**BUTLER UNIVERSITY**

**Institutional Review Board**

**Exempt Application**

**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 in Jordan Hall, Room 116 - one-sided pages only and no staples. You may also submit your application electronically. Once the application is complete, including all of the required signatures, you may scan the entire application package into one PDF file and send an electronic version to** **IRB@butler.edu****.**

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

**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.**

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 | [ ]  | [ ]  | [ ]  | [ ]  |

**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 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

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)

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:

Does the research require approval from other organizations or IRBs? [ ]  Yes [ ]  No

If yes, state from where:

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

Is this project being funded?

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

**C. KEY PERSONNEL**

List all additional investigators involved in this project. This includes all personnel involved in collecting data from participants and/or analyzing the data.

Name:

Department:

Position:

Phone:

Mailing Address (if not at Butler):

E-mail:

Name:

Department:

Position:

Phone:

Mailing Address (if not at Butler):

E-mail:

**D. EXEMPT CATEGORY**

Below are the categories of research that are considered to be exempt from the regulations designed to protect human subjects. These categories come from the United States Code of Federal Regulations 45CFR: Protection of Human Subjects. Section 46.101.

Review these categories and check the category (or categories) that you believe apply to your research. **Please note that the final determination of the exempt status of your research is made by the IRB.**

Top of Form

|  |  |
| --- | --- |
| [ ]  | **Category 1:** Research, conducted in established or commonly accepted educational settings that specifically involves normal educational practices that are not likely to adversely impact students' opportunity to learn required educational content or the assessment of educators who provide instruction. This includes most research on regular and special education instructional strategies, and research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods. |
| **[ ]**  | **Category 2:** Research that only includes interactions involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior (including visual or auditory recording) if at least one of the following criteria is met:1. The information obtained 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;
2. Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; or
3. The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination required by § 46.111(a)(7).
 |
| **[ ]**  | **Category 3:** (i) Research involving benign behavioral interventions in conjunction with the collection of information from an adult subject through verbal or written responses (including data entry) or audiovisual recording if the subject prospectively agrees to the intervention and information collection and at least one of the following criteria is met:(A) The information obtained 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;(B) Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; or(C) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination required by § 46.111(a)(7).(ii) For the purpose of this provision, benign behavioral interventions are brief in duration, harmless, painless, not physically invasive, not likely to have a significant adverse lasting impact on the subjects, and the investigator has no reason to think the subjects will find the interventions offensive or embarrassing. Provided all such criteria are met, examples of such benign behavioral interventions would include having the subjects play an online game, having them solve puzzles under various noise conditions, or having them decide how to allocate a nominal amount of received cash between themselves and someone else.(iii) If the research involves deceiving the subjects regarding the nature or purposes of the research, this exemption is not applicable unless the subject authorizes the deception through a prospective agreement to participate in research in circumstances in which the subject is informed that he or she will be unaware of or misled regarding the nature or purposes of the research. |
| **[ ]**  | **Category 4**: Secondary research for which consent is not required: Secondary research uses of identifiable private information or identifiable biospecimens, if at least one of the following criteria is met:(i) The identifiable private information or identifiable biospecimens are publicly available;(ii) 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;(iii) 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 parts 160](https://www.federalregister.gov/select-citation/2017/01/19/45-CFR-160) and 164, subparts A and E, for the purposes of “health care operations” or “research” as those terms are defined at [45 CFR 164.501](https://www.federalregister.gov/select-citation/2017/01/19/45-CFR-164.501) or for “public health activities and purposes” as described under [45 CFR 164.512](https://www.federalregister.gov/select-citation/2017/01/19/45-CFR-164.512)(b); or(iv) The research is conducted by, or on behalf of, a Federal department or agency using government-generated or government-collected information obtained for nonresearch activities, if the research generates identifiable private information that is or will be maintained on information technology that is subject to and in compliance with section 208(b) of the E-Government Act of 2002, [44 U.S.C. 3501](https://api.fdsys.gov/link?collection=uscode&title=44&year=mostrecent&section=3501&type=usc&link-type=html) note, if all of the identifiable private information collected, used, or generated as part of the activity will be maintained in systems of records subject to the Privacy Act of 1974, [5 U.S.C. 552](https://api.fdsys.gov/link?collection=uscode&title=5&year=mostrecent&section=552&type=usc&link-type=html)a, and, if applicable, the information used in the research was collected subject to the Paperwork Reduction Act of 1995, [44 U.S.C. 3501](https://api.fdsys.gov/link?collection=uscode&title=44&year=mostrecent&section=3501&type=usc&link-type=html) et seq. |
| [ ]  | **Category 5:** Research and demonstration projects that are conducted or supported by a Federal department or agency, or otherwise subject to the approval of department or agency heads (or the approval of the heads of bureaus or other subordinate agencies that have been delegated authority to conduct the research and demonstration projects), and that are designed to study, evaluate, improve, or otherwise examine public benefit or service programs, including procedures for obtaining benefits or services under those programs, possible changes in or alternatives to those programs or procedures, or possible changes in methods or levels of payment for benefits or services under those programs. Such projects include, but are not limited to, internal studies by Federal employees, and studies under contracts or consulting arrangements, cooperative agreements, or grants. Exempt projects also include waivers of otherwise mandatory requirements using authorities such as sections 1115 and 1115A of the Social Security Act, as amended**.**(i) Each Federal department or agency conducting or supporting the research and demonstration projects must establish, on a publicly accessible Federal Web site or in such other manner as the department or agency head may determine, a list of the research and demonstration projects that the Federal department or agency conducts or supports under this provision. The research or demonstration project must be published on this list prior to commencing the research involving human subjects.(ii) [Reserved] |
| **[ ]**  | **Category 6:** Taste and food quality evaluation and consumer acceptance studies if:1. wholesome foods without additives are consumed or
2. a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U. S. Department of Agriculture
 |
| **[ ]**  | **Category 7:** Storage or maintenance for secondary research for which broad consent is required: Storage or maintenance of identifiable private information or identifiable biospecimens for potential secondary research use if an IRB conducts a limited IRB review and makes the determinations required by § 46.111(a)(8). |
| **[ ]**  | **Category 8 :** Secondary research for which broad consent is required: Research involving the use of identifiable private information or identifiable biospecimens for secondary research use, if the following criteria are met:(i) Broad consent for the storage, maintenance, and secondary research use of the identifiable private information or identifiable biospecimens was obtained in accordance with § 46.116(a)(1) through (4), (a)(6), and (d);1. Documentation of informed consent or waiver of documentation of consent was obtained in accordance with § 46.117;

(iii) An IRB conducts a limited IRB review and makes the determination required by § 46.111(a)(7) and makes the determination that the research to be conducted is within the scope of the broad consent referenced in paragraph (d)(8)(i) of this section; and (iv) The investigator does not include returning individual research results to subjects as part of the study plan. This provision does not prevent an investigator from abiding by any legal requirements to return individual research results. |

Bottom of Form

**E. PARTICIPANTS**

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, SONA announcement, recruitment email etc., if applicable.

**F. SUMMARY OF PROJECT**

1. Provide a brief summary, in lay terms, of the purpose of your study.

2. Describe the procedures participants will undergo, including the data that will be collected from (or about) each participant, where and how the data will be collected, and the approximate time involvement for each participant.

3. Does the research involve deception of any kind?

[ ]  Yes [ ]  No

If YES, then your research does not qualify for exempt review. Submit your application using the expedited/full review application form.

 **G. CONFIDENTIALITY ISSUES**

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

 [ ]  Yes [ ]  No

 If YES, explain the procedures used to ensure anonymity.

 If NO, 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 multiple settings?

 [ ]  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 ensure that participant data will be kept confidential.

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?).

**H. CONSENT OF PARTICIPANTS**

1. Describe how you will obtain consent from participants to take part in your research or provide a rationale for why it is not needed. It is important that your consent procedures describe what participation in your research will involve and make it clear to participants that their participation in your research is voluntary. If you use a consent statement, make sure it is free from grammatical errors, and that it is written clearly and at a level that will be understandable to your participants.

**I. CERTIFICATION**

I certify that I understand the Butler University Policies and Procedures for research involving human participants and will comply with them. I will adhere to all standards of professional behavior and participant confidentiality.

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

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

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

IRB DECISION

 Project is exempt from review (cite exempt category)

 Resubmission for expedited review requested

 Resubmission for full review requested

 Not Approved

 IRB approval not required

IRB REVIEWER: ­­\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date