LONG ISLAND UNIVERSITY
BROOKLYN CAMPUS & C.W. POST CAMPUS
INSTITUTIONAL REVIEW BOARD

ANNUAL REVIEW/RENEWAL APPLICATION

All research involving human participants must be reviewed at least annually. Periodic review of research activities is necessary to determine whether approval should be continued or withdrawn. It is only after research has begun that the real risks can be evaluated and the preliminary results used to compute the actual risk/benefit ratio; the IRB can then determine the correctness of the initial judgment. Federal policy requires that investigators inform subjects of any important new information that might affect their willingness to continue participating in the research. The IRB must make a determination whether any new findings, new knowledge, or adverse effects should be communicated to subjects. Any necessary changes to the consent document(s) must be reviewed and approved by the IRB.

Our records indicate that the approval period for your project is scheduled to expire. The enclosed form and any necessary attachments should be completed and returned as soon as possible to the address shown below. Receipt by this date will allow for IRB review and approval without disruption to your project.

Please return to:

Inter-campus Mail:

Patricia Harvey
Office of Sponsored Research
Bush-Brown Hall
University Center
Attn: IRB Review

Regular Mail:

Patricia Harvey
Long Island University
Office of Sponsored Research
Bush Brown Hall
700 Northern Blvd.
Greenvale, NY 11548

IRB ID#_____

INSTITUTIONAL REVIEW BOARD
ANNUAL REVIEW

Title of Project:_____

_____

_____

Faculty Investigator:_____

Department:_____

Campus:_____

Telephone Number:_____

Student Investigator:_____

Department:_____

Campus:_____

Telephone Number:_____

Current Period of Approval_____

Section A. Will this project continue beyond the currently approved project period?

_____ No, please skip to Section C.

_____ Yes, please complete the rest of the form and return as indicated.

Section B. Source of funding (if title of grant differs from above, please provide below).

Grant Title:_____

_____

_____ Externally Funded

Sponsor:_____

LIU Account Number:_____

_____Internally Funded

_____Seeking Funding

Sponsor:_____

Sponsor Deadline:_____

_____Not Seeking Funding

Section C. Status of Study

1) Active Projects with Enrollment of Human Subjects

   _____Enrollment and research intervention will continue (Complete rest of form **and** submit a copy of the current consent/permission/assent form(s) to be used during the upcoming approval period.)

   _____Enrollment is complete, but research intervention continues with those enrolled (Complete rest of form **and** submit any consent/permission/assent addenda that may be used during the next approval period.)

   _____Enrollment and research intervention is complete; follow-up data collection continues. (Complete rest of form.)

   _____Enrollment, research intervention, and data collection complete; data analysis only being conducted. (Complete rest of form.)

2) Active Projects with No Human Subjects Enrolled

   _____No enrollment to date, but recruitment is continuing. (Complete Section E. and submit a copy of the current consent/permission/assent form(s) to be used in the upcoming period.)

   Please provide a reason for no enrollment during the approval period:

3) Completed/Terminated/Withdrawn Studies

_____Completed Study

_____Terminated Study (Ended before completion.)

(If either of the above are checked, complete Section D as a final report (i.e., include information from the entire duration of the study, not just the past approval period).

_____Withdrawn Study (Project has not, and will not be conducted; please complete Section D.)

Section D. Progress Report

1) Enrollment of subjects since Date of last IRB approval and total:

	Since last Approval	Total
Number of Males (18 years or older)	_____	_____
Number of Males (17 years or younger)	_____	_____
Number of Females (18 years or older)	_____	_____
Number of Females (17 years or younger)	_____	_____

2) Adverse Events, Complications, Subject Withdrawal Since Date of Last IRB Approval

Did any subject suffer an unanticipated or serious adverse event, or death?

_____No.

_____Yes (If YES, in the space below summarize the reported events, and briefly describe their nature and relationship to the study. Attach more pages as required.)

Based on your knowledge of adverse events that have occurred in subjects in this study, do you feel there has been a significant increase in risks to subjects?

_____Not Applicable (no adverse events have occurred)
_____Yes (In the space below, please explain your assessment.)
_____No (In the space below, please explain your assessment.)

Were any subjects removed from your study without their consent?

_____No
_____Yes (In the space below, explain how many subjects and what was the reason.)

Did any subjects withdraw themselves from your study?

_____No

_____Yes (In the space below, explain how many subjects and the reasons.)

Did any problems occur in the process of obtaining and documenting informed consent?

_____No

_____Yes (In the space below, explain the nature of the problem.)

Section E. Modifications to the Study

Provide a brief summary of any changes that have been made to the project during the last approval period (changes in consent/assent form or process, investigators, protocol amendments, etc.) Highlight those changes that resulted in an increased risk to subjects. If the study was terminated before completion, please explain why. Attach additional pages as necessary.

Section F. Study Findings

Provide a brief summary of the a)goals and b) results (preliminary or final) obtained in the study. If there are no results to report at this time, so state, and explain why. Attach additional pages as necessary.

Section G. Additional Required Materials Checklist

_____Publications (Attach a reprint of any publications/abstracts derived from your study since last approval.)

_____Consent/Assent Forms (If there has been enrollment in the study, attach a copy of the form used to enroll a subject since the last approval date [redact subject's name and signature to preserve confidentiality]. If you plan to continue to enroll subjects over the next approval period, submit a **clean** original consent/assent form(s) for review.**)**

_____Subject Recruitment Materials (If there will be continued recruitment of subjects, submit copies of all materials [advertisements, letters, flyers] to be used to recruit new subjects.)

_____Audit Reports (Attach a copy of any reports from audits/monitoring visits conducted by external organizations since last IRB review.

Section H. Certifications

Certification of Principal Investigator (and Faculty Advisor if PI is a student):

My signature below certifies that the research described in this application and supporting materials will be conducted in full compliance with Long Island University policies and Federal regulations governing human subjects research. In addition, my signature certifies that I will:

- Conduct all aspects of the project as approved by the IRB
- Promptly report any revisions or amendments to the research activity for review and approval by the IRB prior to commencement of the revised protocol, noting the only exemption to this policy being in situations where changes in protocol are required to eliminate apparent, immediate hazards to the subject
- Promptly report any unanticipated problems or adverse events affecting risks to subjects
- Assume full responsibility for selecting subjects in strict accordance with the inclusion/;exclusion criteria outlined in the application materials, **and**,
- Where consent form(s) have been approved for the research activity, only IRB approved, stamped consent forms will be used in the consent process.

_____ _____

Signature of Principal Investigator (PI) Date

_____ _____

Signature of Faculty Advisor (if Student is PI) Date

Certification of Chair or Division Head:

My signature below certifies that I have reviewed this research protocol and that I attest to the scientific merit of this study and the competency of the investigator(s) to conduct this project.

_____ _____

Signature of Chair or Division Head Date