

IRB Protocol #: \_\_\_\_\_

Date: \_\_\_\_\_

**COMMITTEE ON THE USE OF HUMAN SUBJECTS IN RESEARCH**

OHRP IRB00005900 Eastern Connecticut State U IRB #1      Federalwide Assurance FWA00011898

***Treatment Study Supplemental Form (IRB-1C)***

**Please complete this form if the proposed study is a treatment study; that is, if the study holds forth the possibility of cure or therapy for the subject's condition. This form must be attached to the protocol application when submitted for initial IRB review.**

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Principal Investigator:

Student Investigator:

Study Title:

1. Describe what the standard of care is and how the experimental procedures differ from this.
  
2. State whether all participants will receive current therapy in addition to study procedures, or if current therapy will be stopped. If current therapy will be stopped, provide justification for doing so.
  
3. If applicable, justify inclusion of a placebo group.
  
4. If applicable, justify blinding or not blinding the study.
  
5. Describe the conditions under which participants will be removed from the study or have the experimental procedures stopped.

6. Describe what happens with therapy when study ends (i.e., participant resumes original treatment plan).

PLEASE NOTE:

The “Data Safety Monitoring” section of the IRB-1 (Protocol Application for the Involvement of Human Subjects in Research) must be completed for all treatment studies.

If this study involves the use of drugs, devices, biological agents or proprietary projects, the IRB 1-A form must also be completed and submitted.