**BLACK HILLS STATE UNIVERSITY INSTITUTIONAL REVIEW BOARD (IRB)**

**HUMAN PARTICIPANTS RESEARCH APPLICATION**

|  |
| --- |
| **FOR OFFICE USE ONLY** |
| Application #: |  |  Date Received: |
| Click or tap here to enter text. | Click or tap to enter a date. |
| Review Level: |  |
| Click or tap here to enter text. |
| Approval Status: |  Approval Period: |
| Click or tap here to enter text. | Click or tap here to enter text. |
|  | Click or tap to enter a date. |  |
|  Dr. Cynthia Anderson, IRB Chair |  Date: |

**INSTRUCTIONS FOR INVESTIGATORS:**

The Black Hills State University IRB reviews all requests to conduct research involving human subjects. Be advised that the persons reviewing your application may be entirely unfamiliar with the field of study involved. Therefore, you should present the request in non-technical terms understandable to IRB members. It is the investigator's responsibility to give information about research procedures that may entail risk but not to express judgment about the risk.

Please submit the completed Human Participants Research Application via email to IRB@bhsu.edu and cc to Dr. Cynthia Anderson, IRB Chair (CynthiaAnderson@bhsu.edu). Be sure all necessary information is included, and that required CITI Program training in Research with Human Subjects is up to date. Failure to submit a completed form may result in delayed IRB review and approval.

***You may NOT begin data collection until you have received final IRB approval.***

**SECTION 1: General Project Information**

|  |  |
| --- | --- |
| Project Title: | Click or tap here to enter text. |
| Proposed Start and End Dates: | Click or tap to enter a date. | to | Click or tap to enter a date. |

|  |  |
| --- | --- |
| Is the proposed project being funded through external sources? | [ ]  Yes |
| [ ]  No |

***If yes, please complete APPENDIX A*.**

|  |  |
| --- | --- |
| Will data be collected at external sites (i.e., not BHSU campus)? | [ ]  Yes |
| [ ]  No |

***If yes, please complete APPENDIX B*.**

**SECTION 2: Investigator Information**

Please provide the following information for **all** investigators who will be involved with the proposed project. ***Note that faculty members or qualified professional staff affiliated with Black Hills State University must be listed as the Primary Investigator for student-led research projects.***

***Primary Investigator (PI)***

|  |  |  |  |
| --- | --- | --- | --- |
| Name: | Click or tap here to enter text. | Phone: | Click or tap here to enter text. |
| Department / Unit #: | Click or tap here to enter text. | Email: | Click or tap here to enter text. |
| CITI CompletionDates: | Click or tap to enter a date. |  |

***Additional Investigator***

|  |  |  |  |
| --- | --- | --- | --- |
| Name: |  |  Name: | Click or tap here to enter text. |
| CITI Completion Dates: | Click or tap to enter a date. |  CITI Completion Dates: | Click or tap to enter a date. |
| Name: | Click or tap here to enter text. |  Name: | Click or tap here to enter text. |
| CITI Completion Dates: | Click or tap to enter a date. |  CITI Completion Dates: | Click or tap to enter a date. |
| Name: | Click or tap here to enter text. |  Name: | Click or tap here to enter text. |
| CITI Completion Dates: | Click or tap to enter a date. |  CITI Completion Dates: | Click or tap to enter a date. |

**SECTION 3: Human Participants and Recruitment**

|  |  |
| --- | --- |
| How many participants do you expect to enroll?  | Click or tap here to enter text. |

Briefly describe the proposed study populations (e.g., age, gender).

|  |
| --- |
| Click or tap here to enter text. |

|  |  |
| --- | --- |
| Will you be excluding individuals on the basis of gender, age, race or ethnic group, or any other exclusionary criteria? | [ ]  Yes |
| [ ]  No |

**If yes, please specify the exclusionary criteria and provide a justification.**

|  |
| --- |
| Click or tap here to enter text. |

Will you be recruiting participants from any of the populations below? Check all that apply.

|  |  |
| --- | --- |
|[ ]  Minors |[ ]   Students enrolled in the PI’s courses |
|[ ]  Adults unable to consent |[ ]   Wards of the state / Foster children |
|[ ]  Pregnant women |[ ]   Participants who do not understand English |
|[ ]  Prisoners |[ ]   Inpatients / Outpatients |
|[ ]  Cognitively impaired individuals |[ ]   Individuals with diminished physical capacity |
|[ ]  Employees under the direct supervision of PI |[ ]   Economically / Educationally disadvantaged persons |

***If you are recruiting participants from any of the above populations, please complete Appendix C.***

Briefly describe how you will initially contact and select the participants. **Be sure to include all recruitment materials with your application (e.g., recruitment script / emails, flyers, posters, etc**).

|  |
| --- |
| Click or tap here to enter text. |

|  |  |  |
| --- | --- | --- |
| Will participants be financially or otherwise compensated (e.g., extra credit)? | [ ]  Yes |  |
| [ ]  No |  |

**If yes, please describe the compensation given to the participants.**

|  |
| --- |
| Click or tap here to enter text. |

***NOTE.*** *“If extra credit is given for participation an alternative method to earn that extra credit must be offered, and must be comparable in time and effort required.” BHSU IRB Policy 5/10*

**SECTION 4: Project Description and Procedures**

|  |  |
| --- | --- |
| Does the proposed study involve the collection of data from academic records or pertain to academic practices? | [ ] Yes |
| [ ] No |

***If yes, please complete APPENDIX D*.**

**If yes, please check which of the following types of data you plan to use.**

|  |
| --- |
|[ ]  Behavioral records |
|[ ]  Coursework |
|[ ]  Course grades |
|[ ]  Audio/video recordings taken during a class time (the collection of audio / video data must be disclosed in the consent document) |
|[ ]  Observational information gathered during class time |

Briefly describe the purpose and significance of the proposed study. Provide background information that led to the development of this study.

|  |
| --- |
| Click or tap here to enter text. |

Describe, using non-technical language, the procedures to be used in the proposed study. Be sure to include the nature of the activities in which the subject will engage, frequency and length of the involved activity, as well as any data gathering instruments (i.e., questionnaires or interview questions). ***Attach all data collection materials (i.e., questionnaires, surveys) to the end of this application.***

|  |
| --- |
| Click or tap here to enter text. |

Describe the facilities or setting in which the research will be conducted. Please include the name of the location and a description about how the facilities provide adequate protection of participant privacy. **Note** – privacy is about the participant, not the data. The facilities should be adequate to protect the privacy of individuals as they participate in the study (e.g., ample room between participants during surveys administered to large groups; location of participation ensures privacy; etc).

|  |
| --- |
| Click or tap here to enter text. |

|  |  |
| --- | --- |
| Does the proposed procedure involve the use of deception? | [ ]  Yes |
| [ ]  No |

***Deception:*** *A procedure in which investigators deliberately mislead participants during research by withholding information or providing false information. As a result, participants are not fully informed about the research when they consent to participate.*

***If yes, please complete Appendix E*.**

**SECTION 5: Risks and Benefits**

Describe any foreseeable risks to participants in the proposed study. Be sure to consider physical, psychological, social, legal, and economic risks. ***Please note that all risks must be disclosed in the informed consent document.***

|  |
| --- |
| Click or tap here to enter text. |

Describe the likelihood and magnitude of each risk listed above and the steps being taken to minimize those risks during and following the study.

|  |
| --- |
| Click or tap here to enter text. |

Describe the anticipated benefits resulting from this study. Include both direct benefits to the participants enrolled in study as well as societal benefits.

|  |
| --- |
| Click or tap here to enter text. |

**SECTION 6: Confidentiality**

Describe your plan to protect the confidentiality of the data collected in this study (e.g., using code-linked identifiers, researcher training, storage of data, etc)

Who will have access to the collected data?

|  |
| --- |
| Click or tap here to enter text. |

How and when will the data be disposed of at the end of the study?

|  |
| --- |
| Click or tap here to enter text. |

**SECTION 7: Informed Consent**

***Please attach copies of all forms and scripts to be used in the consent / assent process to the end of this application. Examples and templates are available on the Research Policies website. You may also create your own form as long as it contains all legally required information.***

Describe when and where participants or legally authorized representatives will be approached to obtain consent.

|  |
| --- |
| Click or tap here to enter text. |

Who will conduct the consent process?

|  |
| --- |
| Click or tap here to enter text. |

|  |  |
| --- | --- |
| Does your study involve collecting data using audio / video recordings? | [ ]  Yes |
| [ ]  No |

**If yes, be sure to include the following statement in your Informed Consent Document**

**“*I hereby consent to release any audio / video recordings collected during this study*.”**

|  |  |
| --- | --- |
| Are you requesting a waiver of consent, alteration of consent, or a waiver of signed consent? | [ ]  Yes |
| [ ]  No |

**If yes, please provide justification why a waiver or alteration to the consent process is necessary.**

|  |
| --- |
| Click or tap here to enter text. |

|  |  |
| --- | --- |
| Does your study involve collecting data from individuals with a limited capacity to consent (e.g., language barriers, limited decision-making capacity)? | [ ]  Yes |
| [ ]  No |

***If yes, please complete the COGNITIVELY IMPAIRED OR PERSONS UNABLE TO CONSENT form found in Appendix C.***

|  |  |
| --- | --- |
| Does your study involve collecting data from children under the age of 18? | [ ]  Yes |
| [ ]  No |

**If yes, describe how you will obtain consent from the participant’s legal guardian. Also, be sure to include a copy of the parental consent form.**

|  |
| --- |
| Click or tap here to enter text. |

**If yes, will the child’s assent be obtained? Will assent be written or oral? Include a copy of script to be used if oral assent is obtained.**

|  |
| --- |
| Click or tap here to enter text. |

**If yes, how will the child’s assent be verified throughout the research protocol?**

|  |
| --- |
| Click or tap here to enter text. |

**APPENDICES**

**DO NOT ADDRESS ANY OF THE FOLLOWING QUESTIONS UNLESS REQUIRED TO DO SO.**

**APPENDIX A: External Funding**

Please provide the grant or contract title, type of funding and the name of the department, agency, or sponsor of the proposed research.

|  |  |
| --- | --- |
|[ ]  Federal Sponsored Project: | Click or tap here to enter text. |
|[ ]  State Sponsored Project: | Click or tap here to enter text. |
|[ ]  Other Sponsored Project: | Click or tap here to enter text. |

Does this project have a contract? (E.g., subcontract on a grant with another institution; Consultant and Services Agreement; etc.)

|  |
| --- |
|[ ]  No |
|[ ]  Yes |

**If yes, please indicate who or what official offices are responsible for signing the contract for both parties (include name(s) and contact information).**

|  |
| --- |
| Click or tap here to enter text. |

**APPENDIX B: Data Collection at External Sites**

|  |  |
| --- | --- |
| Does the external site have an IRB? |  [ ]  Yes |
|  [ ]  No |

If yes, please provide the name and contact information of the IRB official.

|  |
| --- |
| Click or tap here to enter text. |

|  |  |
| --- | --- |
| If the external site has an IRB, have you received IRB approval from the external site? | [ ] Yes |
| [ ]  No |

***If you have received IRB approval, please attach the approval documentation along with your application.***

|  |  |
| --- | --- |
| If you have not received IRB approval, have you submitted an application for review? |  [ ]  Yes |
|  [ ]  No |

|  |  |
| --- | --- |
| If the external site does not have an IRB, have you received permission to collect data at the external site? | [ ]  Yes |
| [ ]  No |

***If you have received permission from the external site, please attach the permission documentation along with your application.***

**APPENDIX C: Use of Vulnerable Populations**

Please provide a justification for using the proposed vulnerable population.

|  |
| --- |
| Click or tap here to enter text. |

Describe any screening procedures that will be used to select participants.

|  |
| --- |
| Click or tap here to enter text. |

Provide a description of any special considerations and safeguards that will be taken to ensure that the vulnerable population will be adequately protected.

|  |
| --- |
| Click or tap here to enter text. |

If the population you selected is cognitively impaired or unable to consent (e.g., coma, intensive care, unconscious, etc.) you must complete the Supplemental Form for Cognitively Impaired or Persons Unable to Consent on the following pages.

|  |
| --- |
| Click or tap here to enter text. |

**SUPPLEMENTAL FORM FOR COGNITIVELY IMPAIRED OR PERSONS UNABLE TO CONSENT**

Submit one Copy with Application

|  |  |
| --- | --- |
| Project Title: | Click or tap here to enter text. |
| Investigator: | Click or tap here to enter text. |

1. **Explain why it is necessary to involve persons who are cognitively impaired and/or persons unable to consent as subjects for this research.**

|  |
| --- |
| Click or tap here to enter text. |

1. **If the research proposes to involve institutionalized individuals, provide sufficient justification for the use of that population.**

|  |
| --- |
| Click or tap here to enter text. |

1. **Explain why non-institutionalized subjects are not appropriate for this research and why they may not be reasonably available.**

|  |
| --- |
| Click or tap here to enter text. |

1. **Does the research pertain to aspects of institutionalization?**

|  |
| --- |
|[ ]  No |
|[ ]  Yes |

*If “Yes”, explain.*

|  |
| --- |
| Click or tap here to enter text. |

1. **Explain the procedures proposed for evaluating the mental status of prospective subjects to determine whether they are capable of consenting.**

|  |
| --- |
| Click or tap here to enter text. |

1. **Is it reasonable to expect that during the course of the study, subjects may lose their capacity to consent or their ability to withdraw (e.g., research involving administration of or withdrawal from psychotropic agents)?**

|  |
| --- |
|[ ]  No |
|[ ]  Yes |

*If “Yes”, what provisions have been made to protect the patient's rights (e.g., power of attorney, consenting caregiver, as well as the patient, etc.)?*

|  |
| --- |
| Click or tap here to enter text. |

1. **Explain how you will identify persons legally authorized to give legally valid consent on behalf of any individual(s) judged incapable of consenting on their own behalf.**

|  |
| --- |
| Click or tap here to enter text. |

1. **Explain how you plan on ensuring that legally authorized representatives are well informed regarding their roles and obligations to protect the incompetent or impaired participant?**

|  |
| --- |
| Click or tap here to enter text. |

1. **Are you planning on obtaining the legal documentation of the person(s) legally authorized to give legal consent on behalf of the individual?**

|  |
| --- |
|[ ]  No |
|[ ]  Yes |

*If “No”, explain.*

|  |
| --- |
| Click or tap here to enter text. |

1. **Will the patients’ physicians or other health care providers be consulted before any individual is invited to participate in the research?**

|  |
| --- |
|[ ]  No |
|[ ]  Yes |

*Explain:*

|  |
| --- |
| Click or tap here to enter text. |

1. **The autonomy of the individual with impaired decision-making capacity should be respected. Do you have plans for obtaining assent to participate in the research, and will the subject’s decision to withdraw from the study at any time be honored?**

|  |
| --- |
| Click or tap here to enter text. |

1. **In your opinion, is the research likely to interfere with the participant’s current therapy or regimens?**

*Explain:*

|  |
| --- |
| Click or tap here to enter text. |

1. **Does the research impose a risk of injury?**

|  |
| --- |
|[ ]  No |
|[ ]  Yes |

If yes, does the research intend to benefit the participant, and is the probability of benefit greater than the probability of harm?

|  |
| --- |
|[ ]  No |
|[ ]  Yes |

*Explain:*

|  |
| --- |
|  |

I agree to contact the legally authorized representative (LAR) and explain that it is the LAR’s responsibility to try to determine what the prospective participant would do if competent; and if the prospective participant’s wishes cannot be determined, it is the LAR’s obligation to do what he/she thinks is in the incompetent person’s best interest.

|  |
| --- |
|[ ]  No |
|[ ]  Yes |

|  |
| --- |
| **Investigator Guidance on Legally Authorized Representatives: South Dakota Codified Law (34.12C-2 and 34-12C-3)** |
| Legally Authorized Representatives to be the following individuals and in the following order of priority: |
| 1. | Power of Attorney or appointed guardian |
| 2. | Next of kin: |
|  |[ ]  Spouse, if not legally separated; |
|  |[ ]  Adult child; |
|  |[ ]  Parent; |
|  |[ ]  Adult sibling; |
|  |[ ]  Grandparent or an adult grandchild; |
|  |[ ]  Adult aunt or uncle or an adult niece or nephew |

**APPENDIX D: FERPA (Family Education Rights and Privacy Act)**

Complete this addendum if the research requires access to education records. Education records are defined as “those records that are: 1) Directly related to a student; and, 2) Maintained by an educational agency or institution, or by a party acting for the agency or institution.” This includes coursework, grades, journals, behavior records, standardized test scores, etc.

It should be noted by those conducting educational research using students enrolled in your own courses, or in the courses of colleagues, that special consideration of “legitimate educational interest” is required. In accordance with federal policy on this issue, as a researcher you may not necessarily have the right to use the educational records you hold personally in your research. Exceptions may be invoked in accordance with BHSU policy. This section will assist you with obtaining the proper exception, if allowable.

In accordance with BHSU policy, a school official is determined to have “legitimate educational interest” if the information requested is necessary for that official to perform appropriate tasks that are relevant and necessary to the accomplishment of an employment responsibility of the inquirer. BHSU administration has interpreted this to include pedagogical research done by faculty.

It is in keeping with human participants research best practices to protect the privacy of research participants. When requesting educational records from faculty, it is best to request the removal of all personally identifiable information prior to provision of the record to the researcher. If the personally identifiable information is necessary to the research, then the students’ written permission should be obtained. Exception may be granted if justified. **A researcher may not share information contained in any educational record with members of the research team that *are not school officials with legitimate educational interest* without the students’ written permission.** Examples of those **who are NOT** considered to be school officials with legitimate educational interest include students assisting with research (even if employed by BHSU), research collaborators not employed by BHSU, or research assistants not employed by BHSU.

* 1. Will the educational records you collect contain *any* information that would permit identification of students and/or parents of students (see list below)?

|  |  |
| --- | --- |
|[ ]  No |[ ]  Yes |
| If “yes” check all that apply: |
|[ ]  Names |
|[ ]  Phone numbers, fax numbers, e-mail addresses |
|[ ]  Student Identification Numbers |
|[ ]  Geographical subdivisions smaller than a state, including street address, city, county, precinct, zip code |
|[ ]  Elements of dates (except year) for dates related to an individual, including birth date, admission date, commencement date; and in the rare case of students over the age of 89, all elements of dates (including year) related to an individual |
|[ ]  Handwritten assignments/tests |
|[ ]  Vehicle identifiers and serial numbers, including license plate numbers |
|[ ]  Audio or video recordings |
|[ ]  Biometric identifiers, including finger and voice prints  |
|[ ]  Full face photographic images and any comparable images |
|[ ]  Any other unique identifying number, characteristic or code (this does not include the unique code assigned by the investigator to code the data) |

* 1. In the research proposed, is the investigator or any member of the research group fulfilling the roles of both educator and researcher?

|  |  |
| --- | --- |
|[ ]  No |[ ]  Yes |

* 1. For research involving educational records from BHSU, will the records you obtain be shared with student research assistants (even if employed by BHSU), or with collaborators not employed by BHSU?

|  |  |
| --- | --- |
|[ ]  No |[ ]  Yes |

* 1. If “yes” to one or more of the questions above, there are three options by which you may legally obtain data from educational records, beyond directory information, for the purpose of research. Please check the option you will use to ensure compliance with FERPA regulations.

[ ]  You may contact and obtain written consent for each individual whose records will be accessed for research purposes. (Note: This option is **required** if the records will contain identifying information *and* will be shared with student assistants.) Please include a FERPA release within the consent document. The FERPA release must contain a checkbox indicating permission for the release of the educational record(s).

**IMPORTANT!**

* + 1. For research at institutions other than BHSU (e.g. an area elementary school) a statement that the release conforms to the institution’s governing agency policy regarding FERPA must be included in the letter of permission to collect data at the site. (e.g. When the elementary school principal drafts a letter granting permission to collect data at the school, s/he should also include a statement that the FERPA release in, or attached to, the consent document conforms to the school district’s FERPA policy.)
		2. A FERPA release must identify all records or record types that will be released. For example “All assignments, tests and quizzes associated with Unit 5”, or “All unit tests from your child’s History class”, or “Behavioral records from grades K – 6”, etc.

[ ]  A school official with legitimate access [other than the researcher(s)] may strip the records of any identifying information and provide the data to the researcher. (Please explain who or what office will be responsible for stripping the records of all identifying information.)

[ ]  The holder of the record may invoke an exception to FERPA under 34 CFR 99.31(a)(1) in order to release the records for use in the research.\*\*

\*\* If you choose to invoke this exception, please provide a FERPA exception letter stating the justification for the exception with your application. If the research is being conducted on students enrolled at BHSU, the exception letter should come from the appropriate institutional official. (BHSU Student Records and Student Directory Information Policy indicate that questions such as FERPA exceptions can be addressed by the VP for Academic Affairs, VP for Student Life, Registrar, Dean of Students, or the dean of the college in which the students are enrolled.) The educational records to be obtained will dictate from whom the letter should come (e.g. a letter from a college dean may be appropriate when a researcher would like to use identifiable data from his/her own course, or from the course of another faculty member). If the research is being conducted by using educational records from primary or secondary schools (e.g. by teachers who are also MSED students enrolled at BHSU, or teachers who are collaborating with BHSU faculty), the FERPA exception letter should come from the school district’s superintendent.

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| Click or tap here to enter text. |

**APPENDIX E: Use of Deception**

**Note**. *If you are proposing a study requiring the use of deception, you must request an alteration to the informed consent process in Section 7*.

Describe how deception is being used in the proposed study (i.e., how are participants being misled)?

|  |
| --- |
| Click or tap here to enter text. |

Provide a justification for why the use of deception is necessary.

|  |
| --- |
| Click or tap here to enter text. |

Describe how and when the participants will be informed about the true purpose of the study.

|  |
| --- |
| Click or tap here to enter text. |

Explain opportunities (if any) for participants to discuss their responses to the deception and/or to withdraw the use of their data from the research once that they find out that they have been deceived.

|  |
| --- |
| Click or tap here to enter text. |