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<td>If deception is employed or students are the primary participants is the procedure adequately described, an appropriate debriefing provided to minimize risks and educate participants, and has the deception and/or use of this participant group been adequately justified?</td>
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**Part II - Consent document.** Does the consent document address all of the following major sections appropriately:

1. Purpose in lay language including a statement that the study involves research.
2. Design including duration, procedures (identified if experimental), alternative treatments, disclosure of new findings if applicable.
3. Risks or discomforts without disclaimers or waivers.
4. Benefits, both direct and indirect.
5. Compensation, Costs to the participants, Medical treatment for injuries available and further information (req. if > minimal risk)
6. Researcher/faculty sponsor, IRB and research related injury contact (if > minimal risk).
7. Voluntary nature with no penalties or loss of benefits, withdrawal/termination methods and consequences.
8. Confidentiality procedures and protections including checks offs for identifiable information (tapes, pictures, quotes)

Rate the overall level of risk involved with this project as **(no greater than minimal or greater than minimal).**

**MAJOR CONCERNS** (risk/benefit analysis, recruitment, confidentiality, waiver of consent, etc.): Describe on back or separate sheet.

**MINOR CONCERNS** (typos, spelling, grammar, punctuation, word choice, etc.): Describe on back or separate sheet.

**Review:** □ Expedited □ Exempt Category # _____ □ Full Board: □ Primary □ Secondary

Does the study already meet the regulatory guidelines for the type of review requested? (yes, no)

If not, in your opinion, can it be amended to do so? (yes, no). Provide details on back or separate sheet.

**Recommendation(s):**

- The application should be approved “as is”
- The application should be deferred until the following major changes are made (write on reverse or attach).
- The application should be approved if the following minor changes are made (write on reverse or attach).
- The application needs to go before the full board for review.
- Check here if you wish to review any changes submitted.

Signature/Date (if not submitted electronically): ___________________
1. Is the purpose of the study clearly described, justified relative to risk and achievable given the scientific design?
   a. Are the objectives clearly specified?
   b. Is enough preliminary data provided/cited to justify the research?
   c. Is there appropriate justification for this research protocol?
   d. Is the scientific design adequate to achieve the stated objective?
   e. Are the objectives likely to be obtained within the stated time period?
   f. Is the scientific design described and adequately justified?
   g. Is the rationale for the proposed number of participants provided and reasonable?
   h. If warranted, are the plans for data and statistical analysis defined and justified, including stopping rules and endpoints when needed?
   i. Are there adequate provisions for monitoring data collection and analysis?
   j. If the study is restricted to or excludes individual groups (minors, vulnerable populations, gender) is this appropriate for this study and does the project description include proper procedures for protection of these participants?

2. Are methods of recruitment and participant selection (location, timing, personnel, screening, etc.) and their associated materials specified in the project description, appropriate for the study and non-coercive?
   a. Are the methods for recruiting potential participants well defined?
   b. Are the location and timing of the recruitment process described and acceptable?
   c. Is the individual performing the recruitment identified and appropriate for the process?
   d. Are all recruitment materials submitted and appropriate?
   e. If necessary, are there acceptable methods for screening participants before recruitment?
   f. If screening is used, is the process well defined in the protocol?
   g. Is the individual obtaining consent appropriate?

3. Are safeguards for vulnerable populations described, appropriate for the study and adequate for protecting the participants?
   a. If used, are inclusion and exclusion criteria clearly specified and appropriate?
   b. If women, minorities, or children are specifically included or excluded, is this justified by the PI?
   c. Is the choice of participants appropriate for the question being asked?
   d. Is the principle of distributive justice adequately incorporated into the inclusion and exclusion criteria for the research protocol (that is, is participant selection equitable)?
   e. If a vulnerable population is involved, are appropriate additional procedures and safeguards described and acceptable?

4. Is enough research procedure information (including training of study personnel, differentiation between research and standard care, and plans to inform participants of research results) provided for determining that participants' safety will be ensured?
   a. Are the rationale and details of the research procedures adequately described and acceptable?
   b. If standard interventions are involved, is there a clear differentiation between research procedures and standard methods of care and evaluation?
   c. Are the individuals performing the procedures appropriately trained, and is the location for performing procedures acceptable?
   d. Are there adequate plans to inform participants about specific research findings/results if necessary (clinically relevant results; risk of depression, suicidality, incidental findings, etc.)?

5. Are all reasonable physical, psychological, social, legal, employment or other risks to participants identified, minimized with appropriate safeguards and stated in both the project description and the consent forms?

6. Have potential adverse events and the minimization of their effects on participants been adequately and consistently considered and described in the project description and consent forms?

7. Are benefits adequately identified, evaluated, and maximized and is the risk/benefit ratio acceptable for proceeding with this research?

8. Is compensation handled appropriately, non-coercive and adequate to avoid significant out-of-pocket expenses for participants unless this is justified?
   a. Is the amount or type of compensation or reimbursement reasonable?
   b. Are there adequate provisions to avoid out-of-pocket expenses by the research participant, or is there sufficient justification to allow participants to pay?
   c. If children or adolescents are involved, is there a specification of who receives the compensation, and is this appropriate?

9. Are adequate provisions described to protect the privacy and assure the confidentiality of the research participants including storage, coding procedures, destruction of and methods of dealing with identifiable records (tapes, pictures, etc.)?
a. Are there adequate provisions to protect the privacy and assure the confidentiality of the research participant?
b. Are there adequate plans to store and code the data?
c. If used, are the use of identifiers or links to identifiers necessary?
d. If identifiers or links to identifiers are used, are these adequately protected?
e. If audio or videotapes are produced, is the disposition of the tapes described adequately?

10. Is the consent process (written, oral, implied, waived) described, appropriate and adequate given the level of risk in this study?
   a. Are the issues of participant's comprehension and autonomy considered and adequately addressed?
   b. Is the consent document written in plain language and at an age-appropriate level?
   c. Is the form legible? Are there any mechanical problems of grammar, spelling, punctuation, etc?

11. If participants are unable to give consent (e.g., children or mentally incompetent), is the permission/assent process described and the associated documentation provided and appropriate?
   a. If assent is required, are assent procedures described?
   b. Are the children who are potential participants all capable of providing assent?
   c. Is the method of obtaining assent appropriate?

12. If a waiver or modification of the consent process is requested, does it meet with federal guidelines for granting this waiver and is the waiver adequately justified in the project description?
   a. Are criteria for waiver of parental consent provided and acceptable?
   b. Are criteria for waiver of written informed consent and/or waiver of verbal/written informed consent provided and acceptable?
   c. If procedures for modification or alternation of written and/or verbal consent are described, are these justified and acceptable?

13. If deception is employed or students are the primary participants is the procedure adequately described, an appropriate debriefing provided to minimize risks and educate participants, and has the deception and/or use of this participant group been adequately justified?
   a. If participants are actively deceived in any way, is the deception described in the protocol and is the justification acceptable?
   b. If deception is used, does the protocol provide for a Debriefing Statement?
   c. If used, does the Debriefing Statement adequately describe and justify the use of deception and seek to minimize the potential costs to the participant of the deception?
   d. Does the debriefing statement include at least two references for use as educational materials?

14. Is adequate supplementary documentation (consent forms, screening instruments, survey/interview questions, data collection forms used by participants) included for a critical review of this protocol?

15. Are all parts of the protocol consistent?

Does the consent document address all of the following major sections appropriately:

1. Purpose in lay language including a statement that the study involves research.
   a. Statement that the study involves research.
   b. Purpose of research stated in lay language.

2. Design including duration, procedures (identified if experimental), alternative treatments, disclosure of new findings if applicable.
   a. Expected duration of study.
   b. Study design described that is appropriate to the level of disclosure justified by the protocol.
   c. Study procedures or treatments are described.
   d. Statement that significant new findings will be disclosed (If applicable).
   e. For student participants, alternatives to study participation are presented if available.
   f. For student participants, alternatives to study participation are presented if available.

3. Risks or discomforts without disclaimers or waivers.
   a. Potential risks or discomforts to the participant.
   b. IF RISK IS GREATER THAN MINIMAL, statement that the informed consent form is to provide the information participants need to know in order to make a good decision about study participation and that it is NOT to execute a waiver of liability on behalf of the research or sponsor and that by signing the form the participant is NOT waiving any legal rights.

4. Benefits, both direct and indirect.
   a. Potential direct benefits or benefits to individual participants or society.

5. Compensation, Costs to the participants, Medical treatment for injuries available and further information (req. if > minimal risk)
   a. Compensation or reimbursement.
   b. IF RISK IS GREATER THAN MINIMAL, statement included regarding policies for compensation in the event of injury.
   c. Additional costs associated with participating-who will pay for what (if applicable).
6. Researcher/faculty sponsor, IRB and research related injury contact (if > minimal risk).
   a. Information for research & faculty sponsor contact.
   b. Information for SBSIRB contact.

7. Voluntary nature with no penalties or loss of benefits, withdrawal/termination methods and consequences.
   a. Statement that participation is voluntary and participant may withdraw at any time.
   b. Consequences to participant of withdrawal before, during, or after study initiation.
   c. Anticipated circumstances under which a participant's participation may be terminated and policies relating
termination to compensation.

8. Confidentiality procedures and protections including checks offs for identifiable information (tapes, pictures, quotes)
   a. How confidentiality will be protected and who has access to the data.