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|  | | **General Project Information (IRB-A)**  **Institutional Review Board**  **for Human Subjects Research** | | | (For Committee Use Only)  IRB Proposal #: |
| **Lead Investigator** | | | **Faculty Sponsor(s)**  **(Required for Student PI’s and Non-CU Affiliated Researchers)** | | |
| Name: |  | | Name(s): |  | |
| Email: |  | | Email: |  | |
| Phone: |  | | Phone: |  | |
| Status: | Undergraduate Student  Graduate Student  CU Faculty  CU Staff  Non-CU Affiliated Researcher | |  |  | |
| **Co-Investigator(s)** | | |  |  | |
| List Names: |  | | | | |

**Project Information:**

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| **Project Title:** |  | | |
| **Anticipated Start Date:** |  | **Anticipated Completion Date:** |  |
| **Research Question – State your research questions and (if applicable) your hypotheses.** | | | |
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| **Research Subjects – Describe the subjects your investigation will interact with. Could any be under 18 years old? How will subjects be selected? How many will be selected? Could they be considered to be part of a vulnerable population (e.g. prisoners, pregnant women, mentally impaired individuals, low income individuals, elderly)** | | | |
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| **Purpose, Population, and Methods – Describe your plan for conducting research; methods you will use; what subjects will do; types of questions they will be asked; behaviors you would expect to observe.** | | | |
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| **Potential Risks – What are the risks associated with participating in your study? Consider not only physical discomfort/harm, but also risks associated with emotional stress or confidentiality of information.** | | | |
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| **How do the investigators intend to minimize those risks? If physical or emotional risks are present, what resources will the investigators have available to deal with those possibilities?** | | | |
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| **What are the potential benefits of your study to: 1) the participants themselves; 2)persons other than the participants. If there are none, indicate “None”** | | | |
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| **Consent Process – Describe the consent process that will be used to ensure participants freely agree to participate. Attach a copy of an informed consent statement or text of a verbal request for consent where applicable. Provide rationale if requesting consent is to be waived (e.g. no connection between participant and the data collected).** | | | |
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| **External Consent – If your research is being conducted outside of Cedarville University list the agencies/locations at which research will be conducted. Approval from the CU IRB would be provided contingent on receiving documentation indicating approval from an official of that agency/location (e.g. signed permission document on letterhead). If no external agencies are involved, indicate “NONE.” For researchers requesting to conduct research under the primary supervision of another University or organization with their own Institutional Review Board, please provide documentation of the approval of that Board.** | | | |
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| **Submission of Materials – List below or provide (as an attachment) information that will be used with your subjects including survey or interview questions.** | | | |
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| **Dissemination – Describe your plan for any dissemination, publication, or presentation of your data and the results of your study.** | | | |
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**Other Documentation:**

All research projects involving human subjects conducted at, or in association with Cedarville University require submission of this General Project Information (Form IRB-A) and at least one of the two IRB forms indicated below. Indicate which of the following are being included with this general project information:

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| Form IRB-B – Request for Exempt Status  Form IRB-C – Request for Full or Expedited Review | Additional materials such as surveys, test questions, etc.  Proposed statement of informed consent |

The following assurance statements apply to this document and any associated documents indicated above or otherwise submitted to the Institutional Review Board as part of this proposal.

**Assurance Statements:**

I have read Cedarville University’s policy concerning research involving human subjects and by signing below:

1. I agree to accept responsibility for the ethical conduct of research conducted in this project;
2. I agree to obtain approval from the Institutional Review Board prior to modifying procedures that might substantially affect this project.
3. I attest that the information submitted in this application and all associated documents is true to the best of my knowledge.

**Students:** send your application to your faculty advisor. Submission using your CU email account serves as your signature and pledge to abide by the conditions stated above. No original signatures are required. If submitting electronically please type names and date of submission below.

**Non-CU Affiliated Researchers:** Cedarville University requires that those wishing to conduct research using CU students, faculty, or staff as subjects be sponsored by a CU faculty member or office with expertise or responsibilities related to the subject matter of the study. Applications should be sent to the sponsoring faculty member or department supporting your research.

**Faculty or Sponsoring Departments:** submit applications and attachments by email to [arunyan@cedarville.edu](mailto:arunyan@cedarville.edu). Submission using your CU email account serves as your signature and pledge to abide by the conditions stated above. No original signatures are required. If submitting electronically please type names and date of submission below.

Lead Investigator Signature:                                           Date:

(Submitting through your CU email account serves as your signature.)

Faculty Sponsor Signature:                                               Date:

(Submitting through your CU email account serves as your signature.)

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|  | | | | **Request for Exempt Status (IRB-B)**  **Institutional Review Board**  **for Human Subjects Research** | (For Committee Use Only)  IRB Proposal #: |
| **Lead Investigator Name:** | | |  | | |
| **Project Title:** | | |  | | |
| All research involving human subjects must be submitted to the Institutional Review Board for review and approval prior to implementation. While such research may be exempt from review, the principal investigator must still submit general project information (Form IRB-A), to the Review Committee or its designated representative along with this form (IRB-B) which provides justification for an exemption. We do this for the purpose of documenting all research on human subjects, for the protection of human subjects and the researchers. Determination on exemption must be made by the review committee or its designated representative. It is not at the discretion of the investigator and research may not be conducted without prior approval.  **To be exempt from review, the research must satisfy the following conditions. Please check to indicate that each condition is satisfied:** | | | | | |
|  | The research does not pose more than a minimal risk to the research participants, where minimal risk is defined as follows:  “A risk is minimal where the probability and magnitude of harm or discomfort anticipated in the proposed research are not greater, in and of themselves, than those encountered in daily life or during the performance of routine physical or psychological examinations or tests.” | | | | |
|  | The research does not involve pregnant women, fetuses, human invitro fertilization, or prisoners. | | | | |
| **The research must fit into at least one of the categories for research that is exempt from review. At least one category must be selected and sub-requirements must be selected where applicable.** | | | | | |
| 1 |  | Research will be conducted in established or commonly accepted educational settings (e.g. schools, training centers) involving normal educational practices, such as research on instructional strategies or research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods. The activities in which the students engage will be practices that would occur in the absence of any research. Interacting with students about those educational practices (surveys, interviews, etc.) would disqualify research from being exempt within this category. | | | |
| 2 |  | Research will involve the use of 1) educational tests (e.g. cognitive, diagnostic, aptitude, achievement) OR, 2) survey procedures OR, 3) interview procedures (which includes focus groups) OR, 4) observation of public behavior uninfluenced by the research.  **Check the appropriate boxes below**  This category can only apply if:  This research will not include subjects less than 18 years of age OR  the research involves the observation of public behavior and the researcher will not participate in the observed activity (no surveys or interviews and no videotaping of students during instruction)  AND EITHER:  information obtained will be recorded in such a manner that subjects could not be identified directly or through information obtained that could be used to identify the subject. (Note: Audio Recording of subjects is considered and identifiable record)  OR:  any disclosure of the subjects’ responses outside the research could not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects’ financial standing, employability, reputation, or put them at risk of disciplinary action at Cedarville University. | | | |
| 3 |  | Research will involve the use of educational tests survey procedures, interview procedures, or observation of public behavior that is NOT exempt under category 2 but is exempt in this category because:  the subjects will be elected or appointed public officials or candidates for public office OR,  federal statutes require without exception that confidentiality of collected information must be maintained beyond the end of the research (e.g. course grades). | | | |
| 4 |  | This research involves the study of existing data or specimens and:  the data is publicly available OR  CU researchers have never or will never have access to data with subject identifying information (original collected data may have identifiers but it must be edited before CU researchers have access and the data must arrive on campus without identifiers to qualify). | | | |
| 5 |  | This research will be funded or conducted at the request of, and approved by the head of a federal agency for the purpose of studying:  A public benefit or service program, OR:  Procedures for obtaining benefits or services under a program, OR:  Changes in payment or alternatives to a public benefit or service program. | | | |
| 6 |  | This research involves taste and food quality evaluation and consumer acceptance studies where:  wholesome foods without additives are consumed OR:  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. | | | |

Research approved as being exempt from IRB review generally do not require additional information beyond the general project information (Form IRB-A) and this Request for Exempt Status. Additional information may be requested to verify the status of your proposal as exempt.

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|  | | **Request for Expedited or Full Review (IRB-C)**  **Institutional Review Board**  **for Human Subjects Research** | (For Committee Use Only)  IRB Proposal #: |
| **Lead Investigator Name:** |  | | |
| **Project Title:** |  | | |
| All research involving human subjects must be submitted to the Institutional Review Board for review and approval prior to implementation. If the research is not found to be exempt from review, the principal investigator must submit general project information (Form IRB-A) and a request for Expedited or Full Review (IRB-C), to the Committee. We do this for the purpose of documenting all research on human subjects, for the protection of human subjects and the researchers. | | | |
| **Subject Population:**  Will any of the following categories of individuals be included in your study? (check all that apply)  Children under the age of 18  Prisoners  Pregnant Women  Research outside the United States  Drug research in human populations  VA Hospitals  Fetuses in Utero  Research in clinical populations where HIPPA applies (e.g. medical, psychiatric) | | | |
| **Research Subjects - Additional Information: Considering what was listed on Form A, provide any additional information required to ensure full information on your subjects including, but not limited to the following questions: What are the proposed demographics of your subjects (include criteria that would include or exclude subjects)?; What incentives are being provided to participate?; If randomization is used, how is it ensured?** | | | |
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| **Procedures - Considering what was listed on Form A, provide any additional information required to ensure full information on your procedures including, but not limited to the following questions: Describe each treatment and control condition; How would the researcher respond to evidence of discomfort or emotional distress?; Attach copies of all instruments, survey forms, interview questions, participant instructions, etc.;** | | | |
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| **Data Retention – Describe how data from the research will be maintained and disposed of after the study. What expectations can subject have regarding confidentiality (potential for disclosure of personal information to others) and privacy (control over the extent, timing, and circumstances of sharing oneself [physically, behaviorally, or intellectually] with others).** | | | |
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| **Participant Informed Consent – Participants must understand the risks and benefits of participation; must be aware of recourse they may have if harm should occur (counseling, medical assistance); must agree to participate freely; must understand that they may discontinue participation at any time during their participation without penalty. Please attach any statements of informed consent that will be provided to participants and how explain researchers will ensure the understanding of that consent (verbal explanation, signature, etc.)** | | | |
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| **Assent of Minors – If minors are involved in the study Informed Consent must be obtained from a parent or guardian and detailed above. In addition, the minor must provide assent to participate in some form. Provide information on how that assent is obtained.** | | | |
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