

Institutional Review Board

IRB Exempt Application

IRB USE

UWG IRB Application Number:

Date Received: Reviewed By:

Review Date: Review Determination:

Questions and instructions are in gray. Important information is below each section. Each section must be completed unless directed otherwise. Enter your information in the box provided or type an “X” in front of the appropriate response. If the question does not apply, type “N/A”.

**SECTION I – PI Information**

|  |  |
| --- | --- |
| Principal Investigator: |  |
| CITI completion date for | Human subjects:  | RCR:  |
| Department: |  |
| Email: |  |
| Home Institution if other than UWG: |   |
| Status: |  Faculty |
|  Student |  Doctoral |  Specialist |  Masters |  Undergraduate |
|  If PI is a student, the Faculty Advisor Information must be included below.  |
| Faculty Advisor: |  |
| CITI completion date for | Human subjects:  | RCR:  |
| Department: |  |
| Email: |  |

\*All student IRB applications must be reviewed and approved by the faculty advisor. Faculty Advisors must submit all IRB materials to irb@westga.edu.

**SECTION II – Project Information**

|  |  |  |
| --- | --- | --- |
| 1. | Review Status: check one |  Original submission  |
|  |  |  Revision/modification – date:  |
| 2. | Study Title: |  |
| 3.  | Anticipated Start Date: | mm/dd/yyyy format:  |
| 4. | Anticipated End Date: | mm/dd/yyyy format:  |
| 5. | Other UWG personnel: |  |
| 6. | Other non UWG personnel: |  |

#1 Include revision date if a revision is requested by the IRB or if the PI needs to make a modification to the study.

#3 Project start date: Recruitment, consent, data collection may not begin until IRB approval has been given. Typically allow 3 weeks for approval.

#4 Project end date: must allow time to complete data collection and analysis.

#5 & #6 List any personnel who will obtain consent and/or have access to participant identifiable information. These personnel must also complete CITI training for Human Subjects and RCR.

**SECTION III – Conflict of Interest**

|  |  |  |
| --- | --- | --- |
|  | YES | NO |
| 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? |  |  |
| 2. | If you answered “yes” to question 1, in the space below, describe how participants will be protected from the influence of competing interests. |
|  |
| 3. | 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 V – Qualifying Statements1**

|  |  |  |
| --- | --- | --- |
|  | TRUE | FALSE |
| 1. | The research will not expose participants to discomfort or distress beyond that normally encountered in daily life (minimal risk). |  |  |
| 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. Explain mitigation steps in Section VI, question 5. |  |  |
| 3.  | The research will not involve individuals that are prisoners (involuntarily confined or detained in a penal institution), with restricted ability to leave the institution. |  |  |
| 4. | The research is not subject to FDA regulations. |  |  |

 1 pregnant women are no longer considered a vulnerable population under the new IRB regulations.

#3 If you are conducting research specifically involving prisoners the exemptions do not apply, you will need to complete a full IRB application.

**SECTION VI – Description of the Research**

|  |  |
| --- | --- |
| 1. | Describe briefly the objectives of the study with the purpose, research question(s) (state your hypothesis), and any relevant background information.  |
|  |
| 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. | How will you store the data during and after you complete the research? |
|  |
| 5. | If the researcher is in a position of authority over any potential participant, explain how you will protect against coercion or undue influence. |
|  |

**SECTION VII – Exempt Categories**

Check the yellow box (mark with an “X”) in each category for which you think your project would be exempt and answer all questions in that category.

|  |  |
| --- | --- |
|  | **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. (research on instructional strategies, or effectiveness or comparison of instructional techniques, curricula or classroom management methods) |
|  |

|  |  |
| --- | --- |
|  | **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 not 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 sensitive (yes to question 2) and 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. \* |  |  |

 #3 If you answered “yes” to question 3, you must answer all questions in section IX Data Security.

|  |  |
| --- | --- |
|  | **Category 3**-Research involving benign behavioral interventions 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 not 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 sensitive (yes to question 2) and 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. \* |  |  |
| 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. |  |  |

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

#3 If you answered “yes” to question 3, you must answer all questions in section IX Data Security

#4 If you answered “no” to question 4, your research does not qualify for exemption. You must submit an Expedited/Full IRB application.

|  |  |
| --- | --- |
|  | **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. |  |  |

SECTION VIII: Participants

|  |  |  |
| --- | --- | --- |
| 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 participants (check all that apply) |
|  | Prisoners  |   |   |
|  | Non-English speaking |  |  |
|  | People with Impaired Decision Making capacity |  |  |
|  | American Indian/Native Americans or indigenous peoples |  |  |
|  | Economically or educationally disadvantaged persons |  |  |
| 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? |
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| 6. | If you checked “yes” to any item in quesiton #3 (above) describe how you will protect those populations from coercion or undue influence. |
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**SECTION IX: Data Confidentiality and Security**

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| Complete this section if you answered “Yes” to question #3 in Exempt Category 2 and/or 3. 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, describe the extent to which pseudonyms, numbering or another coding system will be used and 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. |
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| 7. | Describe when and how identifiable data will be destroyed. |
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**SECTION X: Consent**

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| 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. |
|  |

**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, 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 PI is a student Faculty Advisor Email address

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, 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.
* International Research Application Addendum, if applicable.