Application for Continuing Review of Human Participant Research

University of West Georgia Human Research Protection Program

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. (Incomplete applications will be returned unreviewed.)

Section I: Study Status

1. Study Title: ________________________________

2. IRB Number: ________________________________

3. Indicate all that apply:
   ☐ Active (i.e., study is ongoing)
   ☐ All interactions with participants have ended. Remaining research activities are limited to data analysis
   ☐ No additional risks have been identified
   ☐ Inactive (i.e., study was not started). Anticipated start date is: ________________________________

4. Principal Investigator: ________________________________
   Responsible faculty member if student is the PI: ________________________________
   Department(s): ________________________________

5. 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**

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: ______________________________________________________

---

8. Source of funding:

☐ Not Funded  ☐ Funds Awarded  ☐ Funds Pending

☐ Federally Funded  ☐ University Funded: ______________________________________________________

If funds awarded/pending, provide sponsor name, Sponsored Programs number:

Attach a copy of the contract/grant/agreement.

---

**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:

---
2. Enter each new team member or team member with changed roles (including PI in the table below. (A member of the research team is defined as one who will: 1) access participants’ private identifiable information, 2) obtain informed consent, or 3) interact with participants.)

<table>
<thead>
<tr>
<th>Name</th>
<th>Role (e.g., PI, co-I, Research Assistant, Research Coor., Faculty Advisor, etc.)</th>
<th>Responsibilities: Select all that apply from the list of Responsibilities below (e.g., “a, b, c”)</th>
<th>Receive IRB Correspondence? (Y/N) if yes, provide preferred email address.</th>
<th>Completed CITI training? (Y/N)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

(Note: if you have additional research personnel, please attach a separate sheet with the above information. Personnel changes made after IRB approval can be submitted via email with the above information. Research personnel information must be received by the ORSO office before PARs will be approved for employee pay.)

Responsibilities:

a. Screens potential participants
b. Obtains Informed Consent
c. Has access to identifiable data
d. Administers survey
e. Conducts interviews
f. Enters subject data into research records
g. Analyzes data with identifiable information
h. Conducts physical exams
i. Collects biological specimens (e.g., blood samples)
j. Conducts study procedures
k. Dispenses medications
l. Supervises exercise
m. Educates participants, families, or staff
n. Other: describe

Note: In some cases, expertise to perform study procedures (e.g., blood draws, interviewing participants about sensitive topics) should be documented by the IRB to show that risks to participants is minimized.

3. Since the last review. Select one of the following.
   - There have been no modifications or addendums to the research study or consent.
   - There have been modifications or addendums to the research study and/or consent form. An IRB Study Modification Form is being submitted with this renewal form.

4. 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):

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.*

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.