**Application for Continuing Review of Human Participant Research**

**Instructions**: Complete this form by checking all appropriate boxes, answering questions completely, attaching required documents and signing the Certification Statement.

***Submit application form electronically to*** [***irb@westga.edu.***](file:///C%3A%5CUsers%5Ccharlac%5CDocuments%5CRESEARCH%20%26%20SPONSORED%20PROJECTS%5CIRB%5CForms%5Cirb%40westga.edu) ***(Incomplete applications will be returned unreviewed.)***

**Section I: Study Status**

1. Study Title:

2. IRB Number:

3. IRB Expiration Date:

4. Principal Investigator:

 Responsible faculty member if student is the PI:

 Department(s):

5. Indicate all that apply:

 Active (study is ongoing with no changes)

 Active with changes (changes are highlighted in attached documents-modification form attached)

 Inactive (study was initiated but data collection and analysis are inactive)

 Inactive - study was not started. Anticipated start date is:

6. Since the last review, are there any new relationships between the researcher(s) and agencies (e.g., schools, hospitals, homes) involved in the research?

 No Yes

 If yes, explain and attach a current statement of approval (e.g., letter of agreement) from any agencies that will be involved with the research:

7. Since the last review, have any new or known or potential conflicts of interest related to this research been identified?

 Conflict of interest relates to situations in which financial or other personal considerations may compromise or involve the potential/have the appearance for compromising an employee’s objectivity in meeting University responsibilities including research activities.

 No Yes

 If yes, describe the known or potential conflicts of interest and explain how participants will be protected from the influence of competing interests:

**Section II: Study Modifications/Amendments**

1. Since the last review:

 There have been no changes in research personnel or their roles and responsibilities.

 There have been changes in research personnel and/or their roles and responsibilities as indicated below:

The following research personnel are no longer associated with the study:

The following research personnel are new or have changed roles with the study:

New team members or team member with changed roles must complete the required CITI training if they will: 1) access participants’ private identifiable information, 2) obtain informed consent, or 3) interact with participants.)

2. Since the last review. Select one of the following.

 There have been no approved modifications or addendums to the research study or consent.

 There are requested modifications or addendums to the research study and/or consent form. *An IRB* *Study Modification Form is being submitted with this renewal form and revised application materials reflecting these changes are attached*.

3. Select one of the following.

 This is not a funded study

 There have been no amendments or modifications to the grant since the last review

 There have been amendments or modification to the grant since the last review. A copy of the updated grant materials with changes outlined or highlighted is attached.

**Section III: Participant Activity/Complaints/Adverse Events**

1. Number of participants approved by the IRB:

2. Number of participants accrued to date:

3. Describe any difficulties in participant enrollment is enrollment goals have not been met. How will this impact the study? (attach additional pages if necessary)

4. If you have exceeded the sample size initially proposed, explain why (attach additional pages if necessary submit a revised application reflecting change in the number of participants):

5. Number of participants withdrawn prior to completing the study:

5b. If applicable, provide specific details about any participant withdrawals from the study, whether voluntary or initiated by the investigator: (attach additional pages if necessary)

6. Were there any complaints regarding the research?

 No Yes

 If yes, please provide a detailed explanation and include copies of the complaints.

***Attach as separate sheet.***

7. Were there any adverse events or unanticipated problems involving risks to the subjects or others?

No Yes

If yes, please provide a detailed explanation: ***Attach as separate sheet.***

**Certification:**

By submitting this request, the Principal Investigator (and responsible faculty member if PI is a student) accepts responsibility for ensuring that all members of the research team:

• Complete the required CITI training and any other necessary training to fulfill their study responsibilities.

• To follow the study procedures as described in the IRB approved application letter and comply with the University of West Georgia’s Guidelines for the Review of Research Involving Human Subjects and all IRB communication.

• To uphold the rights and welfare of all study participants.

The parties (i.e., the IRB and the Principal Investigator and responsible faculty member if PI is a student) have agreed to conduct this application process by electronic means, and this application is signed electronically by the Principal Investigator and by the responsible faculty member if a student is the PI.

My name and email address together constitute the symbol and/or process I have adopted

with the intent to sign this application, and my name and email address, set out below, thus

constitute my electronic signature to this application.

PI Name PI Email address

Application should be completed by student and sent to the Responsible Faculty member. To approve the research proposed, the responsible faculty member should type their name and email, and submit the application to the UWG IRB at irb@westga.edu.

By signing this application I acknowledge that I have reviewed and approved the protocol for scientific merit, rational, and significance. I further acknowledge that I approve the ethical basis for the study.

Responsible Faculty Name if PI is a student Responsible Faculty Email address

Please send an electronic attachment of this application and any accompanying materials to irb@westga.edu. Questions or comments, please contact Charla Campbell, 678/839-4749.