|  |
| --- |
| **IRB Office use only**  **Date received: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**  **IRB expiration date:\_\_\_\_\_\_\_\_\_\_\_\_**  **Convened review:**  **Expedited review (pre-2018):**  **If subject to 2018 requirements, justification:**  **IRB Determination:**  **FDA:** |

**Submit the original paper application and all supporting documents to the IRB office (1035 Cambridge Street, 2nd floor, Cambridge). Original signatures are required on the paper submission. Please also email all documents to** [**CHAIRBOffice@challiance.org**](mailto:CHAIRBOffice@challiance.org)**.**

**This form is to be typed. Handwritten forms will not be reviewed and will be returned to the PI. Complete each field; do not leave fields blank. Indicate N/A, as needed.**

**Section A: General Study Information**

1. CHA-IRB-
2. Protocol Title:
3. Principal Investigator (PI):

Email address:

Telephone number:

1. Additional Contact Person:

Email address:

Telephone number:

1. Funding Source:

|  |  |  |
| --- | --- | --- |
| Federal  Grant title:  Grant #:  Primary grant recipient name:  Primary grant institution name:  Is CHA a sub-contract site?  Yes  No | Secured  Pending  If funding is secured, submit a copy of the most recent progress report. | Agency Name: |
| State | Secured  Pending | Agency Name: |
| Industry | Secured  Pending | Company Name: |
| Foundation – requires a contract be executed with the CHA Office of Sponsored Research. Call (617) 806-8709 to address. | Secured  Pending | Foundation Name: |
| CHA Internal | Secured  Pending | Describe: |
| Personal Funding | Secured  Pending | Describe: |
| Other: | Secured  Pending | Describe: |
| None | | |

1. Study Registration

Is this study registered on [www.clinicaltrials.gov](http://www.clinicaltrials.gov)?  Yes No

If YES: Provide the ClinicalTrials.gov Identifier: NCT      **and**

check here to confirm that the ICF contains the language required by Federal law

For more information about study registration on [www.clinicaltrials.gov](http://www.clinicaltrials.gov) please refer to the [CHA Office of Sponsored Research website](https://www.challiance.org/academic/clinicaltrials-govinfo) or the [International Committee of Medical Journal Editors](http://www.icmje.org/) website.

1. Web posting of IRB-approved ICF

Is the study a federally funded clinical trial (as defined by 45 CFR 46.102(b))?  Yes No

If YES: Federal regulation (45 CFR 46.116(h)) requires one IRB-approved informed consent form used to enroll subjects to be posted on a publicly available Federal website. Please provide the web address where the ICF will be posted:

1. Please provide a brief summary of the study in lay, non-technical language; please limit to ~250 words:
2. Per 45 CFR 46.103(b) ANY change to a study must be reviewed and approved by the IRB prior to implementation of the change except when necessary to eliminate apparent immediate hazards to the subject. Briefly summarize all modifications that have been approved by the IRB since the last continuing review:
3. Is a modification being requested at this time?  Yes No

* If yes, please state the amendment number:
* Detail the proposed changes:
* Submit a tracked and untracked copy of the study protocol reflecting the change(s); to assist with version control, protocols are to have a version date or number.
* If the study is funded by a Federal grant, please be aware of the 2012 NIH *[Guidance on Changes That Involve Human Subjects in Active Awards and That Will Require Prior NIH Approval](https://grants.nih.gov/grants/guide/notice-files/not-od-12-129.html).*

1. If this study is federally funded (e.g. NIH), complete the following table by double-clicking on it (actual enrollment to date):

If this study is not federally funded, please check here:



[[1]](#footnote-1)[1] The numbers entered in the table should add up to the total enrolled number in the first or second row.

**Section B: Research Protocol**

1. Please submit the study protocol detailing the proposed study. CHA has created protocol template guidance and a protocol template for researchers, if needed, to help ensure the minimum necessary required information is provided for IRB review. It is not required that researchers use the template; however, all required information must be present in the submitted protocol. Provide the version date/# of the protocol submitted with the application:

**Section C: Locations of Study**

1. List ALL CHA location(s) where this study is conducted:
2. Is this study being conducted at any non-CHA site?  Yes No

If YES, name of institution(s):

A copy of the other institution’s IRB approval is enclosed.

SMART IRB Reliance Agreement (“Cede Review”)

Other IRB Authorization Agreement (IAA) executed

NOTE: If an IAA was executed for this study, please complete and submit to the IRB with this application the corresponding Continuing Review Supplement form (available on the IRB website).

**Section D: Current Study Team Human Subject Training and Conflict of Interest**

1. Research Staff and Personnel

CHA Research Team- if additional space is needed, please attach and additional piece of paper with the information below.

NOTE: Any member of the research team who conducts human research at CHA, but is not an employee, consultant, etc., of CHA must undergo the CHA volunteer on-boarding process. Please contact the Volunteer Services department about research volunteer requirements.

|  |  |  |
| --- | --- | --- |
| **ALL CHA Research**  **Team Members[[2]](#footnote-2)** | **Individual’s role (*e.g.,* Co-I, coordinator)** | **Human Subject Training[[3]](#footnote-3)** |
|  |  | [CITI](http://www.challiance.org/Academics/HumanSubjectTraining.aspx#CHA)  Other­­­­[[4]](#footnote-4)  Most Recent Date Completed: |
|  |  | [CITI](http://www.challiance.org/Academics/HumanSubjectTraining.aspx#CHA)  Other­­­­3  Most Recent Date Completed: |
|  |  | [CITI](http://www.challiance.org/Academics/HumanSubjectTraining.aspx#CHA)  Other­­­­­­­­3  Most Recent Date Completed: |
|  |  | [CITI](http://www.challiance.org/Academics/HumanSubjectTraining.aspx#CHA)  Other­­­­­­­­3  Most Recent Date Completed: |
|  |  | [CITI](http://www.challiance.org/Academics/HumanSubjectTraining.aspx#CHA)  Other­­­­­­­­3  Most Recent Date Completed: |
|  |  | [CITI](http://www.challiance.org/Academics/HumanSubjectTraining.aspx#CHA)  Other­­­­­­­­3  Most Recent Date Completed: |
|  |  | [CITI](http://www.challiance.org/Academics/HumanSubjectTraining.aspx#CHA)  Other­­­­­­­­3  Most Recent Date Completed: |
|  |  | [CITI](http://www.challiance.org/Academics/HumanSubjectTraining.aspx#CHA)  Other­­­­­­­­3  Most Recent Date Completed: |
|  |  | [CITI](http://www.challiance.org/Academics/HumanSubjectTraining.aspx#CHA)  Other­­­­­­­­3  Most Recent Date Completed: |

**NOTE:** Each individual is to keep a copy of his/her documentation of completion from the “CITI gradebook.” Principal Investigators are to retain a copy of education certificates for all research team members; these documents are subject to audit. A copy does not need to be submitted to the IRB office.

1. **Conflict of Interest**

As the PI of this study, I confirm that all personnel at CHA who are responsible for the design, conduct, or reporting of this project have completed the required financial conflict of interest disclosure forms and training, as applicable, [per CHA policy](http://www.challiance.org/Academics/ConflictofInterest.aspx). Completed and signed COI disclosure forms for all applicable personnel are (check all that apply):

Enclosed with this application (list names of personnel for whom COI form are enclosed):



Have been completed in the CHA Cayuse system:



**Section E: Current Study Status (Choose only one option below)**

|  |  |
| --- | --- |
|  | Enrollment has not started **or** no enrollment to date at CHA and no additional risks have been identified. |
|  | Actively enrolling participants. |
|  | Permanently closed to enrollment of new subjects. Participants are still completing study procedures and/or data collection (active follow-up) is ongoing. Date study closed to enrollment:       (mm/yyyy) |
|  | Permanently closed to enrollment of new subjects. All subjects have completed all study-related procedures and data collection is complete; the **only** remaining research activities are data analysis, which is proceeding in accordance with the IRB-approved research protocol. Date study closed to enrollment:       (mm/yyyy) |

**Section F: Subject Enrollment**

**CHA considers a person enrolled once s/he has signed the research consent/assent form, regardless of whether the participant completes the study. In determining the number of subjects to be enrolled, the PI should take into consideration the likely subject attrition rate. Screening to determine eligibility should not be counted in determining the number to be enrolled.**

**REMINDER: If there is a reliance agreement in place for this study, ALL questions under this subheading apply to ALL sites under the authority of the CHA IRB.**

1. Total number of subjects *currently* approved for enrollment at *all sites* under the authority of the CHA IRB:
2. Complete the table:

|  |  |  |
| --- | --- | --- |
|  | **Since last Continuing Review** | **From initial IRB approval to present** |
| **TOTAL # of subjects enrolled at CHA sites** |  |  |
| **TOTAL # of subjects enrolled at ALL sites** |  |  |
| # of subjects ineligible after signing/giving consent |  |  |
| # of subjects currently active in study or follow-up |  |  |
| # of subjects lost to follow-up |  |  |
| # of subjects withdrawn by PI due to toxicity, serious adverse events (AE), or AEs |  |  |
| Briefly describe the circumstances if subjects were withdrawn from the study due to SAEs or AEs: | | |
| # of subjects withdrawn by PI due to other reasons (e.g., did not follow protocol instructions, pregnancy, death due to disease progression) |  |  |
| Briefly describe the reasons why any subjects were withdrawn from the study by the PI *other than* due to toxicity, SAEs, or AEs: | | |
| # of subjects who voluntarily withdrew from the study (*e.g.,* subject signed consent and changed mind or decided to drop out) |  |  |
| Briefly describe the reasons why any subjects voluntarily withdrew from the study: | | |
| # of subjects who completed study |  |  |

1. The following potentially vulnerable populations have been or will be targeted for enrollment in this study:

Pregnant women, neonates, or fetuses ([45 CFR 46](https://www.ecfr.gov/cgi-bin/retrieveECFR?gp=&SID=83cd09e1c0f5c6937cd9d7513160fc3f&pitd=20180719&n=pt45.1.46&r=PART&ty=HTML), Subpart B)

Prisoners ([45 CFR 46](https://www.ecfr.gov/cgi-bin/retrieveECFR?gp=&SID=83cd09e1c0f5c6937cd9d7513160fc3f&pitd=20180719&n=pt45.1.46&r=PART&ty=HTML), Subpart C)

Minors ([45 CFR 46](https://www.ecfr.gov/cgi-bin/retrieveECFR?gp=&SID=83cd09e1c0f5c6937cd9d7513160fc3f&pitd=20180719&n=pt45.1.46&r=PART&ty=HTML), Subpart D)

Decisionally impaired

Students

Staff/employees of CHA

1. Has subject enrollment reflected the ethnic and racial demographics of CHA, or the demographics of the alternate site(s) where this research is being conducted?  Yes No
   1. If NO, provide:
      1. Justification for the failure to accrue subjects in accordance with these ethnic and racial demographics:       and
      2. The steps to be taken to correct this deficiency:
2. Since the last IRB review, are there any recent scientific publications or other outcome data, published or unpublished, that may potentially impact the continued conduct of this research study or the benefit-to-risk ratio of study participation?  Yes No
   1. If YES, please describe:
3. Since the last IRB review, has any new information related to the potential risks and/or benefits of study participation been identified that may affect the willingness of current or future research subjects to participate in this study?  Yes No
   1. If YES, summarize new information:
4. Since the last IRB review, have there been any subject complaints?  Yes No
   1. If YES, please summarize:
5. Since the last IRB review, have there been any [SAEs or AEs](http://staffnet/Reference/Policies/RegulatoryCompliance/A-COM-0007.pdf) involving risks to subjects or others?

Yes No

* 1. If YES, please briefly summarize:
  2. Was the AE previously reported to the IRB? Yes No

1. Since the last IRB review, have there been any [unanticipated problems (UP)](http://staffnet/Reference/Policies/RegulatoryCompliance/A-COM-0007.pdf) involving risks to subjects or others?  Yes No
   1. If YES, please briefly summarize:
   2. Was the UP previously reported to the IRB? Yes No
2. Is there a Data and Safety Monitoring Board (DSMB) for this study?  Yes No
   1. If YES, please submit a copy of the most recent DSMB reports/findings.

**Section G: Informed Consent Form (ICF)**

|  |  |
| --- | --- |
|  | This study is open to enrollment and actively recruiting subjects; a copy of the ICF is enclosed for re-approval. **NOTE: Submit a current copy of the ICF for validation and future use with subjects. The ICF used to enroll a subject is to have the IRB validation stamp/approval date present. To assist with version control, ICFs are to have a version date or number.** |
|  | This study is open to enrollment and actively recruiting subjects; however, a waiver of consent was previously granted. |
|  | This study is closed to enrollment; no ICF submitted at this time. |

**Section H: Health Insurance Portability and Accountability Act (HIPAA)**

Please check the appropriate box, and attach any additional forms as indicated and necessary.

Accessing and utilizing de-identified data only

Waiver of research authorization request

Research authorization required (enclose informed consent/permission form)

Limited data set (enclose executed Data Use Agreement)

HIPAA does not apply – Protected Health Information will not be collected

**Section I: Attachments**

Please indicate which documents are being submitted with this application for IRB review and approval; check all that apply. As a reminder, the documents listed below must be re-submitted for re-approval at the time of continuing review. If the study is closed to enrollment, the documents do not need to be submitted.

|  |  |
| --- | --- |
|  | If study is federally funded, copy of most recent progress report; version dated: |
|  | Advertisements; # enclosed: |
|  | Study Instruments (questionnaires, surveys, focus group questions, instructions, etc.); # enclosed: |
|  | Recruitment Material (e-mails, scripts, letters, etc.); # enclosed: |
|  | Consent Form/Script; # enclosed: |
|  | Assent Form/Script; # enclosed: |
|  | Other: |

**Section J: Principal Investigator Assurance**

**By signing below, I, the study Principal Investigator, confirm and acknowledge that:**

* I have reviewed the information in this form and in this submission; it is complete and accurate.
* I am responsible for the conduct of this research study, including the protection of the rights and welfare of the human participants. I will execute the research plan as described in the study protocol.
* I will ensure that this research is conducted in accordance with applicable laws, regulations, and CHA research policies governing human research.
* Neither I, nor any member of the study team, will make **any** change to this project without first confirming with the IRB whether it will change the exempt classification, except when necessary to eliminate apparent immediate hazards to a subject. I will obtain the confirmation in writing from the IRB.
* I will ensure that consent/assent/permission, as applicable to this study, is ethically obtained and is documented in accordance with applicable laws and CHA policies.
* I will promptly submit any changes in study status (*e.g.,* closed to enrollment, termination) to the IRB office.
* I am responsible for ensuring that the study is supported and conducted by trained and qualified research staff and in accordance with the current IRB-approved protocol.
* I will supervise the study team.
* I am responsible for reporting to the IRB [adverse events and unanticipated problems, per CHA policy](http://staffnet/Reference/Policies/RegulatoryCompliance/A-COM-0007.pdf).
* The study team and I will comply with CHA [conflict of interest policies](http://www.challiance.org/Academics/ConflictofInterest.aspx), as applicable.
* I will maintain study records, including signed informed consent form, copies of IRB submissions, etc., for at least 7 years after the termination of the study or longer if required by the study sponsor, funding agency, or Federal law.
* I will comply with internal or external research auditors; please refer to the CHA [Research QA/QI Program – Auditing and Monitoring](http://www.challiance.org/Academics/QualityAssuranceQualityImprovement.aspx) webpage for study management tools.
* I will designate a qualified co-investigator to assume direct responsibility of this study if I will be unable to personally direct this study, as when on sabbatical leave or vacation.

**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_**

**Principal Investigator Signature Date**

**For IRB Office Use Only: Conflict of Interest (COI) Disclosure Review**

I confirm that:

* COI disclosure forms are on file in the IRB office for all of the study team members listed above in this application.
* I have reviewed each submitted COI disclosure form.
* Based on applicable COI policies, I determined that no member of the study team has a COI that prevents him/her from participating in the conduct of this project.

OR

A potential COI has been identified and is being reviewed by \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_.

Date of COI disclosure review: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Reviewer signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_

Reviewer printed name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

1. [↑](#footnote-ref-1)
2. CHA defines “research team members” as those who contribute to design, conduct, or reporting of a research study; have direct contact with study participants; contribute to the research in a substantive way; have contact with a study participant’s identifiable data or biological samples (*e.g.,* tissue, blood, urine); or use participants’ personal information. CHA expects the PI to make a good faith effort to meet the spirit of research education training requirements by assuring all research team members receive research-related education & training appropriate to project role. See the [IRB Research Education](http://www.challiance.org/Academics/HumanSubjectTraining.aspx) site for additional info. [↑](#footnote-ref-2)
3. See CHA research education requirements on the [IRB Research Education](http://www.challiance.org/Academics/HumanSubjectTraining.aspx) website. [↑](#footnote-ref-3)
4. If the research team member did not complete the CHA CITI education requirements, submit a copy of the certificate of completion with the application. [↑](#footnote-ref-4)