Continuing IRB Review / Request to Renew IRB Approval

Progress Report

Submit this form to (1) request a *renewal* of IRB approval for research studies not completed prior to the approval expiration date and to (2) notify the IRB that the study is *completed*.

IRB ID#: _____

Principal Investigator: _____

Faculty Advisor: _____

Project Title: _____

Federal Regulations mandate that all human subjects research protocols receive continuing review and approval not less than once a year (45CFR46.109(e)); (OHRP Guidance on Continuing Review, January 15, 2007). Sufficient information must be collected to allow the IRB to conduct a "substantive and meaningful" review of human subjects research projects. Therefore, to grant a renewal of IRB approval of your research project, the following information/ documents are required: *a completed continuing review questionnaire; a summary of previous project activities and future project plans; and, if subjects are still being recruited, copies of all Informed consent documents, surveys, interview questions, and/or questionnaires currently being used.*

See instructions on last page for submitting completed form.

All items must be adequately addressed before the IRB can proceed with the continuing review and renewal of approval of this research project. If a question does not apply to your research project, indicate with "Not Applicable" or "N/A".

If you do not respond to this questionnaire, your IRB file will be placed on *inactive* status, and your faculty advisor and the dean's office will be notified. When IRB approval expires without receiving a renewal of IRB approval, you must suspend all research study activities until receiving renewal of IRB approval.

Original Approval Date	Latest Approval Date	Approval Expiration Date

Respond to the Following Four Sections First:

I. Dates covered by this progress report: ☐ Previous 12 months ☐ Other period as described: _____

II. This research project is (check one category):

- ☐ Active, continuing to enroll participants or gather new data (attach copy of current informed consent form)
- ☐ Temporarily inactive
  - a. Date project will be reactivated: _____
  - b. Reason project is currently inactive: _____
- ☐ Analyzing existing data only; no new participant enrollments or new data collected. *Not necessary to complete Section V.*
- ☐ Study is completed. *Not necessary to complete Section V.*
- ☐ Study was approved as ***Exempt***, and it has not been changed in any way. *No need to complete Section V.*
- ☐ Study is terminated (never started, or closed before data collection was complete). Reason for termination:

  _____

III. Number of participants enrolled since "Latest Approval Date" shown above: _____

IV. Unanticipated events during the study

- ☐ Yes (describe in Section V.D.)
- ☐ No unanticipated events occurred

V. Renewal of IRB Approval: Project Summary – Complete to request a renewal

A. Have any changes been made in the study design, procedures, or documents? Yes ☐ No ☐

B. If Yes, concisely summarize any changes in procedures, recruitment materials, instruments, and/or informed consent documents that occurred during the previous period. Provide documentation of IRB approval of these items. If applicable, provide details of any changes in: study locations or participants. Attach additional page(s) if required. If no changes, enter "none."

C. Research Subjects:

1. If recruitment of subjects has been lower than anticipated over the past year, explain how your ability to complete the research objectives will be impacted:

2. Have any subjects withdrawn from the study since it began? Yes ☐ No ☐

   If Yes, explain: How many? Why?

3. Did any breach in confidentiality occur (e.g., unauthorized access to study record(s))? Yes ☐ No ☐

   If Yes, describe:

D. Unanticipated Events: If previously reported to the IRB, please indicate the reporting date(s): _____

Summarize any unexpected events or problems, the number of occurrences, and indicate whether they required consent document changes, particularly in the "risks" section. If risks are affected, describe how they are minimized and reasonable relative to expected benefits. If available, attach copies of data safety monitoring procedures.

E. Comment briefly about plans for this research project for the next twelve months:

Investigator's Statement:

As Principal Investigator, I acknowledge that I am responsible for reporting any unanticipated problems or serious effects or reactions; that I will submit any proposed procedural modifications to the IRB for its review and approval and, except where necessary to eliminate apparent immediate risks, no such modifications will be put into effect without prior Institutional Review Board (IRB) approval; that unless otherwise directed by the IRB, I will renew this application with the IRB no less than annually; that the research project is being conducted in compliance with the IRB's guidelines and recommendations; that the IRB is provided all information on the research project necessary for its complete review; and that this research project will not continue until final IRB approval is received.

__ _____ ____

Principal Investigator – Typed name is acceptable if e-mailing form Date

__ _____ ____

Faculty Advisor (if applicable) – Typed name is acceptable if e-mailing form Date

For electronic submissions, a check in this box will constitute a written signature: ☐

Instructions: When form is completed, please attach supporting documents (e.g., current consent form, questionnaires and/or survey forms, interview questions, and recruitment materials) and submit via e-mail or fax to the IRB Coordinator.