff) *Required if investigator is student*

Student Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_

IRB DECISION

 Approved as Expedited

 Approved as Full

 Resubmission requested

 Not Approved

IRB Chair: ­­\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date