**INSTITUTIONAL REVIEW BOARD (IRB) OF**

**GEORGIA GWINNETT COLLEGE**

**Human Subject Protocol Renewal and Continuing Review Form**

DATE:

IRB NUMBER: PI’s Email Address:

INVESTIGATOR(s)/RESEARCHER(s) NAMES:

DEPARTMENT:

PROJECT TITLE:

The above human subjects protocol is due for renewal. Please answer the following questions listed and return this form to the IRB Chair. You may contact the IRB Chair by email at irb@ggc.edu.

Do you want to renew the above named protocol?

Yes [ ]  No [ ]

If you want to renew your protocol, please address the following questions listed below. If the answers to any one of the below questions is “YES” please elaborate the specific details on this form or on a separate piece of paper and attach to this form.

In accordance with federal regulations for continuing review ([45 CFR 46.109(e)),](http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#46.109) the GGC IRB conducts an annual review of all currently approved projects. Please answer the questions below.

1. Total number of subjects enrolled to date:
2. Number of subjects anticipated to participate during the next approval period:

3. Have there been any adverse events, unanticipated risks or complaints? Yes [ ]  No [ ]

 If yes, please explain.

4. Have any project personnel left the project? Yes [ ]  No [ ]

If yes, please list the names of personnel that have left the project. This includes student researchers.

5. Have any project personnel joined the project? Yes [ ]  No [ ]

If yes, please list the names of personnel who have joined the project. This includes student researchers. Also, note that any new personnel must complete CITI training.

6. Have any changes been made to the original protocol? Yes [ ]  No [ ]

If yes, please outline the changes below, and attach any supporting documents. Depending on the nature of the changes this renewal may need to be reviewed by the full IRB committee.

Investigator(s) Assurance:

The information and answers to the questions above is true and accurate to the best of my knowledge and I understand that prior IRB approval is required before initiating any changes that may affect the human subject participant(s) in the originally approved research protocol. I also understand that in accordance with federal regulations I am to report to the IRB or administrative designee any adverse events or unanticipated events that may arise during the course of this research.