St. Cloud State University Institutional Review Board (IRB)

Protocol Modification/Continuing Review/Final Report

St. Cloud State University requires all research activities involving human subjects— whether or not they are supported by Federal funds— to comply with the Federal Policy for the Protection of Human Subjects (45 CFR 46). According to this policy, ongoing research activities involving human subjects must be reviewed by the IRB, at a minimum, of at least once per year. In some cases, such as when research poses a significant risk, the IRB may require more frequent reviews.

This form must be submitted, before your study expiration date (as indicated on your approval letter).

Principal Investigator: **First name** **Last name**

Project Title:

SCSUIRB# (if known):

1. Please indicate the status of your project. Choose only one of the following, then continue on to question #2.

   This form serves as a ***Continuing Review*** -
   ☐ Subject recruitment/enrollment continues; current consent/assent required, please attach.
   ☐ Data collection continues with enrolled subjects; no additional subjects will be recruited.

   This form serves as a ***Final Report*** -
   ☐ Project has been completed.
   ☐ Data collection has been completed but data analysis continues.
   ☐ The project has not and will not be conducted. (Explain below.)

2. How many subjects have participated in your study?

3. Have any unexpected reactions, complications, or problems occurred during this research?

   ○ No ○ Yes (If yes, explain below.)

4. Have any subjects withdrawn from the research—either voluntarily or at the researcher's request?
   ◯ No ◯ Yes (If yes, explain below.)

5. Have any subjects complained about the research?
   ◯ No ◯ Yes (If yes, explain below.)

6. Has any new information been identified that may affect the willingness of current or future subjects to participate in this research?
   ◯ No ◯ Yes (If yes, explain and indicate how it was or will be conveyed to subjects.)

7. Have any changes been made to your research (including changes to informed consent documents, debriefing statements, recruitment materials, etc.) since it was approved by the IRB?
   ◯ No ◯ Yes (If yes, explain and indicate whether changes were submitted to the IRB.)

Principal Investigator's Signature

Date