

ADDING EXTERNAL INVESTIGATORS FROM INSTITUTIONS  
WITHOUT A FEDERALWIDE ASSURANCE NUMBER  
TO YOUR INSPIR STUDY

“Collaborating Institutional Investigator Agreement (CIIA)”

I confirm that all the CIIA External Investigators are “engaged in research” (interacting with directly with subjects for the purpose of collecting research data; and/or accessing individually identifiable data for research purposes. If they are not “engaged in research”, then they do not require IRB oversight, do not need to be listed on my INSPIR application, and do not require a CIIA agreement.

I understand that I will be required to submit amendments to add additional CIIA External Investigators, even if there is an existing signed CIIA Agreement in place for their institution for the INSPIR study under “Other Study Documents – IAA/IIA Agreement.”

I confirm that I will verify that all CIIA External Investigators have completed BU Medical Campus CITI training (and GCP training for clinical trials) before adding them to the INSPIR study.

I confirm that I will request that all CIIA External Investigators complete a CIIA template provided by the IRB, and attach their BU Medical Campus CITI certificates (and GCP certificates for clinical trials) to their completed CIIA template.

**INSPIR APPLICATION SECTIONS**  
**For Institutions with no Federalwide Assurance Number**  
**Collaborating Institutional Investigator Agreement (CIIA)**

<input type="checkbox"/>	<p><b>CITI Training</b>  CIIA External Investigators have completed BU Medical Campus CITI Training (and GCP Training if the INSPIR study is a clinical trial) See <a href="#">Initial Certification</a> and <a href="#">GCP Training through CITI (Collaborative Institutional Training Initiative)</a>.</p>
<input type="checkbox"/>	<p><b>Completing Amendment Description (if adding to an approved INSPIR study): List the names of all added CIIA External Investigators</b></p>
<input type="checkbox"/>	<p><b>Section 9.0 Study Site Information</b></p> <p><input type="checkbox"/> Section 9.1 Multi-site research (3<sup>rd</sup> option) : Select this option because research activities will require a CIIA agreement with a Relying Site.</p> <p><input type="checkbox"/> Section 9.2 IRB Authorization Agreement: Select YES</p> <p><input type="checkbox"/> Section 9.3 Details of all other research sites: Click ADD A NEW ROW for each Relying Site, then complete the information for PI and Institution name. Check off “Requesting an appropriate Authorization Agreement for this Relying Institution.”</p> <p><input type="checkbox"/> Section 9.4 Management of Information: Complete this text box as it relates to all your Relying Sites.</p> <p><input type="checkbox"/> Section 9.5 Study Attachments: Attach the CV for each external site PI.</p> <p><input type="checkbox"/> Click SAVE AND CONTINUE TO NEXT SECTION.</p>
<input type="checkbox"/>	<p><b>Section 10.0 IRB Authorization Agreement</b></p> <p><input type="checkbox"/> Check the box for “B. External Investigators who fall into any of these Special Categories:”</p> <p><input type="checkbox"/> Section 10.2 Table of External Investigators</p> <ul style="list-style-type: none"> <li><input type="checkbox"/> Click ADD EXTERNAL PERSONNEL TO THE STUDY for each individual added</li> <li><input type="checkbox"/> Complete all the fields for each CIIA External Investigator. In the Institution column, enter “CIIA”. Assign the applicable Role.</li> <li><input type="checkbox"/> Complete the next section for Role/Institution/Role Description. <ul style="list-style-type: none"> <li><input type="checkbox"/> Select the same Role as in the Table.</li> <li><input type="checkbox"/> For Institution, select “none”</li> <li><input type="checkbox"/> In the Role Description text box, enter a detailed description of research activities explaining how the External Investigator is “engaged in research” (interacting</li> </ul> </li> </ul>

	<p>directly with subjects for the purpose of collecting research data; and/or accessing individually identifiable data for research purposes); and add that BU Medical Campus CITI training has been completed.</p> <p><input type="checkbox"/> Section 10.4 Conflicts of Interest: Answer NO or YES and provide an explanation in the text box. For BU studies, be sure to include these External Investigators in the study disclosure (see the <a href="#">Financial Interest Disclosure form</a> for <a href="#">Boston University</a>). For BMC studies, contact <a href="mailto:COI-Compliance@bmc.org">COI-Compliance@bmc.org</a> to request that the External Investigator be added to COI Smart to complete their disclosure.</p> <p><input type="checkbox"/> Section 10.5 PI Agreement: Complete this section. It is important to understand your responsibilities as the Lead PI:</p> <p><b>I understand that, if this request is approved, the BMC/BU Medical Campus IRB (“the IRB”) will be the IRB of record responsible for conducting the initial and continuing review of this protocol. I understand that the decision to cede IRB review is made jointly with the IRBs of the Relying Institution (or the Independent External investigator) and will not be the decision of the PI. The IRB, as the IRB of record, will have full responsibility for oversight of all aspects of the protocol EXCEPT for the following: The PI will have full responsibility for ensuring that the engaged research staff of the Relying Site Principal Investigator(s) in OPTION A have met all their home institutional requirements for ceded research. I will comply with the applicable policies of the IRB. I understand that this agreement is NOT considered approved until a formal Authorization Agreement is signed by the Institutional Officials of both institutions (or with each Independent External Investigator), and the fully signed Agreement is attached to this protocol.</b></p> <p><b>I understand that as PI for this study I am responsible the ethical conduct of this study. Oversight responsibilities include:</b></p> <ul style="list-style-type: none"> <li>• Ensuring that all OPTION B External Investigators are listed in the Table of External Investigators of this application</li> <li>• Ensuring that all the investigators follow the IRB protocol as approved and make no changes to the protocol without the approval of the IRB (except to eliminate immediate harm to subjects)</li> <li>• Reporting to the IRB (per policy) any adverse events, protocol deviations, or unanticipated problems related to the research activities conducted by the External Investigators</li> <li>• Reporting to the IRB any changes related to the status of the External Investigators</li> <li>• Following all applicable HIPAA rules and using appropriate safeguards to prevent the unauthorized use or disclosure of PHI (Protected Health Information)</li> <li>• Ensuring that External Investigators follow any determinations related to conflict of interest from BMC/BU Medical Campus or from their own Relying Institution.</li> </ul> <p><input type="checkbox"/> Click SAVE AND CONTINUE TO NEXT SECTION.</p>
<input type="checkbox"/>	<p>Update any other sections as needed.</p>

	<input type="checkbox"/> Click SAVE AND CONTINUE TO NEXT SECTION TO THE END OF THE APPLICATION.
<input type="checkbox"/>	<p><b>CIIA Agreement</b></p> <ul style="list-style-type: none"><li><input type="checkbox"/> The IRB will review your amendment or new initial submission with the addition of the CIIA External Investigators.</li><li><input type="checkbox"/> If the IRB agrees to be the IRB of record for the CIIA External Investigators., then the IRB will provide you with a CIIA agreement template for completion and signature by the CIIA External Investigator(s) and an official representing the CIIA non-assured institution.</li><li><input type="checkbox"/> You will then send back the completed CIIA to the IRB to complete the signature process.</li><li><input type="checkbox"/> No research activities can begin by the CIIA External Investigators until you receive confirmation from the IRB that the IRB submission is approved; and the fully executed CIIA Agreement is attached under “Other Study Documents – IAA/IIA Agreement.”</li></ul>