# CREATING YOUR INSPIR CEDE APPLICATION

Principal Investigators (or their research staff on behalf of the Principal Investigator) should follow the step-by-step instructions, and check off each step. These are basic cede application instructions for ceding to another IRB for a study with a Lead Principal Investigator (PI) from an outside institution.

Go to the IRB website at [http://www.bumc.bu.edu/irb/submission-requirements/when-to-submit/ceding-review/](http://www.bumc.bu.edu/irb/submission-requirements/when-to-submit/ceding-review/) for special application instructions for the following types of research studies:

- Multi-center Industry-sponsored studies involving an Investigational drug (IND) or investigational device (IDE) using Commercial IRBs; or
- NIH federally-funded studies requiring a Single IRB; or
- Studies initiated by special consortium groups with a central institutional review board.

For questions, send an email to medirb@bu.edu.

|☐| 1. Has the IRB contacted you to inform you that you have been invited by a SMART IRB member institution to participate as a Relying Site to their approved protocol (this contact will include the SMART IRB request and study documents for you to review)?
|☐| NO. Proceed with Step 2.
|☐| YES:
|☐| Respond to the IRB’s email and confirm whether or not you wish to participate in the study. If you answer YES, then proceed with Step 4.

|☐| 2. Will you be “engaged in research” in the Lead PI’s study (interacting directly with subjects for the purpose of collecting research data; and/or accessing individually identifiable data for research purposes)?
|☐| NO.
|☐| YES:
|☐| Will you be recruiting and consenting subjects at BMC or BU Medical Campus? ☐ NO – proceed with Step 4. ☐ YES – proceed with Step 3.

|☐| 3. Is the IRB of Record selected by the Lead PI from a SMART IRB member institution AND has AAHRPP accreditation?

Name of Lead PI’s IRB of Record:

SMART IRB member: ☐ NO ☐ YES

(Look up at [www.smartirb.org](http://www.smartirb.org), then click the Participating Institutions tab)
AAHRPP accreditation:  ☐ NO  ☐ YES

(Look up at http://www.aahrpp.org/learn/find-an-accredited-organization)

☐ If you answered NO to either question, then send an email to medirb@bu.edu to ask whether the IRB will be willing to cede review to this IRB of Record (Step 3 continued)

  . Provide the name of the IRB of Record; whether it is a SMART IRB member or AAHRPP accredited, a brief description of the study, and a detailed description of your research activities, including that you are recruiting and consenting subjects at BMC or BU Medical Campus.

☐ If you answered YES to both questions, then proceed with Step 4.

☐ 4. ☐ Reconfirm your home institution (either Boston Medical Center or Boston University Medical Campus) by looking up your name in the “PI’s Home Institution Finder” at http://www.bumc.bu.edu/PIfinder (you will need to log in). If you are not listed in the PI’s Home Institution Finder, then contact Diana Lehman at dlehman@bu.edu for assistance. The IRB is the IRB of Record for both Boston Medical Center and Boston University Medical Campus, and refers to the PI’s Home Institution Finder to code new INSPIR studies to the local PI’s correct home institution. Also, if the Lead PI’s online SMART IRB request is made to the wrong home institution for you, then it will be rejected by the IRB. See special instructions at the PI’s Home Institution Finder for when the Principal Investigator is a student, resident, or fellow.

  The correct home institution is ☐ BMC ☐ BU Medical Campus

☐ Confirm that you can log in to INSPIR and have created an INSPIR account with either your bu.edu or bmc.org email address. See How to get access to INSPIR II.

☐ Confirm that you have completed your INSPIR profile in the following fields: Name, Degree (select from the dropdown menu), Gender, Specialty, Relationship to the Institution, Affiliation, Department, Phone, and Mailing Address Text box (insert your Department, Building Name, and Street Address). See How to update your Personal Profile

☐ Confirm that you and your internal study staff for this cede application have completed the required Medical Campus CITI training for the study:

  ☐ For all studies, see Initial Certification. If this training was previously taken at another institution, then you need to transfer your CITI credits to the institution, “Boston University Medical Campus/Boston Medical Center”. Instructions can be found here.

  ☐ For clinical trials, see CITI Good Clinical Practice (GCP) training
☐ Confirm that you do not have any expired INSPIR studies as the Principal Investigator. If you are not sure, then send an email to medirb@bu.edu. The IRB will not be able to approve any new INSPIR studies for you until a final report is submitted to close the expired INSPIR study; or appropriate action is taken as directed by the IRB to reactivate the study.

☐ Proceed with step 5.

☐ 5. If the IRB of Record is a SMART IRB member, then contact the Lead PI and request that he/she initiate an online SMART IRB request to add you/your home institution (specify Boston Medical Center or Boston University Medical Campus) as a Relying Site to the study if this has not already been done.

☐ The IRB has already notified me of the Lead PI’s online SMART IRB request. Proceed with Step 6.

☐ The Lead PI has confirmed that an online SMART IRB request will be submitted to add me/my home institution as a Relying Site to the study. Proceed with Step 6.

☐ Not applicable. The Lead PI’s home institution or IRB of Record is not a SMART IRB member, and I will not be recruiting and consent subjects at BMC or BU Medical Campus. Proceed with Step 6.

☐ 6. Confirm that you have the following documents from the Lead PI, or request any missing documents from the Lead PI so that you can create your INSPIR cede application (if the Lead PI’s study has not yet received approval from the IRB of Record, then request the versions of the available documents that were submitted to the IRB of Record):

- Initial approval letter from the IRB of Record
- Current renewal approval letter from the IRB of Record (if applicable)
- Application submitted to the IRB of Record
- Separate Protocol document (if applicable)
- Consent template from the IRB of Record so that you can create your site-specific consent (if applicable).

☐ Proceed with Step 7.
☐ 7. INSPIRE CEDE APPLICATION

☐ Gather all the Lead PI’s documents from the IRB of Record.
☐ Create a new INSPIRE protocol draft. See How to create a new protocol draft in INSPIR II
☐ Answer all the questions in the application as they appear, then click SAVE AND CONTINUE TO NEXT SECTION after each section. Note special instructions for some of the sections below. The INSPIRE application will “hide” or “add” sections to the cede application, depending on your answers to the questions:

SECTIONS

☐ 1.0 General Information: Name the study with the identical title as the Lead PI’s study.

☐ Study Nickname: If this cede application corresponds with an online SMART IRB request from the Lead PI, then enter the SMART IRB ID number followed by any other Nickname text (for example, “Smart IRB ID 2548”).

☐ 2.0 Department Access: Complete this section.

☐ 3.0 Key Personnel: Do not add anyone from the Lead PI’s home institution or IRB of Record. Only add personnel from BMC or BU Medical Campus. You can also add BU-CRC students who are not seeking BU-CRC academic credit. If you are trying to add someone with a bu.edu or bmc.org email address but cannot find their name in the INSPIRE database, then provide them with these instructions to create an INSPIRE account: How to get access to INSPIR II. They should notify you when their INSPIRE account is activated. You can then try to add them again to your INSPIRE application and should be able to find their name in the INSPIRE database.

☐ 4.1 Review Path Determination: Select the 2nd option: BMC/BU Medical Campus (the Relying Institution) cedes IRB review to another institution (the Reviewing Institution) under an Authorization Agreement.

☐ 4.2, 4.3, and 4.4: Complete these sections

☐ 5.0 Required Training and Conflict of Interest: Complete these sections

☐ 6.1 Reviewing Institution IRB approval: Answer YES, then enter the study number in the text box (refer to the approval letter from the IRB of Record).

☐ 6.2 Engaged in research: Answer YES

(Step 7 continued)
☐ 6.3 Option 1 Commercial Institutional Review Board: Answer NO.

☐ 6.4: Option 2 Central Institutional Review Board: Answer NO.

☐ 6.5: Option 3 Other Reviewing Institutions: Answer YES.

☐ IAA List: Select the name of the Lead PI’s IRB of Record or home institution (refer to the approval letter from the IRB of Record). If you do not see the name of the institution, send an email to medirb@bu.edu to request that it be added to the list.

☐ Reviewing Institution Federalwide Assurance Number:
  ☐ If the Lead PI’s IRB of record of home institution is a SMART IRB member, then just enter “SMART IRB”.
  ☐ If the Lead PI’s IRB of record of home institution is not a SMART IRB member, then obtain the Federalwide Assurance Number from the PI.

☐ Reviewing Institution Protocol/Study Title: Enter the same title as the Lead PI’s study (refer to approval Letter from the IRB of Record).

☐ Reviewing Institution Principal Investigator Last Name, First Name: Refer to approval letter from the IRB of Record.

☐ Reviewing Institution IRB Contact Name:
  ☐ If this cede application is for the Lead PI’s online SMART IRB request, then enter the SMART IRB ID number (for example, “SMART IRB ID 2548”; then leave remaining fields blank (Reviewing Institution IRB Contact Name, Phone Number, Email address)
  ☐ If the Lead PI’s IRB of Record or home institution is not a SMART IRB member, then obtain the Reviewing Institution IRB Contact Name, Phone Number, and Email address from the Lead PI.

☐ 6.6 Location and 6.7 Recruiting subjects: Answer both questions as appropriate for the study. Depending on how you answer these questions, the INSPIR application will “hide” unnecessary sections.

☐ 6.8 Attach all of the Lead PI’s study documents that you have available

☐ ANSWER THESE SECTIONS IF THEY APPEAR IN YOUR CEDE APPLICATION:

  ☐ 7.1 Research activities: Provide a detailed description of the research activities that will take place at BMC.

  ☐ 7.2 Protocol Type: Complete all the questions in this section

(Step 7 continued)
☐ 7.3 Compensation for Research Related Injury:

☐ 8.0 Funding Source: Complete all the questions in Sections 8.1 to 8.4. Refer to the approval letter from the IRB of Record or IRB application in the Funding Source section to complete the Funding Details; or request the details from the Lead PI.

☐ 9.0 Recruitment Procedures/Materials: Complete sections 9.1 to 9.4.

☐ 10.1 Access to protected health information (PHI): Answer No or YES. If YES, then complete all the additional questions.

☐ Initial Review Submission Packet
  ☐ Scroll down to “Additional Special Routing”, then answer all the questions.

☐ When you have submitted your INSPIR cede application, then please also send an email to medirb@bu.edu with your INSPIR H- number and the SMART IRB ID # if applicable, so that it can be identified as a cede application in the INSPIR queue. You can also send an email to medirb@bu.edu if you have any questions about the cede application or on the INSPIR system.