**Purpose:** This application is designed to facilitate the Institutional Review Board (IRB) review of proposed human subjects research. The IRB serves to protect the rights and welfare of human subjects in research in accordance with federal, state, and institutional regulations and policy.

**Instructions:** Complete this application as part of the initial protocol submission. A complete protocol submission initiates the IRB review of research involving human subjects. Incomplete or unreadable applications will extend the IRB review process. Submit this application (including the checklist below) and all applicable research materials (research protocol, attachments, consent form(s), surveys, interview guides, etc.) using the [insert website link]. Direct any question regarding this form or human subjects research to the IRB by email at or phone (910) 893-7780. Save this form before proceeding. When you have completed and saved this form please submit using the following link: <https://cphsadmin.wufoo.com/forms/zkthc20k1gury/>.

Effective 3/1/2019 all initial protocol submissions will require project personnel to indicate that research personnel have completed human subjects research training.

**Submission Date:** Click or tap to enter a date.

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| **Section 1: Project and Investigator Information** | | | |
| Project Title: Title | | | |
| Principal Investigator (PI): | Name | School/Department: | School/Department |
| PI CU Email: | Email address | PI Telephone: | Number |
| Role at CU: | Role | If other, specify role: | Text |
| Faculty Advisor: | Name | Faculty Advisor Department: | Department |
| Faculty Advisor CU Email: | Email address | Faculty Advisor Telephone: | Number |

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| **Section 2: Introduction** |
| 2.1 Briefly describe in lay language the purpose of the proposed research (include objectives and aims) and why it is important. |
| Click or tap here to enter text. |
| 2.2 If student research, indicate whether for a course, thesis/dissertation, capstone project, or independent research. |
| Click or tap here to enter text. |
| 2.3 Provide the anticipated start and end date for human subject research (month and year): |

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| Start (month and year): | Month & Year | End (month and year): | Month & Year |

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| **Section 3: Subject Population and Recruitment** |
| 3.1 Please list your estimated maximum enrollment/sample size. |
| Click or tap here to enter text. |
| 3.2 Describe in detail how subjects will be recruited (please include if you will be accessing or using identified information). See the [CU IRB webpage](https://www.campbell.edu/about/leadership/provost/institutional-review-board/) for further details on using identified information for recruitment, Letters of Support, etc. Please attach all recruitment materials (scripts, flyers, ect.) to the electronic application form. You may be required to complete a [Request for an Alteration/Waiver of Consent Process](https://assets.campbell.edu/wp-content/uploads/2018/12/Request-for-Alteration-Waiver-of-Consent-Process.docx), [Request for an Alteration/Waiver of HIPAA authorization](https://assets.campbell.edu/wp-content/uploads/2018/09/Request-for-HIPAA-Alteration-Waiver1.docx). |
| Click or tap here to enter text. |
| 3.3 List specific eligibility criteria for subjects (or describe screening procedures) and how eligibility requirements will be documented, if applicable. |
| Click or tap here to enter text. |
| 3.4 List specific exclusion criteria, if applicable. |
| Click or tap here to enter text. |
| 3.5 Is there any relationship between the Principal Investigator and the research subjects? (i.e., teacher/student, employer/employee, physician/patient) |
| Click or tap here to enter text. |
| 3.6 Vulnerable Populations (check any vulnerable populations targets, not incidental) included in the project:  minors (under age 18) - if so, have you included a line on the consent form for the parent/guardian signature  fetuses  pregnant women  persons with mental, psychiatric or emotional disabilities  persons with physical disabilities  economically or educationally disadvantaged  prisoners  elderly  students from a class taught by the principal investigator  subjects with diminished mental capacity  other vulnerable population |
| 3.6.1 If any of the above are used, state the necessity for doing so. Please indicate the approximate age range of the minors to be involved.  Click or tap here to enter text. |
| 3.6.2 Please explain how you will reduce risks associated with working with this vulnerable population. *(Such as reducing coercion, etc.) Signing a consent document does not reduce the potential for coercision.* |
| Click or tap here to enter text. |

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| **Section 4: Consent, Assent, and Permissions** |
| 4.1 Considering all participant groups, indicate the consent/assent process(es) involved in the research (check all that apply). |
| In Person  Remote (e.g., online, phone, etc.)  Other: enter text |
| 4.2 Will the consent process include all the elements of informed consent? |
| Yes  No If “no,” a waiver of informed consent or an alteration of the elements of informed consent must be approved by the IRB. Provide [Request for Alteration/Waiver of the Consent Process](https://assets.campbell.edu/wp-content/uploads/2018/12/Request-for-Alteration-Waiver-of-Consent-Process.docx) must be attached to this submission. |
| 4.3 Will the consent and/or assent process be documented using a written consent form that will be signed by the subject or the subject’s legally authorized representative? |
| Yes  No If “no,” a waiver of documentation of informed consent must be approved by the IRB. |
| 4.3.1 If “no,” check only one:  The only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject will be asked whether to the subjects wants documentation linking the subject with the research, and the subject’s wishes will govern.  Explain: Click or tap here to enter text.  The research present no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally require outside the consent. |
| 4.4 Does this research involve the access, use and/or recording of Protected Health Information (PHI)?  Yes  No If “yes” and if applicable, attach [Request for Waiver of HIPPA required authorization Form](https://assets.campbell.edu/wp-content/uploads/2018/09/Request-for-HIPAA-Alteration-Waiver1.docx) |
| 4.5 Does this research involve the use of CU students’ Personal Identifying Information (PII) that is not included in the CU student directory?  Yes  No If “yes,” submit to the Registrar or owner of the student records for approval. *See* [*CU IRB website*](https://www.campbell.edu/about/leadership/provost/institutional-review-board/) *for further instructions.* |

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| **Section 5: Procedures to be followed.** |
| 5.1 In lay language, describe completely all research activities (chronologically) to be followed during the course of the project. Provide sufficient detail so that the IRB reviewer is able to assess potential risks to human subjects. In order for the IRB to completely understand the experience of the subjects in your project, please provide a detailed outline of all research activities subjects will experience as a result of participating in your project, including how much time will be required of each subject. Please be specific and include information on all aspects of the research, through subject recruitment and ending when the subject's role in the project is complete. All descriptions should include the informed consent process, interactions between the subjects and the researcher, and any tasks, tests, etc. that involve subjects. If the project involves more than one group of subjects (e.g. teachers and students, employees and supervisors), please make sure to provide descriptions for each subject group. |
| Click or tap here to enter text. |

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| **Section 6: Potential Risks** |
| 6.1 Detail the potential risks (psychological, social, physical, financial, legal or other) connected with the proposed procedures and explain the steps taken to minimize these risks. *There is always the potential for minimal risk in any human subject research project, primarily regarding privacy and confidentiality issues, a response of “NA” or “none” will not be accepted.* |
| Click or tap here to enter text. |
| 6.2 Will there be a request for information that subjects might consider to be personal or sensitive (e.g. private behavior, economic status, sexual issues, religious beliefs, or other matters that if made public might impair their self-esteem or reputation or could reasonably place the subjects at risk of criminal or civil liability)?  Yes  No |
| 6.2.1 If “Yes”, please describe and explain the steps taken to minimize these risks.  Click or tap here to enter text. |
| 6.3 Could any of the study procedures produce stress or anxiety, or be considered offensive, threatening, or degrading?  Yes  No |
| 6.3.1 If “Yes”, please describe why they are important and what arrangements have been made for handling an emotional reaction from the subject.  Click or tap here to enter text. |
| 6.4 How will research materials and data be recorded and stored? |
| *Please be specific. The IRB requires that all research materials be stored and maintained in a locked CU room, on a CU secured computer/server, or in an IRB dedicated protocol Egnyte file. All research materials are to be maintained for a minimum of 3 years following the completion of research activities and be readily accessible to the CU IRB or other agencies for auditing purposes. The IRB highly suggests the use of password protected file(s) and encryption. Research materials are not to saved or maintained on personal computers or portable drives. The use of Google Forms and Files does not meet IRB data security requirements and their use will not be approved. Please use Qualtrics or SurveyMonkey when applicable.* |
| Click or tap here to enter text. |
| 6.5 Use if identifiers – indicate the level of “subject identification” you require to **BEGIN** this work |

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| * If any element of your records, data files, or administrative records contains an identifier, you should select Identified Data. * If you plan to de-identify data at any time other than the first day you access the information, you should select Identified Data. * If different levels apply, choose the “most identified” one, e.g., if level A and level B apply, choose level A. |
| **A** – **IDENTIFIED DATA:** Utilizes one or more identifiers, including those defined by HIPAA Privacy Rule but not using a “limited data set” or defined by FERPA regulation.  **B** – **CODED DATA, KEY held by project team:** Data is coded; **and** key code held by any person at CU whether or not they are part of the project team.  **C** – **CODED DATA, KEY not held by project team:** Data is coded; key code not held by any CU faculty member, employee, fellow, resident, or student; key code not held by any member of the project team; **and** the key code will never be accessible to any member of the project team.  **D** – **LIMITED DATA SET**: The only HIPAA identifiers utilized are dates or certain allowable geographic subdivisions; an IRB “limited data set” data use agreement has been executed by the PI; and is uploaded into this IRB application.  **E** – **DE-IDENTIFICATION PROCESS:** The IRB application describes how the project will de-identify data in one of two approvable methods: 1) reliance on a CU-sanctioned “honest broker” or 2) receiving coded data/biospecimens without identifiers and without a key code. To use these two options, no code keys may be created or saved and the resulting dataset can never be re-identified. In addition, a complete list of project variables must be uploaded in the electronic application form.  **F** – **ANONYMIZED**: The investigator receives data in anonymized form and no other party has the potential or re-identify data (i.e., no code key exists anywhere in the world). In this case, the IRB application must include a detailed description of how the data was collected, e.g., anonymous surveys, or who provided the anonymized data or biospecimens, so the IRB can verify the source and the irreversibility of anonymization. In addition, a complete list of variables, e.g., data recording sheet, Case Report Form, anything that summarizes all the information that will be recorded, must be included in the electronic application form.. |
| 6.6 How will identifiers be used in the research materials?  Click or tap here to enter text. |
| 6.7 How will reports be written? *(In aggregate terms, or will individual responses be described)*  Click or tap here to enter text. |
| 6.8 If audio, video or image recordings are collected, will you retain or destroy the recordings? How will recordings be stored during the project and after, as per your destruction/retention plans.  Click or tap here to enter text. |
| 6.9 Will anyone besides the PI or the research team have access to the data from the moment they are collected until they are destroyed.  Yes  No |
| 6.9.1 If “yes,” explain: Click or tap here to enter text. |

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| **Section 7: Use of deception** |
| 7.1 Is there any deception of the human subjects involved in this project?  Yes  No |
| 7.1.1 If “yes,” please describe why it is necessary.  Click or tap here to enter text. |
| 7.1.2 Will you be requesting prospective approval from research participants? *(Orally or with written consent document)*  Yes  No  7.1.2.1 If “no,” explain: Click or tap here to enter text. |
| 7.1.3 Please describe debriefing procedures:  Click or tap here to enter text. |

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| **Section 8: Potential Benefits** |
| *This does not include any form of compensation for participation.* |
| 8.1 What, if any, direct benefit is to be gained by the subject? If no direct benefit is expected, but indirect benefit may be expected (knowledge may be gained that could help others), please explain. |
| Click or tap here to enter text. |

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| **Section 9: Compensation** |
| *Please keep in mind that the logistics of providing compensation to your subjects (e.g., if your business office requires names of subjects who received compensation) may compromise anonymity or complicate confidentiality protections. If, while arranging for subject compensation, you must make changes to the anonymity or confidentiality provisions for your research, you must contact the IRB office prior to implementing those changes.* |
| 9.1 Describe compensation *(For information regarding cash or gift cards for use as compensation see CU website for* [*Use of Gift cards as Compensation*](https://assets.campbell.edu/wp-content/uploads/2019/01/Guidance-Use-of-Gift-Cards-as-Compensation.pdf)*)* |
| Click or tap here to enter text. |
| 9.2 Explain compensation provisions if the subject withdraws prior to completion of the research activities. |
| Click or tap here to enter text. |
| 9.3 Will class credit be given?  Yes  No  NA |
| 9.3.1 If “yes,’ explain: Click or tap here to enter text. |
| 9.3.2 List alternative ways to earn the same amount of credit for students that do not participate in research activities. |
| Click or tap here to enter text. |

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| **Section 10: Project Personnel (effective 4/1/2019)** |
| *All personnel conducting research activities are required to be listed and effective 4/1/2019, have completed human subject research training certification prior to IRB approval. See* [*CU IRB website*](https://www.campbell.edu/about/leadership/provost/institutional-review-board/) *for further information.* |
| 10.1 Will there be any addition staff conducting research activities?  Yes  No |
| 10.1.1 If “yes,” Complete and attach Appendix A: Research Personnel Form |

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| **Section 11: Human Subject Conflict of Interest** |
| * Please see Sponsored Research & Programs website, [Conflict of Interest Policy](https://assets.campbell.edu/wp-content/uploads/2016/12/04170357/Conflict_of_Interest_Policy_Draft_111314.pdf) |
| No conflicts are identified.  Yes, conflicts are identified and are explained for the following individuals:  Click or tap here to enter text. |

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| **Section 12: Additional Information** |
| Please attach all required documents to the electronic submission form. *(Application should include: questionnaires, surveys or interview instruments to be used; consent documents; requests for waivers of consent process or documentation, waiver of HIPAA required authorizations, various appendices, recruitment documents, letters of support, external IRB authorizations, etc.)* |
| List documents here:  Click or tap here to enter text. |

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| * **Continue to Investigator Agreement on following page** |

**Investigator Agreement**

**A. Conduct of Research**

1. I accept responsibility for the ethical conduct of this research and protection of participants as set forth in the Belmont Report, Declaration of Helsinki, the Nuremberg Code, the Common Rule, and the ethical principles of my discipline.

2. I accept responsibility for the conduct of this research ensuring this research is conducted according to:

a. sound research design and methods;

b. the IRB approved protocol including the informed consent process;

c. the applicable terms of the grant, contract and/or signed funding agreements; and

d. applicable laws and regulations, including those for protecting the rights, safety, and welfare of human subjects.

3. I certify that I am or my faculty advisor is sufficiently qualified by education, training, and/or experience to assume responsibility for the proper conduct of this research. I accept responsibility for ensuring that members of this research team, including project staff and trainees, are appropriately qualified, trained and supervised.

4. I accept responsibility to personally conduct and/or directly supervise this research. I certify that I have sufficient time and resources to properly conduct and/or supervise this research for which I am responsible.

**B. Ensuring and Maintaining Compliance**

1. I will comply with relevant regulatory and institutional requirements, including those relating to conflicts of interest, responsible conduct of research and research misconduct.

2. I understand it is my responsibility to ensure that any research personnel, including myself, responsible for the design, conduct, and reporting of research declare any potential conflicts of interests related to the research and to maintain current records. I will ensure changes in conflicts of interest are promptly disclosed to the IRB.

3. I will ensure that informed consent is obtained as approved by the IRB and a copy is provided to participants, unless the IRB waives these requirements.

4. I will obtain initial IRB approval prior to implementing human subject research activities as well as prior approval for any amendments to this research.

5. I will conduct this research within the approval period issued by the IRB. I agree to submit a request of continuing review of this research at least 45 days in advance of the expiration date, if required by the IRB.

6. I will submit a closure report form prior to protocol expiration or within 45 days of completion of all activities involving human subjects or identifiable participant data.

7. I will maintain approval, as applicable, with collaborative entities.

8. I will promptly report to the IRB (no later than 7 days of discovery) any instances of noncompliance with the approved protocol or requirements of the IRB and any unanticipated problems.

9. I will assist in the facilitation of any monitoring and/or auditing of project activities and/or records as required by the IRB, funding entities, sponsors, and any federal and state regulatory agencies.

**C. Investigator Records, Reports and Documentation**

1. I will maintain research records, all protocol materials, and any other documents associated with this research (e.g., research plan, signed consent forms, and IRB correspondence).

2. I will maintain records for at least three years after this research ends, or for the length of time specified in applicable regulations or institutional or sponsor requirements, whichever is longer. I will take measures to prevent accidental or premature destruction of these documents.

3. I will ensure the safe and secure storage of this research data (whether in paper or electronic format) and for protecting the confidentiality of the data in accordance with the approved protocol.

4. I will submit written reports to the IRB and permit inspection of the research records as required by the IRB.

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| * By signing below, the Principal Investigator attests to having read and agrees to uphold the responsibilities and duties as outlined above. In addition, the materials provided in support of this application are an accurate reflection of the proposed research. |
| Click or tap here to enter text. Click or tap here to enter text.  PI Name Date |
| Required for Student Research   * By signing below, the Faculty Advisor attests he/she has read and approves the attached protocol submitted for IRB review. In addition, he/she agrees to provide appropriate education and supervision of the student investigator, and share the Principal Investigator responsibilities as stated above. |
| Click or tap here to enter text. Click or tap here to enter text.  PI Name Date |

**Submit this form by filling out an application for IRB review here:** [**https://cphsadmin.wufoo.com/forms/cu-irb-application/**](https://cphsadmin.wufoo.com/forms/cu-irb-application/)