**Institutional Review Board (IRB) Application: Research Involving Human Subjects**

**INSTRUCTIONS**

All submissions ***must be electronic*** unless pre-approved by the IRB chair. If you are having difficulties with the electronic form, please contact the IRB chair. Once complete, email the entire proposal as a PDF file to irb@uwgb.edu and the IRB Chair. The PI must submit this protocol and all correspondence will take place with the PI. The proposal must be sent as **one** complete document. Please include all relevant forms as well as the IRB certifications and signatures of all investigators involved.

**PART I: PROJECT INFORMATION**

**A. Research Project Information**

Study Title:

Date Submitted:

Estimated Start Date:

*Note: Please allow at least 14 days for exempt or expedited review. Protocols requiring approval from the full board will be reviewed at the next scheduled meeting.*

Estimated Completion Date:

*Note: Projects continuing for longer than one year will require an Extension Form and Annual Progress Report.*

**B. Principal Investigator (PI)\***

**\****please note this cannot be a student*

Name:       Email:

Program/Unit:       Phone: (     )       -

Status: [ ]  Full-time Faculty Member [ ]  Administrator/Staff Member

 [ ]  Full-time Lecturer [ ]  Other, please explain:

Was this proposal primarily prepared by a student-investigator(s)? [ ]  Yes [ ]  No

If so, did you (as PI), review and/or edit the document to assure that it contains the required information as requested by the IRB? [ ]  N/A [ ]  Yes [ ]  No

**C. Determination of Risk/Review Status**

For a description of these categories, please review the IRB Policies and Procedures Manual on the IRB website.

[ ]  Full Board Review – requires full IRB approval – requires a progress report.

[ ]  Expedited Review – can be reviewed by any member of the IRB – requires a progress report.

[ ]  Exempt - can be reviewed by any member of the IRB – does NOT require a progress report.

*Exempt status means that once approved the proposal is exempt from any further IRB review.*

**D. Signatures**

|  |  |  |  |
| --- | --- | --- | --- |
| NAME | SIGNATURE | EMAIL | STATUS - Please Choose One |
| (PI):  | [ ]  Electronic Signature |  | Status |
|       | [ ]  Electronic Signature |       | Status |
|       | [ ]  Electronic Signature |       | Status |
|       | [ ]  Electronic Signature |       | Status |
|       | [ ]  Electronic Signature |       | Status |
|       | [ ]  Electronic Signature |       | Status |
|       | [ ]  Electronic Signature |       | Status |
|       | [ ]  Electronic Signature |       | Status |
|       | [ ]  Electronic Signature |       | Status |

Please check “Electronic Signature” box if you are submitting an electronic signature.

**PART II: PROJECT NARRATIVE**

**A. Purpose and Significance of the Project**

Provide a brief background statement and describe the purpose of the research project and the importance of the knowledge to be gained from it. Include several citations from literature to establish a research history (please provide citations/references).

**B. Participants in the Project**

1. Identify all participant groups (e.g. teacher, elementary school students, administrators, patients, etc.).

2. Describe the basic characteristics of potential participants, (e.g. college students, administrators, clients, etc. and the anticipated number of participants, age range, gender, racial/ethnic background).

3. Describe any special criteria for including or excluding individuals form participation and justify those criteria; example: including only individuals with hypertension as that is pertinent to the intervention to address hypertension.

4. If a requirement of the research is that the participants are to be in good mental or physical health, indicate who will determine and how.

5. If the participants are minors, mentally incompetent, or legally restricted groups, give an explanation as to the necessity for using these particular groups (please note that the research with any of these groups requires Full Board Review).

6. Indicate the total amount time required of each participant. If you will be using multiple instruments/procedures, state the amount of time required for each instrument/procedure.

7. If you will reward (e.g., provide money, extra credit, gift, etc.) participants, indicate the type of reward, when participants will receive the payment, and whether or not your participants will receive the payment if they drop out of the study. In case of course credit(s), indicate how students who do not participate will be able to earn equal credit.

**C. Methodology**

1. Describe all the procedures used to identify, recruit subjects. Include who will make contact, how the contract will be made, and how subjects will be enrolled in the study.

2. Describe what constitutes data (quantitative or qualitative) for this research.

3. Describe what participants will be asked to do, e.g., interventions, educational programs, testing, observation, interviews, or laboratory procedures.

4. Indicate any personnel who will be involved in the research process, e.g., those who will be present during a participants’ participation, those involved in analyzing the data. State the qualifications (must be IRB certified) and roles of all personnel.

5. If the project involves invasive medical procedures and/or stress testing, please indicate the qualifications of the person(s) performing the procedure.

6. Indicate the location(s) where the research will take place, e.g., UWGB, in participants’ homes, the Brown County Library, etc.

7. If you are using an online survey (such as Qualtrics) you must provide a pdf of the survey. Please append to the end of this document. Additionally, please provide the link here.

**D. Risks to Participants**

1. Describe, in detail, any risks you foresee (physical, emotional, psychological, social, legal, economic, etc.).

2. If more than minimal risk, provide the rationale for the necessity of such risks, i.e., why the value of the information to be gained outweighs the risk involved.

3. If more than minimal risk, describe what actions that will be taken to minimize the risk(s).

4. If you will utilize deception (of any kind) in gathering your data, justify and support the use of deception AND provide a detailed description of the debriefing process used to explain the deception and the rationale for using it.

**E. Safeguarding the Participants**

1. Collection of information can identify or potentially identify individual participants through surveys, interviews, or tests (including demographic data)? If YES, please explain & justify.

 [ ]  No [ ]  Yes, Explain:

2. Will archival data containing identifying information or codes that could be linked to individuals be used? If YES, please explain and justify.

[ ]  No [ ]  Yes, Explain:

3. Will information be gathered or recorded in such a manner that participants can be identified, either directly or through identifiers linked to them? If YES, please explain and justify.

[ ]  No [ ]  Yes, Explain:

4. Explain how and where you will store the data and who will have access to it. FYI – it is not necessary to destroy data. Note that electronic storage MUST be password protected.

5. Describe specific procedures you will use to safeguard participants’ data from unauthorized access.

6. If applicable, explain how you will link the data to participants during your study.

7. State what you will do with the information obtained from the study (participants), e.g., use aggregate data to publish in a scientific journal, present at a conference.

8. Describe which elements of your project might be openly accessible to other agencies or appear in publications.

**F. Benefits to Participants**

Describe any potential benefits of participation (to participants, to society, and/or to a particular field of study) and evaluate the risk-benefit ratio of participation in the project, e.g., ERLP credit, gift card, etc.

**G. Cooperating Institutions**

If applicable, please provide information about any cooperating institutions (hospitals, prisons, social welfare agencies, etc.) that are involved in the project. Include information about the subjects and/or researchers’ affiliation with the institution(s). Provide a copy of the affiliation (agreement) letter. The affiliation letter(s) should be written by a supervisor at the particular agency and serve as evidence that the primary investigator has been given permission to conduct research at the institution. You may NOT begin participant recruitment or data collection until you have submitted the signed affiliation letter(s) to the IRB.

 [ ]  If applicable, signed affiliation letter(s) are attached.

**H. Special Considerations**

|  |  |  |
| --- | --- | --- |
| **Does your research involve:**  | **YES** | **NO** |
| 1. Use of instructional strategies that are NOT commonly used and well accepted, or the addition of assessment procedures that are NOT routinely used in established or commonly accepted educational settings? If YES, please explain and justify.       | **[ ]**  | **[ ]**  |
| 2. Inclusion of questions about topics that the participant might consider sensitive or personal (e.g., questions about ethical or religious beliefs, questions about (intimate) relationships, questions about health status, health practices, or medical history, etc.). If YES, please explain and justify.      | **[ ]**  | **[ ]**  |
| 3. Placing the participants at risk of criminal or civil liability or damaging the subjects’ financial standing, employability, or reputation if their responses were to be were to be disclosed outside of the research project? If YES, please explain and justify.       | **[ ]**  | **[ ]**  |
| 4. Any procedures that could impose stress or expose participants to risks beyond what they encounter in everyday life? If YES, please explain and justify.       | **[ ]**  | **[ ]**  |
| 5. Use or presentation of materials that might be considered to be offensive, threatening, or degrading? If YES, please explain and justify.       | **[ ]**  | **[ ]**  |
| 6. Risk of physical injury or discomfort to participants, including physical exertion beyond normal activity? If YES, please explain and justify.       | **[ ]**  | **[ ]**  |
| 7. Manipulation of physiological requirements (nutrition, sleep, etc.) or of ethically sensitive psychological and social variables (sensory deprivation, isolation, stress, self-esteem)? If YES, please explain and justify.       | **[ ]**  | **[ ]**  |
| 8. Participants taking internally, or having applied externally, any substances, drugs, or other controlled substances? If YES, please explain and justify.      | **[ ]**  | **[ ]**  |
| 9. Collection and/or removal of any fluids or tissue from participants? If YES, please explain and justify.      | **[ ]**  | **[ ]**  |
| 10. Use of participants with whom the researcher has another relationship (e.g. administrator-teacher, teacher-student, psychotherapist-client, supervisor-employee, nurse-patient, professional-client, parole officer-parolee, etc.)? If YES, please explain and justify.       | **[ ]**  | **[ ]**  |
| 11. Access to health care records, legal records, or educational records.  | **[ ]**  | **[ ]**  |
| 12. Photographing, videotaping, or audiotaping **participants** and/or individuals who will serve as **models** (actors) in the research? | **[ ]**  | **[ ]**  |
| 13. A Quality Improvement Project? | **[ ]**  | **[ ]**  |

**PART III: DOCUMENTATION**

**A. Documentation Needed for ALL Proposals**

|  |  |
| --- | --- |
|  | **Check if attached** |
| 1. Copy of informed consent.  | **[ ]**  |
| 2. Copy of all data collection instruments (instructions to participants, observational coding sheets, data sheets, etc.).  | **[ ]**  |
| 3. Copy of Certification of Human Subjects Training for PI (current within past 5 years).  | **[ ]**  |
| 4. Copy of Certification of Human Subjects Training for ALL co-investigators (current within the past 5 years).  | **[ ]**  |
| 5. A copy of any documents or verbal scripts used in recruiting subjects, e.g., email, Facebook, posting, posters, announcements, or script of verbal invitation to participate.  | **[ ]**  |
| 6. Signature page with signatures of ALL researchers. | **[ ]**  |

**B. Informed Consent**

1. Describe the process involved in obtaining informed consent, e.g., when, where, and by whom consent will be obtained.

2. Describe the procedures used to ensure that the consent is informed and voluntary (particularly if the student involves the use of vulnerable populations or the use of deception).

3. If research involves “in class” consent/participation, describe how you will protect subjects from being identified as non-participants (or participants) to you, other faculty, and other students. Additionally, describe how you will ensure that student do not feel compelled (via authority or peer pressure) to participate, e.g., PI leaving the room, having staff or other faculty participate.

4. If not obtaining “signed informed consent” (obtaining the signature of the subject on the informed consent document), explain why that is not necessary, e.g., it compromises anonymity because it is the only way that a subject might be identified as having participated as a subject.

|  |  |  |
| --- | --- | --- |
| **Does your informed consent….** | **YES** | **NO** |
| 1. Indicate the NAME of the researchers, including the PI? | **[ ]**  | **[ ]**  |
| 2. State the PURPOSE of the research?  | **[ ]**  | **[ ]**  |
| 3. Include a PROCEDURES section that explains (in some detail) what is expected of the subject, including the time commitment? | **[ ]**  | **[ ]**  |
| 4. Explain the RISKS of the research – even if only minimal?  | **[ ]**  | **[ ]**  |
| 5. Explain the BENEFITS of the research – even if only contributing to knowledge of the discipline?  | **[ ]**  | **[ ]**  |
| 6. Include a SAFEGAURDS section that:  | **[ ]**  | **[ ]**  |
| 6a. explains how anonymity and/or privacy will be preserved? | **[ ]**  | **[ ]**  |
| 6b. indicates that the subject has the option of discontinuing participation at any time? | **[ ]**  | **[ ]**  |
| 6c. (if a survey or interview is involved), indicates that the subject has the option of NOT answering questions? | **[ ]**  | **[ ]**  |
| 7. Provide contact information for the investigator (PI)? | **[ ]**  | **[ ]**  |
| 8. Include a statement as to how the participant can access the results of the study? | **[ ]**  | **[ ]**  |
| 9. Provide contact information for the chair of the IRB? | **[ ]**  | **[ ]**  |

**C. Documentation that MIGHT be Needed**

|  |  |  |  |
| --- | --- | --- | --- |
| **Does your research involve:**  | **YES** | **NO** | **Check if attached** |
| 1. A (simple) survey instrument; if yes, please provide a hard copy of the survey. Online surveys should also include the link. | **[ ]**  | **[ ]**  | **[ ]**  |
| 2. Gaining access to health care records, legal records, or educational records? Please include a copy of letter of authorization.  | **[ ]**  | **[ ]**  | **[ ]**  |
| 3. Photographing, videotaping, or audiotaping individuals who will serve as **live models** and/or **participants** in the research? Please provide copy of authorization to photograph.  | **[ ]**  | **[ ]**  | **[ ]**  |
| 4. Using ERLP (Experiential Research Learning Program), please provide a copy of the recruitment text to be posted on ERLP website. | **[ ]**  | **[ ]**  | **[ ]**  |
| 5. Any VERBAL scripts used as a part of the research, including verbal recruiting scripts or verbal directions used in carrying out the study.  | **[ ]**  | **[ ]**  | **[ ]**  |
| 6. A copy of the transcript of any oral presentation used in the place of a written consent statement, accompanied by the statement which participants or legal representatives, and an auditor-witness sign indicating their agreement to participate in the study described orally.  | **[ ]**  | **[ ]**  | **[ ]**  |
| 7. A request for waiver or modification of the typical consent procedures outlined above, with appropriate rationale and justification, because typical consent procedures would adversely affect the experimental design or procurement of data.  | **[ ]**  | **[ ]**  | **[ ]**  |
| 8. Use of archival data, and if not publically available, please provide documentation of your authorization to access and use this data.  | **[ ]**  | **[ ]**  | **[ ]**  |
| 9. Other relevant materials that will be used in the study.  | **[ ]**  | **[ ]**  | **[ ]**  |

**PART IV: EXEMPT, EXPEDITED, OR FULL-BOARD?**

Proposals will be reviewed by a member or all members (*Full Board*) of the IRB. However, some categories of research *may*, under certain circumstances, be exempt from the need for further review once approval is granted. *Note: majority of proposals will be reviewed and approved as Expedited*. Rarely will proposals be approved as *Exempt*. Please review the IRB manual for further descriptions of each designation. If your research can be categorized below, it may be eligible for review as *Exempt*.

1. Research conducted in established or commonly accepted educational settings, involving normal education 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.
3. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior wherein (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 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 in such a manner that subjects cannot be identified, either directly or through identifiers linked to the subjects.
5. Research and demonstration projects which are conducted by or subject to the approval of Department or Agency heads which are designed to study, evaluate, or otherwise examine: (i) Public benefit of service programs; (ii) procedures for obtaining benefits or services under these 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.
6. 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 containment 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.

**NOTE: Research projects characterized by *use of vulnerable populations, threats to participants’ anonymity, confidentiality, or privacy, by exposure of participants to more than minimal risk*, and/or research NOT falling into the categories listed above, may require review by the full IRB.**