

**PROCEDURE FOR PREPARING
COMMERCIAL IRB SUBMISSIONS THROUGH SMART IRB
FOR MULTI-CENTERED INDUSTRY-SPONSORED SUBMISSIONS
WHERE THE INDUSTRY SPONSOR HOLDS THE IND OR IDE**

Commercial IRBs provide independent central IRB services for institutional and commercial clients.

Principal Investigators wishing to submit a multi-centered industry-sponsored protocol for which the Industry Sponsor is the holder of an investigational drug (IND) or an investigational device (IDE), have the option of submitting to the Commercial IRB selected by the Industry Sponsor as an INSPIR cede application PROVIDED:

- a. The Commercial IRB is AAHRPP-accredited (you can look this up here: <http://www.aahrpp.org/learn/find-an-accredited-organization>) AND
- b. The Commercial IRB is a participant in the SMART IRB reliance platform (you can look this up here: <https://smartirb.org/participating-institutions/>).

We are no longer accepting new IND or IDE submissions under the traditional WIRB agreement (non-SMART IRB) or for Hummingbird IRB (HIRB).

In summary, your options for IRB review for multi-centered industry-sponsored IND/IDE studies are the industry-sponsored Commercial IRB (provided they are accredited and are a SMART IRB Participating Institution), or the BMC/BU Medical Campus IRB.

INSTRUCTIONS:

STEP ONE	<ul style="list-style-type: none">• Look up your Principal Investigator at this website to reconfirm whether the PI's Home Institution is Boston Medical Center or BU Medical Campus (the IRB uses this website for the same purpose). http://www.bumc.bu.edu/ohra/look-up-an-investigators-home-institution/• Determine the industry sponsor's Commercial IRB for the protocol.• Determine if the Commercial IRB is AAHRPP-accredited (use the following link: http://www.aahrpp.org/learn/find-an-accredited-organization); and is a SMART IRB participant. <p><u>Instructions for Searching for a Commercial IRB through SMART IRB</u></p>
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	<ol style="list-style-type: none"> 1) Open the following link: https://smartirb.org/participating-institutions/ 2) In the Search text box, enter the name of the Commercial IRB 3) A link will appear with the name of the Commercial IRB if it is a SMART IRB Participating Institution. Click on the link to open up a pop-up window with the Commercial IRB’s Point of Contact information – you will need this information later. <p>If the Commercial IRB is not AAHRPP accredited or is not listed on the SMART IRB list of Participating Institutions, then your multi-centered industry-sponsored IND or IDE submission cannot be submitted to the sponsor’s Commercial IRB</p> <ul style="list-style-type: none"> • If the above conditions are met, then inform the sponsor that your submission can go through the sponsor’s Commercial IRB if your PI’s home institution (state BMC or BU Medical Campus) enters into a protocol-specific SMART IRB Agreement directly with the Commercial IRB, since both are SMART IRB Participating Institutions. The SMART IRB Agreement will replace any authorization agreements provided by the sponsor, and the sponsor should not bill BMC or BU Medical Campus. <p>NOTE: Smart IRB is a platform to enable IRB reliance among over 500 Participating Institutions who agree to collaborate in research studies with one another under a pre-signed master SMART IRB global reliance agreement. A protocol-specific SMART IRB Agreement is then created for each study. (see www.smartirb.org).</p> <ul style="list-style-type: none"> • If the sponsor approves of the SMART IRB Agreement with the Commercial IRB, then send an email to the Commercial IRB’s SMART IRB Point of Contact (copy the sponsor) to confirm their willingness to enter into a SMART IRB agreement with our institution for their review of the sponsor’s protocol (provide the sponsor’s name, protocol number, and protocol title). You will be attaching the Commercial IRB’s approval email to your INSPIR cede submission (See Step Five, 15d). • Inform the sponsor that you must now obtain approval from your BMC/BU Medical Campus IRB through an internal cede application for the sponsor’s IND or IDE submission BEFORE completing any additional forms or applications requested by the sponsor or the Commercial IRB.
STEP TWO	Customize the industry sponsor’s consent form template with the BMC/BU

	<p>Medical Campus specific information from the Adult Consent Form Template:</p> <p>Open the BMC/BUMC Adult Consent Form Template from the IRB website and copy the following items into the sponsor’s consent form template:</p> <ol style="list-style-type: none"> 1. The Basic Information at the beginning of the form must include the following fields: <ol style="list-style-type: none"> a. Principal Investigator: <i>(this should also include the PI’s email and mailing address)</i> b. BMC/BUMC IRB Submission Number (if sponsor will allow): c. Study-Related Phone Numbers: <ol style="list-style-type: none"> i. Regular Business Hours: ii. 24 Hours: 2. The HIPAA Authorization language must include Boston University and Boston Medical Center, as appropriate, among the organizations with access to PHI. 3. If the sponsor’s consent form includes language about the Genetic Information Nondiscrimination Act (GINA) and the research will take place in Massachusetts, the GINA language must be edited to include the Massachusetts-specific information (see Section 8.2.4). 4. In the QUESTIONS section: questions should be referred to the commercial IRB instead of the BMC/BUMC IRB. Please copy the following block of text (without quotations) into the questions section, and replace the italicized text with the commercial IRB’s information: <p>“You may also contact <i>(name of commercial IRB)</i> IRB:</p> <p><i>Commercial IRB name</i> <i>Commercial IRB Mailing address</i> <i>Commercial IRB Phone Number</i> <i>Commercial IRB Email</i></p> <p>The IRB is a group that helps monitor research. You should call or email if you want to talk to someone who is not part of the study about your rights as a research subject, questions, and/or concerns or complaints regarding this research study.”</p>
<p>STEP THREE</p>	<ol style="list-style-type: none"> 1. Create a Velos application (“Study Initiated” state) and upload the four required documents: <ol style="list-style-type: none"> a. Budget b. Protocol c. The Consent Form that was modified in STEP TWO d. Clinical Trial Agreement

	<p>2. In the Consent Form, the Clinical Trial Office will review the “Costs” section, and potentially the “Compensation for Injury” sections (if the PI’s Home Institution is BMC). The CTO may contact you with changes made to these sections based upon their review of the study documents uploaded into Velos; if this happens, you must send the modified Consent Form to the sponsor for approval of any changes.</p> <p>3. If your home institution is BU Medical Campus (see STEP ONE), please also send your Consent Form to BU-OSP for review of the “Compensation for Injury” language:</p> <p><u>OSP-MED</u> (Attorney Bill Segarra; Phone: (617) 353-6151; email segarra@bu.edu)</p> <p>4. Please attach the Consent Form you uploaded into Velos into the INSPIR cede application (see next STEP FOUR). You do not need to wait for the BMC CTO Consent Form review process to be completed to move on to STEP FOUR.</p>
<p>STEP FOUR</p>	<p>Prepare your INSPIR application. Answer all questions in each section.</p> <p>*Note: if you created your Velos application in STEP THREE BEFORE you created your INSPIR application, you will have received an IRB Number (H#) from INSPIR associated to your submission in Velos. Please use this H# for the below instructions.</p> <p>NOTE: All study-related documents should be attached in the Initial Review Submission Packet screen <u>after</u> the Application is completed.</p> <p>APPLICATION</p> <ol style="list-style-type: none"> 1. Section 1.0 – General Information <ol style="list-style-type: none"> a. Study Nickname: Enter the name of the commercial IRB and add any additional text (e.g., Advarra Study Nickname) 2. Section 2.0 – Set up Department(s) Access 3. Section 3.0 – Grant Key Personnel access to the study 4. Section 4.0 – Review Path Determination <ol style="list-style-type: none"> a. Section 4.1 – Be sure to check the 2nd option, “BMC/BU Medical Campus (the Relying Institution) cedes IRB review to another institution (the Reviewing Institution) under an Authorization Agreement.” b. Section 4.2, 4.3, and 4.4 – must answer NO.

5. Section 5.0 – Required Training and Conflict of Interest
6. Section 6.0 – BMC/BUMC to cede review
 - a. Section 6.1 – must answer YES. Leave text box blank
 - b. Section 6.2 – must answer YES.
 - c. Section 6.3 – must answer YES, then select the commercial IRB from the dropdown menu.
 - If the commercial IRB you are looking for is not included in the dropdown menu, please contact the IRB at medirb@bu.edu.
 - d. Section 6.6 – Make a selection based on whether the BMC/BUMC investigators will conduct research activities at BMC/BUMC.
 - e. Section 6.7 – Make a selection based on whether subjects will be recruited at BMC/BUMC.
7. Section 7.0 - Research Activities By BMC/BUMC Researchers
 - a. Section 7.1 – Insert “See industry sponsor protocol.”
 - b. Section 7.2 – Answer all questions in this section.
 - c. Answer any additional new application sections which will appear based on your answers in Section 7.2.

Note: The section numbering may be different going forward, depending on your answers to the previous Sections.

8. Section – Special Populations
9. Section – Funding Source
 - a. 1 – Select “Industry”
 - b. 2 – Study Type: Select “Other”
 - c. “Does this study meet the definition of a clinical trial as defined by NIH?” – If you answer “yes,” then insert the NCT number in the text box, if available.
 - d. 3 – Insert the details for your industry sponsor funding
 - e. 4 – Select the appropriate Grants Office
10. Section – Recruitment Procedures/Materials: Provide a description of how you will recruitment participants at BMC/BUMC. Do not reference the attached protocol.

Complete the section which appears in your application:

11. Section – Drug or Biological Agents; OR
12. Section – Device Studies

Note: Once you complete the drug or device section, you will be taken to the Initial Review Submission Packet.

INITIAL REVIEW SUBMISSION PACKET

	<p>13. Study Application Form</p> <p>14. Consent Documents:</p> <ul style="list-style-type: none"> a. Adult Consent b. Parental Permission Form (consent for child) c. Assent <p>15. Other Study Documents:</p> <ul style="list-style-type: none"> a. The industry sponsor’s protocol. b. The Investigator Brochure for the study drug (if applicable). c. The sponsor’s consent templates, as approved by the commercial IRB. d. The email from STEP ONE that documents the commercial IRB’s willingness to use SMART IRB. e. Any form(s) from the commercial IRB regarding permission to submit to a central IRB that require signature from either BMC or the BMC/BU Medical Campus IRB. <p>16. Additional Special Routing:</p> <ul style="list-style-type: none"> a. Please select ‘Yes’ for all of the applicable Special Routing sign-offs. <p>17. When the application is ready, ask the PI to submit it in INSPIR.</p>
STEP FIVE	After your INSPIR application is reviewed, the BMC/BUMC IRB will send the SMART IRB form to the Commercial IRB for signature.
STEP SIX	Once the BMC/BUMC IRB has received the signed SMART IRB agreement from the Commercial IRB, it will then inform you to proceed with any processes that are required by the sponsor or the Commercial IRB (such as completing a separate application in their electronic system).
STEP SEVEN	<p>Once you complete any processes required by the Commercial IRB, they will send you the following:</p> <ul style="list-style-type: none"> 1. Approval documentation that BMC/BUMC has been added as a site; and 2. Approved versions of the BMC/BUMC-specific consents. <p>Send these documents to the Analyst assigned to your cede submission.</p>
STEP EIGHT	The Analyst will upload the Commercial IRB’s approval documents from Step Eight to your INSPIR cede application, and confirm whether the compensation for injury language matches the language sent by your OSP-Med or BMC attorney. If so, then the Analyst will send you a cede approval outcome letter. YOU ARE ONLY APPROVED TO BEGIN

	STUDY ACTIVIES ONCE YOU HAVE RECEIVED THE CEDE APPROVAL OUTCOME LETTER FROM THE BMC/BU MEDICAL CAMPUS IRB.
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STEP NINE	<p>POST-APPROVAL PROCESS:</p> <ol style="list-style-type: none"> 1. If you add study personnel to a ceded study, then you must submit an Internal Study Personnel Change form in INSPIR before submitting the change to the Commercial IRB, so that we can comply with our agreement with the Commercial IRB by ensuring training certifications and COI disclosures are completed. 2. If there is an amendment that requires review and sign-off from a department that has not previously been involved in the review of the study (e.g., radiation safety, biosafety, pharmacy, departmental approvals, nursing review, Clinical Trials Office), then you must submit an INSPIR Change Request and Amendment form to notify us before implementing the amendment. You must also submit an INSPIR Change Request and Amendment for local context review of any proposed recruitment methods (including changes in populations such as Cognitively Impaired or Non-English Speakers) that differ from what had been submitted initially to the IRB. 3. If an Unanticipated Problem occurs at this site that involves potential harm to a local subject, then you must submit a RENI to report the incident to us, as well as reporting to the reviewing IRB. The purpose of this is to give us an opportunity to help mitigate the harm without delay. 4. When the study is closed by the Commercial IRB, then submit a Final Report for your INSPIR ceded application. (This Final Report is a very short form to close the ceded study in INSPIR.)
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MAKE SURE THAT REQUIRED TRAINING IS UP TO DATE

- Study personnel must be current with CITI Medical Campus certification/recertification.
 - See [Human Subjects Protection training](#).
- Study personnel must be current with GCP Medical Campus training for clinical trials.
 - See [Good Clinical Practice \(GCP\) training](#).

ADDING EXTERNAL INVESTIGATORS FROM BU CHARLES RIVER CAMPUS, OTHER OUTSIDE INSTITUTIONS, AND INDEPENDENT UNAFFILIATED EXTERNAL INVESTIGATORS

- Under the revised BU-CRC Student policy of 12/2018, BU-CRC students can be added as internal study personnel if they are engaged in research (interacting with subjects for the purpose of collecting data or accessing identifiable data) and have a BMC ID#, or if they are conducting research activities on behalf of BU Medical Campus and not for BU-CRC academic credit.
- BU-CRC students seeking BU-CRC academic credit; BU-CRC faculty, physicians, and employees; and independent or volunteer investigators cannot be added to Commercial IRB IND or IDE submissions through SMART IRB. These individuals would normally require reliance agreements to add them as External Investigators when the BMC/BU Medical Campus is the IRB of record, but these reliance agreements cannot be done for ceded studies.

MASSACHUSETTS CONTROLLED RESEARCHERS LICENSE

Effective 01/01/2020, BMC and BU Medical Campus Principal Investigators must have their own Massachusetts Controlled Research Licenses for IND protocols to be in compliance with updated Massachusetts state law.

See:

<https://www.mass.gov/orgs/massachusetts-controlled-substances-registration>

<https://www.mass.gov/how-to/apply-for-or-renew-a-podiatrist-optometrist-researcher-or-veterinarian-mcsr>

KEY CONTACTS

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BMC-Clinical Trials Office budget preparation, Industry Sponsor Contacts, Velos determination, and Informed Consent language review

For immediate assistance, identify and contact assigned departmental Clinical Trial Financial Analyst:

http://www.bmc.org/sites/default/files/Research/documents/Combined_Assignment_List.xlsx

And/or send an email inquiry to the CTO central mailbox: cto@bmc.org

INSPIR Submission Documentation for BMC/BU Medical Campus IRB Pre-review

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