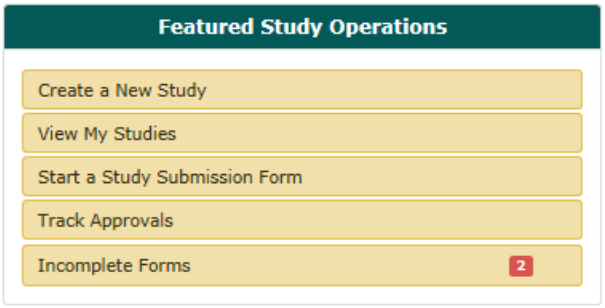
Submitting to the Main Line Hospitals Institutional Review Board (MLH IRB)

Main Line Health®

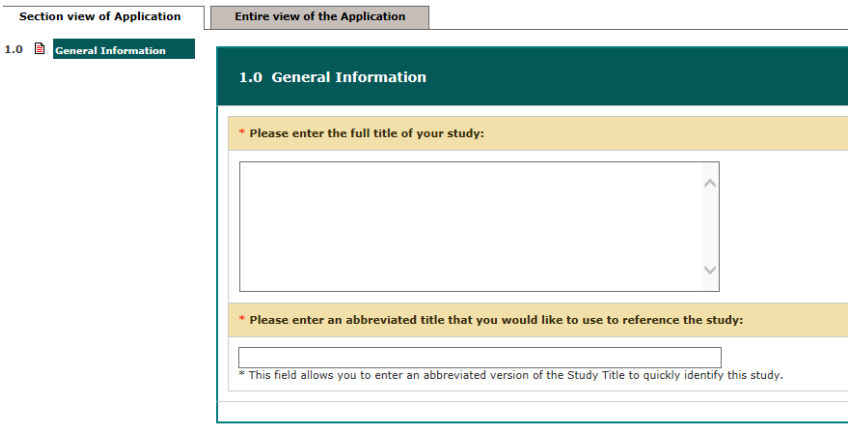
New Study Submissions

NOTES: Study documents including Informed Consent, HIPAA Authorization, and Protocol are uploaded into the system at the end of the application. The Help icon at the top of each page will list all guidance documents in the system. Have all relevant study documents prepared and ready to upload after completing the study application. You can always create a new study and save and return at any point in the application process.

After logging into iMedRIS, you will be taken to the Study Assistant page. Click "Create a New Study."

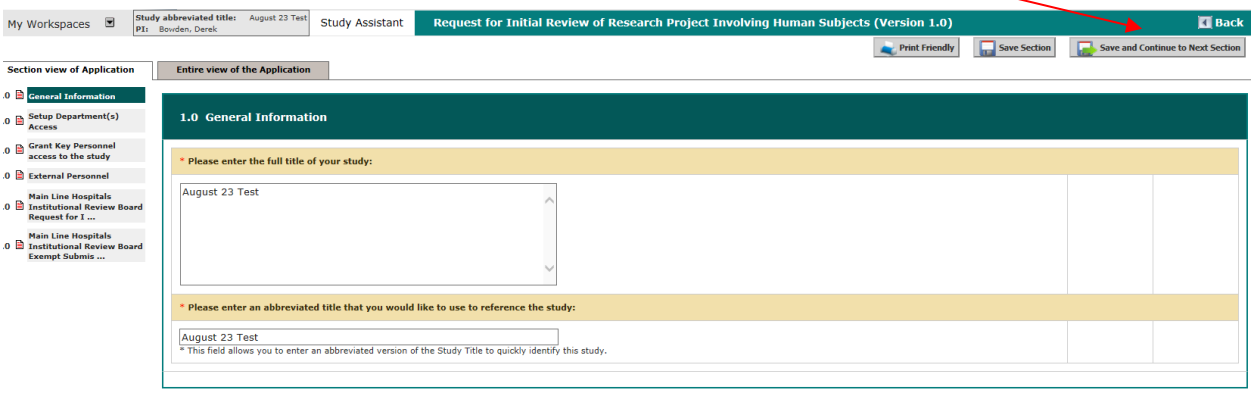


1.0 General Information – Enter the full title of you study. When entering the abbreviated title, keep in mind that this is the title that will follow each page of the submission packet.

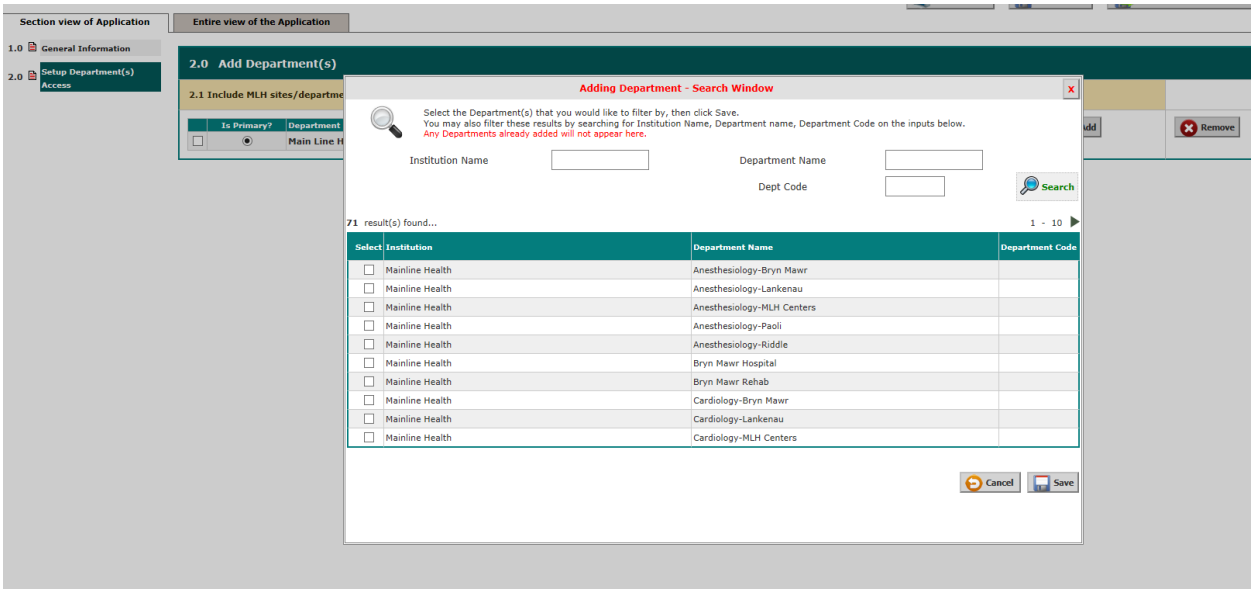


Questions? Contact the Main Line Health Office of Research Protections at 610.225.6222.

To advance to the next section of the application, click the “Save and Continue to Next Section” button. This button will appear on each page through the application.



2.0 Add Departments – include all departments/sites where the proposed research will take place. The system defaults to the department associated with your iMedRIS registration. All Main Line Health employees are entered in the system as affiliated with the generic “Main Line Health-MLH” as their department. Departments are organized in the system by institution (Main Line Health); Department; then Hospital. Scroll through the sites before selecting to familiarize yourself with the options. Select multiple departments if applicable. If your department is not listed, select the hospital(s) where the research will occur (each hospital is listed separately).



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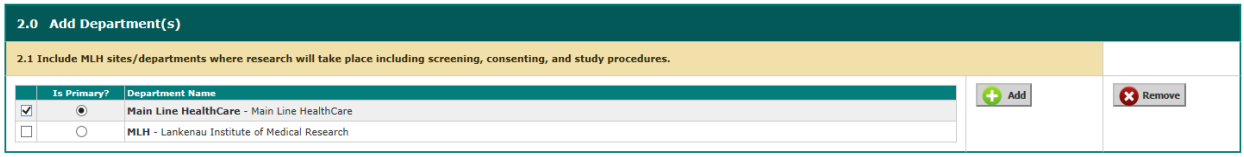
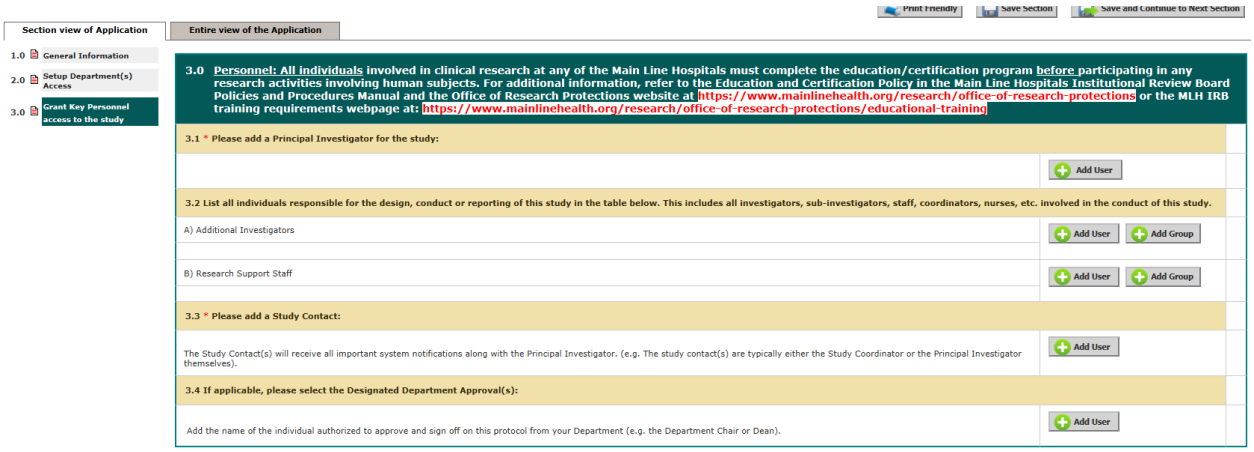
Selected departments can be removed by checking the box and clicking “remove”

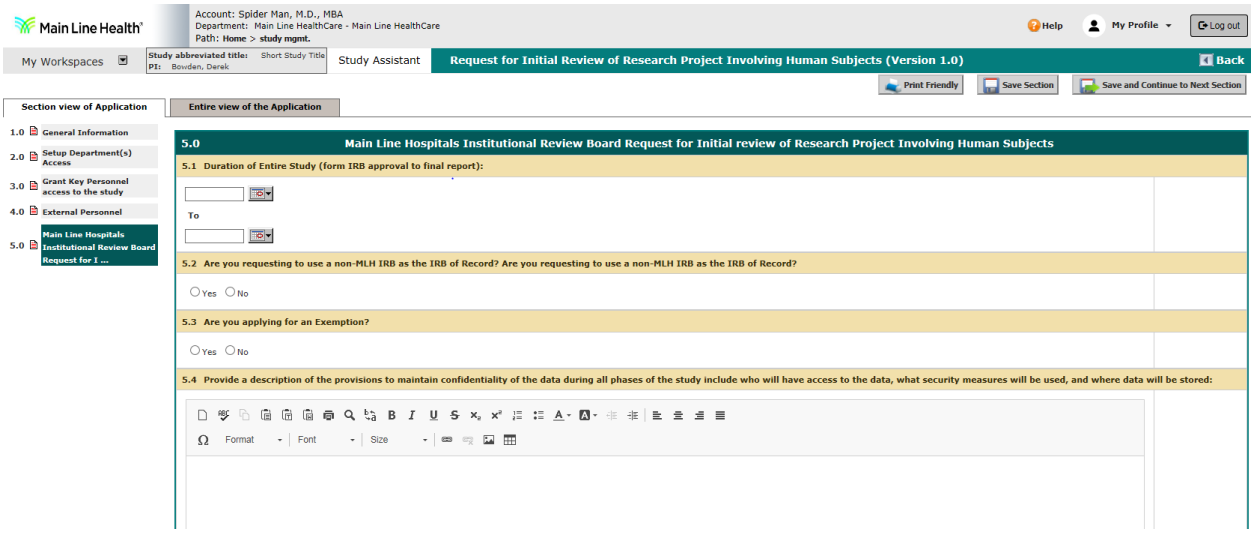


3.0 Personnel—list all study team members participating in the protocol. Include any additional personnel in the Study Contact section (3.3) you want to receive system notifications regarding this study (e.g. research coordinators). If you are unable to find a user in the system, contact ORP.



4.0 External Personnel—list any personnel involved in the research who is not affiliated with Main Line Health.

5.0 – This page asks for additional study information. NOTE: the response to question 5.3 will alter the questions on the sections that follow. If you are unsure whether your project qualifies for an Exemption, click the Help icon in the upper right hand corner for a description of the Exempt categories.

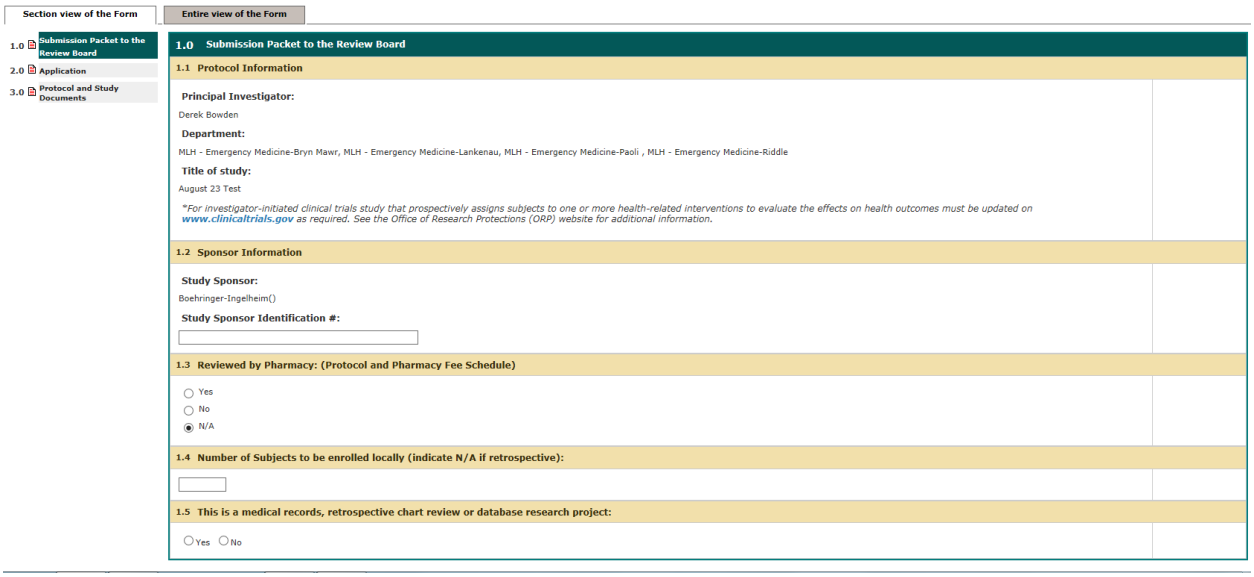


For Non-Exempt research, **6.0** asks for specific funding/sponsor information and **7.0** includes the Human Subjects Research questionnaire (formerly “Form 002 Initial Submission Form”).

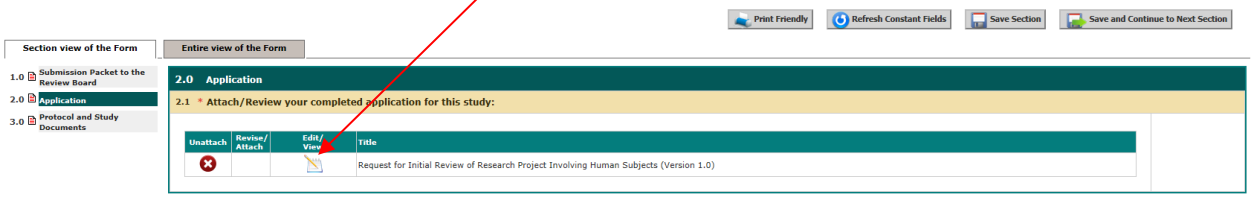
For Exempt research, 6.0 asks for the specific Exempt category and confidentiality information. The Exempt research form does not include a section 7.0.

Submission Packet to the Review Board

Once you have completed the IRB application, you are taken to the Submission Packet. Think of the Submission Packet as the envelope that will house your study application, protocol, consent/HIPAA, and other study documents. Section 1.0 of the Submission Packet will pre-populate some of the information you provided in the study application such as PI, Department, Title of Study, and Sponsor. Complete Sections 1.3-1.5.



Section 2.0 of the Submission Packet includes the Application that you completed at the beginning of the submission process. Clicking on the Edit/View icon will take you back into the study application.



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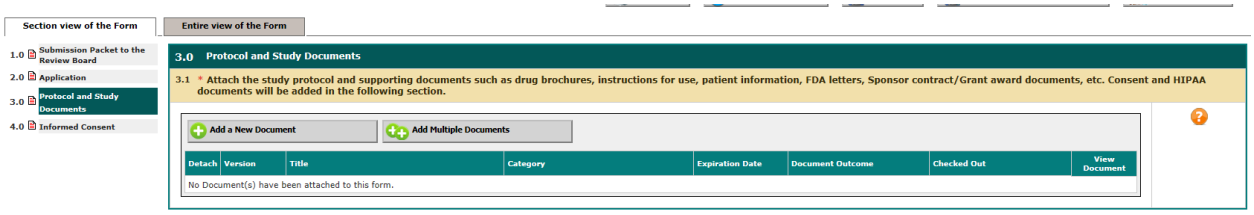
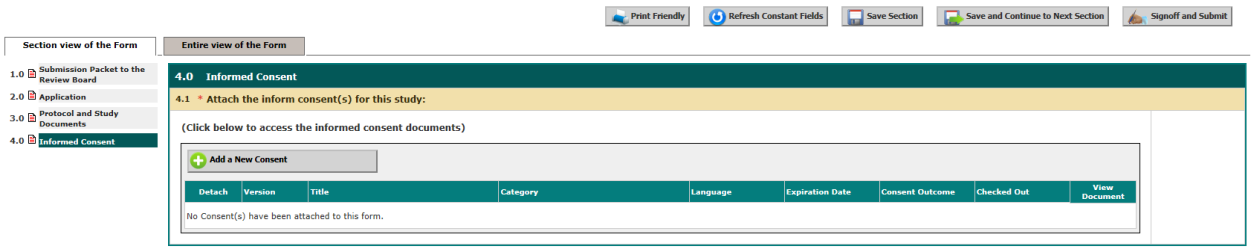
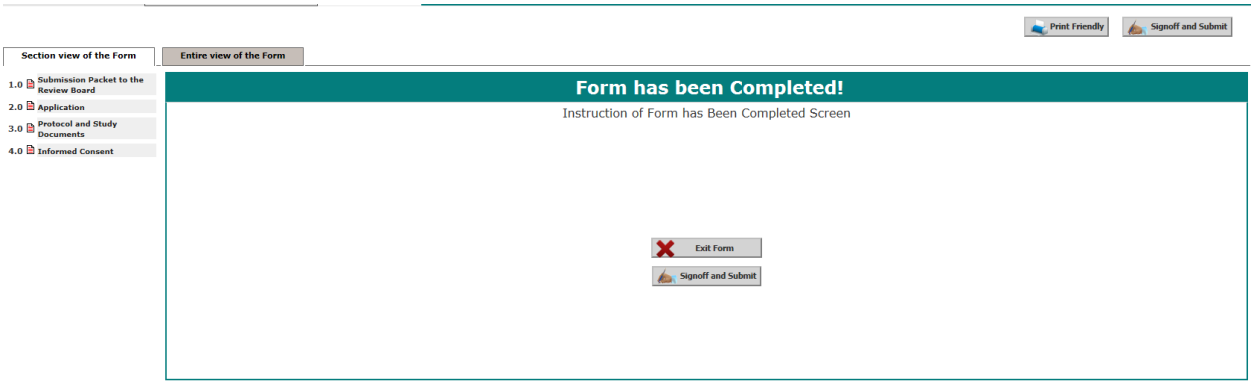
Sections 3.0 and 4.0 of the Submission Packet are where all study documents will be uploaded. Section 3.0 is where you upload the Protocol and any other study documents, including the required Transmittal Form.



Section 4.0 of the Submission Packet is where you upload the Consent and HIPAA documents. Note: clicking "Add an informed consent from the list of Informed Consent Template Documents" will simply download the consent guide. You will need to create your consent form first, save in a file folder, then upload into the system.



After all study documents have been uploaded, the last screen allows you to exit the form or advance to signoff and submit. Exiting the form will not submit the package to the IRB for review. You may save and exit at any point while completing the application and submission package if you prefer to work on the submission in stages.



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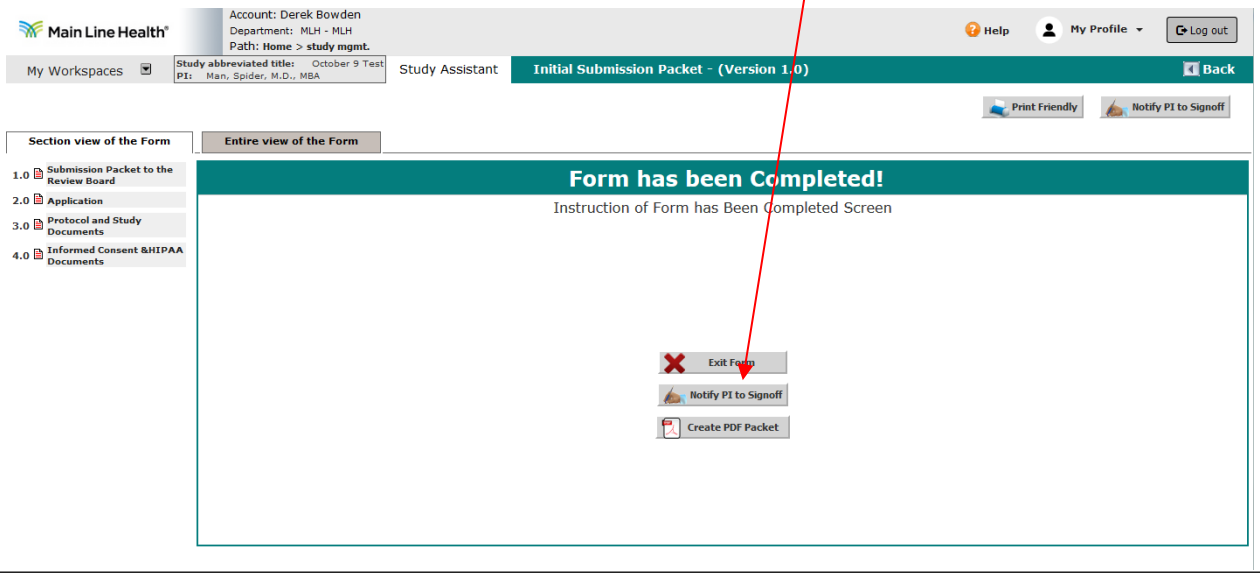
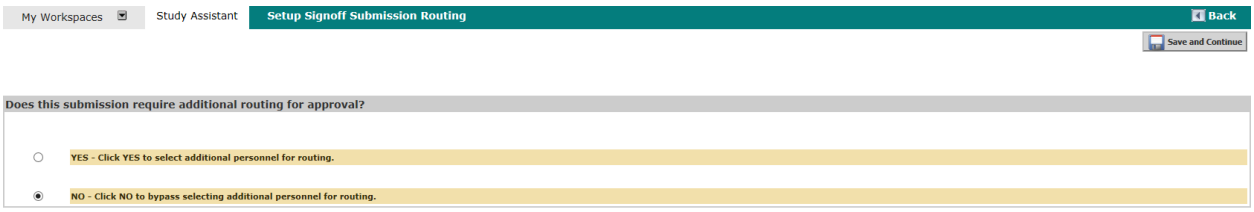
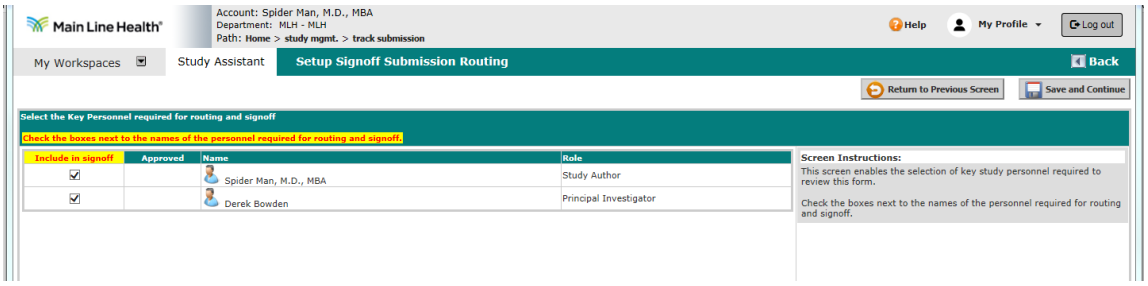
If you are submitting on behalf of a PI, the PI will need to Approve, Sign, and Submit before the IRB will receive the submission for review. As study author, you will be able to create a PDF of the study submission and Notify the PI to Signoff. When you click Notify PI to Signoff, they will receive a task notification to sign and submit the application. Refer to Tip Sheet "PI Signoff Instructions."



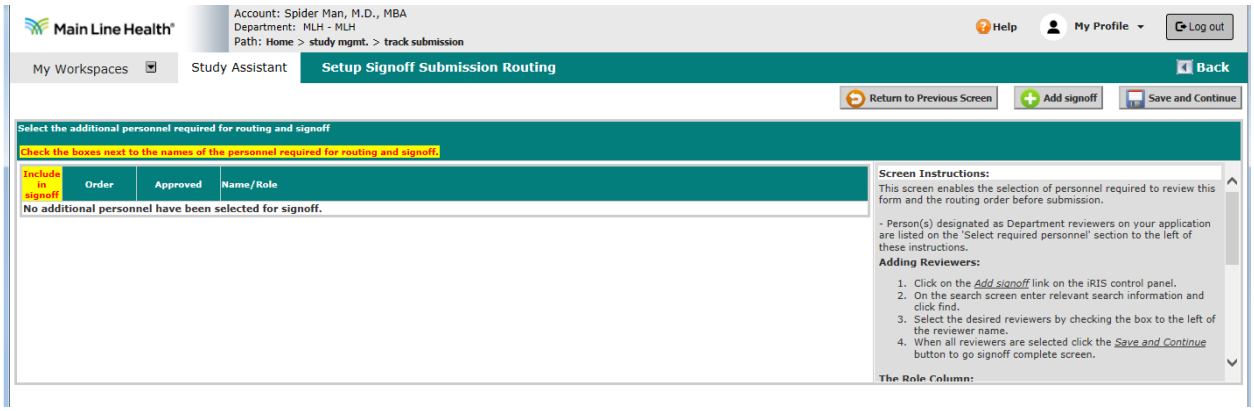
If you click Signoff and Submit, you will be asked whether this submission requires routing. To route electronically to your department chair or any other user who is required to review and approve your submission, click "YES." If you are using the Transmittal Form to capture these approvals, select "No" and continue.



If you indicate routing is required above, you are first asked to select any “key study personnel” (KSP) required for sign-off. Listed here are any study personnel you included in the study application. Select if applicable, then save and continue.



Next, you will be asked to include any additional personnel required for sign-off, such as a department chair. This will require the selected personnel to be activated in the system. Your leadership sign-off may also be documented on the paper Transmittal Form that is uploaded in the study documents. Contact ORP staff if you have questions about study sign-off.



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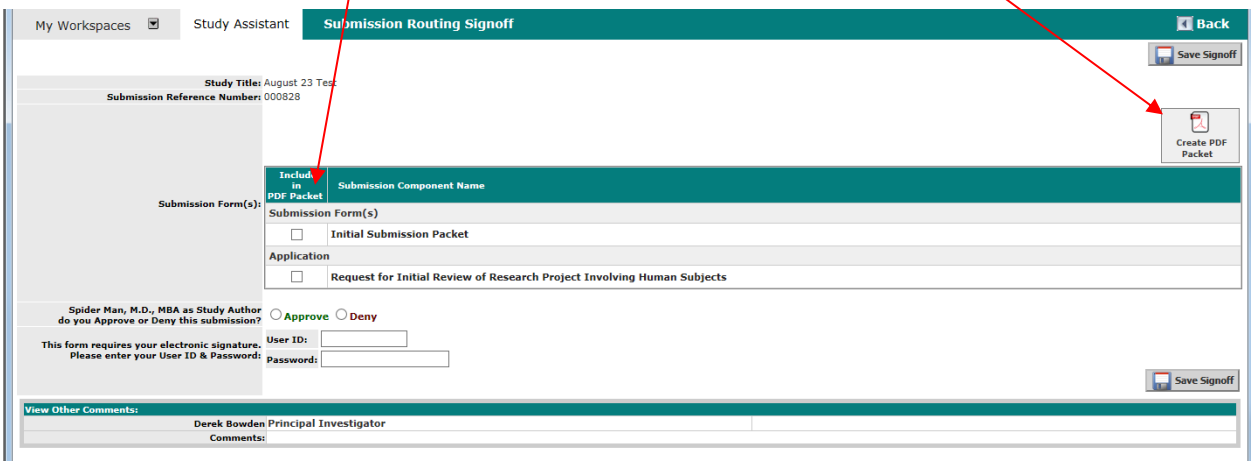
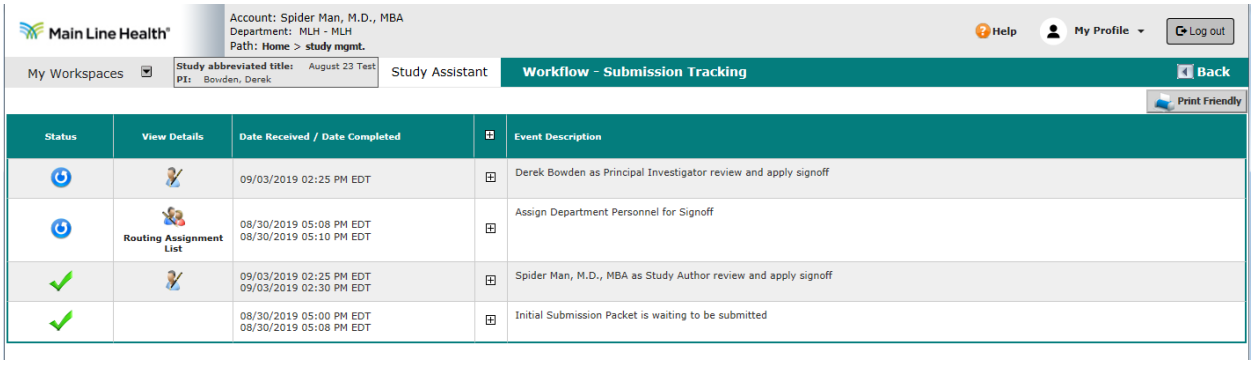
After completing the study-sign off pages, you will be brought to a final page to sign-off as study author before the study packet is submitted to the IRB. If you wish to create a collated PDF of your study submission, select which components to include in the PDF, *then* click "Create PDF Packet."



Select "Approve" or "Deny," enter your user ID and Password, and click "Save Signoff."

The submission is now complete. The next screen you will see is the Submission Tracking, which outlines the path for your study packet. As you see in the example below, the submission packet was initiated on August 30th, reviewed and signed by the study author on September 3rd, and assigned to the study PI for sign-off. Note the pending status of the PI signature.



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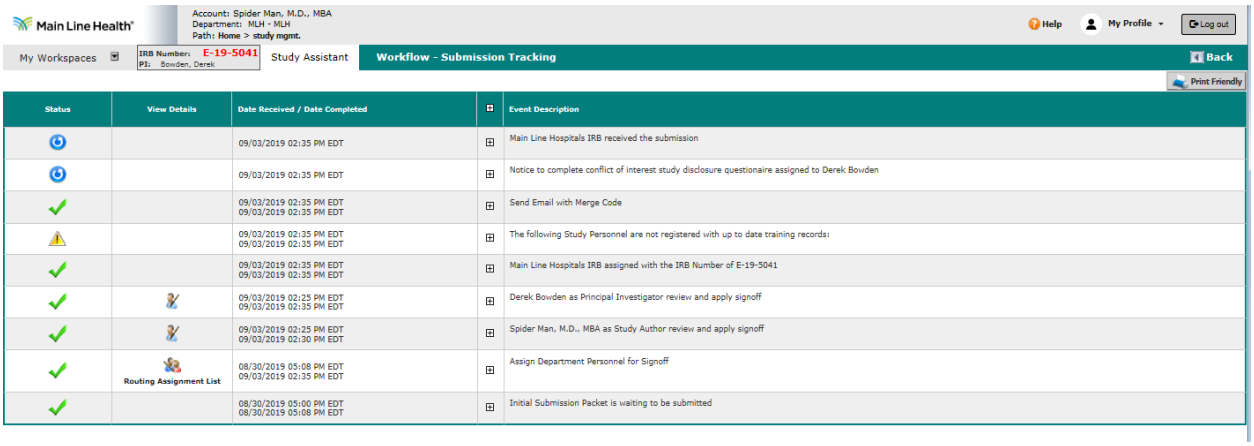
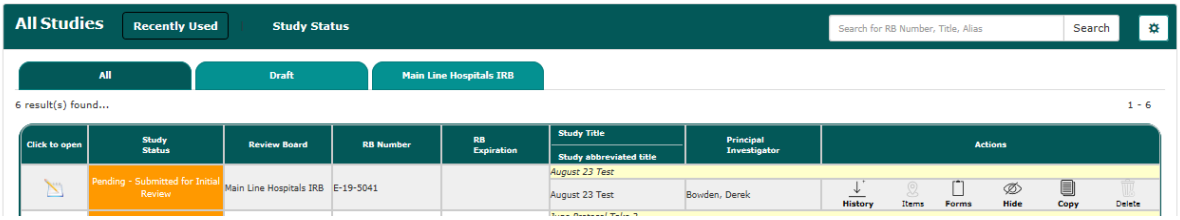
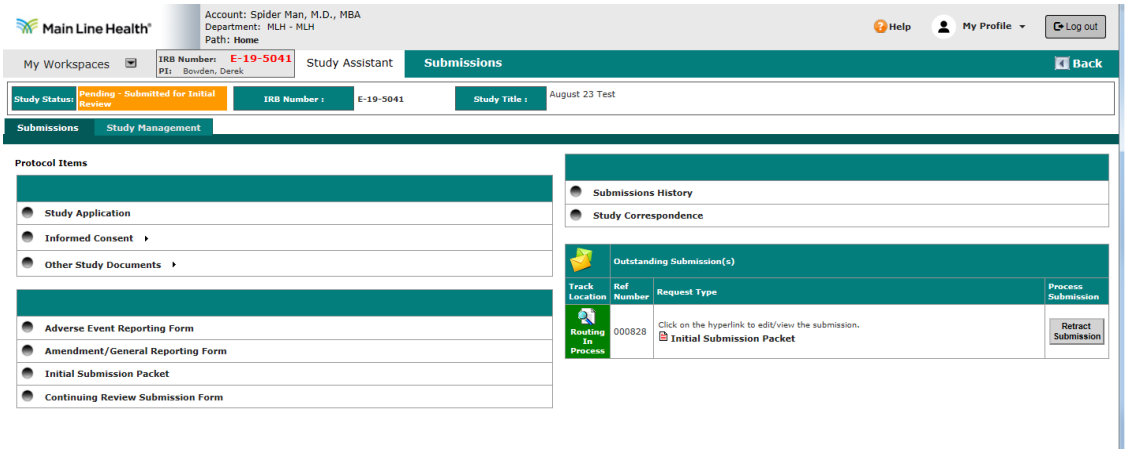
Once the PI signs-off on the submission, additional steps will be included in the Submission Tracking. Note, the IRB assigned a study number, training records and COI are checked for all study personnel included in the submission, and the MLH IRB receives the submission.



Your submission will appear under the “All Studies” tab from the system homepage. Yellow=IRB has received and review is pending. Red=returned for corrections. Green=approved and the study is open.



Clicking into the submission will take you to the study submission components. This is also where you will be able to submit continuing reviews, amendments, adverse event reports, etc. Questions? Contact ORP Staff.



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