ADDING EXTERNAL INVESTIGATORS FROM INSTITUTIONS WITH A FEDERALWIDE ASSURANCE NUMBER TO YOUR INSPIR STUDY

☐ I confirm that all the External research sites involve at least one External Investigator who is "engaged in research" (interacting directly with subjects for the purpose of collecting research data; and/or accessing individually identifiable data for research purposes). If no investigator is "engaged in research", then the External Site does not require IRB oversight, does not need to be listed on my INSPIR application, and does not require a SMART IRB or traditional reliance/IAA agreement.

☐ I understand that I will not be required to submit amendments to add additional External Investigators where their institution has already been approved as an External Site. I confirm that I will maintain records of these additional External Investigators and will ask them to verify that they meet the ceded research requirements of their home institution and have completed required CITI training (either through the Medical Campus or through their home institution).

☐ I understand that as the Lead Principal Investigator, I will be required to submit an online SMART IRB request when requesting a reliance agreement to add a new SMART IRB member institution, as instructed by the IRB.

INSPIR APPLICATION SECTIONS
For Institutions with a Federalwide Assurance Number

IMPORTANT: Before using this checklist, verify that the IRB of Record or home institution has a Federalwide Assurance Number. Ask the External Investigator for the Federalwide Assurance Number, or look it up at the OHRP FWA Number database at http://ohrp.cit.nih.gov/search/FwaDtl.aspx.

☐	**CITI TRAINING** ☐ External Investigators from BU Charles River Campus and Boston HealthNet Community Health Centers should 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). ☐ External Investigators from other Institutions should consult with their home IRBs on whether to take CITI training from their own institutions; or our BU Medical Campus CITI training (and GCP training if the study is a clinical trial). ☐ The Lead PI is responsible for maintaining documentation that External Investigators have complied with applicable training requirements.
☐	**Completing the Amendment Description (if adding a new external site to an approved INSPIR study): name the external site(s) being added in the amendment**
☐	**Section 9.0 Study Site Information** ☐ Section 9.1 Multi-site research (3rd option): Select this option because research activities will require a SMART IRB or traditional reliance /IAA agreement with a Relying Site. ☐ Section 9.2 IRB Authorization Agreement: Select YES ☐ 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." If the PI is a student obtaining academic credit, then add "Student" after the Student's name in the PI text box. ☐ Section 9.4 Management of Information: Complete this text box as it relates to all your Relying Sites. ☐ Section 9.5 Study Attachments: Attach the CV for each external site PI. This is not needed if the only external investigator(s) is a student(s). ☐ Click SAVE AND CONTINUE TO NEXT SECTION.
☐	**Section 10.0 IRB Authorization Agreement**

	☐ Check the box for 10.1."A. Relying Institution(s) with an FWA Number." If there is no FWA number, this checklist does not apply; please see the separate checklist for "Individual Investigator Agreement" for External Investigators who are working on the study independent of and/or not affiliated with any employer, institution, or organization or "Collaborating Institution Investigator Agreement" for External Investigators who are affiliated with an institution that does not have an FWA. ☐ IAA List: Select the External Investigator's home institution from the dropdown list. If it is not listed, send an email to medirb@bu.edu to request that the institution be added to the list. ☐ Determine whether the External Investigator's home institution is a SMART IRB member). See www.smartirb.org, then click on the Participating Institutions tab, then look for the name of the institution. ☐ Is a SMART IRB member: click on the link to the institution to find a pop-up screen with the FWA number in the upper righthand corner ☐ Answer YES to the question, "Is this institution a participating SMART IRB member?" ☐ FWA Number: Enter the FWA Number ☐ For Contact Name for IRB Authorization Agreement: Enter, "SMART IRB ID #" if available, or "SMART IRB." Leave the rest of the IRB contact fields blank. ☐ Not a SMART IRB member. ☐ Select NO for the question, "Is this Institution a participating Smart IRB member?" ☐ FWA Number: Enter the FWA Number (from the External Investigator or http://ohrp.cit.nih.gov/search/FwaDtl.asp ☐ Complete name, phone and email for Contact for IRB Authorization Agreement. ☐ You do not need to list any additional External Investigators other than the Relying Site Principal Investigator in Section 9.3 because the home institution has a Federalwide Assurance Number. ☐ Section 10.4 Conflicts of Interest: Answer NO or YES and provide an explanation in the text box. ☐ 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.**
☐	Update any other sections as needed. ☐ Click SAVE AND CONTINUE TO NEXT SECTION TO THE END OF THE APPLICATION.
☐	Reliance Agreement(s) After reviewing this amendment or new initial submission in which you have requested an initial reliance agreement for External Investigators from an outside institution with a Federalwide Assurance Number, the IRB will then determine whether it will agree to be the IRB of Record for the External Investigators. If so, the IRB will proceed with the reliance agreement process: ☐ SMART IRB: The IRB will provide you with instructions for initiating an online SMART IRB request for those External Investigators from SMART IRB member institutions. ☐ Traditional Reliance Agreement: The IRB will provide you with a traditional reliance agreement for those External Investigators from institutions who are not SMART IRB members but have a Federalwide Assurance Number. You can forward it to the institution contact for signature; then return it to the IRB to complete the signature process. ☐ No research activities can begin by any External Investigator until you receive IRB approval for the amendment or new initial submission; and you receive confirmation from the IRB that the fully executed reliance agreement is attached to the INSPIR study under "Other Study Documents – IAA/IIA Agreement."