

Application to utilize human subjects

General Guidance

The IRB, operating through the Office of Research Integrity and Compliance (ORIC) at Gardner-Webb University, voluntarily adheres to pertinent federal guidelines related to the protection of human participants in research.

All researchers and faculty sponsors of research must have active CITI certification. Certifications must remain valid throughout the investigation process.

Individual schools/departments/programs may also have a pre-submission process. Researchers should consult with their faculty advisor to determine and follow all pre-submission requirements before submitting to the IRB. Once pre-submission requirements have been met, all complete IRB applications should be submitted to irb@gardner-webb.edu.

Submission of a complete application will begin a Pre-Review process. Applications will be returned immediately if they contain:

1. Missing documentation
2. Grammatical errors
3. Spelling errors
4. Inconsistencies or components which lack clarity
5. Components which utilize inappropriate jargon from the perspective of the reader (this is primarily focused upon in the Informed Consent Documentation)

The Pre-Review process will assign one of 3 possible research categories to each complete application.

1. Exempt with limited review 2. Expedited 3. Full Review

The IRB application process can be lengthy. Time to process will vary depending upon the research category assigned and application load at any given time. Substantial planning is necessary. An estimate of turnaround time can be requested upon submission of a complete application. Each successive review process requires more lead time.

1. Exempt with limited review – 2 week minimum

2. Expedited – 4 week minimum

3. Full Review – 90 days minimum

Please be efficient but detailed while completing the IRB application. Spacing between application items does not necessarily reflect the space necessary to adequately address the item.

Do not copy and paste directly from your research proposal documentation. While some jargon is necessary for clarity in the application, the IRB application is fundamentally different than a research proposal. Brevity is appreciated but detailed efficiency is critical.

It is important for the IRB application to include details related to who, what, when, where, and how. Its primary concerns are related to discovery of Conflicts of Interest and the protection of human participants.

Please direct all questions about forms and application process to irb@gardner-webb.edu

Documentation Checklist – Please initial below when complete. Both researcher and faculty sponsor should review all materials and initial confirmation.

Do not submit an application until you are confident each appropriate component is included. An application which is missing any component will be returned without further review. This will substantially increase the time a project spends under review by the IRB. Applications are reviewed in the order they are received. Returned applications return to the bottom of the cue when they are resubmitted.

Complete applications should be submitted to irb@gardner-webb.edu with “*Insert Name* - new application” in the subject line. *Applications should be submitted as one file in the original Word document format with appendices included.*

|  |  |  |  |
| --- | --- | --- | --- |
|  Component | Researcher Initials | Faculty Sponsor Initials | N/A |
| Researcher and faculty sponsor signatures are included on application. |   |   |   |
| All components of application are complete and free from typographical and grammatical errors. |   |   |   |
| All abbreviations utilized in text are introduced/defined the first time they appear in text. |   |   |   |
| [Appropriate consent form/s](https://gardner-webb.edu/resources/academic-support/institutional-review-board/) are included in the appendix. |   |   |   |
| Consent forms are separated by instrument and audience - each type of instrument and each participant group has its own consent form  |   |   |   |
| Consent forms are written in accessible language |   |   |   |
| Consent forms refer to “I” and “you” rather than “researcher” and “participant” |   |   |   |
| Consent form purpose matches purpose on the IRB application |   |   |   |
| Consent form procedures match procedures on the IRB application |   |   |   |
| If applicable, copy(s)of child subject assent form is included in the appendix. |   |   |   |
| Copies of all recruitment materials are included in the appendix. This includes, but is not limited to, letters, announcements, proposed social media posts, emails, fliers, and verbal request scripts. |   |   |   |
| Copies of all proposed instruments are included in the appendix. This includes, but is not limited to, surveys, tests, interview questions, protocol description, and timeline(s). |   |   |   |
| Permission(s) to conduct research at specific sites or facilities (e.g. schools, churches, clinics, hospitals etc.) **OR** a statement noting that university IRB approval is required prior to site approval is included in the appendix. |   |   |   |
| If applicable – Permission to use published instruments is included in the appendix. |   |   |   |
| If applicable – Copies of post participation debriefing forms and/or instructions are included in the appendix. |   |   |   |
| Evidence of CITI Certification from both researcher(s) and faculty sponsor(s) are included in the appendix |   |   |   |

# Application to utilize human subjects

**Remember, a Pre-Review of your application cannot begin until a completed application is received.**

Please save this document to your computer before completing and submitting.When completing the application, please type directly into the document and leave the greyed components intact.

Name of Researcher: **Please place all answers here.**

Date: **Please place all answers here.**

GWU ID#: **Please place all answers here.**

GWU Email Address Only: **Please place all answers here.**

Phone: **Please place all answers here.**

Department or School research is originating from: **Please place all answers here.**

What purpose does this project serve? **Please check one below**

|  |  |  |  |
| --- | --- | --- | --- |
|  | Faculty Research |  | Master’s Project |
|  | Dissertation |  | Honors Thesis |
|  | Doctoral Project |  | Summer Scholars |
|  | Master’s Thesis |  | Undergraduate Thesis |

Name of Faculty Sponsor (if student research): Type name here. Signature will be included at end of document

GWU Email Address Only: **Please place all answers here.**

Phone Number: **Please place all answers here.**

Title of Project: **Please place all answers here.**

1. Using 5-10 sentences, what is the purpose of your research? Inclusion of your purpose statement and hypothesis is encouraged. **Please place all answers here.**

2. How many subjects do you expect to use? **Please place all answers here.**

3. How do you plan to gain access to your subjects? Who will be providing you with access to subjects?

**Please place all answers here.**

4. Are any of the subjects vulnerable to coercion or undue influence, such as children, prisoners, individuals with impaired decision-making capacity, or economically or educationally disadvantaged persons?

Please use yellow highlighter for response. If Yes, check which vulnerable population(s) are part of the study.

Yes or No

 Children \_\_\_\_\_

 Prisoners \_\_\_\_\_

Individuals with impaired decision-making capacity \_\_\_\_\_

Economically or educationally disadvantaged persons \_\_\_\_\_

5. Please describe specific safeguards which have been included in the study to protect the rights and welfare of all subjects (whether vulnerable or not). Also describe your role with regard to the research site and subjects. Include any potential conflicts of interest. In addition, include this information in your Informed Consent. **Please place all answers here.**

6. What is your research methodology? Please describe data collection method and plan to analyze data. Do not cut and paste from your proposal. Be clear and concise. Attach any surveys, instruments, or tests to this form with the appropriate references. **Please place all answers here.**

7. Describe the research procedure. Please be specific with regard to what the subject/s will do and/or experience. Inclusion of a graphic (timeline, infographic, or flow chart) might be an efficient way to describe your intentions. The IRB needs to understand who, what, when, where, how, and how long. Do not cut and paste from your proposal. **Please place all answers here.**

8. Does this research pose risk to the subject? Risks included those which are physical or psychological in nature. Risks can also include job security or an alteration in workplace conditions related to participation. If risks are possible, please describe them in detail. Include measures which your study will deploy in order to reduce those risks. **Please place all answers here.**

9. Does this research involve deception of any kind? If yes, please describe. **Please place all answers here.**

10. Will any incentives to participate be used? This could include but is not limited to money, extra credit for student grades, gift cards, or entry in a raffle or drawing. If incentives will be used, please explain. Use of incentives is not inherently inappropriate but the details must be disclosed and reviewed by the IRB.

**Please place all answers here.**

11. How will you protect the subject’s right NOT to participate in your research? Briefly describe the procedure which a subject will be instructed to follow. **Please place all answers here.**

12. How will you protect the subject’s confidentiality of results? Please indicate how and where data will be stored and secured; please include the process for destruction of data.

**Please place all answers here.**

13. How, when, and where will the research results be reported? Please be broad in your scope. Research must be approved even if publication will not occur. If your publications intentions change, the IRB must be contacted and updated of your new publication intentions. **Please place all answers here.**

14. Will data collected be made available to other parties for the purpose of further research? Please make sure this information is included in the Informed Consent.

Yes \_\_\_\_\_

No \_\_\_\_\_

15. Are there any external funding sources supporting this study? If yes, please describe source and form of support.

 Yes \_\_\_\_\_

 No \_\_\_\_\_

 External funding description:

Application Signatures

Applicant signature below verifies that all information submitted related to this application is accurate and complete. Initial project approval is valid for one year from the date of issue. Changes to an approved protocol require submission of a “Change of Approved Protocol” form (available on the IRB website). **Signatures may be electronic signatures but must be accompanied by the individual’s GWU ID#.**

Researcher Name: Date:

Researcher Signature GWU ID#:

*Faculty Research Advisor, please note in signing this document, you verify the following:*

* The faculty sponsor/advisor’s signature should indicate approval of concept, content, and syntax.
* *All information on the documentation checklist is included.*
* *You have reviewed the protocol and approve of the procedures described therein.*
* *CITI verification for both student researcher and faculty sponsor is attached.*
* *All school/department/program pre-submission requirements (e.g. successful proposal defense, internal review) have been met.*
* *You are aware of reasons for an application to be returned in the pre-review process and you believe this application to be ready for IRB submission.*

Faculty Sponsor Name: Date:

Faculty Sponsor Signature: GWU ID#:

Below is an opportunity for the faculty signatory of this application to provide a recommendation to the IRB regarding the research category that should be assigned to the application. Only the faculty signatory of the application should make this recommendation as that individual is capable of demonstrating completion of CITI certification and has intimate knowledge of the research procedure contained in the application. Suggestions are reviewed, but final review level will be made by the IRB.

Indicate faculty sponsor/advisor recommendation below. Please use yellow highlight tool to suggest Exempt, Expedited, or Full review.

Add electronic signature and GWU ID below.

Using the yellow highlight tool, please indicate the suggested review category along with the appropriate rationale from the list below.

**Exempt Review Suggested– choose all appropriate rationale (1-6) below.**

**Please review the Exempt categories below and indicate the category that applies to your research.** Please note: if your study does not fall into one of the categories below it cannot be reviewed as exempt.

1. Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (i) research on regular and special education instructional strategies, or (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.
2. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless: (i) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and (ii) any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.
3. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under paragraph (2) of this section, if: (i) the human subjects are elected or appointed public officials or candidates for public office; or (ii) federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.
4. Research involving the collection or study of **existing data**\*, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.

 *\*Existing data is defined as materials that are “on the shelf” at the time*

 *the research is submitted to the IRB.*

1. Research and demonstration projects which are conducted by or subject to the approval of Department or Agency heads, and which are designed to study, evaluate, or otherwise examine: (i) public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs.
2. Research involving taste and food quality evaluation and consumer acceptance studies, (i) if wholesome foods without additives are consumed or (ii) if a 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

**Expedited Review Suggested**

Federal regulations provide that certain types of research may be considered for review through an expedited process (45 CFR 46.110). A primary criterion for expedited review is that the research be of minimal risk. The Office of Human Research Protections (OHRP) defines minimal risk as risk where the probability and magnitude of harm or discomfort anticipated in the proposed research are not greater, in and of themselves, than that ordinarily experienced in daily life or during the performance of routine physical or psychological examinations. In addition, the purpose of the research must fit within a series of categories as stipulated by DHHS regulations.

**Please confirm statements A and B are true for your study (by highlighting the appropriate items below)**

(A) The research poses no greater than minimal risk.

(B) The identification of the subjects/and or their responses would not reasonably place the subject at risk of criminal or civil liability or be damaging to the subject’s financial standing, employability, insurability, reputation, or be stigmatizing, unless reasonable and appropriate protections will be implemented so that the risk to privacy and breach of confidentiality are no greater than minimal.

(C) Review the Expedited categories below and indicate the category that applies to your research.

**Expedited Categories:**

1. Clinical studies of drugs and medical devices.
2. Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture

from (a) healthy, non-pregnant adults who weigh at least 110 lbs.; (b) other adults and

children, considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency of collection. *For these subjects, the amount drawn may not exceed 550ml in an 8-week period and collection may not occur more frequently than 2 times per week.*

1. Prospective collection of biological specimens for research purposes by noninvasive means. For example: hair/nail clippings, external secretions, saliva, mucosal skin collected by buccal swab.
2. Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. For example: (a) physical sensors that are applied to the surface of the body; (b) weighing or testing sensory acuity; (c) magnetic resonance imaging: (d) electrocardiography, electroencephalography, ultrasound, Doppler blood flow, and echocardiography; (e) moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual. ***Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications).***
3. Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for non-research purposes (such as medical treatment or diagnosis).
4. Collection of data from voice, video, digital, or image recordings made for research purposes.

Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.

**IRB Full Review Suggested**

Applications that do not meet the definition of Minimal Risk (see definitions above) to the participants or do not meet the qualifications of Exempt or Expedited review must be presented to the Full IRB for discussion and vote.

Faculty Sponsor Name: Date:

Faculty Sponsor Electronic Signature: GWU ID#:

Once pre-submission requirements have been met, all complete IRB applications should be submitted to irb@gardner-webb.edu.To facilitate and expedite the review process, please complete and submit this application as one file in the original Word document format including appendices.