

1.0 General Information

1.1 *Please enter the full title of your study (Spell out acronyms):

Enter Parent Grant (Training Grant) Title

1.2 *Please enter the Study Nickname you would like to use to reference the study:

Enter Parent Grant (Training Grant) Nickname

2.0 Add Department(s)

2.1 List of Departments associated with this study:

Select primary department of PI. (If your Department is Medicine then please list your Section and indicate that as Primary Department)

Primary
Dept?

Department Name



3.0 Assign key study personnel (KSP) access to the study

3.1 *Please add a Principal Investigator for the study:

Enter name of PI who is listed as PI on Training Grant

Select if applicable -- *No need to select*

☐ Student

☐ Resident

☐ Fellow

If the Principal Investigator is a Student, Resident, or Fellow, the name of the Faculty Advisor must be supplied in Section 3.4 below.

3.2 If applicable, please select the Protocol Staff personnel: Leave Blank

A) Additional Investigators *Leave Blank*

B) Research Support Staff *Leave Blank*

No Research Staff have been added.

3.3 *Please add a Study Contact:

Optional.

Enter name of anyone you wish to also get notices from IRB about this protocol, for example, PI's administrator.

The Study Contact(s) will receive all important system notifications along with the Principal Investigator. (e.g. The study contact(s) are typically either the Study Coordinator or the Principal Investigator themselves).

3.4 If applicable, please add a Faculty Advisor: *Leave Blank*

3.5 If applicable, please select the Designated Department Approval(s):

Enter name of person to sign as Section Chief or Dept. Chair. (Note: PI cannot sign off on his/her own protocol)

3.6 If applicable, please select the Administrative Assistant(s) *Leave Blank*

List here anyone performing administrative tasks only (not engaged in research and having no contact with subjects or identifiable data; where certification/recertification and COI disclosure form are not required)- Click on (?) icon for more info.

4.0 External non-BU/BMC Investigators

4.1 In this section, only list non-BU/BMC investigators (not a full-time or permanent part-time employee of BMC, BU, BPHC, etc.). Any BU/BMC personnel should be listed in the KSP section (3rd section)

List here all non-BU/BMC persons working on the protocol who will be *engaged in the research on behalf of BU/BMC*. This includes all persons who are conducting research *under an Authorization Agreement (IAA) with BU/BMC IRB*.

Leave Blank

4.2 Does this study involve participation of non-BUMC investigators who are determined to be “not-engaged” in the research?

Answer No

Yes No



If you answered Yes above, indicate in the text box below; the names of the non-BUMC investigators, all study activities they will be performing, the names of their institutions, and why they are determined to be NOT-Engaged in the research (based on the OHRP engagement guidance).

4.3 Study Attachments

Click on the link below to attach any necessary documents related to external non-BU/BMC personnel.

Do not attach anything here

No electronic document has been associated.

5.0 Investigator Information from INSPIR I

5.1 This section had been migrated from INSPIR I.

- If this is a new study, please skip this section (click Save and Continue).
- If this is a study that was migrated from INSPIR I, DO NOT ADD ANY MORE INVESTIGATORS IN THIS SECTION. YOU CAN ONLY DELETE INVESTIGATORS HERE. All BU/BMC personnel should be listed in the KSP section (3rd section), and all non-BU/BMC investigators should be listed in the External non-BU/BMC Investigators section (4th section).

Leave Blank -Do not complete

KSP Info Additional Personnel Info

No records have been added.

6.0 Conflict of Interest

6.1 Conflict of Interest Disclosure

By approving this protocol, as Principal Investigator, I am confirming that the **appropriate individuals** have filed a BU **Project Specific Disclosure (PSD)** with the **appropriate office**. I understand that this is a continuing obligation as **new** individuals join my research team in the future.

☒ Agree *Check agree (and be sure COI disclosure has been submitted to COI Office)*

Of the BU PSDs submitted, have any *significant financial interests* been disclosed?

☐ Yes ☐ No

If yes, please specify who has disclosed a COI.

*****Do NOT submit COI disclosures to IRB. Do NOT attach disclosures with this IRB submission.***

7.0 Funding Source

7.1 Funding Source *Check funding source*

What is the source of your research funding? If you have multiple sources of funding (including sub-awards), check all that apply.

- ☐ Unfunded Student Research
- ☐ Dept/Internally funded
- ☐ Government
- ☐ Industry
- ☐ Foundation/Other
- ☐ Training Grant (e.g. T32, K-award)

7.2 Funding Details

For instructions on how to complete this section, click on the Help icon. *Complete this section*

Sponsor List

It is important that you answer all the questions in this section. Click the ? (help icon) for assistance.

Sponsor Name:

Sponsor Type:

Is Primary Grant

Holder?
Contract Type:
BU Source Number
or BMC AU Number:
Award Number:
Grant Title:
PI Name:

7.3 Grants Office *Check the appropriate grants office*

In the check boxes below, please indicate which grants office is handling your award/ sub-award.

- ☐ BU Office of Sponsored Programs (OSP-med)
☐ BMC Grants Administration (OGA)
☐ Charles River Campus Office of Sponsored Programs (OSP-CRC)
☐ Other

Funding Notifications: *Check the appropriate box*

- ☐ I have received a fundable score for this study.
☐ I have received a Just In Time notice (JIT)
☐ I have received a Notification of Award (NoA)

7.4 Study Attachments *Attach a copy of the training grant. *Attachment must include face page with the grant. You may exclude CVs and budgets.*

Click on the Help (?) icon for information on what you're required to attach in this section.

No electronic document has been associated.

7.5 Funding Source Info from INSPIR I - STOP! Do not complete this section below; this section will soon be removed. Please complete section 7.2 above instead. *Do not complete section 7.5*

This table is read-only. It will only be populated if this study was migrated from INSPIR I. If there are entries in this table, please use them to enter the funding information into the new Funding Source table above.

Funding Type Sponsor Name Award # PI of Award Industry Protocol Number

Dept/Internally Funded	=	=		
Government	=	=	=	
Industry	=	=	=	=
Foundation/Other	=	=	=	

Industry Protocol Number:

BU Source # or Record #:

BMC AU # or Record #:

ARRA Award:

☐ Please check here if this protocol will be funded through an ARRA award

8.0 Study Summary

8.1 Provide a brief summary of the project in lay terms (in 300 words or less).

Use the following wording for your study summary (as long as you agree).

This protocol is being submitted for this training grant. A copy of the grant is attached.

This is being submitted as Not Human Subjects Research because there are no specific human subjects research activities described in this grant. Any human subjects research involving subjects, their data or specimens conducted by any of the trainees listed on this training grant will be submitted separately to the IRB for review once the research has been developed.

The trainees have all been informed that they may not begin any human subjects research activities (including but not limited to recruitment, consenting, enrollment, data/sample collection, interventions, data analysis or follow-up) until full IRB approval has been obtained. Conditional approval and deferral do not represent full IRB approval.

9.0 Study Site Information

9.1 Select one: *Select "single site"*

- ☒ **Single site research** conducted by BUMC investigator(s) (skip question #2 below)
- ☐ **Multi-site research project** - BUMC is a research site but is NOT the main study site (Skip question #2 below)
- ☐ **Multi-site research** - BUMC is the main research site and/or BUMC investigator is the overall PI of the entire study or the FDA sponsor (must complete #2 below)

9.2 Provide details of all other research sites involved in this study.

Leave blank

Institution & PI Information IRB approval for site

No records have been added

9.3 Institution(s) where work will be performed in the U.S: (Please skip this question for new studies - The following data was migrated from INSPIR I (if any). Eventually, the box below will go away. So please remove your answer from the box below and place it in the corresponding table above in section 9.2 by cutting and pasting it. The box below should be left blank)

Leave blank

List below all other U.S. sites where study activities (e.g., recruitment, enrollment, testing procedures) will take place. For each institution that is engaged in the research (see DHHS 1/26/99 guidance memorandum on Engagement of Institutions in Research), provide their FWA number and confirm that IRB approval has been or will be obtained for each site engaged in the research. This does not include multi-center studies, unless the PI is the PI for all sites in this study.

9.4 Does this study involve Community Based Participatory Research?

Select "No"

☐ Yes ☒ No

9.5 Indicate below if any recruitment, consenting, and/or study interventions/procedures/data collection will take place in any of the following places (check all that apply)

Leave blank

- ☐ Boston Healthnet CommunityHealth Centers (click on ? icon for listing)
- ☐ MD offices or clinics (not part of BUMC campus)
- ☐ Subjects' places of residence including nursing homes, assisted living facilities, etc.
- ☐ Community centers or other 'community' locations (homeless shelters, daycare, etc.)
- ☐ International sites
- ☐ Veterans Administration (VA)

9.6 Study Attachments ***Do not attach anything here***

Here you can attach any study sites related documents. Attach IRB approval letters from other institutions (If you answered question #2).

No electronic document has been associated.

10.0 Navigation Menu

Please note: Questions in the Navigation Menu section determine which subsequent sections will be displayed and which ones will be hidden. If later you make any change to the Navigation Menu section, you will need to click on the "Save and Continue to Next Section" button throughout the whole application to display any new required section or hide any sections that are no longer required.

Check "No" boxes for all questions in Section 10 except question 10.3. Answer question 10.3 as shown below

10.1 Emergency Use

Is this application for an FDA approved EMERGENCY USE of an Investigational Drug or Device?

☐ Yes ☒ No

10.2 Individual Patient IND or Humanitarian Use Device

Is this application for an FDA approved Individual patient (single use) IND or Humanitarian Use Device?

☐ Yes ☒ No

10.3 Review Path Determination

- ☒ This project meets the regulatory definition of Not Human Subject Research (NHSR). Examples are Quality Assurance, Quality Improvement projects, or studies involving obtaining data/tissue.
- ☐ BUMC has delegated IRB review to another institution (BUMC is Institution B). (Please note: this relationship requires an Authorization Agreement.)
- ☐ According to the Engagement of Institutions in Research guidance by OHRP, neither BUMC (Boston University, Boston Medical Center) nor affiliated institutions/organizations for which the BUMC IRB has oversight responsibilities is "engaged" in human subjects research.
- ☐ This study fits into one or more of the Federal Exempt categories.
- ☐ None of the above. This study requires Expedited review or the review of the Full Board.

10.4 IRB Authorization Agreement (IAA) - BUMC is Institution A

Does this study have or require an IRB Authorization Agreement (IAA) where investigators from another institution will rely on BUMC IRB review ? ***

☐ Yes ☒ No

**If this study has or will require an IRB Authorization Agreement (IAA) where BUMC investigators will rely on IRB review by another institution, do not check YES here, but instead, go to Exempt-BUMC is Institution B and check yes there.

***If the study is Exempt, then there should not be an IAA.

10.5 International Research

Are any BU/BMC investigators involved in any way in any research activities at any non-US (international) sites, including oversight of international research activities?

☐ Yes ☒ No

10.6 HIPAA Compliance

Is the PI a member of the covered entity and the study involves the collection of protected health information (PHI)? Is any investigator or member of the study staff, whether a member of the covered entity or not, using (i.e. accessing, recording) and/or disclosing PHI as part of this research? If your answer to either question is YES then select Yes below.

☐ Yes – This study is subject to the HIPAA Privacy Rule
☒ No – this study is HIPAA Exempt

10.7 Genetics

Does this research involve genetic testing, gene therapy, or collection of genetic information?

☐ Yes ☒ No

10.8 Biological Samples Collection

Does this study involve collecting, banking, and/or distributing biological samples?

☐ Yes ☒ No

10.9 Drugs/Biological Agents

Does this study involve administering drugs or biological agents?

☐ Yes ☒ No

10.10 Device Does this study involve testing or use of a medical device?

☐ Yes ☒ No

10.11 Repositories

Will you be collecting data or samples that will be placed into a repository, or will you be establishing a repository (either as a new protocol or to be added to an existing protocol)? *(Do not check yes if this protocol involves ONLY obtaining samples FROM a repository to conduct this research)*

☐ Yes ☒ No

10.12 StudyFinder Listing

Do you agree to have the study title, summary, and PI name and e-mail address listed on StudyFinder, a publicly viewable medical campus website for general publicity and collaboration purposes? (If you also want to use StudyFinder to recruit subjects, there is another question to answer in the Recruitment section.)

☐ Yes ☒ No

11.0 NHSR (Not Human Subjects Research)

Answer questions 11.1-11.4 as answered below (as long as you agree).

11.1 Some studies may be determined to be Exempt from further BUMC IRB review because they do NOT meet the federal definitions of HUMAN SUBJECTS or RESEARCH.

Provide a detailed explanation of the planned project including a description of the proposed study population and the goals of the project.

Purpose of this submission is to submit the training grant for IRB review as NHSR.

11.2 Provide a detailed explanation as to why this project does not meet the definition of human subjects research.

No human subjects research activities are specified in the parent grant.

11.3 Describe any plans for publication or presentation of any data collected as a result of this project.

None specified.

11.4 Describe any risks/potential risks associated with this project.

None- no human subjects activities specified in the parent grant.

11.5 Study Attachments

Provide any supporting materials as attachments

- If this project is funded please attach a copy of the grant (if not already attached in the Funding Source section)
- Attach other supporting documents (e.g. a letter from Red Cross or industry vendor verifying that human tissue samples are anonymous samples provided for commercial use)

If you didn't already attach a copy of the training grant with Section 7, attach it here.