Institutional Review Board Protocol
For
Use of Existing Data involving Human Subjects

ST. CLOUD STATE UNIVERSITY
EDUCATION FOR LIFE.

PROJECT

Project Title:

Project Start Date: Project End Date:

RESEARCHER(S)

Principal Investigator(s) *Also referred to as PI(s)* *First Name* *Last Name*	Status (select one)	SCSU Email	Phone Number	IRB Training Completed	Training Date
	◯ faculty/staff ◯ undergraduate ◯ graduate masters ◯ graduate doctoral			☐ Yes	
	◯ faculty/staff ◯ undergraduate ◯ graduate masters ◯ graduate doctoral			☐ Yes	
	◯ faculty/staff ◯ undergraduate ◯ graduate masters ◯ graduate doctoral			☐ Yes	

Faculty Mentor/Course Instructor (if Principal Investigator is a student): First name Last name

☐ Yes, ALL Principal Investigator(s) completed SCSU's required CITI IRB training, https://www.citiprogram.org/

If you collaborate with an individual from another institution, we may be able to use an Authorization Agreement with anther institution's IRB. Contact ResearchNow@stcloudstate.edu for more information.

SPONSORS

Is there external funding source(s) for this research project? ◯ No ◯ Yes ◯ Pending

Funding Agency/Sponsor: Account #:

PROTOCOL SUBMISSION CHECKLIST

To submit a complete packet to the IRB, INCLUDE all of the following:
☐ Complete, signed IRB protocol form
☐ *If applicable,* support letter from individual/organization providing existing dataset
☐ Submit **completed IRB protocol with all attachments** to Research & Sponsored Programs (AS 210) or scan packet to ResearchNow@stcloudstate.edu.

CERTIFICATION STATEMENT

PI Initial here	**As principal investigator**, I certify that the information provided in this protocol represents a complete and accurate description of the proposed research, this research will not begin until IRB approval has been received, and this research will be conducted in compliance with IRB recommendations and requirements.
PI Initial here	**As principal investigator**, I understand that modifications, significant new findings which develop during the course of the study or increase the risk to participant, or reporting to the IRB any adverse or unexpected events, and that protocols approved as expedited or full require an annual/final report (*protocols approved as exempt do not require continuing review/final report process*). To submit a Continuing Review/Final, please complete the Continuing Review Form
Faculty Mentor Initial here	**As faculty advisor**, I certify that I have reviewed this research protocol and that I attest to the scientific merit of this research study. I will advise and provide continued guidance to support the research/study as appropriate for the student's academic development.

Signature of Principal Investigator	Date
Signature of Faculty Mentor/Course Instructor	Date

PROJECT DESCRIPTION

1. Project Summary/Abstract (Limited to 250 words):

2. Purpose of the research (Limited to 1 sentence):

3. Research question(s), if applicable include hypothesis:

4. Research design, if applicable, include independent/dependent variables:

5. Describe all methods and procedures you will perform:

PARAMETERS OF EXISTING DATA

6. To proceed with this form, **ALL** of the following must apply to request an existing data IRB review:

Yes	NO	
○	○	Proposed project is a systematic investigation, including research development and testing
○	○	Proposed project is designed to develop or contribute to generalizable knowledge
○	○	Research involves the analysis of existing data, documents, records, pathological specimens or diagnostic specimens which was gathered from human beings.
○	○	No new data will be collected from participants for this project. – *If new data will be collected, stop here and complete the "IRB protocol for Conduct of Research Involving Human Subjects."* – *If no new data will be collected, continue with this protocol.*

7. How was the date originally collected:

Yes	N/A	
○	○	Existing data from the classroom was NOT obtained through: active manipulation, testing a research question, course activities, outcomes and/or evaluations which deviated from those defined in the original syllabus, or having a research agenda when the data was gathered. If YES, complete:

Yes	No	Data was obtained through the classroom using standard educational practices/classroom/workshop/data/ program evaluation (check all that apply):
○	○	All students received the same syllabus at the beginning of the course
○	○	All students were expected to participate and complete the activities outlined in the syllabus
○	○	Classroom procedures did not involve a control group
○	○	Anonymous data obtained from the SCSU Office of Strategy, Planning and Effectiveness
○	○	Other – please explain:

○	○	Sources for the data are publicly available but the dataset is not. If YES, complete:

Yes	No	
○	○	Dataset from federal or state government program/agency available to the general public (census data, etc.)
○	○	Dataset used for public sources such as newspapers, reports, books or journals
○	○	Dataset used for published documents such as thesis or dissertations
○	○	Other – please explain:

○	○	If no dataset is involved AND only publicly available works will be used for a book or literature review, an IRB protocol or review is not required. STOP HERE.
○	○	OTHER, please explain how data was obtained:

8. What/who is the source from which the dataset was obtained?

9. What does the dataset consist of (include as much detail as possible; i.e. list of specific questions asked, etc.)?

10. What was the intent when the original data was collected?

11. When was the original data collected? (timeframe)

12. Was IRB approval obtained for the original data collection?

Yes	No	
○		Provide name of institution which approved the research, PI name and IRB approval date. Also, attach IRB approval letter:
	○	No and data was collected six months or more prior to this proposed use
	○	No and data was collected less than six months from this protocol date; explain why IRB approval was not obtained: Dataset used for published documents such as thesis or dissertations

13. If dataset is not publicly available, explain the process taken to gain permission to use the dataset.

    a. Attach a letter of cooperation from the entity/person to state their involvement with the initial data collection, how data will be de-identified prior to its release, why data currently exists, where was it collected, etc.

SUBJECT POPULATION

14. Number of participants:

15. Age range of participants (if age 17 or under, explain why minors' data is being used):

16. Describe the participants' understanding of the use of the data as originally collected:

PARTICIPANT PERSONAL IDENTIFIERS

17. Does the dataset you will have access to contain direct or indirect personal identifiers?

- ○ Yes ○ No Direct (i.e. name, local address, permanent address, email address, phone number, social security number, date of birth, identification number, tech ID, medical record number, license number, photograph(s), biometric information, etc.)
- ○ Yes ○ No Indirect (i.e. race, gender, age, language, ethnicity, zip code, IP address, major, associated organization(s), etc.)

18. If yes to direct or indirect identifiers, please describe the personal identifiers:

19. If direct or indirect identifiers will be removed prior to you obtaining the dataset, list which identifiers the set will represent:

20. Will you remove identifiers from the dataset or otherwise aggregate the data in such a manner whereby participants cannot be identified either directly or indirectly?

    ○ If yes, explain how:

    ○ If no, provide justification why identifiers are necessary:

21. Are you using any direct quotes from previous participants?
    ○ No, direct quotes will not be taken from any existing data
    ○ Yes, participant direct quote(s) will be used. Explain when and how approval was received or why consent can no longer be obtained:

22. Describe those who will have access to the data other than the principal investigator or other investigators.

23. How will you securely store the dataset and how long do you intend to keep it?

24. Do you anticipate any future use of the data? ◉ No ○ Yes If yes, please explain: