**Human Research Application**

**Section A: Project Information**

1. **Title of Project:**
2. **Application Type:**

New Project

Resubmission of Withdrawn Project

Continuing Project (Previous IRB number:      )

1. **Principal Investigator:**

(There is only one principal investigator. List the primary contact person as the PI. Include a copy of human subjects research training certificate in the addendum.)

Name:

Title:

Department Name:

Mailing Address:

Phone:        E-Mail:

1. **Co-Principal Investigator:**

(For student project, thesis, or dissertation, the faculty supervisor serves as the Co-PI.

If you are not affiliated with CSU, then you must list a faculty member as the Co-PI. Include a copy of human subjects research training certificate in the addendum.)

Name:

Title:

Department Name:

Mailing Address:

Phone:       E-Mail:

1. **Indicate whether personnel from an approved lab setting will be involved in this research.**

Yes  No

**B) If *Yes*, identify the name of the approved lab:**

1. **Other Personnel of the Research Team:**

(If additional space is needed, insert more rows in the table. Include a copy of human subjects research training certificates for all listed personnel in the addendum.)

|  |  |
| --- | --- |
| **Name** | **Email** |
|  |  |
|  |  |

1. **A) Do any of the Investigators or Other Personnel listed in this application have a real, potential, or perceived conflict of interest associated with this study?** (See the [FAQ webpage](http://research.columbusstate.edu/irb/faq.php) for more information.)

Yes  No

**B) If *Yes*, identify the individual(s) and explain:**

(The conflict must be disclosed in the informed consent process.)

1. **What is the expected duration of the project?**

**Section B: Project Summary**

**Within 100 words, clearly describe the purpose of the study using lay terminology.**

**Section C: Human Research PARTICIPANTs**

1. **Number (or Range) of Participants Needed:**
2. **Age of Participants:**

under 18 (Specify age(s):      )

18 to 64

65 and older

1. **Identify the criteria for including, or selecting, participants.**
2. **A) Are there any criteria for excluding potential participants?**

Yes  No

1. **If *Yes*, identify the criteria for excluding potential participants.**
2. **A) Indicate whether any of these groups will be targeted participants.** (Check all that apply.)

Pregnant women, neonates, or fetuses

Prisoners

Individuals who are cognitively impaired

Individuals who are economically disadvantaged

Individual who are mentally ill

Individuals who are terminally ill

Individuals who have HIV or AIDS

Individuals who have limited English proficiencies

**B) Explain the justification for targeting the group(s) checked above in this research project.**

**C) What additional safeguards will be added to protect the rights and welfare of these groups?**

1. **A) Do you plan to target individuals who belong to a particular gender, racial, or ethnic group?**

Yes  No

1. **If *Yes*, specify the targeted group(s) and explain the justification for targeting the particular group(s) in this research project.**
2. **What is your current and/or future relationship to the participants?**

**Section D: Recruitment Procedures**

1. **How will the participants be recruited?** (Check all that apply.)

In person  Printed Materials  Television/Radio

Phone call  Letters  Listserv/Email

Social Media/Web-based  SONA  Other (Specify:     )

1. **Describe when, where, and how participants will be initially contacted for each method selected in #1 above.** (Attach a copy of any printed and/or electronic materials that will be used for recruiting in the addendum.)
2. **Describe any follow-up recruitment procedures for each method selected in #1 above.** (Attach a copy of any printed and/or electronic materials that will be used for recruiting in the addendum.)
3. **A) Will participants receive any incentives and/or compensation for their participation?**

Yes  No

1. **If *Yes*, describe amount and quantity:**

**Section E: Informed Consent Process**

1. **Describe the specific procedures (i.e., how, where, and when) for obtaining informed consent.** (Use provided templates available on the CSU IRB website to create an informed consent form(s) and attach a copy in the addendum. Studies involving minor participants must include parental consent and minor assent.)
2. **If applicable, provide justification for requesting a waiver to document informed consent.** (*See the* [*FAQ webpage*](https://aa.columbusstate.edu/research/irb/faq.php) *for more information.*)

**Section F: outside performance site**

1. **A) Does this project involve any collaborating institution and/or performance site outside of the CSU campus (e.g., local public school, participants’ workplace, military base, or hospital)?**

Yes  No

1. **If *Yes*, list all institutions and sites involved with this research project.**

(If additional space is needed, attach a separate sheet as an addendum. For each listed site, attach a Letter of Cooperation **written on the institution’s letterhead** and signed by the appropriate authorized official(s) in the addendum. See the [FAQ webpage](https://aa.columbusstate.edu/research/irb/faq.php) for more information.)

|  |  |  |
| --- | --- | --- |
| **Name of Institution** | **Location (City, State)** | **written permission and/or current IRB approval** |
|  |  | Attached  Pending |
|  |  | Attached  Pending |
|  |  | Attached  Pending |
|  |  | Attached  Pending |
|  |  | Attached  Pending |

**Section G: Methods**

1. **Basic Design and Procedures**

**Outline the research project procedures in concise and sequential lay terminology. The outline should include the basic design and the sequence of procedures the participants will follow from their entry through their completion of the project.**

1. **Description of Data Collection / Instrumentation**

**For each item selected, you must address all of the required components.** (Check all that apply.)

Physiological, Anthropometric, Specimen, or related Measurements (e.g., EEG, body composition, blood, and urine)

*Describe the procedure used to conduct each measurement. For specimen samples (e.g. blood) make sure to include the frequency of collection, amount for each collection, and total volume to be collected.*

Document and Artifact Collection

*Describe any documents or artifacts (e.g., historical papers, educational records, or student writing samples) that will be collected and used.*

Behavioral Observations (e.g., classroom observations)

*Describe the*

* *focus,*
* *duration,*
* *number of observations,*
* *and how the observations will be recorded*.

Survey, Interviews, and Questionnaires (Attach a participant copy of each measure in the addendum. If your survey, interviews, and questionnaires will be administered online, you must answer the Internet Surveys and Research section below.)

*For each measure, describe*

* *setting,*
* *mode of administration,*
* *and anticipated duration.*

Internet Surveys and Research

*Describe the measures*

* *that will be taken to ensure security of data transmitted over the internet (e.g., internet surveys)*
* *to remove IP addresses*
* *and to protect from unauthorized access.*

Audio or Video Recording

*Describe the setting and anticipated duration.*

1. **Is it possible for any of the collected data to be used for future research projects?**

Yes  No

**Section H: Risks and Benefits**

1. **A) Estimate the level of risk for participants.**

|  |  |  |  |
| --- | --- | --- | --- |
| **Potential Risk** | **Not applicable** | **No More than Minimal Risk** | **Greater than Minimal Risk** |
| 1. Physical |  |  |  |
| 1. Psychological |  |  |  |
| 1. Social or Economic |  |  |  |
| 1. Use of deceptive technique |  |  |  |
| 1. Other (Specify:      ) |  |  |  |

1. **If any of the above risks are greater than minimal risk, describe the severity and likelihood of the indicated risk(s).**
2. **Explain what steps will be taken to reduce the impact of the indicated no more than minimal and/or greater than minimal risks and protect the participant’s welfare.**
3. **Describe the potential benefits to the participants as a direct result of this research project. (*Note:* Compensation is not considered a benefit).**
4. **Describe the potential benefits to research or practitioner community a direct result of this research project.**

**Section I: Confidentiality of Data**

1. **A) Will demographic information be collected?**

Yes  No

1. **If *Yes*, list all demographic information that will be collected.** (Check all that apply.)

gender  racial classification  age

education level  employment status  Other (Specify:     )

1. **If *Yes*, describe how the information will be used.**
2. **A) Indicate the degree of confidentiality.** (See the [FAQ webpage](https://aa.columbusstate.edu/research/irb/faq.php) for more information.)

De-identified

Anonymous

Coded – Indirect

Coded – Direct

Data will not be confidential.

1. **If the *data will not be confidential*, explain the rationale.**
2. **If the *data will be de-identified*, explain the procedures for completing that process.**
3. **If *indirect or direct coding*, indicate**

* **in what format (e.g., paper or electronic files) will the data be kept,**
* **where will the data will be stored,**
* **how long will the data will be stored,**
* **and how the data will be destroyed.**

1. **If *indirect or direct coding*, explain why it is necessary to keep indirect or direct identifiers.**
2. **If *indirect or direct coding*, identify who will have access to the coding and/or individually identifiable information.**

**Section J: Electronic Signatures**

The Research Team, including the Principal Investigator, Co-Principal Investigator, and other personnel, must read and comply with all Columbus State University Institutional Review Board (IRB) Policies and Procedures. In addition, they must abide by all federal, state, and local laws regarding protection of human subjects in research. As the Principal and Co-Principal Investigators, if applicable, you agree to follow these governing guidelines that include, but not limited to, the following policies and procedures. Failure to follow these guidelines may result in delays with the processing of this application and/or future applications.

1. Complete the Human Subjects Research training and submit a training certificate as an addendum.
2. Merge all addendums into one file.
3. Begin recruitment and data collection after receiving notification of final IRB approval.
4. Obtain approval from the IRB prior to instituting any change in project protocol.
5. Obtain informed consent from all participants, and legal parent or guardian, prior to commencing this research study when applicable.
6. Maintain copies of all records and signed consent forms, if required, from each participant for the duration of the project.
7. Notify the IRB regarding any adverse events, unexpected problems, or incidents that involve risks to participants and/or others.
8. Submit the Final Report Form within 12 months from the date of IRB approval using the template available on the CSU IRB website (if applicable).

**If this research study is a student-led project, the Co-Principal Investigator, the student’s faculty supervisor, must agree to complete the following tasks prior to the submission of the Human Research Application:**

* Collaborate with the student to develop the research study.
* Read and review this application with its addendums for content and clarity.
* Guide and oversee the procedures outlined in this application.
* Ensure that all of the Research Team responsibilities are fulfilled.

**Principal Investigator’s Email Address as an electronic signature.** (For authentication purposes, the email address must match the email address on file with Columbus State University.)

Email Address:       Date:

**Co-Principal Investigator’s Email Address as an electronic signature.** (For authentication purposes, the email address must match the email address on file with Columbus State University.)

Email Address:       Date: