DAKOTA STATE UNIVERSITY

605-256-5100
IRB@DSU.edu

INSTITUTIONAL REVIEW BOARD HUMAN SUBJECTS APPLICATION

Submit this application and all required materials to irb@dsu.edu

Today's Date:

Project Title:

Attach a current CV or résumé for each investigator. CVs should include role(s) in previous research.

Principal Investigator:

College / Department:

DSU email:

Phone: CITI Training Date:

CITI Training is valid for 3 years from the date of completion

Other Investigator:

College / Department:

DSU email:

Phone: CITI Training Date:

Other Investigator:

College / Department:

DSU email:

Phone: CITI Training Date:

DO NOT SUBMIT THIS FORM

UNTIL CURRENT/VALID CITI TRAINING DATES AND CERTIFICATES FOR THEM ARE READY TO BE SUBMITTED ALONG WITH IT.

If additional researchers are involved, please attach a list with your project name and investigator information.

1. **Do you or any other investigators listed have a potential conflict of interest associated with this study?**
   Contact the IRB (irb@dsu.edu or 605-256-5100) with questions. Definitions are available on the IRB web page.

- ☐ Yes
- ☐ No

If the answer to this question is Yes, please describe the potential conflict of interest in detail.

2. **Is this study externally funded? (If yes, please attach documentation)**

- ☐ Federal Tuition Reimbursement / Scholarship
- ☐ Federally Sponsored
- ☐ Industry Sponsored
- ☐ State Sponsored
- ☐ Other _____
- ☐ No

3. **Is this research project required to earn a DSU academic degree?**

- ☐ Yes
- ☐ No

If the answer to this question is Yes, your thesis, dissertation, or other research proposal must be approved and documentation of that decision included with your application.

4. **Have you submitted, or plan to submit, this study to another IRB?**

- ☐ Yes
- ☐ No

If the answer to this question is Yes, please submit copy of that IRB's approval and any related forms assessed by that IRB, along with your application.

5. **Attach letters of approval from any (non-IRB) committees, schools or external organizations involved (Required prior to IRB approval).**

- ☐ Attached
- ☐ Not applicable

6. What is the purpose of this research?

7. Please describe all tasks that participants will be expected to perform.

8. Please describe how you will contact potential participants. Include all steps in your process and describe how participant privacy will be maintained.

9. What is the maximum number of participants you will enroll in your study?

10. Please check all study populations that apply.

- ☐ Children (younger than 18 years old)
- ☐ Persons with disabilities
- ☐ Pregnant
- ☐ Prisoners
- ☐ Persons with medical conditions related to your research
- ☐ Non-English Speaking
- ☐ Students in Grades K-12
- ☐ University Students
- ☐ Specific Genders

If Specific Genders is chosen, provide details:

- ☐ N/A
- ☐ Individuals with diminished mental/physical capacity
- ☐ Economically/educationally disadvantaged persons
- ☐ Your students
- ☐ Your employees
- ☐ Pregnant women
- ☐ Prisoners
- ☐ N/A

If you checked "Your students" and/or "Your employees", they must be allowed to refuse participation without penalty. Describe how you will ensure equal treatment of participants and non-participants.

11. Are you specifically targeting an ethnic group? Check any that apply.

- ☐ American Indian
- ☐ African American
- ☐ Caucasian
- ☐ Alaskan Native
- ☐ Asian
- ☐ Hispanic/Latinx
- ☐ Pacific Islander
- ☐ Other:
- ☐ N/A

12. Age ranges of subjects to be enrolled:

- ☐ Birth to 3 years
- ☐ 3 to 5 years
- ☐ 5 to 10 years
- ☐ 10 to 13 years
- ☐ 14 to 17 years
- ☐ 18 to 64 years
- ☐ 65 years and older

13. Please describe any inclusionary and exclusionary criteria and how participants will be chosen for your study:

14. Where will the research take place?

If your research will take place outside the U.S., please contact irb@dsu.edu for more information.

15. Will participants receive compensation?

- ☐ Yes
- ☐ No

If yes, please describe:

16. What direct benefits (other than compensation) do you expect participants to receive from your study? If there is no direct benefit to the subjects, simply state that.

17. Check all private information that you plan to collect:

Please give a brief explanation of any items checked.

- ☐ Names
- ☐ Phone numbers; fax numbers
- ☐ Email addresses
- ☐ Medical record numbers
- ☐ Medical diagnoses or related information
- ☐ Device identifiers
- ☐ Full face photographs
- ☐ Web Universal Resource Locators (URLs)
- ☐ Social Security Numbers
- ☐ Serial numbers or other unique identifiers
- ☐ Geographical subdivisions smaller than a State: street address, city, county, precinct, zip code
- ☐ Birthdates, medical admission dates, medical discharge dates, dates of death
- ☐ Health plan beneficiary, account, or certificate/license numbers
- ☐ Vehicle identification, serial, or license plate numbers
- ☐ Educational records/information

18. Will there be any way that anyone, including an investigator, could start with a data record and trace it back to the person being studied?

- ☐ Yes
- ☐ No

If the answer to this question is Yes, describe why this is necessary and describe specific procedures to prevent inappropriate use of study data. Please think this through thoroughly. This issue is closely evaluated by the IRB and will cause delays in processing your application if it is not completely/properly answered.

19. Do you agree to destroy data that can identify participants when your study is concluded?

- ☐ Yes
- ☐ No

If the answer to this question is No, describe why this is necessary and how participant identities will be protected.

20. Do you agree to keep a copy of de-identified data for 3 years after your study is concluded?

- ☐ Yes
- ☐ No

21. Are any of the following risks associated with your research? Please check all that apply.

- ☐ Use of identifiable audio or video for data collection.
- ☐ Physical Risk
- ☐ Economic Risk, Risk to Employability
- ☐ Psychological Risk
- ☐ Legal Risk
- ☐ Social/Reputation Risk
- ☐ Use of private records (including educational records or medical charts)
- ☐ None of the above

22. Check all consents required below for your project. Attach forms/scripts for review.

- ☐ Informed Consent (Adults)
- ☐ Consent Statement (This can only be used on adults, and when no identifiers are collected)
- ☐ Parental Consent
- ☐ Assent (must be obtained from participating children in addition to parental consent)

Please utilize templates for these documents that are posted on the DSU IRB web page.

23. How will you obtain consent?

- ☐ Verbal/Handout (face to face)
- ☐ Verbal/Telephone
- ☐ Web-based
- ☐ Email
- ☐ Postal Mail

24. Does your study require authorization or waiver related to the Health Insurance Portability and Accountability Act (HIPAA)? (Contact irb@dsu.edu for additional information)

- ☐ Full Waiver
- ☐ Partial Waiver
- ☐ Authorization Addendum ***(attach form)***
- ☐ N/A

SIGNATURES

By signing below, I attest that:

» The information provided in this form is correct and complete. I agree to seek and obtain prior written approval from the IRB for any modifications to this proposal, including changes in procedure, co-investigators, consent statements, survey/interview questions, etc.

» I will immediately report any unexpected or unanticipated problems or incidents that occur during the study. I will report in writing any significant findings which develop during the course of the study which may affect the risks and benefits to the participants.

» I will not proceed with the research until I have received approval from the IRB. I will abide by IRB requests for reports on the status of the study. I will maintain the records and documents of this research. If the above conditions are not met, I understand that approval of this research could be suspended or terminated, and that those statuses mean that all activity on the project must immediately cease.

Principal Investigator: _____ _____
Signature Date

Co-Investigator: _____ _____
Signature Date

Attach a separate form that includes your project name if you have additional co-investigators.

Supervisor Assurances:
By signing below, I attest that I reviewed this application and found:

» the research scientifically and scholarly sound

» that competencies and resources are adequate

» that conflicts of interest do not exist.

Supervisor Name (print/type): _____

Supervisor signature: _____ _____
Date