Request for Approval of Research Involving Human Participants

*Please download and open in Adobe to complete and save this form.

Title of Project

Beginning Date: Ending Date:

Type of Review Requested: ◯ Administrative ◯ Expedited ◯ Full-board

Is external funding being sought? ◯ Yes ◯ No Potential supporting agency:

Is internal funding being sought? ◯ Yes ◯ No Internal grant sought:

Principal Investigator:

Name E-mail

Department Campus Box

◯ Faculty/Staff ◯ Student

Faculty Sponsor (if student) Faculty Sponsor E-mail

Additional Project Personnel:

Name E-mail

Name E-mail

Name E-mail

Name E-mail

Additional project personnel may be added as an Appendix to this submission form

Investigator Training:

☐ ***CITI Course Completion Reports for all project personnel are attached as an Appendix to this protocol submission***

Participant Information:

Number of Participants: Female ☐ Male ☐

Age Range: ☐

How will participants be recruited?

☐

Recruitment Materials:

☐ ***All recruitment materials (e-mails, flyers, etc.) are attached as an Appendix to this submission form.***

Participant Time Commitment (min or hours, number of sessions, days/weeks of participation)

☐

Characteristics: (Select all that apply)

- ☐ Adults
- ☐ Cognitively/Psychologically Impaired*
- ☐ Minors*
- ☐ Institutionalized Residents*
- ☐ Students (classroom research)
- ☐ Pregnant Women*
- ☐ Non-English Speakers
- ☐ Prisoners*

*If the study includes a protected population, provide additional information about this population on the following page.

If including minors, provide a rationale for the age ranges to be included, the expertise of the investigator dealing with children of that age range, and the adequacy of the setting to accommodate children of those ages:

If including protected populations (other than minors), provide a justification for their inclusion, how they will be protected, and a thorough explanation of how their autonomy will be respected:

Data Collection and Storage - Basic Information

Where will the study take place?

- ☐ Berry College
- ☐ Berry Elementary/Middle School*
- ☐ Berry Child Development Center*
- ☐ Other*

***Site Permission**

☐ *Documentation of authorization to conduct research at this site (Berry Elementary/Middle School, Berry Child Development Center, or Other) is attached to this form.*

Alternate Site IRB Requirements:

☐ *This study also requires local IRB approval from the alternate site. This approval is either attached as an Appendix to this form or will be submitted to the Berry College IRB once received.*

Methods/Measures (select all that apply):

- ☐ Surveys or Questionnaires
- ☐ Interviews, Focus Groups, and/or Oral Histories
- ☐ Secondary Data Analysis
- ☐ Video, Photography, and/or Voice Recording
- ☐ Physiological (Health, Performance, etc.) Tests
- ☐ Other
- ☐ Standardized Tests
- ☐ Public Observations
- ☐ Non-Public Records (Health, Education, etc.)
- ☐ Perceptual/Psychological Tests
- ☐ Biological Specimens (Blood Samples, etc.)

Methods/Measures:

☐ ***All materials that participants will interact with during data collection (surveys, questionnaires, focus group questions, interview questions, standardized test questions, images, descriptions of videos) are attached as an Appendix to this submission form.***

Confidentiality - explain how the data will be coded and stored to protect participant's confidentiality:

Data Storage Agreement:

☐ ***I acknowledge that data must be stored with two-level protection (e.g. password-protected computer kept in a locked office) and only be accessed/viewed/analyzed by the project personnel.***

Specific Project Information

Introduction to the Topic

**Provide enough background information that the purpose statement/research question seems justified to someone unfamiliar with the project or field of study.*

Purpose Statement and/or Research Question(s)

**This should be a clear purpose or testable hypothesis/hypotheses flowing from the information provided in the introduction*

Study Design

**How will the purpose be accomplished or the research question(s) tested?*

Will deception be used in this study?

◯ Yes ◯ No

If deception will be used, provide a rationale and include how participants will be debriefed:

Provide a detailed description of all measures, procedures, interventions, etc. included in this study:

**Provide clear details of all Methods/Measures selected in the "Data Collection and Storage - Basic Information" section.*

Risks

Describe any risks to participants from completing this study. These could be risks to their physical, mental, emotional, intellectual, spiritual, and/or occupational health or status.

Provide specific steps or precautions that will be taken in order to minimize the risks described above. Include information on any emergency or contingency plan that would be followed if necessary due to adverse events.

Adverse Event Documentation:

☐ ****Documentation of emergency plans, copies of resources provided to participants, etc. are attached as an Appendix to this protocol submission form.***

Benefits

Describe any direct benefits and/or compensation provided to the participants due to their involvement in or completion of the study:

Describe the benefits of the project to the discipline, profession, and/or society:

Informed Consent

Informed consent is a critical part of conducting ethical research. This is the primary method by which the project personnel show respect for the autonomy of the potential participants.

Participants should be provided with written information about the study, including (but not limited to):
- *a statement indicating that their participation is completely voluntary*
- *the purpose of the research project*
- *the specific requirements for participation, including details on all surveys/measurements/tests/interventions etc. they will complete, including any relevant information on video/photograph/audio recording, along with their time commitment*
- *any discomforts and risks due to participating, along with how the risks are being managed by the project personnel*
- *the benefits they can reasonably expect by participating*
- *contact information for both the Principal Investigator and the Director of Research and Sponsored Programs*

Templates for informed consent documents may be found on the Berry IRB web page, but note that a proper informed consent document should be specific to the project and include enough detail for participants to make a well-informed decision about their participation.

For studies involving minors or others with impaired autonomy, consent must be obtained by a parent/guardian and assent (either verbal or written) must be obtained from the participant.

By default, documentation of informed consent is required. This is accomplished by obtaining the signature of the participant on the informed consent, which is delivered, explained, and witnessed by one of project personnel. However, in some cases a waiver of documentation of informed consent (obtaining signatures) may be granted - though participants should still receive all of the elements of informed consent before beginning their participation. In some rare occasions, a waiver/alteration of providing all the elements of informed consent may be granted.

Informed Consent:

◯ I will obtain documentation of informed consent

◯ I request a waiver of documentation of informed consent

◯ I request a waiver of some/all of the informed consent elements

**Note that requests for waivers may or may not be granted*

Justification for a waiver of documentation of informed consent (at least one of the following must be true):

☐ The signature on the informed consent document would be the only record linking the participant to the research, and the principle risk of harm to the participant would be a breach of confidentiality (e.g. research on illegal activities).

☐ The research presents no more than minimal risk of harm to participants, and involves no procedures for which written consent is normally required outside the research context (e.g. online surveys)

Justification for a waiver of some/all of the informed consent elements (each of the following must be true):

☐ The research involves no more than minimal risk to participants

☐ The research could not be practicably carried out without the waiver or alteration

☐ The waiver or alteration will not adversely affect the rights and welfare of the participants

☐ When appropriate, participants will be provided with additional information about their participation (e.g. studies involving deception)

Informed Consent Document:

☐ ***The informed consent document (and assent script/document, where appropriate) is attached as an Appendix to this form.***

Signatures

Principal Investigator Responsibilities:

- ☐ I am cognizant of, and will comply with, current federal regulations and IRB requirements governing research with human participants, including adverse event reporting requirements.
- ☐ I have reviewed this protocol submission in its entirety and certify that it contains all pertinent information.
- ☐ I will conduct this research study in strict accordance with all submitted statements except where a change may be necessary to eliminate an apparent immediate hazard to a given research participant.
- ☐ I will request an obtain IRB approval of any proposed modification to the research protocol prior to implementing such modification.
- ☐ I will ensure that all co-investigators and other personnel assisting in the conduct of this research study have been provided a copy of the entire current version of the research protocol.
- ☐ I will not enroll any individual into this research study until I have received approval of this application from the IRB.
- ☐ I will respond promptly to all requests for information or materials solicited by the IRB.
- ☐ I will maintain adequate, current, and accurate records of research data.

Principal Investigator Signature:

Faculty Sponsor/Mentor Assurance:

- ☐ I certify that the Principal Investigator named above will conduct this research under my supervision and guidance. I further certify that I will assume final responsibility for the conduct of this protocol in accordance with all Berry College policies and procedures regulating human participant research.

Faculty Sponsor/Mentor Signature:

Approvals

Department Chair Signature:

Dean Signature:

For office use only:

IRB Chair Signature:

Protocol number: ☐ Approval end date: ☐

Protocol Submission Checklist

- [ ] Completed protocol submission form
- [ ] CITI Course Completion Reports for all project personnel are attached
- [ ] (If applicable) Documentation of authorization to conduct research at the site (Berry Elementary/Middle School, Berry Child Development Center, or Other) is attached
- [ ] All participant recruitment materials (e-mails, flyers, etc.) are attached
- [ ] All materials that participants will interact with during data collection (surveys, questionnaires, focus group questions, interview questions, standardized test questions, images, descriptions of videos) are attached
- [ ] Emergency/contingency plan documents, copies of resources provided to participants, etc. are attached
- [ ] The informed consent document (and assent script/document, where appropriate) is attached