INSTITUTIONAL REVIEW BOARD FOR THE PROTECTION OF HUMAN PARTICIPANTS IN RESEARCH
Request for **Continuing Review Status** for an approved research project

Instructions: Submit completed form, with signatures, and any applicable attachments, to the IRB Office.

Section I: General Information

Date: _____ **IRB Number** (*Assigned by IRB office*): _____

Study Title: _____

Principal Investigator or Faculty Advisor: _____

Department: _____

Campus Address: _____

Email Address: _____ Phone: _____

Co-Principal Investigator: _____

Department: _____

Campus Address: _____

Email Address: _____ Phone: _____

Type of research, check all that apply:

☐ Faculty Research ☐ Dissertation/Thesis/Honor's Thesis

☐ Product of Learning/Capstone Research ☐ Class Project – Course Number: _____

☐ Other (describe): _____

Section II: Study Status

☐ Active

☐ Enrollment closed. Participants are receiving study treatment.

☐ Enrollment closed. Participants are not receiving study treatments. Follow-up involves procedures that would not be done if the patient/participant is followed off-protocol. Explain below.

_____

☐ Enrollment closed. Participants are not receiving study treatment. Follow-up procedures are the same for patients/participant managed on or off protocol. Study will be terminated.

☐ Other (explain)

_____

Number of enrollees in past year at ECSU: _____ Female _____ Male _____ Total

Total number of participants since starting study at ECSU: _____ Female _____ Male _____ Total

All sites if multi-center: _____ Female _____ Male _____ Total

Section III: Revision Request

Please respond to the following questions in detail sufficient for appropriate review. Use additional pages as needed. If study is being terminated, provide final summary.

1. Summarize revisions previously reviewed and approved by IRB.

_____

2. Summarize revisions not yet reviewed by IRB.

_____

3. Synopsis of activities to date: (include process of study compared to hypothesis).

_____

4. Have unexpected events, toxicities or complications occurred that may indicate a need for a change in the protocol or consent. ☐ No ☐ Yes (if yes explain)

_____

5. Has information (publications, etc.) become available since starting this study that indicate a need to modify this study?

_____

6. Were grievances or complaints received about this study? ☐ No ☐ Yes (if yes explain)

_____

FOR IRB OFFICE USE ONLY

IRB Protocol #: _____ ☐ Project qualifies for exemption. Category #: _____

IRB Signature: _____ Date: _____

Comments: