IRB APPLICATION FOR HUMAN PARTICIPANT RESEARCH

**1. Project Title**

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| Title of Project: |  |

**2. Project STATUS & Dates**

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| --- | --- | --- | --- | --- | --- | --- |
| **a.** Project status: | New | | Revision | | | |
| **b.** Anticipated starting and completion dates: | | **Upon IRB approval** | | | to | **May 2021** | | |
| **NOTE: Project may not start prior to approval from the IRB.** | | | | | | | | |
| **c.** This project may be conducted on an annual basis: | | | | Yes | | | |

**3. Principal Investigator Information**

**a. Status**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Affiliation: | BW member | Outside Researcher | |  |  |
| Status: | Undergraduate | Graduate | Faculty | Staff | Other |

**b. Contact Information**

|  |  |  |  |
| --- | --- | --- | --- |
| Principal Investigator: |  | | |
| School: |  | | |
| Department or Affiliation: |  | | |
| Telephone: |  | Email: |  |
| Address: |  | | |
| Name of chair/supervisor: |  | | |
| Email of chair/supervisor: |  | | |

**c. All primary investigators must complete CITI Training. PLEASE INCLUDE A COPY OF YOUR CITI TRAINING CERTIFICATE WITH YOUR APPLICATION.**

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| I certify that I have completed the necessary CITI Training Modules. | Yes | No |
| I have included a copy of my CITI Training Certificate with my materials. | Yes | No |

**d. Student / Outside Researcher Information**

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| If you are a student or outside researcher, please provide the following as applicable: | | | | |
| Type of project (check one): | Thesis/Essay | Independent Study | Class Project | Other |
| NOTE: An application by a student or outside researcher must have a BW faculty sponsor and check the following statements.   |  | | --- | | The BW faculty sponsor has reviewed all documents prior to submission. | | The BW faculty sponsor is cc’d on the IRB Application submission. | | | | | |

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| Course # & Name: |  | | |
| Faculty Sponsor: |  | Department: |  |
| Faculty email: |  | Phone: |  |

**4. funding**

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| Is this project being funded? | | Yes | No |
| If yes, list the funding source: |  | | | |
| If yes, provide the grant #: |  | | | |

**5. CATEGORY OF SUBMISSION:** Category descriptions can be found at <https://www.bw.edu/about/offices/responsible-research/> (look for document under Types of IRB Reviews).

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| --- | --- | --- |
| **Type**  ***(check one)*** | | **Submission Type Category**  ***(you must check one for Exempt or Expedited and explain in box below)*** |
|  | Exempt | 1. Education  2. Tests, surveys, interviews  3. Public officials  4. Existing data  5. Demonstration projects  6. Food |
|  | Expedited | 1. Drugs & devices  2. Blood draw  3. Prospective biol. specimen  4. Non-invasive data  5. Existing data  6. Recordings  7. Group Behavior  8. Other: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
|  | Full Review | Explain in box below. |
|  | Other | Explain in box below. |
| Justification/explanation for indicated submission type and category: | | |
|  | | |

**6. Research Statement:** Include the purpose statement and hypothesis of the project.

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**7. Participants**

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| **a.** | No special groups will be research participants. |

**OR**

**b**. The following special groups will be research participants (check all that apply):

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| --- | --- | --- | --- |
| Minors (under 18) | | Senior Citizens (over 65) | Terminally Ill |
| Non-English Speakers | | Mentally/Physically Disabled | Pregnant Women |
| Single Subject Populations (by Race, Ethnicity, Sex, or Religion) | | | | |
| Other (specify): |  | | | |

**(i.)** If any of the above special groups are selected, state the rationale for using those groups.

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| **c.** What is the approximate number of participants to be recruited? |  |  |

**d.** How will the participants be solicited? (check all that apply)

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| Advertisements | Letters | Random Calls |
| Telephone Lists | Notices | Direct Solicitation |
| BW Psych Pool | Other (specify): |  |

8. Informed Consent. See [www.bw.edu/research/responsible/irb/](http://www.bw.edu/research/responsible/irb/) for detailed information on consent and assent forms, the required consent elements, and to view sample consent forms. If the materials do not meet the requirements for informed consent, a revision may be requested.

a. Type of Consent/Minor Assent Requested (check all that apply):

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| --- | --- |
| **(i)** | Adult Consent |

**And/Or**

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| --- | --- | --- |
| **(ii)** | Use of Minors (under 18 years of age) | |
|  | Parent/Guardian Consent |
|  | Child/Minor Assent (Non-readers: Not able to read or not-proficient at reading) |
|  | Child/Minor Assent (Proficient readers: Can read & understand a simple assent form) |

**And/Or**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **(iii)** | In certain circumstances, a waiver of informed consent/minor assent may be requested. In this case, participants are not informed or only partially informed about a study. To request that informed consent or assent be waived, indicate category below (check all that apply). | | | |
|  | Informed consent will not be obtained | | |
|  | Parental consent will not be obtained | | |
|  | Child/minor assent will not be obtained | | |
|  | Partial Consent/Assent (check one): | | |
|  | | Deception: This study involves deception of participants (i.e., intentional misleading of subjects) |
|  | | Concealment: Some information about the study will not initially be disclosed to participants |

Justify why informed consent will not be obtained. If only partial consent/assent will be obtained, explain why this is necessary for this study and include plans for how and when participants will be debriefed. Also include how consent from subjects to use their data will be obtained at the time of debriefing. If a debriefing statement will not be used, explain why.

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| **b.** **Method** to obtain consent/minor assent.(check one) | | | | |
| **(i)** | Written Consent/Assent (written signature will be obtained from participants) | | |
| **OR** |  | | |
| **(ii)** | No Written Consent/Assent Obtained (a written signature will not be obtained from participants. Documentation of a signature is waived.) | | |
| If a waiver of a signature is requested, indicate below how participants will be informed: (check one) | | | | |
|  | | An Information Sheet will be used. Explain rationale below. |
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| Oral Consent will be obtained. Explain rationale below. |
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| Electronic Consent/Assumed Consent upon completion of survey. |

9. Data & CoNSENT Collection

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| **a.** Data collection methods (check all that apply): | | | | | |
|  | Questionnaire or Survey | | Archival Data |
|  | Web or Internet | | Intervention |
|  | Interview | | Focus Groups |
|  | Observation | | Testing/Evaluation |
|  | Video or Audio Taping | | Instruction/Curriculum |
|  | Computer Collected Task Data | | Physical Tasks |
|  | Other: |  | | |

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| --- | --- | --- | --- |
| **b.** Will the data be collected with identifiers? | | Yes | No |
|  | i. **If yes to b.**, will the data be rendered anonymous for  analysis? | Yes | No |
|  | ii. **If yes to b.**, will the data be rendered anonymous for  reporting? | Yes | No |
|  |  | | | |

**c.** Describe how the consent forms and other study material (e.g., data instruments, computer task data, interview questions) will be distributed and collected to protect the privacy of the participants and how confidentiality/anonymity will be maintained throughout the consent and data collection process.

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**d.** Describe security of the data, including where the consent forms and other study material will be stored, who will have access, and how and when the material will be destroyed. Note that signed consent forms must be retained for **three years** after the end of the study. State who will maintain the consent forms for the specified three years. (Note: faculty/staff sponsors should retain the original or a copy of signed consent forms collected from student projects.)

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10. Methodology: Describe in detail how the research will be conducted making sure to address (1) how participants will be identified and the process of contacting, selecting and excluding participants; (2) how consent will be obtained, and if children will be used, describe how parental consent and child assent will be obtained; and (3) how data will be collected, including how data instruments, if used, will be distributed and collected, and the location where the study will take place. Essentially, describe how the study will be practically implemented step by step.

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**11.** **Risk Factors:** A research participant is considered to be at risk if he or she may be exposed through the procedures of the planned experiment to the possibility of physical or mental harm, coercion, deceit or loss of privacy. The most obvious examples of placing participants at risk of harm include administration of unusual physical exertion, deceit and public embarrassment or humiliation. Coercion may be present when the potential participants are not able to exercise their right to decline participation, particularly when the researcher is in a relationship of greater power over the participants.

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| **a.** | **Risk Criteria** | **CHECK ONE** | |
|  | Deceit may be employed in the study. | Yes | No |
|  | Coercion to participate may exist. | Yes | No |
|  | Experimental drugs will be used. | Yes | No |
|  | Potential for medical problems exist. | Yes | No |
|  | Participants may experience physical discomfort. | Yes | No |
|  | Participant may experience embarrassment/humiliation. | Yes | No |
|  | Participants may experience mental discomfort. | Yes | No |
|  | Electrical equipment will be used. | Yes | No |
|  | Participants will be tape recorded, photographed, or videotaped. | Yes | No |

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| **i.** If you indicated YES to any of the above Risk Criteria, explain and describe proposed  safeguards to protect participants. |

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**b.** Assess the likelihood and seriousness of any risks (physical, mental, or other) to the participants. Describe alternative methods that would not entail comparable risks and why these were not used.

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**c.** Description of the anticipated benefits to participants and contributions to general knowledge in the field of inquiry (incentives, rewards & compensation are discussed in d. below- NOT HERE):

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**d.** If the research participants will be eligible for incentives, compensation or reward for their participation in the study, indicate the type and amount of compensation and the milestone for each payment. If participants are being recruited from BWU classes or Psychology courses, indicate whether students are receiving course credit (regular or extra credit) and, if so, what alternatives are offered to those students who do not wish to participate in the research.

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| **12.** **Submission Material**  The IRB will only review materials submitted as a SINGLE WORD DOCUMENT. The IRB cannot approve a project without a complete and accurate application and all supporting materials. Please indicate below what materials have been included with this application (check all that apply): |

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|  | Recruitment material (flyer, announcement, oral script, email, letter, etc.) |
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|  | Data instruments (surveys, interview questions, tests, web-survey, etc.) |
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|  | Informed consent (consent and assent forms, information sheet, oral consent script,  psych-pool electronic consent, etc.) |
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|  | Debriefing statement |
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|  | Video clips, music CDs, photos, etc. |
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| Grant Description (if project is grant funded) |

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| Other: (specify) |  |

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| **13. Certification Statement** *In making this application, I certify that I have read and understood Baldwin Wallace University’s policies and procedures governing research with human participants (specifically, those as described in Baldwin Wallace University’s Institutional Review Board Policy). I shall comply with the letter and spirit of those policies and will not undertake the research without IRB approval. Furthermore, I am aware that certain departments may have their own standards for conducting research, and it is up to me to familiarize myself with them. I further acknowledge my obligation to: (1) obtain written approval of significant deviations from the originally approved protocol BEFORE making those deviations; (2) report immediately all adverse effects of the study on the participants to the Chairperson of the Institutional Review Board and the Chairperson or Supervisor of my Department; ( 3) to retain the original signed consent forms for 3 years after completion of the study; and (4) ensure that all approved informed consent forms given to subjects have the IRB archival code (see below).*   |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | |  | | |  | |  | | Principal Investigator signature | | |  | | Date | | **Sub-Investigators:** | | | | | | | **a.** Name: |  | Title: | |  | | | Affiliation: |  |  | |  | | | **b.** Name: |  | Title: | |  | | | Affiliation: |  |  | |  | | |  | | | | | | |

**14. Submission Information**

**Upload all submission materials COMPILED AS A SINGLE PDF Document within the Formsite link.**

An incomplete submission may significantly delay the review process. Forms and policy guidelines are available at: [[www.bw.edu/research/responsible/irb/](http://www.bw.edu/research/responsible/irb/)](http://sites.jcu.edu/research/pages/irb/help/privacy/)

For questions, comments, or assistance in completing the form, contact the IRB Administrator at [IRB@bw.edu](mailto:IRB@bw.edu) .