



Application for the Use of Human Subjects

Part A – Application Information

1. Title of the Study:		Date: Click or tap to enter a date.	
2. Principal Investigator:			
Title:		Dept:	
Address (+ ZIP):			
Phone:		Email:	
3. Co-Investigator(s): (Name & Affiliation)			
4. Research Originated By: (Check One) <input type="checkbox"/> Faculty <input type="checkbox"/> Student <input type="checkbox"/> Staff <input type="checkbox"/> Outside Researcher (non-SENM employee/student)			

Part B - Research Study Synopsis

1. Short Study Description:

2. Study Length

What is the duration of the study?

3. Location of Research

Where will the research take place?

4. Subject Information:

a. Number of Subjects:

b. Gender of Subjects:

c. Ages of Subjects:

5. Potentially Vulnerable Populations: (Check All that Apply)

- ☐ Children ☐ Pregnant Women ☐ Cognitively Impaired ☐ Prisoners ☐ Institutionalized
- ☐ Faculty's Own Students ☐ Other. Please describe:

6. Non-English-Speaking Subjects

- a. Will subjects who do not understand English participate in the research: ☒ Yes ☐ No
- b. If yes, describe your resources to communicate with the subjects:

c. Into what language(s) will the consent form be translated? (Attach translations)

7. Dissemination of Research Findings

- a. Will the research be published? ☐ Yes ☐ No If yes, where?
- b. Will the research be presented? ☐ Yes ☐ No If yes, where?
- c. Will the research be presented to the SENMC community? ☐ Yes ☐ No

8. External Funding

- a. Are you seeking external funding? ☐ Yes ☐ No What agency?
- b. Have you received funding? ☐ Yes ☐ No Dollar amount?

9. Method of Recruitment: (Check All that Apply)

- ☐ Flyer ☐ Classroom Announcement ☐ Letter to Subjects ☐ Third Party ☐ Random ☐ Other

10. Payment to Subjects

- a. Will subjects be compensated for participation? ☐ Yes ☐ No If yes, please indicate amount:
- b. Form of Payment: ☐ Cash ☐ Check ☐ Gift Certificate ☐ Voucher ☐ 1099 ☐ Other
- c. Will Payment be prorated? ☐ Yes ☐ No If yes, please explain:

- d. When will the subject be paid? ☐ Each Visit ☐ Study Completion ☐ Other

11. Extra Credit

- a. Will subjects be offered extra credit? ☐ Yes ☐ No
- b. If yes, describe the alternative:

12. Risks: Identify all potential risks/discomforts to subjects.

13. Benefits:

- a. Are there direct benefits to participants? ☐ Yes ☐ No If yes, please list.
- b. Are there potential benefits to society? ☐ Yes ☐ No If yes, please list.

14. Study Procedures:

- a. What will be the duration of the subjects' participation?
- b. List all procedures/questionnaires used for the research study. (if are not enough spaces, you can attach)

15. Informed Consent:

- a. Briefly describe your process to obtain consent:

16. Confidentiality:

- a. Are the subject's social security number or is any identifier being used?

☐ Yes ☐ No If yes, describe and explain the reasons.

- b. Briefly describe provisions made to maintain confidentiality of data, including who will have access to raw data, what will be done with the data files, survey instruments, discs, CD's, tapes, etc.

- c. Will raw data be made available to anyone other than the PI and immediate study personnel? ☐ Yes ☐ No
If yes, describe the procedure for sharing data. Include with whom it will be shared, how and why.

Part C – Assurance Document

The attached investigation involves the use of human subjects. I understand the college's policy concerning research involving human subjects and I agree:

1. To obtain voluntary and informed consent of all subjects who are to participate in this project.
2. To report immediately to the IRB any unanticipated effects on subjects which become apparent during the course of, or as a result of, the experimentation and the actions taken.
3. To obtain prior approval from the IRB before amending or altering the scope of the project or implementing changes in the approved consent document.
4. To safeguard the confidentiality of research subjects and the data collected when the approved level of research requires it.
5. All surveys must be scheduled through the Office of Institutional Research as per SENMC procedures. This process is necessary to ensure the consideration of staff, faculty, student, and community members' time and avoid duplication of effort. Please contact Narmin Ghalichi @ nghalichi@senmc.edu or 952-217-9227 if your research involves a survey.

Signature of the Principal Investigator: _____ Date: _____

Faculty Sponsor Signature Necessary for All Student Submissions.

"I have read and reviewed this proposal and certify that it is ready for review by the IRB. I have worked with the student to prepare this research protocol. I agree to mentor the student during the research project. I have received Human Subjects in Research training." (PLEASE ATTACH A COPY OF THE TRAINING CERTIFICATE)

Faculty Sponsor: _____
Signature Printed Name

Part D - Summary of Research Proposal

Part D should only be **5** pages or less (not including instruments, consent forms, etc.). Please use **12pt** font, **page numbers** and the **headings** noted below.

1. Specific Aims
2. Hypothesis
3. Background and Significance
4. Description of Subjects
5. Confidentiality
6. Method or Procedures
7. Risks
8. Benefits
9. Compensation
10. References
11. Qualifications

Include the following information as necessary in the appropriate appendix.

Part E - Consent Forms

Part F - Research Instruments

For IRB Use

☐ Exempt from further IRB review

☐ Expedited review

☐ Full-committee review

Date: Click or tap to enter a date.

☐ Reviewed

☐ Approved

☐ Rejected

☐ Returned for Revision

☐ Returned for Additional Information _____

Signatures:

_____, IRB Chair

_____. Member

_____. Member

_____. Member

_____. Member