

## 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/>, 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](mailto:medirb@bu.edu).

<input type="checkbox"/>	<p>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)?</p> <p style="margin-left: 20px;"><input type="checkbox"/> NO. Proceed with Step 2.</p> <p style="margin-left: 20px;"><input type="checkbox"/> YES:</p> <p style="margin-left: 40px;"><input type="checkbox"/> 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.</p>
<input type="checkbox"/>	<p>2. Will you be “engaged in research” in the Lead PI’s study (<u>interacting directly with subjects</u> for the purpose of collecting research data; and/or <u>accessing individually identifiable data</u> for research purposes)?</p> <p style="margin-left: 20px;"><input type="checkbox"/> NO.</p> <p style="margin-left: 40px;"><input type="checkbox"/> Send an email to <a href="mailto:medirb@bu.edu">medirb@bu.edu</a> to confirm that you do not need to submit an INSPIR cede application to participate in the Lead PI’s study: Provide a brief description of the study and a detailed description of your research activities, and how you will NOT be “engaged in research.”</p> <p style="margin-left: 20px;"><input type="checkbox"/> YES.</p> <p style="margin-left: 40px;"><input type="checkbox"/> Will you be recruiting and consenting subjects at BMC or BU Medical Campus?   <input type="checkbox"/> NO – proceed with Step 4.   <input type="checkbox"/> YES – proceed with Step 3.</p>
<input type="checkbox"/>	<p>3. Is the IRB of Record selected by the Lead PI from a SMART IRB member institution AND has AAHRPP accreditation?</p> <p style="margin-left: 20px;">Name of Lead PI’s IRB of Record:</p> <p style="margin-left: 20px;">SMART IRB member:   <input type="checkbox"/> NO   <input type="checkbox"/> YES</p> <p style="margin-left: 40px;">(Look up at <a href="http://www.smartirb.org">www.smartirb.org</a>, then click the Participating Institutions tab)</p>

	<p>AAHRPP accreditation: <input type="checkbox"/> NO <input type="checkbox"/> YES          (Look up at <a href="http://www.aahrpp.org/learn/find-an-accredited-organization">http://www.aahrpp.org/learn/find-an-accredited-organization</a>)</p> <p><input type="checkbox"/> If you answered NO to either question, then send an email to <a href="mailto:medirb@bu.edu">medirb@bu.edu</a> 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.</p> <p><input type="checkbox"/> If you answered YES to both questions, then proceed with Step 4.</p>
<input type="checkbox"/> 4.	<p><input type="checkbox"/> 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 <a href="http://www.bumc.bu.edu/PIfinder">http://www.bumc.bu.edu/PIfinder</a> (you will need to log in). If you are not listed in the PI’s Home Institution Finder, then contact Diana Lehman at <a href="mailto:dlehman@bu.edu">dlehman@bu.edu</a> 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.</p> <p>The correct home institution is <input type="checkbox"/> BMC <input type="checkbox"/> BU Medical Campus</p> <p><input type="checkbox"/> 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 <a href="#">How to get access to INSPIR II</a>.</p> <p><input type="checkbox"/> 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 <a href="#">How to update your Personal Profile</a></p> <p><input type="checkbox"/> Confirm that you and your internal study staff for this cede application have completed the required Medical Campus CITI training for the study:</p> <p style="padding-left: 40px;"><input type="checkbox"/> For all studies, see <a href="#">Initial Certification</a>. If this training was previously taken at another institution, then you need to transfer your CITI credits to the institution, “<b>Boston University Medical Campus/Boston Medical Center</b>”. Instructions can be found <a href="#">here</a>.</p> <p style="padding-left: 40px;"><input type="checkbox"/> For clinical trials, see CITI Good Clinical Practice training <a href="#">Good Clinical Practice (GCP) training</a></p>

	<p><input type="checkbox"/> Confirm that you do not have any expired INSPIR studies as the Principal Investigator. If you are not sure, then send an email to <a href="mailto:medirb@bu.edu">medirb@bu.edu</a>. 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.</p> <p><input type="checkbox"/> Proceed with step 5.</p>
<input type="checkbox"/>	<p>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.</p> <p><input type="checkbox"/> The IRB has already notified me of the Lead PI's online SMART IRB request. Proceed with Step 6.</p> <p><input type="checkbox"/> 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.</p> <p><input type="checkbox"/> 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.</p>
<input type="checkbox"/>	<p>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):</p> <ul style="list-style-type: none"> <li><input type="checkbox"/> Initial approval letter from the IRB of Record</li> <li><input type="checkbox"/> Current renewal approval letter from the IRB of Record (if applicable)</li> <li><input type="checkbox"/> Application submitted to the IRB of Record</li> <li><input type="checkbox"/> Separate Protocol document (if applicable)</li> <li><input type="checkbox"/> Consent template from the IRB of Record so that you can create your site-specific consent (if applicable).</li> </ul> <p><input type="checkbox"/> Proceed with Step 7.</p>



## 7. INSPIR CEDE APPLICATION

- Gather all the Lead PI's documents from the IRB of Record.
- Create a new INSPIR 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 INSPIR 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 INSPIR database, then provide them with these instructions to create an INSPIR account: [How to get access to INSPIR II](#). They should notify you when their INSPIR account is activated. You can then try to add them again to your INSPIR application and should be able to find their name in the INSPIR database.
- 4.1 Review Path Determination: Select the 2<sup>nd</sup> 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](mailto: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](mailto: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](mailto:medirb@bu.edu) if you have any questions about the cede application or on the INSPIR system.