ADDING INDEPENDENT EXTERNAL INVESTIGATORS TO YOUR INSPIR STUDY
"Individual Investigator Agreement (IIA)"

☐ I confirm that the IIA External Investigators are performing research activities independent of, or unaffiliated with, any academic requirements, or any connection with an employer, institution, or organization.

☐ I confirm that all the IIA External Investigators are "engaged in research" (interacting 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 an IIA agreement.

☐ I confirm that I will verify that all IIA External Investigators have completed BU Medical Campus CITI training (and GCP training for clinical trials).

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

INSPIR APPLICATION SECTIONS
For Independent External Investigators
Individual Investigator Agreement (IIA)

☐	**CITI Training** IIA External Investigators have completed BU Medical Campus CITI Training (and GCP Training if the INSPIR study is a clinical trial) See Initial Certification and GCP Training through CITI (Collaborative Institutional Training Initiative).
☐	**IIA Agreement** ☐ Send an email to IRB Coordinator Roz Schomer (roz@bu.edu) to request an IIA template for each of your IIA External Investigators. Provide the INSPIR H- number and the full name of the External Investigator (no nicknames). ☐ Upon receipt of the IIA template(s), forward them to the IIA External Investigators for completion on Page 2 in the highlighted sections. They can type in their information, but they must manually handwrite their signature. ☐They should add their CITI certificates to the end of their completed IIA template, then scan the pages into one PDF file and forward the PDF file to you to attach to the INSPIR submission (either a new initial submission or to an amendment to an approved study). ☐ The IIA External Investigators cannot begin research activities until you receive IRB confirmation that the INSPIR submission is approved; and that the fully signed IIA Agreements are attached under "Other Study Documents – IAA/IIA Agreement."
☐	**Completing Amendment Description (if adding to an approved INSPIR study): List the names of all added IIA External Investigators**
☐	**Section 9.0 Study Site Information** ☐ Section 9.2 IRB Authorization Agreement: Select YES ☐ Click SAVE AND CONTINUE TO NEXT SECTION.
☐	**Section 10.0 IRB Authorization Agreement** ☐ Check the box for "B. External Investigators who fall into any of these Special Categories:" ☐ Section 10.2 Table of External Investigators ☐ Click ADD EXTERNAL PERSONNEL TO THE STUDY for each individual added ☐ Complete all the fields for each IIA External Investigator. In the Institution column, enter "IIA". Assign the applicable Role. ☐ Complete the next section for Role/Institution/Role Description.

☐ Select the same Role as in the Table.

☐ For Institution, select "none"

☐ In the Role Description text box, enter a detailed description of research activities explaining how the External Investigator is "engaged in research" (interacting 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.

☐ 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 **Financial Interest Disclosure form** for **Boston University**). For BMC studies, contact COI-Compliance@bmc.org to request that the External Investigator be added to COI Smart to complete their disclosure.

☐ Section 10.5 PI Agreement: Complete this section. It is important to understand your responsibilities as the Lead PI:

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.

I understand that as PI for this study I am responsible the ethical conduct of this study. Oversight responsibilities include:

- **Ensuring that all OPTION B External Investigators are listed in the Table of External Investigators of this application**
- **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)**
- **Reporting to the IRB (per policy) any adverse events, protocol deviations, or unanticipated problems related to the research activities conducted by the External Investigators**
- **Reporting to the IRB any changes related to the status of the External Investigators**
- **Following all applicable HIPAA rules and using appropriate safeguards to prevent the unauthorized use or disclosure of PHI (Protected Health Information)**
- **Ensuring that External Investigators follow any determinations related to conflict of interest from BMC/BU Medical Campus or from their own Relying Institution.**

	☐ Click SAVE AND CONTINUE TO NEXT SECTION.
☐	Update any other sections as needed. ☐ Click SAVE AND CONTINUE TO NEXT SECTION TO THE END OF THE APPLICATION.
☐	Attach the completed IIA templates with the CITI certificates attached.
☐	IRB review of completed IIA templates ☐ When the IRB has completed its review of your amendment or new initial submission adding the Independent External Investigators, it will determine whether it will agree to be the IRB of Record. ☐ If there are no issues, then the IRB will certify the CITI training and sign the IIA templates on the 2nd page. ☐ No research activities can begin by any Independent External Investigator until you receive confirmation from the IRB that the amendment or new initial submission has IRB approval; and that the fully signed IIA templates are attached to the INSPIR study under "Other Study Documents – IAA/IIA Agreement."