

| Section | Instructions | Comments /Warnings |
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| Save and continue | Between each section you must SAVE AND CONTINUE TO MOVE TO THE NEXT SECTION | If you wish to "save" and keep working on a section, click the "save and continue button" in the upper right hand corner and then go back to that section to continue working |
| Study attachments | At the end of most sections there will be an opportunity to attach document(s) related to that section | <ul style="list-style-type: none"> Click on the green "bar" to add a study document. That will pull up an attachment "cover" page. Complete the questions on this page (doc name, version number, version date, etc.). Then click "upload" to find document from your files. Once you locate the file from your browser click SAVE. You will see VIEW THE DOCUMENT in the upper right hand corner (open this to verify that you have the correct document). Then click SAVE DOCUMENT |
| HELP ! | In many sections of the application there will be a ?symbol in the right hand column. | Click on this ? symbol to obtain helpful information for completing the application. |
| General Information 1.1 | Provide the Title of the Study Spell out acronyms | If the protocol has a version number (e.g. sponsor's version) be sure to add this to the title |
| General Information 1.2 | Provide a study nickname This is optional | (will be able to search the system using the nickname instead of the study number) |
| Section 2.0 Set Up Department Access | In this section indicate all departments associated with this study (departments of all investigators/study staff). Click on the radial button to indicate the primary department (most often this will be the department of the PI). To add departments, click on the ADD button. Either scroll through the list of departments (there are 10 pages) or use the buttons at the top to search for the appropriate department(s). There are duplicates on the list. Simply select the department(s) that most closely match the investigator(s) department(s). | The system will automatically default to the department noted in INSPIR I of the person completing the application. If this department is incorrect, add the correct department and remove the default department. |
| Section 3 Assign Key Study Personnel to the study. | This is the section to add all study staff. People are added to this section by clicking on the ADD button and then finding the people in the INSPIR database or BU active directory. In | Use this section to add BU, BMC study staff. Also add Boston Public Health Commission and Boston Healthnet Community Health Center Researchers. Do not add |

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| | <p>order to locate people they MUST have a BU user-name and Kerberos password. If an investigator does not have a BU-username and Kerberos password they must go to www.bumc.bu.edu/inspir and click on "getting started" and follow the instructions to obtain one.</p> <p>For EACH section below, to add people Click on the ADD button, put in the first few letters of the first OR last name and then click FIND. Then, when you find the correct person on the list, click on the ✓symbol to select the person to the application.</p> | <p>investigators from other institutions (they should be added to Section 4)</p> |
| 3.1 Principal Investigator | <p>Click on ADD to find the PI's name from the directory and add her/him to the protocol.</p> <p>Select the appropriate boxes ONLY if the PI is a student, resident or fellow.</p> | <p>You may only list one PI for each study.</p> <p>If the PI is a student, resident or fellow then he/she will need to have a faculty advisor (to be listed in Section 3.4) who will need to sign off on the protocol.</p> |
| 3.2 Protocol staff | <p>A. Add additional investigators by clicking ADD button and selecting people from one of the directories</p> <p>B. Add other study staff by clicking ADD button and selecting people from one of the directories</p> | <p>If a member of the study team has more than one role- select one that is appropriate</p> <p>List in "A" or "B" all BU/BMC investigators who will be engaged in the research including those who will have access to subjects or their identifiable data.</p> |
| 3.3 Add study contact | <p>List here all persons who you wish to receive email notifications about the study. If someone is NOT listed in this section (even if he/she is listed in another section) then he/she will not receive the emails.</p> | <p>The PI will automatically be listed in this section and should not be removed. (Even if his/her name is removed the PI will receive some emails related to the study.)</p> |
| 3.4 Add faculty advisor | <p>Add the PI's faculty advisor by clicking ADD and selecting the person from one of the directories.</p> | <p>This section ONLY needs to be completed if the PI is a student, resident or fellow (as indicated in Section 3.1.</p> |
| 3.5 Designated Department Approvals | <p>Here is where you must list ALL persons who need to sign off on the protocol; the Department Chair/Section Chief of the PI AND any required special routing signatories.</p> | <p>Add the Department Chair's name. Add the NAMES of all the people who must do special routing sign-off. Click on the ?symbol to the right side to find the names of the special</p> |

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| | | routing signatories. |
| 3.6 Administrative Assistant | List here all persons who need access to the protocol (read/write) but who ARE NOT investigators on the protocol. Ignore the words "Administrative Assistant Note" written in this section. | These persons will need a BU user-name and Kerberos password. The persons in this section are NOT investigators or study staff engaged in human subjects research. |
| 4.0 External non-BU/BMC investigators | 4.1 List here all persons who are engaged in the research ON BEHALF OF BU/BMC who are NOT from BU/BMC. Click on the green "bar" that says "Click here to add any External Personnel". This will pull up the Study External Personnel Page. Click on the button on the upper right corner that says "add external personnel". This will bring you to a page with 5 questions about the person. Answer these questions and then click on "save external personnel info". This will bring you back to the external personnel page. Either add someone else or return back to the application. | Do not list investigators from other institutions who are "covered" under their own IRB approvals. |
| Section 4.2 | Answer yes or no about whether or not there are external personnel related to this study who are "not engaged". If yes, click the green bar to open the text field to provide details. | External personnel who are not engaged might be persons from other institutions who will receive coded data but will not be given the mastercode/link to data. |
| Section 5 | If this is a new application - do NOT complete this section. Simply click on Save and Continue to move to the next section. | This section is reserved for information migrated from INSPIR I |
| Section 6.0 Conflict of Interest | 6.1 Verify that all necessary COI PSDs have been submitted. Indicate if any investigators have disclosed a COI and if yes, specify who in the text box. 6.2 Is read only (for information from INSPIR I). If this is a new application then this section will be blank. | Click the ? for more information about who must submit COI Project Specific Disclosures (PSDs) and where to submit them. Do not submit them to the IRB and do not attach them with this application. All questions about COI should be directed to the COI office and not the IRB. |
| Section 7.1 Funding | Select the appropriate source(s) of funding. Non-externally funded research by faculty /staff (not students) - select | In most instances you may NOT list multiple grants or sponsors' agreements on the same IRB protocol. Separate IRB protocols are |

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| | <p>department or internal funding.</p> <p>Section 7.2: Click on the green bar to open a screen to provide details about the funding source.</p> <p>On this "study sponsor" page- click the Add a New Sponsor" at the top. Then select the sponsor from the menu (by scrolling through the list or searching). Once you find your sponsor on the list- click on the icon in the left hand column to open. Complete the form and save sponsor info.</p> <p>When you are done, click the button to "return back to the application".</p> | <p>required. The ability to list multiple sources of funding are for situations where the study is funded by NIH but there is a sponsor's drug donation, etc.</p> <p>If the sponsor is NOT on the list you can "add" the sponsor by clicking on the button in the upper right hand column which says "Add new sponsor to the master list".</p> |
| Section 8 Lay Summary | <p>In the text box write a brief lay summary of the study. After writing the summary you must click "ok" at the bottom of the text box.</p> <p>This section should be limited to 300 words and technical jargon should be limited.</p> | <p>This summary is presented to the IRB with each submission (future amendments and Progress Reports) so it should be as precise and accurate as possible.</p> <p>The text box is in Rich Text Format so will allow for spell check.</p> |
| Section 9- Study site information | <p>9.1 Indicate if the study is single site or multi-site.</p> <p>9.2 If multi-site and BU is the main site- indicate the details by clicking on the button that says "add a new site" and adding information here.</p> <p>9.3 answer the question</p> <p>9.4 answer the question (check all that apply)</p> | <p>If BU/BMC investigator(s) is/are the main investigators on the study or if BU/BMC is the prime awardee of the grant then select option 3 and provide details in section 9.2</p> <p>Click ? for definition of community based participatory research. This is specifically when members of the community or community organizations are participating in some of the research activities in roles other than as subjects (e.g. they are surveying subjects, running focus groups, actively recruiting subjects, etc.) Attach a document under "attachments" to describe the community based participatory research activities.</p> |
| Section 10 Navigation Menu | <p>From the answers selected on this page of the application the INSPIR system will determine which additional "pages/sections" are needed to the application.</p> | <p>If the questions are answered incorrectly, unnecessary questions may be added to the INSPIR application or necessary sections of the application may be skipped.</p> |
| Section 10 | 10.1 and 10.2 Select the correct answer. | |

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| | In most instances the answer will be NO. These first two occurrences are very rare. | |
| Section 10 | <p>10.3 These questions will determine whether the protocol will be reviewed as Exempt or Non-Exempt (expedited or full board)</p> <p>If you know your study does NOT qualify for exempt review- select the 5th option (this is the default option).</p> | If you have questions about the first four options in this section click on the ? for guidance |
| Section 10 | 10.4 Only answer yes if there will be another institution engaged in this research and you are requesting that the other institution (Institution B) rely on the BUMC IRB review instead of obtaining their own IRB review. | BUMC will not allow other institutions to rely on BUMC IRB review in all cases. This is a case by case decision. Check the IRB website for more information about this topic. |
| | 10.5 Select this if this study involves international research (non-US sites). | Do not select yes, if this is a multi-site study and BU/BMC is just one of the other sites (not the main site or not the main PI) |
| | 10.6 This is a two part question. If the answer to either question is YES then you must select the Yes option. | For more information about "covered entities" or HIPAA consult the HIPAA website at www.bumc.bu.edu/hipaa . |
| | 10.9-10.11 Answer yes or no to each of these questions as appropriate. | If you answer YES then additional pages/sections will be added to the IRB application to obtain more details about each of these topics. |
| | <p>10.12 Study Finder</p> <p>The Study Finder is a publicly accessible website that provides listings of clinical research studies taking place at BUMC for purposes of recruitment, collaboration, or general publicity.</p> | Indicate yes if you wish for this study to be listed on an internal website (just to be accessed by other BUMC investigators) AND /OR indicate yes if you wish for this study to be listed on a website for recruitment from the general public. |
| Rest of the application | <p>The first 10 sections of the application are REQUIRED SECTIONS that are completed for ALL INSPIR submissions.</p> <p>The rest of the application will vary based on your answers to the questions in the navigation menu.</p> | See the separate instruction sheet for instructions about the additional pages/sections in INSPIR II. |