Institutional Review Board

IRB Exempt Study Application

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| **IRB USE ONLY** |
| UWG IRB Application ID: |
| Date of Receipt: | Date of Review: |
| Reviewed by: | Review Determination: |
| [Exempt Research Category](https://www.ecfr.gov/current/title-45/subtitle-A/subchapter-A/part-46/subpart-A/section-46.104): [ ]  1 [ ]  2 [ ]  3 [ ]  4 [ ]  5 [ ]  6  |

***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.*

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| **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: |  |

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| **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 |

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| **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:* |
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| 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. |
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| **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*). |[ ] [ ]

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| **SECTION V – DESCRIPTION OF RESEARCH** |
| 1. | Describe briefly the objectives of the study with the purpose, research question(s) (state your hypothesis), and any relevant background information.  |
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| 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. The procedures should be clear enough that someone unfamiliar with your research would be able to replicate the entire study from the description provided. |
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| 3.  | Describe the methods of recruiting participants. |
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| 4. | If the researcher is in a position of authority over any potential participant, explain how you will protect against coercion or undue influence. |
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| 5. | 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. |
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**SECTION VI – EXEMPT CATEGORIES**

Check only the yellow box (mark with an “X”) for the categories you believe apply to your project. Answer all questions in that category. Do not check boxes or answer questions that do not apply to your project.

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|  | **Category 1**-Research, conducted in established or commonly accepted educational settings. This includes most research on regular and special education instructional strategies, and research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.\*NOTE: If you are obtaining identifiable student records, FERPA regulations apply. For the use of identifiable student records (grades, scores, homework, etc.) you must either obtain the direct, written consent (if adults) or the student’s parent permission (if minors), or you must obtain an exception from the local educational agency who holds the records. Submit a copy of this exception with the IRB application.  |
|  | YES | NO |
| 1. | The research will only be conducted in established or commonly-accepted educational settings, including but not limited to, schools & colleges? |[ ] [ ]
| 2. | The research will specifically involve normal educational practices that are not likely to adversely impact students' opportunity to learn required educational content? |[ ] [ ]
| 3. | The research is not likely to adversely affect the assessment of educators who provide instruction? |[ ] [ ]
| 4. | In the space below, explain why the research procedures are normal educational practices in a commonly accepted educational setting. **Studies on professional development of teachers does not meet the requirements for this category, unless you are specifically studying the instructional strategies, or effectiveness or comparison of instructional techniques used in the professional development.** |
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|  | **Category 2**- Research that only includes interactions involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior (including visual or auditory recording) if at least one of the following criteria is met:NOTE: This category is not available for surveys or interviews (focus groups) with minors. |
|  | YES | NO |
| 1. | The information obtained is recorded by the investigator in such a manner that the identity of the participants cannot readily be ascertained, directly or through identifiers linked to the subjects. |[ ] [ ]
| 2. | Any disclosure of the human subjects' responses outside the research would reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation. |[ ] [ ]
| 3. | The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination required by [§ 46.111(a)(7)](https://www.ecfr.gov/current/title-45/subtitle-A/subchapter-A/part-46/subpart-A/section-46.111#p-46.111(a)(7))[[12]](#footnote-12) |[ ] [ ]

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|  | **Category 3**-Research involving benign behavioral interventions[[13]](#footnote-13) in conjunction with the collection of information from an adult subject through verbal or written responses (including data entry) or audiovisual recording if the subject prospectively agrees to the intervention and information collection and at least one of the following criteria is met: |
|  | YES | NO |
| 1. | The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects. |[ ] [ ]
| 2. | Any disclosure of the human subjects' responses outside the research would reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation. |[ ] [ ]
| 3. | The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination required by [§ 46.111(a)(7)](https://www.ecfr.gov/current/title-45/subtitle-A/subchapter-A/part-46/subpart-A/section-46.111#p-46.111(a)(7))[[14]](#footnote-14) |[ ] [ ]
| 4. | If the research involves deception regarding the nature or purpose of the research the subjects will sign a consent form, which specifically indicates the participant will be unaware of, or misled regarding the nature or purposes of the research.[[15]](#footnote-15) |[ ] [ ]

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|  | **Category 4**- Secondary research for which consent is not required: Secondary research uses of identifiable private information or identifiable biospecimens, if at least one of the following criteria is met: |
|  | YES | NO |
| 1. | The identifiable private information or identifiable biospecimens are publicly available. |[ ] [ ]
| 2. | Information is recorded by the investigator in such a manner that the identity of the participants cannot readily be ascertained directly or through identifiers linked to the subjects, the investigator does not contact the subjects, and the investigator will not re-identify subjects. |[ ] [ ]
| 3. | The research involves only information regulated by HIPPA. |[ ] [ ]
| 4. | The research is conducted by or on behalf of a federal department or agency using government collected information obtained for non-research purposes. Private identifiable information will be maintained in systems of records subject to the Privacy Act of 1974, 5 U.S.C.552a. |[ ] [ ]
| 5. | In the space below, provide an overview of the data/records that will be accessed that apply to this category. Include the source and purpose for which they were originally collected. If personal identifier are associate with the data, describe the de-identification procedures. |
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|  | **Category 5**- Research and demonstration projects that are conducted or supported by a Federal department or agency, or otherwise subject to the approval of department or agency heads. |
|  | YES | NO |
| 1. | Project is designed to study, evaluate, improve, or otherwise examine public benefit or service programs, including procedures for obtaining benefits or services under those programs, possible changes in or alternatives to those programs or procedures, or possible changes in methods or levels of payment for benefits or services under those programs |[ ] [ ]
| 2. | Projects include, but are not limited to, internal studies by Federal employees, and studies under contracts or consulting arrangements, cooperative agreements, or grants. Exempt projects also include waivers of otherwise mandatory requirements using authorities such as sections 1115 and 1115A of the Social Security Act, as amended. |[ ] [ ]

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|  | **Category 6**- Taste and food quality evaluation and consumer acceptance studies |
|  | YES | NO |
| 1. | Wholesome foods without additives are consumed |[ ] [ ]
| 2. | Food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture. |[ ] [ ]

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| **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)[[16]](#footnote-16) |
|  | 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? |
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| 5. | In the space below, describe exclusion criteria. What would make a subject ineligible to participate? |
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| 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. |
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| **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. |[ ] [ ]

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| **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. |
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| 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.
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| 3. | Describe the extent to which the identifiable private information will be de-identified and the risk that the information could be re-identified. |
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| 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.). |
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| 5. | Describe how results will be reported (using coding or pseudonyms, aggregate reporting, etc.,)  |
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| 6. | Describe plans for monitoring the data collected to ensure safety of subjects. |
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| 7. | Describe how/where data will be stored during the research. |
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| 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.
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| 9. | Describe when and how identifiable data will be destroyed. |
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| **SECTION X – CONSENT** |
| When exempt research involves interactions with participants, an informed consent process should be followed. 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. |
| 1.  | Describe how consent will be obtained. Include information regarding any exceptions to the required elements of consent and whether a signature will be obtained. |
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**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 determination of your application.

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 (sPI), 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

The IRB must review all documents used in the data collection. Review the list below and attach all documents that will be used in this research project to the email being submitted to irb@westga.edu.

**Supporting Documents:**

* Application
* Consent documents (Consent Document(s), Assent Document(s), Debriefing Statements (applicable when using deception), etc.)
* Recruiting documents (e.g. advertisements/poster/flyers, scripts, emails, social media posts, letters, etc.)
* Study instruments (e.g. surveys, questionnaires, interview guides, observation logs, 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 (CITI), which is required for all principal investigators.
* 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. *If* ***yes****, answer all questions in section IX Data Security* [↑](#footnote-ref-12)
13. *Benign behavioral interventions are brief in duration, harmless, painless, not physically invasive, not likely to have a significant adverse lasting impact on the subjects, and the investigator has no reason to think the subjects will find the interventions offensive or embarrassing.* [↑](#footnote-ref-13)
14. *If* **yes***, answer all questions in section IX Data Security* [↑](#footnote-ref-14)
15. *If* ***no****, this research does not qualify for exemption. You must submit an Expedited/Full IRB application.* [↑](#footnote-ref-15)
16. *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-16)