

THIS SECTION FOR IRB USE ONLY
Protocol Number: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Review Type**: Exempt Expedited Full

Approval Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Expiration Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Berry College

Request for Approval of Social/Behavioral Research

Involving Human Participants

*Submit* ***two*** *typed, signed originals of the application and supporting material (if applicable). All Applications must be approved* ***prior*** *to the initiation of any investigation involving human participants.*

PART A: Information about you and your faculty sponser (if applicable), as well as basic project information

Choose one: [ ] Faculty/Staff [ ] Graduate Student [ ] Undergraduate Student

**Principal Investigator:** Name**:** Click here to enter text. Department: Click here to enter text.

Campus Box/Phone: Click here to enter text. Email Address: Click here to enter text.

If PI is a student, list the name of the **faculty sponsor or mentor** who will take responsibility for overseeing this research, and has signed the attached Faculty/Mentor Assurance:

Name: Click here to enter text. Email: Click here to enter text.

**Additional Project Personnel (coPI, student assistants, ect.):**

*(Attach training certificates for each –see C:8.)*

|  |  |  |
| --- | --- | --- |
| Name | Department | Email Address |
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**Title of Project:** Click here to enter text.

Approximate Beginning Date: Click here to enter text. Ending Date: Click here to enter text.

Is external funding being sought? [ ] No [ ] Yes Potential Supporting Agency: Click here to enter text.

**Type of Review Requested:** **[ ]** Administrative [ ] Expedited [ ] Full Board\*

\*Research Activities that Must Receive Expedited or Full Board Review:

* Studies involving prisoners
* Studies of classroom activities that involve students other than your own
* The review of records if the information is recorded in such a way that participants can be identified, directly or indirectly through identifiers linked to the participants
* Survey or interview techniques which include minors as participants
* Research involving the observation of the public behavior of minors, in which the researcher interacts with participants
* Studies which involve videotaping, photographing, or voice recording
* Techniques which expose the participant to discomfort(s) beyond levels encountered in daily life
* Studies which involve the deception of the participants

Note: Georgia and federal laws define a minor as persons who have not attained the age of 18.

For a full listing of requirements for all types of review, see the *Faculty Research Handbook*.

PART B: General Project Information

**Where will your study take place?** [ ] Berry College [ ] Berry Elementary School\*

 [ ] Berry Child Development Center\*

 [ ] Other\* (specify): Click here to enter text.

*\*Documentation authorizing conduct of research at this site must be attached.*

**Participants:**

Number of Participants/Gender: Male:Click here to enter text. Female:Click here to enter text.

Participants Age Range:Click here to enter text. Each participant’s approximate time commitment:Click here to enter text. Estimated duration of entire study:Click here to enter text.

Participants will be: (Check all that apply)

[ ] Adults (>18 years old) [ ] Prisoners

[ ] Minors (<18 years old) [ ] Non-English Speaking

[ ] Berry College Students [ ] Institutionalized residents

[ ] Participants at other Colleges/Universities [ ] Other:Click here to enter text.

[ ] Cognitively or psychologically impaired

**Methods/Measures: (please check all that apply)**

[ ] Surveys/Questionnaires**[ ]** Interviews: (circle one) Phone In Person

[ ] Focus Groups [ ] Standardized tests

[ ] Public Observations [ ] Deception

[ ] Secondary Data Analysis [ ] Video/Photography

[ ] Non-Public Records (Health, Education, ect.) [ ] Voice Recording

[ ] Oral Histories [ ] Other:Click here to enter text.

PART C: Specific Project Information. *Summarize, in non-technical terms, as clearly and completely as possible.*

1. **RESEARCH QUESTION.** Please give a brief summary of the research question you are investigating, in non-technical language.

Click here to enter text.

1. **PARTICIPANTS.**
	1. Who will be studied?Click here to enter text.
	2. If minors are included: [ ] Not Applicable
		1. Provide a rational for the specific age ranges of children to be included.

Click here to enter text.

* + 1. Describe the expertise of the investigator(s) for dealing with children of that age range.

Click here to enter text.

* + 1. Describe the adequacy of the specific project setting to accommodate children of that age range.

Click here to enter text.

1. **PROCEDURES.**

3a. Provide a complete, detailed summary of the procedures you will use to answer your research question.

 Click here to enter text.

3b. Will deception be used in your study? [ ] Yes [ ] No

 If yes, give rationale for deception and describe how participants will be debriefed.

 Click here to enter text.

1. **RISKS.** Describe any immediate or long-term risks to participants. Include risks of both a physical and psychosocial nature. Describe how you will deal with these risks.

Click here to enter text.

1. **CONFIDENTIALITY.** Confidentiality of information from or about participants must be safeguarded. Even anonymous surveys conducted in a small community like Berry College may contain combinations of demographic information that could lead to identification. Please state explicitly how you will safeguard these data.

Click here to enter text.

1. **CONTENT/ASSENT.** Informed consent is required by Berry College policy. Consent is implied when anonymous data are collected, but a statement should appear on all questionnaires clearly stating that consent is given when the form is filled out and returned. Written consent is the default for all applications; however, the committee will consider alternatives. Expedited or Full Board review research involving minors must have both parental consent and participant assent.

6a. [ ] I will obtain written consent. *Append a copy of your consent form (See* [*Faculty Research website*](http://www.berry.edu/academics/services/Faculty_Research/humansubjects.asp) *for examples).*

 **Note: If requesting consent from non-English speakers, consent form must be translated**.

 [ ] I request a waiver of written consent. *Provide justification for not obtaining written consent* ***and*** *attach a copy of the script/letter you will use to inform participant, parents, and/or legal guardians.*

 Click here to enter text.

6b. Assent (oral or written) is a very important component of research with human participants. If your participants are unable to give legal consent themselves (i.e., they are minors or mentally impaired), you are obligated to obtain their assent to participate in your study *(See the* [*Faculty Research website*](http://www.berry.edu/academics/services/Faculty_Research/humansubjects.asp) *for examples of an assent document or script).* *Append a copy of your assent document/script. Take care to use language that your participants can understand.*

1. **BENEFITS OF RESEARCH.**

7a. Describe the benefits of the research to the participants.

 Click here to enter text.

7b. Describe the benefits of the research to the discipline, profession, or society.

 Click here to enter text.

1. **INVESTIGATOR TRAINING.** As of July 1, 2005, Berry College subscribes to the Collaborative IRB Training Initiative (CITI) as our source of training. The website address for this training is: [www.citiprogram.org](http://www.citiprogram.org). The Social/Behavioral Research group has six required modules. Each module takes between 10 and 30 minutes to complete. There are several optional modules, i.e., research with children, research in public elementary and secondary schools, and internet research. If your research involves any of the optional topics, you are required to complete the appropriate optional modules as well.

A passing score of 80% or better is needed to meet the IRB training requirement. A **Course Completion Report** must be printed and submitted with your protocol application as evidence of successful completion of training.

For more detailed instructions and information, please refer to the Berry College [IRB website](http://www.berry.edu/academics/services/Faculty_Research/humansubjects.asp).

**Print two copies of this form, sign, and send to: Donna Davin, Director**

**Faculty Research and Sponsored Programs**

**Campus Box 495006**

 **or**

**McAllister Hall, Room 219**

**CERTIFICATION OF INVESTIGATOR RESPONSIBILITIES.**.

By signing below I agree/certify that:

1. I am cognizant of, and will comply with, current federal regulations and IRB requirements governing research with human participants including adverse event reporting requirements.
2. I have reviewed this protocol submission in its entirety and certify that it contains all pertinent information.
3. 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.
4. I will request and obtain IRB approval of any proposed modification to the research protocol prior to implementing such modification.
5. 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.
6. I will not enroll any individual into this research study until I have received approval of this application from the IRB.
7. I will respond promptly to all requests for information or materials solicited by the IRB.
8. I will maintain adequate, current, and accurate records of research data.
9. I have personally completed the training as required by Berry College policies.

Principal Investigator Name: Click here to enter text. Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date:Click here to enter text.

**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.

Mentor’s Name:Click here to enter text. Signature:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date:Click here to enter text.

Position:Click here to enter text. Email:Click here to enter text. Phone:Click here to enter text.

**Institutional Approvals**

**Department Chairperson: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

Signature and Date

**School Dean: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

Signature and Date

**IRB Chairperson: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

Signature and Date