Institutional Review Board

IRB Application

|  |
| --- |
| **IRB USE ONLY** |
| UWG IRB Application ID: |
| Date of Receipt: | Date of Review: |
| Reviewed by: | Review Determination: |
| Category of Review: [ ]  Expedited [ ]  Convened (for research involving more than minimal risk) |
| [Expedited Research Category](https://www.hhs.gov/ohrp/regulations-and-policy/guidance/categories-of-research-expedited-review-procedure-1998/index.html): [ ]  1 [ ]  2 [ ]  3 [ ]  4 [ ]  5 [ ]  6 [ ]  7 [ ]  8 [ ]  9 |

***Application Instructions:*** *Questions and instructions are in gray. Important corresponding information is indicated with a numbered footnote. Each section must be completed unless directed otherwise. Enter your information in the box provided or check in front of the appropriate response. If the question does not apply, type NA. Do not leave any questions in the application blank.*

|  |
| --- |
| **SECTION I – PROJECT PERSONNEL** |
| Principal Investigator (PI): |  |
| Student Principal Investigator (sPI)[[1]](#footnote-1): |  |
| CITI completion date for | Basic/Refresher:  | RCR:  |
| Department: |  |
| Email: |  |
| Home Institution if other than UWG: |   |
| Status: | [ ]  Faculty:  [ ]  Full-time (tenured, tenure-track, or non-tenured) [ ]  Part-time[[2]](#footnote-2) [ ]  Student: [ ]  Doctoral [ ]  Specialist [ ]  Masters [ ]  Undergraduate |
| **If PI is a student, include Faculty Advisor information:**  |
| Faculty Advisor: |  |
| CITI Completion Dates: | Basic/Refresher:  | RCR:  |
| Department: |  |
| Email: |  |
| **If other personnel will be involved in the project, include their information[[3]](#footnote-3):** |
| Other UWG personnel: |  |
| Other non UWG personnel[[4]](#footnote-4): |  |
| Describe roles/activities of other personnel: |  |

|  |
| --- |
| **SECTION II – PROTOCOL INFORMATION** |
| 1. | Review Status: | [ ]  Original Submission[ ]  Revision (provide date): [ ]  Modification[[5]](#footnote-5) (provide date): |
| 2. | Study Title: |  |
| 3.  | Anticipated Start Date[[6]](#footnote-6): | mm/dd/yyyy format:  |
| 4. | Anticipated End Date[[7]](#footnote-7): | mm/dd/yyyy format:  |
| 5. | Funding Source (list source): | [ ]  External:[ ]  Internal:[ ]  NA |
| 6. | Is the study human subjects research (as defined by the Common Rule)?[[8]](#footnote-8) | [ ]  YES [ ]  NO |

|  |
| --- |
| **SECTION III – CONFLICT OF INTEREST** |
| 1. | Does a member of the research team (PI, Co-PI, key personnel) or their immediate family have a conflict of interest (financial or non-financial) that would reasonably be affected by the research, or a financial interest in any entity (institution or sponsors related to the research) that would reasonably appear to be affected by the research? | [ ]  YES\* [ ]  NO |
| *If* ***yes,*** *describe how participants will be protected from the influence of competing interests:* |
|  |
| 2. | What relationship, if any, exists between the researcher and agencies (schools, hospitals, etc.) involved in the research? If you are employed where the data will be collected, explain your role/position in relation to participants. |
|  |

|  |  |  |
| --- | --- | --- |
| **SECTION IV – QUALIFYING STATEMENTS** | TRUE | FALSE |
| 1. | The research will not expose participants to discomfort or distress beyond that normally encountered in daily life (minimal risk).[[9]](#footnote-9) |[ ] [ ]
| 2. | The researcher is not in a position of authority over potential participants, or if the researcher is in a position of authority, steps have been taken to mitigate possible feelings of coercion of participants.[[10]](#footnote-10) (*if* ***yes****, explain mitigation steps in SECTION VI, Q5).* |[ ] [ ]
| 3.  | The research will not involve individuals that classified as a vulnerable population.[[11]](#footnote-11) |[ ] [ ]
| 4. | The research is not subject to FDA regulations (*if* ***yes****, contact the IRB office*). |[ ] [ ]

|  |
| --- |
| **SECTION V – DESCRIPTION OF RESEARCH** |
| 1. | In no more than 200 words, describe the purpose and goals of the research using plain language (avoid technical terms, acronyms or jargon, unless explained). List the research questions (and hypotheses, if applicable). |
|  |
| 2. | Describe step-by-step each research procedure as they relate to the use of human participants. Information should include all interaction with participants (study logistics), description of all data collection, including if participants will be recorded, what participants will be asked to do, duration of procedures, and frequency of procedures. If your study has more than one phase, clearly map out the different phases. |
|  |
| 3.  | Describe the methods of recruiting participants. |
|  |
| 4. | If the researcher is in a position of authority over any potential participant, explain how you will protect against coercion or undue influence. |
|  |
| 5. | If deception is involved, explain: 1) why deception is necessary to conduct the study, and 2) how participants will be debriefed of the nature of the study and given the option to end participation. |
|  |
| 6. | If the participants will receive any compensation (money, gift card, food, etc.) for participating in this project, provide information regarding the amount of compensation and how and when the participants will receive the compensation. |
|  |
| 7. | Data sources (data collection methods – check all that apply): |

|  |  |
| --- | --- |
| Paper surveys/Questionnaires |[ ]   Online surveys/Questionnaires |[ ]
| Telephone Surveys/Questionnaires |[ ]   Online survey provider: |  |
| Standard Written/oral/visual tests |[ ]   Interviews |[ ]
| Focus Groups |[ ]   Tasks |[ ]
| Public Observation |[ ]   Classroom/worksite observation |[ ]
| Audio, video, digital, or image recordings |[ ]   Moderate exercise and muscular strength  training |[ ]
| Materials that have been or will be collected for **non-research** purposes |[ ]   Materials that have been or will be  collected for other **research** purposes |[ ]
| Materials that are publicly available or if the information is recorded in such a way that participants cannot be identified |[ ]   Other:(describe)  |[ ]

|  |
| --- |
| **SECTION VI – PARTICIPANT INFORMATION** |
| 1. | Number of Participants: |  |
|  | YES | NO |
| 2. | Age range of Subjects: | Adults 18 or older  |[ ] [ ]
| 2a |  If NO, Specific Age Range of participants - | Minimum age:  | Maximum age:  |
| 3. | Does the study **target** any of the following categories of vulnerable participants (check all that apply)?[[12]](#footnote-12) |
|  | Children | [ ]  | [ ]  |
|  | Prisoners |[ ] [ ]
|  | Non-English speaking |[ ] [ ]
|  | People with Impaired Decision Making |[ ] [ ]
|  | American Indian/Native Americans or indigenous peoples |[ ] [ ]
| 4. | In the space below, describe inclusion criteria. What would make a subject eligible to participate? |
|  |
| 5. | In the space below, describe exclusion criteria. What would make a subject ineligible to participate? |
|  |
| 6. | In the space below, describe how the inclusion of subjects identified in question #3 is justified and describe the [additional protections](https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html) in place to minimize risks unique to each population. |
|  |

|  |
| --- |
| **SECTION VII – RISK AND BENEFIT** |
| The risk to participants must be reasonable in relation to anticipated benefits, if any, to participants and the importance of the knowledge that may reasonably be expected to result. |
| 1. | Explain how participants of the study may directly benefit (if there is no reasonable direct benefit to participants, state so) |
|  |
| 2. | Explain how society may benefit from the study (if there is no reasonable direct benefit to society, state so) |
|  |
| 3. | Explain potential risks (include physical, psychological, social, privacy, and economic) to participants (if risk is minimal, state so) |
|  |
| 4. | If risk to participants is above minimal risk, describe procedures for protecting against, or minimizing the potential risks. (include such things as: data safety monitoring plan, the presence of trained personnel who can respond to emergencies, and procedures to protect the confidentiality of the data (e.g., encryption, codes, and passwords) |
|  |
| 5. | If human subject data/specimens will be used for future research that is not described above, please explain (future use must be disclosed in the informed consent documents) |
|  |

|  |  |  |
| --- | --- | --- |
| **SECTION VIII – PARTICIPANT IDENTIFICATION** | YES | NO |
| 1. | Information is collected so that participants **CANNOT** be identified directly (by names, images or other identifiers) or indirectly (by linking responses to participants) |[ ] [ ]
| 2. | Information is collected so that participants **CAN** be identified, directly or indirectly by the research team, but identifying information will not be disclosed publicly. |[ ] [ ]
| 3. | Information is collected so that participants **CAN** be identified, directly or indirectly by the research team, and identifying information will be disclosed publicly. |[ ] [ ]

|  |
| --- |
| **SECTION IX – DATA CONFIDENTIALITY AND SECURITY** |
| When collecting human subjects data, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data. |
| 1. | Explain why private identifiable information is necessary and why the project could not be carried out without those data. Researchers should collect the minimum data elements necessary to effectively conduct their research. Participants can be identified indirectly through deductive disclosure by collecting unique data from participants, particularly from a small or specific population, if this is a possibility address how participants will be protected. |
|  |
| 2. | If collecting survey data using a survey platform other than Qualtrics, provide the following information:1. A statement of the security, privacy, and confidentiality practices of the survey provider;
2. A statement regarding specifically who at the provider may have access to the collected data;
3. A statement regarding the frequency of security audits of the server where data is stored;
4. A statement from the survey provider as to who owns the data collected; and
5. Certification from the survey provider that research data can be deleted/removed from the site and cannot be recovered.
 |
|  |
| 3. | Describe the extent to which the identifiable private information will be de-identified and the risk that the information could be re-identified. |
|  |
| 4. | If using coding (e.g. assigning participant numbers, pseudonyms, etc.), describe this system. Explain how the master list connecting codes to participant names will be protected. List all protections that apply (using coding but master list will be destroyed once coding is complete, password-protected files, password-protected device, encrypted file or flash/thumb drive, in locked drawer, etc.). |
|  |
| 5. | Describe how results will be reported (using coding or pseudonyms, aggregate reporting, etc.,)  |
|  |
| 6. | Describe plans for monitoring the data collected to ensure safety of subjects (e.g. how the PI will monitor data to ensure there is no breach of data).  |
|  |
| 7. | Describe how/where data will be stored during the research. |
|  |
| 8. | Describe how/where data will be stored upon completion of the study. Please note the following:1. Data must be securely maintained for a minimum of 3 years after study closure with the IRB.
2. Research records are property of UWG. If a student PI graduates, primary records must be stored securely for a minimum of 3 years by the faculty advisor. If a faculty PI leaves the institution, primary research records must be securely stored for a minimum of 3 years by a UWG affiliated faculty member.
 |
|  |
| 9. | Describe when and how identifiable data will be destroyed. Data with identifiers should not be stored indefinitely. All attempts to de-identify data should be made by the researcher. |
|  |
| 10. | Describe how long de-identified data be stored. |
|  |
| 11. | Describe the methods by which data will be destroyed (be specific regarding the types of stored data, paper, electronic, cloud storage, audio recordings, etc.)?  |
|  |

|  |
| --- |
| **SECTION X: CONSENT** |
| The researcher is obligated to disclose adequate information, including that the activity involves research, participation is voluntary, a description of the procedures, and investigator contact information. The consent must provide subjects with sufficient information to make a decision to participate. For participants under age 18, parental permission must be obtained prior to obtaining child assent.  |
| 1.  | Who will obtain voluntary informed consent from study participants? |
|  |
| 2. | How will consent be obtained? |
|  |
| 3. | When will consent be obtained? |
|  |
| 4. | How will you verify that the subject fully understands the consent? |
|  |
|  | YES | NO |
| 5. | Are you requesting a Waiver of Informed Consent for some or all of the elements of consent? |[ ] [ ]
|  If you are requesting a waiver of Informed Consent please **address all of the following**: |
| 1. The research involves no more than minimal risk to the privacy of the subjects.
 |
| 1. The waiver or alteration will not adversely affect the rights and welfare of the subjects.
 |
| 1. The research could not practicably be carried out without the waiver or alteration.
 |
| 1. Whenever appropriate, the subjects will be provided with additional pertinent information after participation.
 |
|  | YES | NO |
| 6. | Are you requesting a Waiver of the Documentation of Consent |[ ] [ ]
| The investigator must obtain consent following the same requirements as written consent but the subject does not sign a consent document. To request IRB approval of a consent procedure which does not document consent through a physical signature, provide a response to one of the following. Note that the IRB may require the investigator to provide subjects with a written statement regarding the research, even though the documentation requirement may be waived. Please **address one of the following**: |
| 1. That the only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject will be asked whether the subject wants documentation linking the subject with the research, and the subject’s wishes will govern. Address how this will be accomplished.
 |
|  |
| 1. That the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context. Address why the waiver is being requested and how/why the research could not be conducted without the waiver.[[13]](#footnote-13)
 |
|  |

**Certification**

Sign this application by typing your name and address. By signing, you agree:

1. All research team members have completed the required CITI training.
2. You will follow the study procedures as described in this application and you will notify the IRB prior to implementing any changes.
3. You will uphold the rights and welfare of all study participants.
4. All information submitted in this application is true, complete and accurate to the best of your knowledge.
5. You will notify the IRB regarding any adverse events, unexpected problems or incidents that involve risk to participants or others, or any complaints.
6. You will maintain accurate and complete research records, including all informed consent documents for a minimum of three years from the completion of this study or in compliance with sponsor guidelines or procedures submitted herein.
7. Recruitment and research will only begin after you have received an IRB approval of your project.
8. If required, you will complete an Application for Continuing Review prior to the expiration date of your study.

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.

**Principal Investigator:**

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

**If the Principal Investigator is a student, the student must submit all materials to the faculty advisor for review and approval. It is the responsibility of the Faculty Advisor to submit student IRB materials to the UWG IRB.**

Submit IRB application and all required materials to irb@westga.edu.

If PI is a student

**Faculty Advisor:**

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.

Faculty Advisor Name (if sPI) Faculty Advisor email address

Supporting Documents:

* Application
* Consent documents (Consent Document(s), Assent Document(s), Debriefing Statements (applicable when using deception), etc.)

Ages of Assent:

* + Under 6: No assent is required. Provide to the IRB information about how you will ensure that the children want to participate and are not getting upset.
	+ Ages 6-10: Verbal assent may be obtained. Verbal assent must be documented by PI and procedures for obtaining verbal assent described in the IRB application. Submit an assent script to the IRB for review. The script must be appropriate for the age and cognition of participants.
	+ Ages 11-17: This age group must sign the assent document unless a waiver of signed consent has been submitted to and approved by the IRB.
* Recruiting documents (e.g. advertisements/poster/flyers, scripts, emails, social media posts, letters, etc.)
* Study instruments (e.g. surveys, questionnaires, interview guides, tests, photographs, etc.). Please see the UWG IRB website for instructions on printing surveys from Qualtrics.
* If applicable, Research Site Letter of Acknowledgement, District/Principal Letter of Acknowledgement, MOU’s, letters of support, or other assurances of collaboration.
* Evidence of human subjects protection training, which is required for all principal investigators and anyone who will: 1) access participants’ private identifiable information; 2) obtain informed consent; or 3) interact with participants.
* International Research Application Addendum, if applicable.
1. *All student IRB applications must be reviewed and approved by the faculty advisor. Faculty Advisors must submit all IRB materials to* *irb@westga.edu**.* [↑](#footnote-ref-1)
2. *Part-time faculty members must have a full-time faculty serve as PI and submit a letter of support from their department chair to pursue IRB approved research at UWG.* [↑](#footnote-ref-2)
3. *List any personnel who will obtain consent and/or have access to participant identifiable information. These personnel must also complete CITI training for Basic/Refresher and RCR courses.* [↑](#footnote-ref-3)
4. *Copies of non UWG personnel’s CITI training must be submitted with the application.* [↑](#footnote-ref-4)
5. *The PI or FA must submit a modified application as well as an IRB Modification Form for all modifications to approved IRB studies.* [↑](#footnote-ref-5)
6. *Project start date: Recruitment, consent, data collection may not begin until IRB approval has been given. Refer to the timeline for review and approval listed on the UWG IRB website.* [↑](#footnote-ref-6)
7. *Project end date: must allow time to complete data collection and analysis.* [↑](#footnote-ref-7)
8. *OHRP defines human subjects research as “a systematic investigation, including research development, testing, and evaluation designed to develop or contribute to generalized knowledge.” A human subject is “a living individual about whom an investigator conducting research obtains information or biospecimens through intervention or interaction with the individual or obtains/uses/studies/generalizes identifiable private information or biospecimens” Please follow* *this link* *for examples of what is and what isn’t research. If not research, please complete the Research Determination Form found on the UWG IRB website and submit irb@westga.edu.* [↑](#footnote-ref-8)
9. *If the research involves more than minimal risk, the IRB application must be reviewed by the Full IRB Board.* ***Minimal risk*** *means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.* [↑](#footnote-ref-9)
10. *If the researcher is in a position of authority over potential participants (employer, supervisor, professor, teacher, doctor, etc.) the researcher must have in place a plan to mitigate possible feelings of coercion to participate. Simply stating that participation is voluntary is not sufficient to mitigate coercion.* [↑](#footnote-ref-10)
11. *Further information on vulnerable populations can be found* [*here*](https://www.hhs.gov/ohrp/regulations-and-policy/guidance/vulnerable-populations/index.html)*. Generally,* [*additional protections*](https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html) *are required for research involving pregnant women and fetuses, prisoners, or children.* [↑](#footnote-ref-11)
12. *The mere presence of the appearance of vulnerability should not lead to a presumption that a person is incapable of making a decision regarding participation in research and of giving valid informed consent. Yet sometimes these conditions do impair the decision-making capacity required to give a valid informed consent, raising ethical concerns about the vulnerability of persons in such conditions in research.* [↑](#footnote-ref-12)
13. *This will often apply to surveys and questionnaires where data is collected electronically (subject not able to physically sign a form). Researchers should include information that includes the elements of consent and a box for the participant to check signaling that they agree to participate.* [↑](#footnote-ref-13)