

Institutional Review Board

500 Rutherford Ave

Boston, MA 02129

Phone: 617-873-0490

**Application for Approval to Conduct Research Involving Human Participants**

Before completing this application, please read the *Application Instructions* and *Policies and Procedures for Human Research Protections* to understand the responsibilities for which you are accountable as an investigator in conducting research with human participants. The document, *Application Instructions*, provides additional assistance in preparing this submission. *Incomplete applications will be returned to the investigator.*

*If this research is related to a grant, contract proposal or dissertation, a copy of the full grant, contract proposal or dissertation proposal must accompany this application.*

**REQUIRED TRAINING FOR RESEARCH INVOLVING HUMAN PARTICIPANTS**

 Cambridge College requires the completion of the NIH Office of Extramural Research training for all human subject
 research. Ongoing education in the ethical treatment of research participants, the components of informed consent,
 and the handling of research materials and data is an important component of research and scholarship.

 Upon successful completion of the training, print out 2 copies of the **COMPLETION CERTIFICATE** for your
 records. Please save an electronic copy of the completion certificate before you log off so that you can submit it via
 email. This certificate is required to document that you completed the online course and will be filed with your
 approved consent form and other materials.

 **Principal Investigators, student researchers and key personnel (participants who contribute substantively to the
 scientific development or execution of a project) must include a copy of their certificate of completion for this
 training with this application.**

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[ ] Certificate(s) Attached

 [ ]  Certificate(s) submitted previously – on file with the Cambridge College IRB (training that is more than 2 years old must be renewed)

**1. Title of Research Project**

**2. Contact Information for Principal Investigator (PI). In instances where the PI is a student, research will require oversight by CC faculty or administrator.**

|  |  |
| --- | --- |
| PI Name |  |
| Email address |  | Phone |  |
| Name of Organization, including School Division/Department |  |
| Status | [ ] Cambridge College Faculty/Staff [ ]  Cambridge College Student\* [ ]  Other     **\*If student: [ ]** Undergraduate Student [ ]  Graduate Student [ ]  Doctoral Student |

**3. Members of the Research Team (If more than 3, attach separate sheet with information requested)**

|  |  |  |  |
| --- | --- | --- | --- |
| Name |  | Role | [ ]  Co-PI [ ]  Research Team Member  |
| Email address |  | Phone |  |
| Name of Organization, including School Division/Department |  |
| Status | [ ] Cambridge College Faculty/Staff [ ]  Student\* [ ]  Other      \*If student: **[ ]** Undergraduate Student [ ]  Graduate Student [ ]  Doctoral Student |

|  |  |  |  |
| --- | --- | --- | --- |
| Name |  | Role | [ ]  Co-PI [ ]  Research Team Member  |
| Email address |  | Phone |  |
| Name of Organization, including School Division/Department |  |
| Status | [ ] Cambridge College Faculty/Staff [ ]  Student\* [ ]  Other      \*If student: **[ ]** Undergraduate Student [ ]  Graduate Student [ ]  Doctoral Student |

|  |  |  |  |
| --- | --- | --- | --- |
| Name |  | Role | [ ]  Co-PI [ ]  Research Team Member  |
| Email address |  | Phone |  |
| Name of Organization, including School Division/Department |  |
| Status | [ ] Cambridge College Faculty/Staff [ ]  Student\* [ ]  Other      \*If student: **[ ]** Undergraduate Student [ ]  Graduate Student [ ]  Doctoral Student |

**4. Purpose of Project (select one)**

[ ]  Dissertation Research [ ]  Master Thesis Research [ ]  Undergraduate Capstone Project [ ]  Other Research

**5. Anticipated Start and End Dates of Project**

Approximate start date: Approximate end date:

[ ]  Federal Funding Agency [ ]  Non-Federal Sponsor [ ]  Other Funding Source

Name of external funding agency, if applicable:

**7. Is your project funded by an external sponsor, including a gift or a sponsored award?** [ ]  Yes [ ]  No **If yes, provide the following:**

**It is the policy of Cambridge College that no activity involving human subjects be undertaken until those activities have been reviewed and approved by the College's Institutional Review Board (IRB).**

**Part 2: Study Design, Data Collection Methods, and Procedures**

**Please answer each of the following questions using non-technical language. Missing or incomplete answers will delay your review while we request the information.**

**1. Provide a lay summary of the purpose of your research study. Avoid scientific jargon and acronyms. Do not simply cut/paste from your research proposal.**

**2. State your research question(s) and related hypotheses.**

**3. Provide a detailed description of everything the participant will be asked to do and/or experience. Include the location, number of sessions/observations/visits, time for each session, and total time period anticipated for each participant, including any long term follow up. A copy of all research instruments (surveys, questionnaires, etc.)** **that will be used and permissions for use of these instruments (if they are not the intellectual property of the student researcher) must be provided.**

**4. Who will conduct the experiment or administer the interview or questionnaire?**

**5. How will research participants’ responses be captured? This information must be included on the consent form.**

 [ ]  Audio only [ ]  Video (includes audio) [ ]  Face-to-Face [ ]  Online

 If Audio, Video or Online, describe to tools that will be used (Cell phone, Zoom, Survey Monkey, etc.):

**Part 3: Participants, Recruitment and Compensation**

**1. Describe the human participants of the study, including the following information: the age ranges of participants, the # of participants that will be included in the study, the countries that they reside in, and other descriptive information that is relevant (i.e. organization affiliation, position titles, industry, etc.).**

[ ]  Healthy adult volunteers [ ]  Cognitively impaired persons [ ]  Cambridge College students

[ ]  Pregnant or nursing women [ ] People with limited literacy [ ]  Cambridge College employees

[ ]  Children under the age of 18 [ ]  People with specific health conditions [ ]  People in foreign countries

[ ]  People unable to read, speak or understand English

[ ] Prisoners or individuals under detention or on probation

[ ]  Other category of participants not listed here Please explain:

**2. Please select all the categories of participants that will be included in your study.**

**3. Describe your relationship with the research participants** **(co-workers, subordinates, former co-workers, etc.) and/or the hosting organization, if any.”**

**4. Do you have permission from the hosting organization (if any) to conduct research on their premises and/or within their organization? [ ]  Yes [ ]  No** **If yes, attach letter/forms**

**5. What are the inclusion criteria (*characteristics that must be met) for individuals to be enrolled in study?*** Describe the participants you intend to recruit. Include gender, ethnicity/race, socio-economic level, literacy level and health (as applicable) and reasons for excluding any group.

[ ]  Printed flyers [ ]  Face to face recruitment [ ]  Notices [ ]  TV, radio, print advertisements

[ ]  Email [ ]  Online advertisements [ ]  Mailers (U.S. Post) [ ]  Presentations at meetings

[ ]  Internet, social media or online networking sites

[ ]  None **or** Other tools not listed here Please explain:

**6. Identify all tools that you plan to use to recruit your participants. Copies of all recruitment materials (letters, posters, fliers, ads, website, email, scripts for telephone recruitment etc.), must be attached to this application for stamped approval.**

**7. Describe the procedures that you will use to recruit these participants.** How will participants be identified? Who will ask for participation?

**8.** **Will participants receive monetary compensation, or will material resources/incentives be used to gain or reward participation?** **[ ]  Yes** **[ ]  No If yes, describe them:**

**Part 4: Risks and Benefits**

 [ ]  Use of deception / deceptive techniques [ ]  Risk of injury or bodily harm

 [ ]  Identification of child, spousal, or elder abuse [ ]  Identification of illegal activity

 [ ]  Possible invasion of privacy of subject or subject’s family

 [ ]  Use of private records (i.e. educational or medical records)

 [ ]  Manipulation of psychological or social state such as sensory deprivation, social isolation, psychological stress

 [ ]  Probing for personal or sensitive information in surveys or interviews (e.g., private behaviors, drug use)

 [ ]  Presentation of materials which some participants may consider sensitive, offensive, threatening or degrading

 [ ]  Presentation of materials or questions that might elicit traumatic memories

 [ ]  Social or economic risk (reputational, cultural, financial costs, employability, etc.)

 [ ]  Other risks not listed here. Please describe:

 [ ]  There are no risks of any kind to any participants enrolled in this study.

**1. From the list below, please select ALL of the potential risks of participating in your study.**

**2. Describe the nature and degree of the risks or harms selected above.** All of the risks/harms must be disclosed in the consent form. Consider possible psychological harm, loss of confidentiality, financial, social, or legal damages as well as physical risks. What is the seriousness of these risks and what is the likelihood that they may occur?

**3. Describe the steps that will be taken to minimize any harm and to protect the welfare of participants.** Include a description of how you will handle any unexpected adverse outcomes that could be potentially harmful (for example, discovering that a participant is thinking about suicide). What follow-up procedures are in place if harm occurs? What special precautions will be instituted for vulnerable populations?

**4. Describe any personal benefits that participants may reasonably expect from his/her involvement in the research.** Do not exaggerate potential benefits. If there are none, state "None."

**5. Briefly describe the anticipated benefits of this study to society, academic knowledge or both.**

**Part 5: Privacy and Confidentiality**

[ ]  Name [ ]  Social Security number [ ]  License, certificate of vehicle ID

[ ]  Date of birth [ ]  Phone or fax numbers [ ]  Signatures, handwriting samples

[ ]  Biometric identifiers [ ]  Medical records [ ]  Photos, images, audio recordings

[ ]  Mailing or email address [ ]  IP address (often automatically collected by online survey tool)

[ ]  Any unique identifiers not mentioned above. Please explain:

[ ]  No member of the research team will have access to any personal identifiers.

**1. Will you or any member of your research team collect or have access to any of the personal identifiers listed below? Please check all that apply.**

**2. How will you protect any personal information you plan to collect? Describe *in detail* the procedures that will be used to maintain anonymity or confidentiality during collection and entry of data. Who will have access to data? How will the data be used, now and in the future?**

**3. How and where will data be stored? When will data, including audiotapes and videotapes, be destroyed? If data is to be retained, explain why. Will identifiers or links to identification be destroyed? When? Signed consent documents must be retained for 3 years following the end of the study. Where and how will they be maintained?** *For NEIB students, electronic copies of data and informed consent forms are stored in the IRB100 course within the Canvas LMS and are automatically deleted after 5 years.*

**Part 6: Consent Process**

**1. Describe the process of obtaining informed consent.** Be specific. How will the project and the participants’ role be presented to potential participants? By whom? When? Where? In most cases, participants should be asked to read and sign a consent statement only after the researcher provides a detailed oral explanation and answers all questions. The template for informed consent should be customized to reflect the particulars of this study. Attach a copy to this application. A copy of the form used to document consent must be given to the person signing the form.

**2. If your study population includes non-English speaking people, translation of consent information is necessary.** Describe how information will be translated and by whom. You may wait until the consent form is approved in English before having it translated.

**3. If your population includes prisoners, people with limited mental capacity, language barriers, problems with reading or understanding, or other issues that may make them vulnerable or limit their ability to understand and provide consent, describe special procedures that you will institute to obtain consent appropriately.**

**4. Do you plan to recruit children under the age of 18? [ ]  Yes** **[ ]  No Describe how you will obtain assent for children under the age of 18.** If your population includes children under the age of 18, you must ask for parental permission before attempting to recruit a child into your study. Once you obtain parental permission, children must be given the opportunity to provide assent.Templates for the Parental Permission Form and Child Assent Form are available at the IRB website.

**5. Describe procedure for participants who want to withdraw from the study. If data was collected from a participant who withdraws, describe the process, if any, for destruction of data collected from this participant.**

**6. Describe the steps that will be taken to minimize the possibility of coercion or undue influence.**

**7. If incomplete disclosure of the purpose of your study is essential to carrying out the proposed research, please provide a detailed description of the debriefing process.** Be specific. When and by whom will full disclosure of the research goals be presented to participants (e.g., immediately after the completion of all research task(s) or after the completion of the study’s data collection)? Attach a copy of the written debriefing statement that will be given to research participants.

**8. Attachments: Place a check mark next to attachments that have been included.**

*[ ]* Dissertation, research or grant proposal [ ]  Copies of IRB approvals or letters of permission from other sites

[ ]  Parental Permission Form [ ]  Scripts of intended telephone conversations

[ ]  Child Assent Form [ ]  Debriefing Statements

[ ]  Informed Consent Forms [ ]  Letters of Permission to Use Research Instruments

[ ]  Letter of Permission from Host Organization

[ ]  Copy of fliers, ads, posters, emails, web pages, letters for recruitment

[ ]  Copies of all instruments, surveys, focus group or interview questions, tests, etc.

[ ]  NIH Human Subject Training Certificate(s) for all members of research team *(if not already on file at HSRP)*

**Signature(s)**

**The attestation below is to be signed by the person(s) conducting the research. If this person is a student, the faculty member supervisor must also sign in the lower box. Click on the attestation box below, entering your name and today’s date. If there is more than one Principal Investigator,**

 **Principal Investigator**

 I certify that the information I provide in this application is correct and complete. I also pledge that I will not change
 any of the procedures, forms, or protocols used in this study without first seeking review and approval from the
 Cambridge College Institutional Review Board.

 [ ]  Attestation of Investigator

 Date Name / Signature of Investigator

**Faculty Supervisor or Program Chair or Dean (required when student is Principal Investigator)**

 I certify that the information provided in this application is correct and complete to the best of my knowledge.

 [ ]  Attestation of Faculty Supervisor

 Date Name / Signature of Faculty Supervisor/Program Chair or Dean

 **IRB School Supervisor**

 I approve this submission for official review by the IRB Director of Academic Compliance and Strategic Initiatives.

 [ ]  Attestation of IRB School Supervisor: DBA: Dr. Donna Viens, PhD: Dr. Daniel Almedia

 Date Name / Signature of Faculty Supervisor

**IRB Director of Academic Compliance and Strategic Initiatives**

I have reviewed this application as submitted and rule that the research:

* Meets the conditions and has been deemed EXEMPT and is approved
* Qualifies for the EXPEDITED review by a designated review team.
* Requires FULL BOARD and Committee Review due to the nature of the research.
* Rejected

[ ]  Attestation of the IRB Compliance Director

 Date Name / Signature of IRB Compliance Director

**SUBMISSION INSTRUCTIONS**

1. **Prior to submission, carefully review the form to ensure that it is filled out completely and accurately.**
2. **Submit an electronic copy of this application, along with all required attachments to the Faculty Supervisor or Program Dean for approval.**
3. **The email submission must come from your Cambridge College email account.**

**Research compliance requirements are determined by the IRB Co-Committee Chairpersons and are considered final on the date signed.**

**This approval is revoked if changes in the participants' demographics, data, data collection methods, and other pertinent details attested herein are changed.**