**Exemption Application**

**SECTION A: Protocol and Contact Information**

**Protocol Title** : enter text **PI Email Address**: enter text

**PI Name and Degrees**: enter text **Preferred Pronoun:** enter text

**Mailing Address:**  enter text **PI Phone Number:**  enter text

**PI Department/Unit:**  enter text [ ]  Kilachand Honors College

**Additional Contact/Faculty Advisor Name:**  enter text **Contact Email:**  enter text

**SECTION B: Additional Study Personnel (add rows as needed)**

[ ]  There are no additional personnel working on the research study.

[ ]  The PI is a student researcher. If yes, a Faculty Advisor is listed below as a co-investigator and has completed the Human Subjects Training requirements.

1. **CRC Investigators and Study Staff:
Note:** BUMC and other non-CRC personnel should be listed below in the Non-BU Investigator/study staff section.

|  |  |  |
| --- | --- | --- |
| **Name, Degree, & BU-affiliated Department, College or School** | **Study Role****(e.g. co-i, research coordinator, RA, etc.)** | **Human Subjects Training** |
| enter text | Principal Investigator | [ ]  CITI: enter date completed[ ]  Other\*:­­­­­­­­­­­­­­­­­­ enter name and date[ ]  GCP\*\*: enter date and provide copy |
| enter text | enter text | [ ]  CITI: enter date completed[ ]  Other\*:­­­­­­­­­­­­­­­­­­ enter name and date[ ]  GCP\*\*: enter date and provide copy |

\*If CITI was not completed, a copy of the training record must be submitted.

\*\*For NIH-funded clinical trials, Good Clinical Practice (GCP) training is required.

For more information on training requirements, please refer to the CRC [Human Subjects Training Policy](https://www.bu.edu/researchsupport/compliance/human-subjects/human-subjects-training/).

**2. BUMC and Non-BU Study Personnel (add rows as needed)\*:**

|  |  |
| --- | --- |
| 1. | **a. Name, Degrees:**  enter text 1. **Study Role:** Choose an item.
2. **Institutional Affiliation:**  enter text
3. **Is the Institution named above** [**Engaged in Research**](https://www.hhs.gov/ohrp/regulations-and-policy/guidance/guidance-on-engagement-of-institutions/index.html)\*\***?** [ ] Yes [ ] No

**If no,** explain the connection of this person to the research**:**  enter text **If yes,** *mark all that apply*[ ]  IRB approval is being obtained from the home institution [ ]  Request for BU CRC IRB to cover this individual’s involvement in this research [ ]  Request a [Reliance Agreement](https://www.bu.edu/research/ethics-compliance/human-subjects/reliance-agreements-for-multisite-studies/) between the BU CRC IRB and the home institution1. **Study Activities:** *mark all that apply*

[ ]  Interaction or intervention with participants [ ]  Access to identifiable data or specimens [ ]  Obtaining informed consent of participants[ ]  Other; describe: enter text 1. [ ]  CITI or other human subjects protection training is attached
 |

\*Find guidance for adding external investigators on our website [here](https://www.bu.edu/research/ethics-compliance/human-subjects/guidance-for-adding-external-investigators/).

\*\*If you are unsure, complete the [Engagement Checklist](https://www.bu.edu/researchsupport/compliance/human-subjects/#reliance-agreements-for-multisite-studies) on our website and then answer this question.

**SECTION C: Funding Information**

[ ]  The research is unfunded.

[ ]  This research is supported by an Industry Contract or Clinical Trial Agreement.

[ ]  Have you received [Just In Time](https://grants.nih.gov/grants/policy/nihgps/html5/section_2/2.5.1_just-in-time_procedures.htm) (JIT) Notification? ☐ Yes ☐ No

[ ]  The research is funded or pending award: **If yes,** complete the table below for each funding source.

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Funding Source** | **Award Status** | **Grant / Award #** | **Period of Support** | **BU Award Status** | **Awardee Institution\*** | **Grant Title if different from Protocol title** |
|  enter text  | Choose an item. |  enter text  |  enter text  | Choose an item. |  enter text  |  enter text  |
|  enter text  | Choose an item. |  enter text  |  enter text  | Choose an item. |  enter text  |  enter text  |
|  enter text  | Choose an item. |  enter text  |  enter text  | Choose an item. |  enter text  |  enter text  |

[ ] The research is funded by more than 3 sources**.** If yes, provide the above information for each funding source via email to IRB@bu.edu.

**\*NOTES:**

* Provide a copy of the grant application, funding proposal, contract/agreement, scope of work, or sub-award agreement supporting the research. If an award is pending, once the funding has been awarded, submit an amendment to the IRB to add the funding source.
* If this research study is for your dissertation, provide a copy of your prospectus (if available).
* If supported by an Industry Contract or Clinical Trials Agreement, submit a copy of the agreement to the IRB office

**SECTION D: Conflict of Interest**

|  |  |
| --- | --- |
| [ ] Yes**(REQUIRED)** | I confirm that **all** those responsible for the design, conduct, or reporting of the proposed research, including at minimum, all Senior/key personnel in the grant application, have completed financial conflict of interest disclosures and training as required by the [BU FCOI Office](https://www.bu.edu/researchsupport/compliance/conflicts-of-interest/) and as provided under [*the Boston University Investigator Conflicts of Interest Policy for Research*](https://www.bu.edu/researchsupport/forms-policies/investigator-financial-conflicts-of-interest-policy-for-research/)*.*  |
| [ ] No [ ] Yes | Have any Investigators or Study staff on the protocol disclosed a Financial Conflict of Interest related to the research? If yes, provide the name of the individual(s): enter text *If yes, the IRB office will contact the FCOI office for more information.* |

**SECTION E: Exemption Categories**

To qualify for exemption, the study must: be [minimal risk](https://www.ecfr.gov/cgi-bin/retrieveECFR?gp=&SID=83cd09e1c0f5c6937cd9d7513160fc3f&pitd=20180719&n=pt45.1.46&r=PART&ty=HTML#se45.1.46_1102), fall into one of the below categories, and may not involve prisoners or be regulated by the FDA (with the exception of # 6).

***Mark all categories that apply:***

[ ]  (1) Research, conducted in established or commonly accepted educational settings, that specifically involves normal educational practices that are not likely to adversely impact students' opportunity to learn required educational content or the assessment of educators who provide instruction. This includes most research on regular and special education instructional strategies, and research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

**Provide the following information below, \*as applicable:** [ ]  **\*Not applicable**

* Submit documentation of the school/organization permission
* If recruitment/enrollment of the PI’s own students, provide the plan for ensuring that the PI will not know which students are participating (e.g. having a co-investigator obtain consent, etc.)
* If the study will take place during regular class/school time, describe the plan for the students who don’t want to participate and for ensuring that the study activities are not a significant deviation in time or effort from regular school/organizational activities enter text

[ ]  (2) Research that only includes interactions involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior (including visu al or auditory recording) if at least one of the following criteria is met:

[ ]  (i) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects;

 **Note: Research activities involving children under this criterion are those involving educational tests, or observation of public behavior where the investigators do not participate in the activity being observed.**

[ ]  (ii) Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; **OR**

 **Note: Research activities involving children under this criterion are those involving educational tests, or observation of public behavior where the investigators do not participate in the activity being observed.**

[ ]  (iii) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination required by §[46.111(a)(7)](https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/revised-common-rule-regulatory-text/index.html#46.111(a)(7)).

**Note: Research activities under this criterion does not apply to research with children.**

[ ]  (3) (i) Research involving benign behavioral interventions in conjunction with the collection of information from an adult subject through verbal or written responses (including data entry) audiovisual recording if the subject prospectively agrees to the intervention and information collection at least one of the following criteria is met:

[ ]  (A) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects;

[ ]  (B) Any disclosure of the human subjects’ responses outside of the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects’ financial standing, employability, educational advancement, or reputation; **OR**

[ ]  (C) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly through identifiers linked to the subjects, and the IRB conducts a limited IRB review to make the determination required by 45 CFR 46.111(a)(7): when appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.

[ ]  (ii)Benign behavioral interventions are brief in duration, harmless, painless, and not physically invasive, not likely to have a significant adverse lasting impact on the subjects, and the investigator has no reason to think the subjects will find the interventions offensive or embarrassing. Examples include playing an online game, solving puzzles under various conditions, and deciding how to allocate a nominal amount of received cash between themselves and someone else.

[ ]  (iii) The research involves deception. If yes, and the research involves deceiving the subjects regarding the nature or purposes of the research, this exemption is not applicable *unless* the subject authorizes the deception through a prospective agreement to participate in research in circumstances in which the subject is informed that he or she will be unaware of or misled regarding the nature or purposes of the research.

 [ ]  (4) Secondary research for which consent is not required: Secondary research uses of identifiable private information or identifiable biospecimens, if at least one of the following criteria is met:

[ ]  (i) The identifiable private information or identifiable biospecimens are publicly available;

[ ]  (ii) Information, which may include information about biospecimens , is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained directly or through identifiers linked to the subjects, the investigator does not contact the subjects, and the investigator will not re-identify the subjects;

[ ]  (iii) The research involves only information collection and analysis involving the investigator’s use of identifiable information when that use is regulated under 45 CFR parts 160 and 164 (‘HIPAA’), subparts, A and E, for the purposes of “health care operations” or “research” as those terms are defined at 45 CFR 164.501 of for “public health activities and purposes” as described under 45 CFR 164.512(b); **OR**

[ ]  (iv) The research is conducted by, or on behalf of, a Federal department or agency using government-generated of government-collected information obtained for non-research activities, if the research generates identifiable private information obtained for non-research activities, if the research generates identifiable private information that is or will be maintained on information technology that is subject to and in compliance with section 208(b) of the E-Government Act of 2002, 44 U.S.C. 3501 note, if all of the identifiable private information collected, used, or generated as part of the activity will be maintained in systems of records subject to the Privacy Act of 1974, 5 U,S.C. 552a, and if, applicable, the information used in the research was collected subject to the Paperwork Reduction Act of 1995, 44 U.S.C 3501 et seq.

[ ]  (5) Research and demonstration projects which are conducted by or otherwise subject to the approval of federal department or agency heads (or the approval of the heads of bureaus or other subordinate agencies that have been delegated authority to conduct the research and demonstration projects, and which are designed to study, evaluate, or otherwise examine: public benefit or service programs; procedures for obtaining benefits or services under those programs, possible changes in or alternatives to those programs or procedures; or possible changes in methods or levels of payment for benefits or services under those programs. Such projects include, but are not limited to, internal studies by Federal employees, and studies under contracts or consulting agreements, cooperative agreements, or grants. Exempt projects also include waivers or otherwise mandatory requirements using authorities such as sections 1115 and 1115A of the Social Security Act, as amended.

Each Federal department or agency conducting or supporting the research and demonstration projects must establish, on a publicly accessible Federal website or in such other manner as the department or agency may determine, a list of the research and demonstration projects that the Federal department or agency conducts or supports under this provision. The research or demonstration project must be published on this list prior to commencing the research involving human subjects.

[ ]  (6) Taste and food quality evaluation and consumer acceptance studies, if

[ ]  (i) Wholesome foods without additives are consumed; **OR**

[ ]  (ii) 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 FDA or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

**SECTION F: Location of the Research**

List each location where the research will take place:

[ ]  **BU campus** (building and room number): enter text

[ ]  **Field activities** (specific address/organization): enter text

[ ]  **Research to take place outside of the U.S.:** complete [Appendix A - International Research Form](http://www.bu.edu/research/forms-policies/appendices-a-international/)

[ ]  **Additional research sites: complete the below table.**

|  |  |  |  |
| --- | --- | --- | --- |
| Institution Name | Site Investigator | Research Activities | IRB Review |
| enter text  | enter text  | enter text  | [ ]  requesting reliance[ ]  site will review |
| enter text  | enter text  | enter text  | [ ]  requesting reliance[ ]  site will review |

**SECTION G: Study Summary and Participant Population**

**1. Summarize the study in lay language** Do not copy from the grant/scope of work/proposal, etc. This summary should include the research design, purpose, objectives, research question, hypothesis, and any relevant background information. Do not include citations in this section. Please limit this section to no more than 300 words.

enter text

1. **Number of participants to be enrolled** (If different arms or groups will be enrolled, provide the number per group):

enter text

1. **Participant population** (e.g. Adults, children, BU students or employees, non-English speaking, etc.):

enter text

1. **Provide any additional protections for vulnerable participant populations** (e.g. Children, persons with intellectual disabilities, BU students or employees, etc.): [ ]  **N/A**

enter text

[ ]  **No** [ ]  **Yes; The research involves children** (under the age of 18 in Massachusetts). If yes, is the research funded by the Department of Education? [ ]  No [ ]  Yes; If yes, do you intend to survey minors with questions of a personal nature? [ ]  No [ ]  Yes; If yes, your research falls under the [Protection of Pupil Rights Amendment (PPRA)](https://www2.ed.gov/policy/gen/guid/fpco/ppra/parents.html) and parents must additionally be consented for permission to enroll their children in the research and you must confirm that you will comply with the PPRA requirements that are in place at the educational institution where the research will be conducted: [ ]  Yes

1. **Inclusion criteria:**

enter text

1. **Exclusion criteria:**

enter text

**Section H: Recruitment and Informed Consent**

1. **Describe the recruitment process** (Include who will recruit, when, where and how, as well as how participants will be identified, if applicable):

enter text

[ ]  **Recruitment materials are being used in this research study and are included with this application. If recruitment materials will be used but are not included with the submission, describe why:**

enter text

[ ]  **No recruitment process is planned. Describe why:**

enter text

1. **Describe the informed consent process** (Include who will consent, when, where and how, if applicable):

enter text

[ ]  **Interactions with study participants will take place and a consent script will be used and is included with the submission. If consent materials will be used but are not included with the submission, describe why:**

enter text

[ ]  **No consent process is planned. Describe why:**

enter text

**SECTION I: Detailed Study Information**

1. **Study Procedures** (e.g. Methods of data collection, research activities/procedures, duration and types of participant contacts including study visits, phone calls, internet surveys, mailings, etc.)

enter text

1. **Duration of participation** (e.g. How long participants will be involved in the research from start to finish.)

enter text

1. **Risks of participation and plan to mitigate those risks** (e.g. Expected risks to participants or other risks that are related to the study and the plan to protect participants from those risks.)

enter text

1. **Benefits to participants related to the study. (**State if no direct benefits, or if there may be benefits to a larger population.)

enter text

1. **Protection of participant Privacy** (Include where procedures will take place and how participant privacy will be protected.)

enter text

1. **Is this research being conducted in a HIPAA Covered Entity at BU or elsewhere?**

[ ] **No** [ ]  **Yes; if yes, complete the HIPAA Authorization/Waiver form.** BU CRC covered entities include Sargent College Rehabilitation Services, Physical Therapy Center at the Ryan Center for Sports Medicine and Rehabilitation, Sargent Choice Nutrition Center, The Danielsen Institute, and Boston University Health Plan.

1. **Does this research involve student records at BU or elsewhere?**

[ ] **No** [ ]  **Yes; if yes,** I confirm that I will comply with the [FERPA](https://www2.ed.gov/policy/gen/guid/fpco/ferpa/index.html) policy that is in place at the educational institution where I am conducting my research. This includes, if applicable, the requirements for written agreement when requesting a waiver of consent for personally identifiable information. If an agreement is required, this agreement must be submitted to the IRB. **Note:** In accordance with FERPA, written consent must be obtained to access student records; the consent must specify the records that may be disclosed, the purpose of the disclosure, and identify the person or class of parties to whom the disclosure can be made and a signature line must be added to the consent statement.

**Section J: Study Data**

**1. Confidentiality of Data** (Describe whether identifiers will be collected, how data will be stored and protected from unauthorized access. If data will be shared with collaborators, describe how, e.g. RedCap, Sharepoint, etc.)

enter text

1. **Data Storage** (Mark all that apply)

|  |  |  |
| --- | --- | --- |
|  | **YES** | **NO** |
| Are you using BU-managed computers? |[ ] [ ]
| Are you using any non-BU managed computers (e.g. personal computer)? **If yes,** confirm that the non-BU managed computer(s) have the following: | [ ]  | [ ]  |
| * A current and supported Operating System
 | [ ]  | [ ]  |
| * Malware Protection (e.g. Microsoft Defender, BU Crowdstrike – no cost)
 |[ ] [ ]
| * Encryption enabled (i.e. turned on)
 |[ ] [ ]
| * Automatic screen lock to password/code at 15 minutes or less
 |[ ] [ ]

For guidance on securing computers, please see [here](https://www.bu.edu/tech/support/information-security/security-for-researchers/).

1. **Data Classification, Storage, and Transfer**

Under the [BU Data Classification Policy](http://www.bu.edu/policies/data-classification-policy/), personally identifiable health information (e.g., email address, phone number, picture or video recording of face) is classified as Restricted Use, and human subject data with identifiers limited to dates, city, and Zip Code is classified as Confidential.

1. **Does this research involve Restricted Use Data?**

[ ] **No** [ ]  **Yes; if yes,** identify where you will store Restricted Use Data: for example, in BU REDCap; on a BU managed computer or server; on paper in a locked cabinet/office or other services cleared for Restricted Use data by [BU Information Security](https://www.bu.edu/tech/support/information-security/security-for-researchers/). enter text

1. **Does this research involve Confidential Data?**

[ ] **No** [ ]  **Yes; if yes,** identify where you will store Confidential data: for example, using a non-BU, third-party app but with anonymous accounts setup by research project; BU network drive; IS&T/Research Computing, Shared Computing Cluster 4 (SCC4); BU managed computer; or other services cleared for Confidential data by [BU Information Security](https://www.bu.edu/tech/support/information-security/security-for-researchers/). enter text

1. **Will data be transferred to a collaborator or third party?**

[ ] **No** [ ]  **Yes; if yes,** list to whom data will be transferred to, what data will be transferred anddescribe how data will be transferred and confidentiality maintained (e.g. identifying information will not be sent outside, etc.). enter text

1. **Will subjects setup accounts (e.g., personal email address) for a non-BU, third-party app that is not listed on the** [BU Information Securit**y**](https://www.bu.edu/tech/support/information-security/security-for-researchers/) **website?**

[ ] **No** [ ]  **Yes; if yes,** please list the name(s) of the non-BU, third party apps: enter text

**Section K: Costs and Payments**

*Mark all that apply:*

[ ]  **There are no costs or payments to participants in this study.**

[ ]  **Participants will incur costs as a result of participating in this study.
 Describe the costs:**  enter text

[ ]  **Participants will receive compensation for being part of the study.
 Describe the compensation:** enter text

**SECTION L: Pre-Submission Checklist**

This form can be completed, signed and scanned and submitted to the IRB at: irb@bu.edu. Faxed documents and handwritten materials are not accepted.

*Mark all that apply:*

[ ]  If international research, Appendix A - International Research Form

[ ]  If requesting that another institution rely on the CRC IRB, the Single IRB Request Form

[ ]  If research involves a HIPAA Covered Entity, the HIPAA Authorization/Waiver form

[ ]  Recruitment and screening materials

[ ]  Informed Consent Form and related materials (children assent, parental permission, etc.)

[ ]  Data collection materials (surveys, interview questions, assessments, etc.)

[ ]  Other study documentation: enter text

**SECTION M: Principal Investigator Certification / Signatures**

By signing below, you certify that the information contained in this Application is true, complete, and accurate and that you will conduct this research in accordance with applicable laws, regulations, and BU CRC IRB policies.

Principal Investigator Printed Name: enter text

Principal Investigator Signature:  Date:

**FACULTY Research:**

**The Department Chair signature is required:** This application must be signed by the Department Chair for all faculty researchers. If the PI is the Department Chair, then signature by the appropriate Dean is required. Department Chair signature is not required for student research.

**By signing this form, you are indicating that you have reviewed the application, the faculty/staff person listed as PI on this protocol is a member of your department, that he/she is qualified to serve as the PI for this study, he/she has the adequate resources, and the research utilizes acceptable practice for the discipline.**

Department Chair Printed Name: enter text

Department Chair Signature:  Date:

**STUDENT Research**

**Student research:** Student research must be signed by the Faculty Advisor AND the designated School IRB pre-reviewer (if applicable) PRIOR TO submission to the IRB. Students should check with their School to determine if School IRB pre-review is required. Students must submit a copy of their dissertation with the IRB Application

**By signing this form, you are indicating that you have reviewed the application, that you agree to serve as the Co-PI for this study with the student and that you will be responsible for the ethical conduct of this student’s human subjects research.**

Faculty Advisor Printed Name: enter text

Faculty Advisor Signature:  Date:

School Reviewer Name, if applicable: enter text

School Reviewer Signature:  Date: