PROCEDURE FOR PREPARING HUMMINGBIRD IRB (HIRB) SUBMISSIONS

Principal Investigators now have the option of submitting multi-centered industry-sponsored protocols with an investigational drug (IND) or an investigational device (IDE) to Hummingbird IRB (HIRB) through a cede review application in INSPIR. The BUMC/BMC IRB will review the application and indicate its approval to cede review to HIRB. HIRB will then transfer all the information and attachments from the INSPIR cede review application into HIRB’s system.

Hummingbird IRB provides independent central IRB services for institutional and commercial clients.

HOW TO GET STARTED

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<thead>
<tr>
<th>STEP ONE</th>
<th>Contact the appropriate grants office and attorney for your Hummingbird submission:</th>
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<tbody>
<tr>
<td></td>
<td>OSP-MED (Attorney Bill Segarra; Phone: (617) 353-6151; email <a href="mailto:segarra@bu.edu">segarra@bu.edu</a>);</td>
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<td></td>
<td>BMC-CTO (Attorney Meghan Garland; Phone: (617) 414-5110; email <a href="mailto:meghan.garland@bmc.org">meghan.garland@bmc.org</a>).</td>
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<tr>
<td></td>
<td>o Provide your attorney with a copy of the industry sponsor’s consent form template to request that the compensation for injury language be provided to you which conforms with the CTA.</td>
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<td>o If your grants office is OSP-MED, you must also contact BMC-CTO Meghan Garland for reviewing the COSTS section of the consent form if your study uses BMC services.</td>
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<th>STEP TWO</th>
<th>Customize the industry sponsor’s consent form template with the BMC/BU Medical Campus specific information.</th>
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<td>• Open the Adult Consent Form Template from the IRB website and copy into the sponsor’s consent form template:</td>
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<td></td>
<td>o The first-page header with the BMC and BU logos (make sure this appears only on the first page)</td>
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<td></td>
<td>o The Basic Information at the beginning of the form</td>
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<td>o If applicable, the paragraph starting “Your doctor may also be an investigator…” from the Background section</td>
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<td>• Insert your attorney’s language for the COMPENSATION FOR INJURY LANGUAGE or WHAT IF I AM INJURED section.</td>
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<td>• Insert the COSTS section as indicated by BMC-CTO Attorney Meghan Garland.</td>
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</table>
**STEP THREE**

*Obtain the industry sponsor’s approval for your consent to be submitted for review.*

**STEP FOUR**

*Prepare your INSPIR Hummingbird IRB cede review application. Answer all questions in each section. NOTE: All study-related documents should be attached to the Initial Review Submission Packet screen after the Application is completed.*

**APPLICATION**

- **Section 1.0 – General Information**
  - Study Nickname: Enter “HIRB - ” and add any additional text
- **Section 2.0 – Set up Department(s) Access**
- **Section 3.0 – Grant Key Personnel access to the study**
  - **Section 3.3 - IMPORTANT:** List the person whom HIRB should contact for questions regarding this submission as the Study Contact
  - **Section 3.5 – IMPORTANT:** Select only the Department Chair. INSPIR will automatically route the protocol to the remaining appropriate special routing departments for approval, based on the answers to the application questions.
- **Section 4.0 – Review Path Determination**
  - **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.**
  - **Section 4.2, 4.3, and 4.4 – must answer NO.**
- **Section 5.0 – Human Subject Training and Conflict of Interest**
- **Section 6.0 – BMC/BU Medical Campus to cede review**
  - **Section 6.1 – must answer YES. Leave text box blank**
  - **Section 6.2 – must answer YES.**
  - **Section 6.3 – must answer YES for BMC/BU Medical Campus Cede Review to an Independent Institutional Review Board; then select “Hummingbird Institutional Review Board (HIRB) from the dropdown menu.**
  - **Section 6.6 – Must select the 2nd option, BMC/BU Medical Campus researchers will conduct research activities at BMC/BU Medical Campus.**
- **Section 7.0 - Research Activities By BMC/BU Medical Campus Researchers**
  - **Section 7.1 – Insert “See industry sponsor protocol.”**
  - **Section 7.2 – Answer all questions in this section.**
Answer any additional new application sections which will appear based on your answers in Section 7.2.

Note that the Section numbering may be different going forward, depending on your answers to the previous Sections.

Section – Special Populations
Section – Funding Source
  1 – Select “Industry”
  2 – Study Type: Select “Other”
  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.
  3 – Insert the details for your industry sponsor funding
  4 – Grants Office
Section – Recruitment Procedures/Materials
  4 – Screening: If you answer YES, then complete the Screening Procedures Section
Section – Screening Procedures
Section – Privacy and Confidentiality
Section – HIPAA Compliance
  1 – “Do you need access to protected health information (PHI) without signed authorization …”: If you answer YES, then you must complete questions 2 to 6. (If you need access to any medical records in order to identify potential subjects, then you must say YES to this question 1.)
  7 - You must enter “YES” to this question, “Does your research require access to any of the HIPAA identifiers (beyond those needed for recruitment purposes)?”, even if you need the data only for recruitment. This is because HIRB needs to issue a partial waiver of authorization for recruitment, and needs the information in the next five questions in order to grant this waiver. Questions 8 to 12: You must answer these remaining questions in detail.

Complete the section which appears in your application:
  Section – Drugs or Biological Agents; OR
  Section – Devices

NOTE: Once you complete the drug (or device section, if applicable), you will be taken to the INITIAL REVIEW SUBMISSION FORM

INITIAL REVIEW SUBMISSION PACKET
  Study Application Form
| o Consent Documents – create and attach a new form, or revise an existing one (see STEP TWO) |
| o Adult Consent |
| o Assent |
| o Parental Permission (consent) |
| o Other Study Documents – See CHECKLIST |

**STEP FIVE**  
*Ask the PI to submit your Hummingbird INSPIR cede review application.*

**INSPIR PROFILES – UPLOAD CVS AND LICENSES**

Have each study team personnel update their INSPIR profile and upload all required personal documentation. Ensure CITI training is up to date.

- All study personnel must have complete INSPIR profiles, especially the PI and the Study Contact for Hummingbird’s use.
- The PI, physician co-investigators, nursing, and other licensed medical study personnel should upload their CVs and medical licenses.
- Non-licensed study team members with significant research responsibilities should also upload their CVs.
- For IND studies, a Massachusetts Research License is needed. If the Department Chair or PI does not have a current Massachusetts Research License, contact IRB Coordinator Roz Schomer at roz@bu.edu to request a copy of an appropriate Massachusetts Research License for your submission.

**Key Contacts:**

**OSP-MED Industry Sponsor Contracts and Budget Preparation**
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**BMC-CTO Budget Preparation**  
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New INSPIR HIRB Submission Documentation for BMC/BU Medical Campus IRB Pre-review
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