Governors State University
Institutional Review Board

Annual Review Form

Purpose of Annual Review: All research activities that have been approved by the IRB are subject to a minimum of annual review. It is the responsibility of the Principle Investigator to complete the Annual Review Form, as well as to present a summary to the IRB, if requested. The Informed Consent form will also be reviewed at the time of the annual review to ensure that the information contained in it is still accurate and complete, including whether new information that may have been obtained during the course of the study needs to be added.

IRB # _____ **Date**:_____

Project Director: _____

Division or Department:_____

Student researcher (if appropriate): _____

Title of Protocol: _____
_____

Funding Source: (if NIH, specify institute)_____

Most Recent Approval Date by IRB: _____

Present Status of Project: ☐ Active ☐ Inactive ☐ Not begun
☐ Completed (date_____)

_____ Number of subjects that entered this project overall
_____ Number of subjects that entered since last review
_____Number of subjects who withdrew
Reason(s) for withdrawal: _____
_____
_____

Have there been any adverse reactions since the last review? ☐ Yes ☐ No
(Please note that any adverse reactions must be reported immediately to the IRB and the FDA if investigational drugs or devices are involved.) Please describe: _____
_____

Have there been any unanticipated benefits since the last review? ☐ Yes ☐ No
Please describe:_____
_____

Have there been any unanticipated increased risks, or, have there been any anticipated risks that have not materialized, since the last review? ☐ Yes ☐ No

Please describe: _____

_____

The undersigned certifies that no material modification has been made in the approval protocol since the most recent IRB approval date stated above, unless noted below:

☐ No modification ☐ Modification (attach documentation of modification)

☐ Project was completed on _____; data analysis is continuing
(date)

☐ Project and data analysis have been completed, so project was terminated on _____.
(date)

If human subjects were entered, the undersigned principle investigator:

1. Has enclosed with this form a copy of the consent form obtained in connection with the above project in the last year.
2. Certifies that such filings include a consent form for each human subject who has participated in the study, if they are required.
3. Certifies that the filings are completely in accordance with the project protocol except as noted (attach a sheet and explain any exceptions in the signing or witnessing of the consent forms).

PD Signature(s):_____

Type or Print PD name(s):_____

PD Contact Information: email or phone: _____

Date:_____

Date presented to the IRB:_____

IRB representative signature:_____

Please return completed form with signatures and any additional pages to:

Institutional Review Board
c/o Veronica Hunt
Office of the Provost
G 353