**Application Form (Full Board and Expedited Review)**

**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: Funding**

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](mailto: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 C: 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 D: Type of Review**

For Guidance regarding Type of Review please refer to the [CRC IRB website](https://www.bu.edu/research/ethics-compliance/human-subjects/).

1. **FULL BOARD**

Research that is greater than minimal risk and/or does not qualify for exempt or expedited review will be reviewed at a convened IRB meeting. If the study will be reviewed by the full/convened IRB, it will be put on a meeting agenda when the IRB Analyst has determined that the study meets approval criteria.

1. **EXPEDITED**

To qualify for expedited review, the study must be no more than minimal risk (the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests) **AND** must fall into one of the categories below. Check all that apply:

**1**. Clinical studies of drugs and medical devices only when condition (a) or (b) is met.

a. Research on drugs for which an investigational new drug application (21 CFR Part 312) is not required. (Note: Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review.)

b. Research on medical devices for which (i) an investigational device exemption application (21 CFR Part 812) is not required; or (ii) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.

**2**. Collection of blood samples by finger stick, heel-stick, ear stick, or venipuncture as follows:

a. From healthy, nonpregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8-week period and collection may not occur more frequently than 2 times per week; or

b. From other adults and children, considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8-week period and collection may not occur more frequently than 2 times per week.

**3**. Prospective collection of biological specimens for research purposes by noninvasive means. Examples: (a) hair and nail clippings in a nondisﬁguring manner, (b) deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction, (c) permanent teeth if routine patient care indicates a need for extraction, (d) excreta and external secretions (including sweat), (e) uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gumbase or wax or by applying a dilute citric solution to the tongue, (f) placenta removed at delivery, (g) mniotic ﬂuid obtained at the time of rupture of the membrane prior to or during labor, (h) supra- and subgingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques, (i) mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings, (j) sputum collected after saline mist nebulization.

**4**. Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and eﬀectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications.) Examples: (a) physical sensors that are applied either to the surface of the body or at a distance and do not involve input of signiﬁcant amounts of energy into the subject or an invasion of the subject’s privacy, (b) weighing or testing sensory acuity, (c) magnetic resonance imaging, (d) electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood ﬂow, and echocardiography, (e) moderate exercise, muscular strength testing, body composition assessment, and ﬂexibility testing where appropriate given the age, weight, and health of the individual.

**5.** Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for nonresearch purposes (such as medical treatment or diagnosis).

**6.** Collection of data from voice, video, digital, or image recordings made for research purposes.

**7**. Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.

**Note: The IRB will make the final determination on the Type of Review**

**SECTION E: Study Staff and Training**

Instructions:

* List ALL current members of the research team in the table below.
* Add more rows as necessary.
* Student Research: The Faculty Advisor must be listed as a co-investigator in this section and must complete the Human Subjects training requirements. Faculty Advisors are responsible for reviewing the IRB application, agreeing to serve as the Co-PI for this study with the student and are responsible for the ethical conduct of this student’s human subjects research. Faculty Advisors must sign this Application prior to it being submitted to the IRB.

1. **CRC Investigators and Study Staff:**

BUMC and other non-CRC personnel should be listed 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)** | **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 ([or components](https://www.nih.gov/institutes-nih/list-institutes-centers)) clinical trials and [FDA-regulated studies](https://www.fda.gov/science-research/clinical-trials-and-human-subject-protection/regulations-good-clinical-practice-and-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/).

1. **Non-CRC Investigators and Study Staff  N/A**

Instructions:

* BUMC and BMC staff are considered non-BU staff and should be listed in this section.
* Add more rows as necessary.
* All the columns in the box below must be completed.
* You must complete the box that follows with a description of the activities for each staff member.
* If IRB approval will be obtained from a non-BU site, only list the lead investigator from that site.

|  |  |  |
| --- | --- | --- |
| **Name, Degree, Institution** | **Study Role**  **(e.g. co-i, research coordinator, RA)** | **Staff Information** |
| enter text | enter text | This staff will interact with subjects  This staff will have access to subject identifiers  The research is related to the staff role at their home institution. |
| enter text | enter text | This staff will interact with subjects  This staff will have access to subject identifiers  The research is related to the staff role at their home institution. |

**2a. Include a summary of research activities to be conducted by each non-BU staff person listed above.**

enter text

**2b.** **If IRB approval will not be conducted at the home institution of the non-BU study staff, provide the rationale** (e.g. external institution not engaged in research, reliance agreement with BU, etc.):

enter text

**SECTION F: Location of the Research**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **YES** | **NO** | |  | | |
|  |  | | Will this research take place at Boston University?  Provide the location (e.g. building and room number): | | |
|  |  | | Will this research take place outside of Boston University?  If yes, please complete the below table: | | |
| **Institution Name and Address (if known)** | | | | **Site Activities**  **(e.g. recruitment, consent, data analysis, study interventions, etc.)** | **Describe Site IRB/Ethics Approval/Permission** |
|  | | | |  |  |
|  | | | |  |  |
| **YES\*** | **NO** |  | | | |
|  |  | Is the off-site location requesting the CRC IRB review the protocol in place of local IRB review? If **YES**, complete the [Single IRB Review Form.](http://www.bu.edu/researchsupport/forms-policies/single-irb-request/) | | | |
|  |  | Will this research be conducted outside of the United States?  If **YES**, complete the [International Research Form](http://www.bu.edu/researchsupport/forms-policies/appendices-a-international/). | | | |
|  |  | Is the CRC PI the lead investigator **OR** is BU the lead site for this research?  If yes, complete the below information. | | | |
| Provide the following information in the box below:   * The plan for collection and management of data from all the sites * The plan for evaluating and reporting: * Unanticipated problems * Serious and/or continuing non-compliance * Suspensions and terminations of research * Interim results * Protocol modifications * The name of the Principal Investigator from each site * If IRB approval will be obtained at the site, confirmation that you have a copy (or will obtain a copy) of the IRB approval letters and the IRB-approved protocols from each site * If IRB approval will be obtained at the site, confirmation that the site IRB has a FederalWide assurance (FWA) | | | | | |
| enter text | | | | | |

**SECTION G: Study Summary**

|  |
| --- |
| **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 a list of citations in this section. Please limit this section to no more than 300 words. |
| enter text |

**SECTION H: Research Methods and Activities**

Check all that apply and complete any additional forms as needed:

|  |  |
| --- | --- |
|  | Collection of audio, video, digital, or image recordings |
|  | Biological samples → [Complete Biological Samples Form](http://www.bu.edu/researchsupport/forms-policies/appendices-d-samples/)  Examples: blood, hair, cheek swab, urine, tears, saliva, etc. |
|  | Collection of data that may be sensitive and if disclosed could put subjects at risk for legal or social harms. (e.g. Illegal behaviors, HIV status, psychiatric illness, information related to sexual behaviors, etc. |
|  | Coordinating Center/Lead Site |
|  | Deception |
|  | Devices → [Complete Devices Form](http://www.bu.edu/research/forms-policies/appendices-c-device/) |
|  | Drugs → [Complete Drugs Form](http://www.bu.edu/researchsupport/forms-policies/appendices-b-drugs/) |
|  | Ethnographic: The study of people in their own environment via methods such as participant observations and interviews |
|  | Focus Groups |
|  | Genetics Testing → [Complete Genetics Form](http://www.bu.edu/researchsupport/forms-policies/appendices-e-genetics/) |
|  | MRI → [Complete MRI Form](http://www.bu.edu/researchsupport/forms-policies/appendices-f-mri/) |
|  | Placebo |
|  | Pregnancy Testing |
|  | Randomization |
|  | Surveys, interviews, questionnaires |
|  | Secondary Data Analysis |
|  | Other (please describe): enter text |

**SECTION I: Participant Population**

|  |  |
| --- | --- |
| **Provide the Number of Participants to be Enrolled. If you have sub-groups or more than one arm, please specify enrollment numbers for each group/arm.** **Note:** Please account for participants who may drop out or be withdrawn from the study. Anyone who signs a consent form is considered enrolled in the research regardless of whether they complete any study procedures. | |
| enter text | |
| **Check all categories that apply to your participant population:** | |
|  | Adults |
|  | Children (< 18 years of age) |
|  | Adults with Limited Decision-Making Capacity |
|  | Non-English Speaking |
|  | Prisoners |
|  | BU Employees |
|  | BU Students |
|  | Wards of the state |
|  | Other (please describe): enter text |
| **If a population other than ‘Adults’ has been checked, describe the additional safeguards that have or will be put in place to protect those individuals, and provide the rationale for including this population in the research study.** | |
| enter text | |
| **Eligibility Criteria** | |
| Inclusion Criteria: enter text | |
| Exclusion Criteria (criteria which would disqualify an individual from participating in the study; exclusion criteria are not the opposite of inclusion criteria): enter text | |

**SECTION J: Recruitment**

|  |
| --- |
| **Provide a summary of the recruitment process, including who will recruit, when and where recruitment will occur, and how subjects will be identified.**  **Submit all recruitment materials (e.g. advertisements, brochures, flyers, letters/e-mails, scripts, etc.) as separate documents in either Word or PDF format.** |
| enter text |

**SECTION K: Consent and Assent**

Please refer to the [consent](http://www.bu.edu/research/forms-policies/consent-form-template-script/) and [assent](http://www.bu.edu/research/forms-policies/assent-form-template-2/) form templates on the [IRB website](https://www.bu.edu/research/ethics-compliance/human-subjects/) when creating your materials. The templates include the required elements of consent/assent and will help to ensure that your materials meet federal regulations, IRB policies and best practices.

|  |
| --- |
| **Provide a summary of the consent process, including who will consent participants, when and where consent will occur. The summary should include, as appropriate, any waiting period between informing the prospective participant about the research and obtaining consent, such that the prospective participant or the legally authorized representative has sufficient opportunity to consider whether to participate, and steps taken to minimize coercion or undue influence.**  **Submit copies of all consent forms and scripts; materials should be submitted as separate documents in Word format.** |
| enter text |

**Indicate the consent and/or assent process and document(s) to be used in this study.**

Check all that apply:

|  |  |
| --- | --- |
| **Consent: Adults (>18 years old); One of the following MUST apply N/A** | |
|  | Consent Form/Information Sheet |
|  | Verbal Consent (Script)  **Note:** If written consent will not be obtained, complete the ‘Waiver of Written Documentation Consent’ box (Box 1) located further down in this section |
|  | Consent will not be obtained  **Note**: If consent will not be obtained, complete the ‘Waiver or Alteration of Consent’ box (Box 2) located further down in this section |
| **Assent of Children (< 18 years old): One of the following MUST apply N/A** | |
|  | Assent Form or Parental Consent Form/Information Sheet (for children ages 12-17 who may sign, if applicable, with their parents using an age-appropriate form) |
|  | Verbal Assent Script |
|  | Assent will not be obtained;one of the following conditions must exist:  1. The capability of some or all of the children is so limited that they cannot reasonably be consulted;  2.The children are too young to provide assent (i.e. ages 5 and under);  3.The intervention or procedure involved in the research holds out the prospect of direct benefit to the health or well-being of the children and is available only in the context of the research;  4. The research meets the same conditions as those for waiver or alteration of informed consent in research involving adults, as specified in the regulations at [45 CFR 46.116(d)](https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html)\*. Complete the ‘Waiver or Alteration of Consent’ box (Box 2) located further down in this section. |
| **Parental Permission: One of the following MUST apply N/A** | |
|  | Parental Consent Form |
|  | Parental Verbal Consent (Script)  If written consent will not be obtained, complete the ‘Waiver of Written Documentation of Consent’, Box 1, located further down in this section. |
|  | Parental permission will not be obtained; one of the following conditions must exist:  1. The research protocol is designed to study conditions in children or a subject population for which parental or guardian permission is not a reasonable requirement to protect the subjects (for example, neglected or abused children).  2. The research meets the same conditions as those for waiver or alteration of informed consent in research involving adults, as specified in the regulations at [45 CFR 46.116(d](https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html))\*. *Note:* Complete the ‘Waiver or Alteration of Consent’, Box 2, located further down in this section. |
| **Consent of Legally Authorized Representatives N/A** | |
| Describe the consent and/or assent process for enrolling legally authorized representatives and the assent process of those they represent (e.g. adults with limited decisional capacity to consent to research):  enter text | |
| Assent will be obtained from:  All Subjects  Some participants, specify: enter text  No participants. If no participants will assent, provide a rationale: enter text | |
| List who will serve as LAR: enter text | |

|  |
| --- |
| **Consent of Non-English Speaking Subjects N/A** |
| Describe the process for obtaining consent from non-English speaking subjects (a copy of the translated consent along with the [Attestation Form for Translation of Consent](http://www.bu.edu/research/forms-policies/attestation-form-for-translation-of-study-documents/) must be submitted). |
| List who will serve as the interpreter and their qualifications: enter text |

|  |  |  |
| --- | --- | --- |
| **Box 1 - Waiver of Written Documentation of Consent N/A**  **Criteria 1 or 2 must be met to qualify.** | | |
|  | **Yes** | **No** |
| **Criteria 1** | | |
| The research is **NOT** FDA Regulated |  |  |
| The only record linking the subject and the research would be the consent document |  |  |
| The principal risk would be potential harm resulting from a breach of confidentiality |  |  |
| Each subject will be asked whether the subject wants documentation linking the subject to the research and the subject’s wishes will govern |  |  |
| A written statement/information sheet will be provided to subjects. **If NO**, provide rationale for not providing this information: enter text |  |  |
| **Criteria 2** | | |
| The research is **NOT** FDA Regulated |  |  |
| The research presents no more than minimal risk of harm to subjects |  |  |
| The research involves no procedures for which written consent is normally required outside of the research context |  |  |
| A written statement/information sheet will be provided to subjects. If **NO**, provide rationale for not providing this information: enter text |  |  |
| **Criteria 3** | | |
| The research is **NOT** FDA Regulated |  |  |
| The research presents no more than minimal risk of harm to subjects |  |  |
| The subjects or legally authorized representatives are members of a distinct cultural group or community in which signing forms is not the norm |  |  |
| There is an appropriate mechanism for documenting that informed consent was obtained |  |  |
| A written statement/information sheet will be provided to subjects.  If **NO**, provide rationale for not providing this information: enter text |  |  |

|  |  |  |
| --- | --- | --- |
| **Box 2 – Waiver or Alteration of Consent N/A** | | |
| **The IRB may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent or waive the requirements to obtain informed consent provided the IRB finds and documents ALL of the criteria listed below:** | | |
|  | **Yes** | **No** |
| The research is **NOT** FDA Regulated |  |  |
| The research involves no more than minimal risk to the subjects; |  |  |
| The waiver or alteration will not adversely affect the rights and welfare of the subjects; |  |  |
| The research could not practicably be carried out without the waiver or alteration; |  |  |
| If the research involves using identifiable private information or identifiable biospecimens, the research could not practicably be carried out without using such information or biospecimens in an identifiable format; |  |  |
| Whenever appropriate, the subjects will be provided with additional pertinent information after participation. **If NO**, provide rationale for not providing this information: enter text |  |  |
| **Provide the justification/rationale for why this study meets the above criteria for waiving or altering consent (REQUIRED):** enter text | | |

|  |  |  |
| --- | --- | --- |
| **FDA Regulated Research N/A** | | |
| **The IRB may waive or alter informed consent requirements for certain minimal risk clinical investigations when the IRB finds and documents ALL of the criteria listed below.** | | |
| |  |  |  | | --- | --- | --- | |  | **Yes** | **No** | | | |
| The clinical investigation involves no more than minimal risk (as defined in 21 CFR 50.3(k) or 56.102(i)) to the subjects; |  |  |
| The waiver or alteration will not adversely affect the rights and welfare of the subjects; |  |  |
| The clinical investigation could not practicably be carried out without the waiver or alteration |  |  |
| Whenever appropriate, the subjects will be provided with additional pertinent information after participation. **If NO**, provide rationale for not providing this information: enter text |  |  |
| **Additional Comments:** enter text | | |

**SECTION L: Study Procedures**

|  |
| --- |
| **In the box below provide a detailed description of the study procedures to be performed (preferably in sequential order). Be sure to specify which procedures are for research purposes and which procedures are part of standard of care, if applicable. Be sure to include the following information:**   * **Methods of data collection** * **Details regarding research activities/procedures/interventions** * **Number, frequency, duration and types of subject contacts (visits, phone calls, internet surveys, mailings, etc.)** * **Time required from each subject** * **Use of equipment (eye-tracker, treadmill, sensors, etc.). Provide a brief description of equipment that will be used in the study.\***     \*Note: The IRB may request more information about the equipment (including equipment manuals) and/or request that you submit [Appendix C: Device Form](https://www.bu.edu/researchsupport/compliance/human-subjects/#supplemental-forms).  Submit copies of all surveys, interview questions, assessments, screening scripts, etc. that will be used during the conduct of this study; materials should be submitted as separate documents in either Word or PDF format. |
| enter text |

**SECTION M: Risks**

|  |
| --- |
| **List physical, psychological, social, political, legal, economic, or other risks that may be associated with the study.** |
| enter text |
| **List the known or foreseeable risks or adverse events associated with the research, including any drugs, devices and/or procedures. These risks must be described in the consent form. As applicable, please include a copy of the Data and Safety Monitoring Plan, product labeling and package inserts, or investigator brochure with the IRB application.** |
| enter text; if this section is not applicable, put NA |
| **For studies involving the use of devices/drugs (approved and investigational), provide a list of, or references to, all known side effects.** |
| enter text; if this section is not applicable, put NA |
| **List or reference the expected natural progression of any underlying disease, disorder or condition relevant to the participants selected for this study, specifying the predisposing risk factor profile for adverse events likely to emerge during the study period (e.g. waxing and waning of anxiety and mood symptoms for participants with an anxiety disorder; e.g., reference to known adverse event profiles for participants selected for Alzheimer’s disease:** [**https://pmc.ncbi.nlm.nih.gov/articles/PMC2955171/table/T3/**](https://pmc.ncbi.nlm.nih.gov/articles/PMC2955171/table/T3/)  **https://pmc.ncbi.nlm.nih.gov/articles/PMC7135264/table/pone.0231226.t003/)**  **This list informs the distinction between expected and unexpected adverse events for this study.** |
| enter text; if this section is not applicable, put NA |
| **Describe the plan to minimize risks. Include in the description the availability of any medical or psychological resources.** |
| enter text |

**SECTION N: Benefits**

|  |
| --- |
| **Describe the potential benefits to subjects related to the study. State if there are no direct benefits. NOTE:** Compensation and/or course credit are not considered benefits. |
| enter text |
| **Describe the potential benefits to society and/or others related to the study.** |
| enter text |

**SECTION O: Costs and Payments**

|  |  |  |
| --- | --- | --- |
|  | **Yes** | **No** |
| Are there any costs to subjects as a result of participating in this study?  **If YES**, provide a description of the costs: enter text |  |  |
| Will subjects be compensated for participating in the study? Compensation may include cash, checks, gift cards, lotteries, course credit, etc. Payments should be prorated to compensate subjects for time and procedures completed  **If YES**, provide a description of the compensation: enter text |  |  |
| Will identifiable information be sent to Accounts Payable, Post Award Financial Operations, etc. for payment purposes? **If YES**, this information must be disclosed in the consent form. |  |  |

**SECTION P: Confidentiality of Data**

For guidance on securing computers, please review the [InfoSec Safe Computing webpage](https://www.bu.edu/tech/support/information-security/security-for-researchers/).

|  |  |  |  |
| --- | --- | --- | --- |
|  | | **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 | |  |  |
| **Describe how data will be stored (e.g. paper, electronic database, etc.)** | | |
| enter text | | |

|  |  |  |
| --- | --- | --- |
| **YES** | **NO** |  |
|  |  | Will you collect identifiable information? (e.g. names, social security numbers, addresses, email addresses, telephone numbers, photo/video/voice etc.). **If YES**, complete the boxes below. |
| **Describe the coding system that will be used to protect the information including who will have access to the code.** Coding systems are used to: 1) protect the confidentiality of the research data and 2) allow the investigator to link subjects to their responses. Each subject is assigned a unique study ID at the beginning of the study. A separate document (key) should be maintained that links the names of the subjects to the study ID numbers. | | |
| enter text | | |
| **Describe how you will maintain confidentiality of the data (e.g. locked cabinet, password-protected files, encryption, etc.).** This should be consistent with statements made in the consent form regarding how participant’s data, including any identifiable private information, will be handled, managed, and disseminated by the study team. | | |
| enter text | | |
| **YES** | **NO** |  |
|  |  | Will you share data with others outside of the study? **If YES**, complete the box below. |
| **List to whom data will be transferred, what data will be transferred, how data will be transferred, and how confidentiality will be maintained (e.g. no identifying information will be shared, etc.).** | | |
| enter text | | |

Under the [BU Data Classification Policy](http://www.bu.edu/policies/data-classification-policy/), human subject data that is both health-related\* and personally identifiable (e.g., email address, phone number, picture or video recording of face) is classified as Restricted Use, while personally identifiable human subject data that is not health-related is classified as Confidential. Additionally, when direct identifiers are removed from personally identifiable human subject health data (i.e., identifiers are limited to dates, city, and Zip Code) the data is classified as Confidential. \*Health-related information is very broad, including stress or anxiety related to school, but does not typically include social engagement, decision making, number of texts sent per day, or educational practices, strategies, or effectiveness.

|  |
| --- |
| **Please identify where you will store Restricted Use data: for example, in BU REDCap; on a BU Restricted Use network drive; 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 |
| **Please 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 |

|  |  |  |
| --- | --- | --- |
| **YES** | **NO** |  |
|  |  | **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? If yes,** BU Information Security needs to complete a security review before the research protocol is approved. Send an email to [buinfosec@bu.edu](mailto:buinfosec@bu.edu) with the name of the vendor/app and an email address of someone at the vendor/app who can answer security questions. |
| **If YES**, please list the name(s) of the non-BU, third party apps: enter text | | |

**SECTION Q: Certificate of Confidentiality**

|  |
| --- |
| In 2017 the NIH updated its policy for issuing [**Certificates of Confidentiality**.](https://grants.nih.gov/policy/humansubjects/coc.htm#:~:text=Certificates%20of%20Confidentiality%20(Certificate%20or,a%20few%20other%20specific%20situations.)Under the policy, all **eligible** research studies funded by the NIH are automatically issued a certificate of confidentiality. Investigators whose research is not funded or supported by the NIH may request and obtain from the NIH a Certificate of Confidentiality. Investigators who request and receive Certificates must follow the NIH and PHS policies governing such certifications. |

|  |  |  |
| --- | --- | --- |
| **YES** | **NO** |  |
|  |  | Is your research funded by the NIH and eligible for a Certificate of Confidentiality? |
|  |  | If your research is not funded by the NIH, will you be applying for a Certificate of Confidentiality? |

**SECTION R: Privacy**

|  |
| --- |
| **Describe how you will protect the privacy of subjects (e.g. where will consent procedures take place, if interviews or other interventions, where will these procedures take place)** |
| enter text |

**SECTION S: Monitoring Study Data**

|  |  |
| --- | --- |
| **Indicate how data will be monitored.**  The Data and Safety Monitoring Plan should be tailored to the nature, size, and complexity of the research protocol, the expected risks of the research, and the type of subject population being studied. | |
|  | Principal Investigator |
|  | Monitor/Monitoring Group |
|  | Data and Safety Monitoring Board (DSMB)  The DSMB Charter must be submitted with this Application. For more information regarding a DSMB, please refer to the [NIH website](https://www.nidcr.nih.gov/research/human-subjects-research/interventional-studies/data-and-safety-monitoring-board-guidelines). |

|  |
| --- |
| **Describe the plan for monitoring study data. This should include a description of how data will be collected and analyzed as the project progresses to assure the appropriateness of the research, its design, and subject protections.** |
| enter text |

**SECTION T: Health Insurance Portability and Accountability Act/HIPAA**

|  |  |  |
| --- | --- | --- |
| **YES\*** | **NO** | HIPAA is a federal privacy law covering Protected Health Information (PHI). PHI is individually identifiable health information created or received by a Covered Entity/Component. |
|  |  | Is the research being conducted in, or data collected from, a covered entity?  The following BU CRC Departments are considered covered entities:   * Sargent College Rehabilitation Services   + Physical Therapy Center at the Ryan Center for Sports Medicine and Rehabilitation   + Sargent Choice Nutrition Center * The Danielsen Institute * Boston University Health Plan |

\*For guidance on HIPAA, please see [here](https://www.bu.edu/research/ethics-compliance/human-subjects/hipaa/).

\*If applicable, complete the Request for Waiver of HIPAA Authorization Form

**SECTION U: Family Educational Rights and Privacy Act (FERPA)**

FERPA is the federal law that protects the privacy of student education records. Research funded by the Department of Education or research conducted in educational institutions that receive funds from the Department of Education (for research or other purposes) must comply with FERPA.

|  |  |  |
| --- | --- | --- |
| **YES\*** | **NO** |  |
|  |  | Does this study involve collection of information from student school/university records? \*If YES, refer to the following websites for guidance on FERPA:   * <http://www.bu.edu/reg/general-information/ferpa/> * <http://www2.ed.gov/policy/gen/guid/fpco/ferpa/index.html>   **If FERPA applies, you must complete the box below:** |
| In accordance with FERPA, written consent must be obtained to access student records. The consent must: specify the records that may be disclosed, state the purpose of the disclosure and identify the person or class of parties to whom the disclosure can be made. | | |
| YES  **(REQUIRED)** | | I confirm that I will comply with the FERPA 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.** |

**SECTION V: Protection of Pupil Rights Amendment (ppra):**

PPRA is a federal law that affords certain rights to parents of minor students regarding surveys that ask questions of a personal nature. Research funded by the Department of Education or research conducted in educational institutions that receive funds (for research or other purposes) from the Department of Education must comply with the PPRA.

|  |  |  |
| --- | --- | --- |
| **YES\*** | **NO** |  |
|  |  | Does PPRA apply to this study? If YES, refer to the following website for guidance: <https://studentprivacy.ed.gov/resources/protection-pupil-rights-amendment-ppra-general-guidance>  **If PPRA applies, you must complete the box below:** |
| In accordance with PPRA, written parental consent must be obtained prior to subject’s participation in the study. | | |
| YES  **(REQUIRED)** | | I confirm that I will comply with the PPRA policy that is in place at the educational institution where I am conducting my research. |

**Section W: Clinical Trial Registration**

The Food Drug and Administration Amendments Act (known as FDAAA 801) requires that “applicable clinical trials” be registered and have results reported on clinicaltrials.gov. In addition, the International Committee of Medical Journal Editors (ICJME) and the National Institutes of Health (NIH) also have requirements for registration. Please see box below to determine if your study requires registration in accordance with either FDAAA 801, ICJME, or NIH.

|  |  |  |
| --- | --- | --- |
| **YES** | **NO** | **FDAAA 801 Requirements** |
|  |  | Does your study meet the definition of an applicable clinical trial (ACT) and require registration **AND** results submission in accordance with FDAAA 801?  ACTs include:   * Trials of drugs and biologics: Controlled clinical investigations, other than phase 1 clinical investigations, of drugs or biological products subject to Food and Drug Administration (FDA) regulation * Trials of devices [(see note)](https://clinicaltrials.gov/ct2/manage-recs/fdaaa#footnote3): 1) Controlled trials with health outcomes of devices subject to FDA regulation, other than small feasibility studies, and 2) [pediatric post-market surveillance](https://clinicaltrials.gov/ct2/manage-recs/fdaaa#PedPostmarket) required by FDA   **Note\*:** If your study meets the [requirement](https://clinicaltrials.gov/ct2/manage-recs/fdaaa) for registration and reporting, you must submit the National Clinical Trial (NCT) Identifier # to the IRB prior to IRB approval**.** NCT #: enter text |
| **YES** | **NO** | **ICMJE Requirements** |
|  |  | Does your study meet the definition of a clinical trial and require registration in accordance with [ICMJE](http://www.icmje.org/about-icmje/faqs/clinical-trials-registration/)?  **Note\*:** If your study meets the requirement for registration, you must submit the National Clinical Trial (NCT) Identifier # to the IRB prior to IRB approval.  NCT #: enter text |
| **YES** | **NO** | **NIH Requirements** |
|  |  | Does your study meet the definition of an applicable clinical trial and require registration **AND** results submission in accordance with NIH?  For more information on this policy please refer to:   * [NIH Policy on the Dissemination of NIH-Funded Clinical Trial Information](https://s3.amazonaws.com/public-inspection.federalregister.gov/2016-22379.pdf) * [Checklist](https://prsinfo.clinicaltrials.gov/ACT_Checklist.pdf) for Evaluating Whether a Clinical Trial or Study is an Applicable Clinical Trial   **Note\*:** If your study meets the requirement for registration and reporting, you must submit the National Clinical Trial (NCT) Identifier # to the IRB prior to IRB approval.NCT #: enter text |

\*If you have already submitted your study for registration but the NCT identifier is pending, please list “pending” in the relevant sections above and submit an amended IRB application once the NCT number has been issued.

**Certification / Signatures**

* By submitting this protocol I attest to the fact that all research activities to be implemented related to human subjects have been completely and accurately described herein.
* I agree to conduct the describe research in an ethical manner.
* I agree to comply with all institutional policies and procedures related to human subjects research and will not begin any human subjects research activities until I have obtained full approval from the IRB.
* I agree to conduct the research as described in this protocol and not to make any changes (except to eliminate immediate harm to subjects) without first obtaining approval for the changes from the IRB.
* I agree to immediately report any unanticipated problems involving risks to subjects or others, any subject complaints, and any incidents of non-compliance with the requirements of this protocol as soon as I become aware of them.
* I agree to comply with any relevant HIPAA and FERPA regulations if applicable.
* I verify that allthose responsible for the design, conduct, or reporting of the proposed program, including at minimum, all Senior/key personnel in the grant application, have completed the financial conflict of interest disclosures and completed training as required by University [Policy](https://www.bu.edu/researchsupport/compliance/conflicts-of-interest/).

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 they are qualified to serve as the PI for this study, that they have 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 Review Name, if applicable: enter text

School Reviewer Signature:  Date:

**Submission:** Electronic signatures are acceptable, as are emails confirming the certification information. This form can be completed, signed, scanned and submitted to the IRB at [irb@bu.edu](mailto:irb@bu.edu). Faxed documents and handwritten materials are not accepted. Be sure to include all relevant attachments.