

**University of the District of Columbia
Institutional Review Board**

Continuing Review Application for Research Involving Human Participants

IRB No. _____

Date Received: _____

Instructions to applicant for renewal:

1. Please review the UDC IRB *Guidelines for Continuing Review* and complete this application form.
 2. If you wish to continue using human participants or collecting or analyzing data for the approved project, the project must be reviewed by the IRB before the end of the approval period. In addition, all changes to the approved research, which have occurred since the initial review or the last review, must be reported in the renewal application.
 3. The IRB approval for a non-exempt study is effective for one year. The IRB approval for exempt study is effective for three years. A renewal application should be submitted no later than 30 days prior to the last day of the approval period.
 4. Submit a certificate of completion of training in the protection of human research subjects, completed within the last three years, from <http://cme.cancer.gov/clinicaltrials/learning/humanparticipant-protections.asp> or http://www.hhs.gov/ohrp/assurances/assurances_index.html or <http://ohsr.od.nih.gov/cbt/cbt.html> or other source.
 5. Submit completed continuing review application documents in a single file to irb@udc.edu. and deliver a signed original copy to the Institutional Review Board, c/o Dr. Kathleen Dockett, University of the District of Columbia, 4200 Connecticut Avenue, NW Washington, DC 2008, Building 44, Room 200-36. The telephone number is 202-274-5705.
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I. Administration

Principle Investigator: _____ Faculty Rank: _____

Department: _____ Office Phone: _____ e-mail: _____

Co-Investigator: _____ Faculty Rank: _____

Project Title: _____

Date Previous IRB Approval Expires: _____

Date of Submission to IRB: _____

II. A. Status of Research Project

<p><u>Check action requested of the IRB:</u></p> <p>() Renew – actively enrolling participants</p> <p>() Renew – Closed to new participant enrollment, but participants still in research protocol</p> <p>() Renew – All participants completed research protocol, but research open for data analysis and follow-up of participants</p> <p>() Final/Close of Study – All research related activities completed including all data analysis and paper writing. Request termination of research with IRB.</p>

B. Participant Status

Participant Enrollment	Since Last Report	Since Study Initiation
# of participants enrolled*		
# of participants withdrawn**		
# of participants complaints***		
# of participants who completed the study		
# of participants still being Followed		

1. *If none enrolled, explain why:
2. * *If participants were withdrawn from the study, explain reason(s) for withdrawal:
3. ***If participants have complained about the study, provide summary of reasons given:

C. Project Status Since Last Review

1. Summarize study results to date:

2. Has the research protocol, informed consent document, or recruiting material been modified in any way since the previous IRB review?

No

Yes. If yes, please attach additional information to explain changes.

If yes, have all modifications been approved by the IRB.

Yes

No. If no, briefly explain and attach additional information:

3. Summarize any new risk or benefit information not previously reported to the IRB:

2. Attach a list of all study-related adverse events and summarize any study-related adverse events that resulted in changes to the protocol or informed consent documents. Describe any other unanticipated problems that involved risks to study participants or others, participant complaints, or participant withdrawal from research.

Yes there have been adverse events since the previous IRB review and the reports and summaries are attached.

No adverse events have occurred since the previous IRB review.

Continuation of research after expiration of IRB approval is a violation of FDA regulations. Studies will be suspended if the progress report is not received by the expiration date.

This section to be completed by the Principle Investigator or designee:

I acknowledge that this progress Report (or Final Report) represents an accurate and complete description of my research.

Signature of Principle Investigator (or Designee)

Date of Report

Typed or printed name:

For Official Use Only

Exempt

Expedited Review

Full Review

IRB Recommendation: (if disapprove, give reasons)

Approve **Need modification** **Disapprove**

Reason (s)/modification (s):

Signature:

Chairperson: _____ Date: _____

Member: _____ Date: _____

_____ Date: _____

_____ Date: _____

_____ Date: _____

_____ Date: _____

Vice President for the Academic Affairs: Approve Disapprove

Signature: _____ **Date:** _____