**Continuing Review and Progress Report Form**

**SECTION A: Protocol and Contact Information**

**Protocol Title** : enter text **Protocol Number:** enter text

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

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

**BU Mailing Address:**  enter text **PI Department:**  enter text

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

**Contact Information:**  enter text

**SECTION B: Study Staff Information**

**Are Changes being made to the Personnel Roster (CRC or Non-CRC Personnel)**

*Mark which is true:*

☐ Yes, a [Study Staff Amendment Form](https://www.bu.edu/research/ethics-compliance/human-subjects/supplemental-forms/) is attached to this submission

☐ No changes are being made to the personnel roster

**SECTION C: Current Protocol Status (Choose only one option below):**

|  |  |
| --- | --- |
| ☐ | Enrollment has not started |
| ☐ | Open to enrollment |
| ☐ | Enrollment is closed. Subjects are still completing study procedures and/or data collection continues. |
| ☐ | Enrollment is closed. All subjects have completed all study-related procedures and data collection is complete. Analysis of identifiable\* study data is ongoing**.** |
| ☐ | Enrollment is closed. All subjects have completed all study-related procedures and data collection is complete. Analysis of identifiable study data is completed.  Note: If all identifiers (including codes, links, or key to identifiers) have been destroyed OR analysis of identifiable data is complete this study may be closed; please complete the Final Report Form.If analysis of identifiable data is ongoing, the study must remain open. |

**\*Definitions of identifiable:**

* **Identifiable:** Research materials are identifiable (investigators have access to personally identifying information or codes, links or keys to identifying information).
* **Coded:** The specimens/data are not directly individually identifiable to the investigator but contain a code through which identifiers may be linked back to the specimen/data source by anyone who possesses the key to that code.
* **Anonymized:** Data/samples are considered anonymized when the data/samples cannot be linked to a specific individual either (code or key) was never created or the link was destroyed.

**SECTION D: Subject Enrollment**

1. **If the CRC IRB is serving as a Reviewing IRB, the below subject enrollment data includes information for all sites?** ☐ N/A☐ YES ☐ NO (if no, state why):enter text
2. **Total number of subjects approved to enroll in the study**:enter text
3. **Table 1 – Enrollment by Gender, Ethnicity and Race**

If the study involves more than one cohort, copy and complete an enrollment table for each cohort

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Ethnic Categories** | **Females** | **Males** | **Nonbinary/**  **Other Gndr.** | **Unknown/**  **Not Reported** | **Total** |
| Hispanic or Latino | enter text | enter text | enter text | enter text | enter text |
| Not Hispanic or Latino | enter text | enter text | enter text | enter text | enter text |
| Unknown or Unreported | enter text | enter text | enter text | enter text | enter text |
| **Racial Categories** |  |  |  |  |  |
| American Indian or Alaska Native | enter text | enter text |  | enter text | enter text |
| Asian | enter text | enter text |  | enter text | enter text |
| Native Hawaiian or Pacific Islander | enter text | enter text |  | enter text | enter text |
| Black or African American | enter text | enter text |  | enter text | enter text |
| White | enter text | enter text |  | enter text | enter text |
| More Than One Race | enter text | enter text |  | enter text | enter text |
| Unknown or Unreported | enter text | enter text |  | enter text | enter text |
| Total of all Subjects | enter text | enter text |  | enter text | enter text |

\*A subject is enrolled once they have provided informed consent/assent.

1. **Table 2 – Enrollment Status**

|  |  |  |
| --- | --- | --- |
| **Enrollment Status Information** | **Since Initial Approval** | **Since the last CR Approval**  (if applicable) |
| Subjects who voluntarily withdrew | enter number and reasons for withdrawal | enter number and reasons for withdrawal |
| Subjects lost to contact | enter text | enter text |
| Subjects withdrawn by the PI due to eligibility criteria | enter text | enter text |
| Subjects withdrawn by the PI for non-eligibility reasons | enter number and reasons for withdrawal | enter number and reasons for withdrawal |
| Subjects who completed study procedures | enter text | enter text |
| Total Subjects currently active in the study | enter text | |

Note: The total number of subjects in Table 1 should equal the total number of subjects in Table 2.

**SECTION E: Study Progress**

Provide a summary of the study progress to date. Be sure to include any information about publications, presentations, etc. Indicate when you anticipate that the study will be completed.

enter text

**SECTION F: OTHER STUDY INFORMATION**

|  |  |  |
| --- | --- | --- |
| **YES** | **NO** |  |
| ☐ | ☐ | Since the last IRB review, have there been any subject complaints? If yes, please explain or attach a summary.  enter text |
| ☐ | ☐ | Since the last IRB review, have there been any adverse events or unanticipated problems involving risks to subjects or others? If yes, provide a brief summary of the events:  enter text  If these events or problems have not already been submitted to the IRB, submit an [Event Form](https://www.bu.edu/researchsupport/compliance/human-subjects/#reporting-incidents). |
| ☐ | ☐ | Since the last IRB review, has there been any new information or interim findings regarding this research, especially information about risks to subjects that are or could be associated with the research? If yes, please explain or attach a summary.  enter text |
| ☐ | ☐ | Since the last IRB review, in the opinion of the investigator, have the risks or potential benefits of this research changed? If yes, please explain.  enter text |
| ☐ | ☐ | For studies utilizing devices, since the last IRB review, have there been any changes made to the device that have not previously been submitted/approved by the IRB? If yes, please note which devices were changed and provide details about the changes:  enter text |
| ☐ | ☐ | Since the last IRB review, have there been any changes to the study funding? (e.g. new sponsorship, grant ended, etc.). If new sponsorship has been awarded, provide a copy of the grant/agreement. Describe any changes:  enter text |
| ☐ | ☐ | Since the last IRB review, have any changes/amendments been made to the study protocol? If yes, describe the changes:  enter text  If you wish to make a change at this time, you must submit an [Amendment Form](https://www.bu.edu/researchsupport/compliance/human-subjects/#amendments-modifications). |
| ☐ | ☐ | Since the last IRB review, has any Investigator or Study staff on the protocol disclosed a previously unreported Financial Conflict of Interest related to the research? If yes, the IRB Office will contact the FCOI Office for more information.  enter text |

**SECTION G: Application Attachments**

Notes:

* Materials used with study participants must be submitted for re-approval at the time of continuing review/progress report unless noted below.
* If your study is closed to enrollment, you do not need to submit materials that are no longer in use (e.g. consent forms, recruitment materials, study instruments, etc.).

|  |  |
| --- | --- |
| ☐ | Recruitment Materials**.** List names of recruitment materials if more than one: enter text  Submit recruitment materials for reapproval. |
| ☐ | Study Instruments (questionnaires, surveys, focus group questions, instructions, etc.);  List names of instruments**:** enter text.  Do not submit unless changes have been made to these materials. |
| ☐ | Consent Form/Script; List names of consents if more than one:enter text  Submit consent forms and/or scripts for reapproval. |
| ☐ | Assent Form/Script; List names of assents if more than one:enter text  Submit assent forms and/or scripts for reapproval. |
| ☐ | Grant/Sponsor Progress Report |
| ☐ | DSMB Report |
| ☐ | Other; Explain:enter text |

**SECTION H: PRINCIPAL INVESTIGATOR CERTIFICATION**

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 Signature:  Date:

If PI is a student, signature of the faculty advisor is required below. By signing, the faculty advisor is indicating agreement with the above statements.

Faculty Advisor Printed Name: enter text

Faculty Advisor Signature:  Date:

NOTE: Electronic signatures are acceptable, as are emails confirming the above certification information. This form can be completed, signed, scanned and submitted to the IRB at [irb@bu.edu](mailto:irb@bu.edu). Continuing Review Forms should be submitted at least 45 days prior to study expiration.