

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

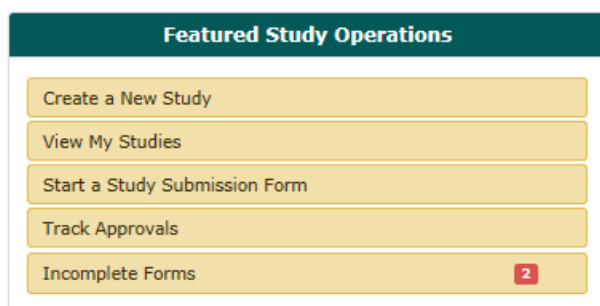


Main Line Health®

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  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.

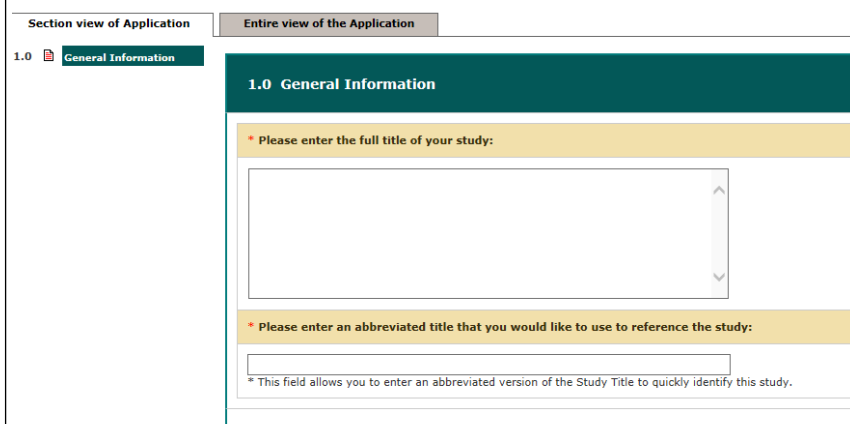
After logging into iMedRIS, you will be taken to the Study Assistant page. Click “Create a New Study.”



Featured Study Operations

- Create a New Study
- View My Studies
- Start a Study Submission Form
- Track Approvals
- Incomplete Forms 2

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



Section view of Application | Entire view of the Application

1.0  General Information

1.0 General Information

* Please enter the full title of your study:

* Please enter an abbreviated title that you would like to use to reference the study:

* This field allows you to enter an abbreviated version of the Study Title to quickly identify this study.

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.

My Workspaces Study Assistant Request for Initial Review of Research Project Involving Human Subjects (Version 1.0) Back

Print Friendly Save Section Save and Continue to Next Section

Section view of Application Entire view of the Application

1.0 General Information

Please enter the full title of your study:

August 23 Test

Please enter an abbreviated title that you would like to use to reference the study:

August 23 Test

* This field allows you to enter an abbreviated version of the Study Title to quickly identify this study.

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).

Section view of Application Entire view of the Application

1.0 General Information

2.0 Add Department(s)

2.1 Include MLH sites/departments

Adding Department - Search Window

Select the Department(s) that you would like to filter by, then click Save. You may also filter these results by searching for Institution Name, Department name, Department Code on the inputs below. Any Departments already added will not appear here.

Institution Name Department Name Dept Code Search

71 result(s) found... 1 - 10

Select	Institution	Department Name	Department Code
☐	Mainline Health	Anesthesiology-Bryn Mawr	
☐	Mainline Health	Anesthesiology-Lankenau	
☐	Mainline Health	Anesthesiology-MLH Centers	
☐	Mainline Health	Anesthesiology-Paoli	
☐	Mainline Health	Anesthesiology-Riddle	
☐	Mainline Health	Bryn Mawr Hospital	
☐	Mainline Health	Bryn Mawr Rehab	
☐	Mainline Health	Cardiology-Bryn Mawr	
☐	Mainline Health	Cardiology-Lankenau	
☐	Mainline Health	Cardiology-MLH Centers	

Cancel Save

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

2.0 Add Department(s)

2.1 Include MLH sites/departments where research will take place including screening, consenting, and study procedures.

Is Primary?	Department Name		
☒	Main Line HealthCare - Main Line HealthCare		
☐	MLH - Lankenau Institute of Medical Research		

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.

Section view of Application | Entire view of the Application

1.0 General Information | 2.0 Setup Department(s) Access | 3.0 Grant Key Personnel access to the study

3.0 Personnel: All individuals involved in clinical research at any of the Main Line Hospitals must complete the education/certification program before participating in any research activities involving human subjects. For additional information, refer to the Education and Certification Policy in the Main Line Hospitals Institutional Review Board Policies and Procedures Manual and the Office of Research Protections website at <https://www.mainlinehealth.org/research/office-of-research-protections> or the MLH IRB training requirements webpage at: <https://www.mainlinehealth.org/research/office-of-research-protections/educational-training>

3.1 * Please add a Principal Investigator for the study:

3.2 List all individuals responsible for the design, conduct or reporting of this study in the table below. This includes all investigators, sub-investigators, staff, coordinators, nurses, etc. involved in the conduct of this study.

A) Additional Investigators

B) Research Support Staff

3.3 * Please add a Study Contact:

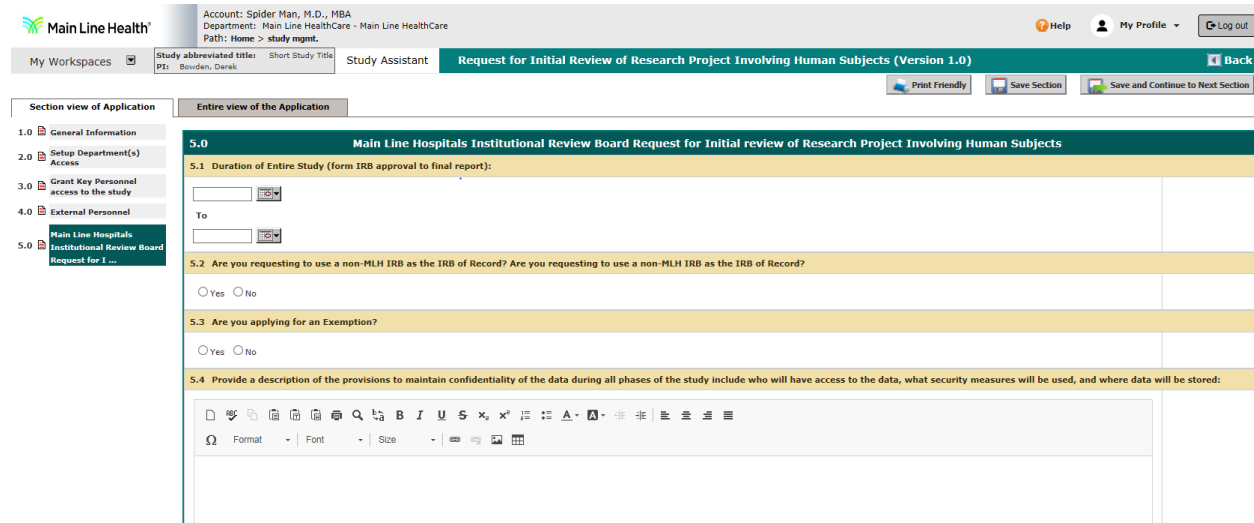
The Study Contact(s) will receive all important system notifications along with the Principal Investigator. (e.g. The study contact(s) are typically either the Study Coordinator or the Principal Investigator themselves).

3.4 If applicable, please select the Designated Department Approval(s):

Add the name of the individual authorized to approve and sign off on this protocol from your Department (e.g. the Department Chair or Dean).

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  icon in the upper right hand corner for a description of the Exempt categories.



The screenshot shows the Main Line Health Institutional Review Board Request for Initial Review of Research Project Involving Human Subjects (Version 1.0) form. The form is titled "5.0 Main Line Hospitals Institutional Review Board Request for Initial review of Research Project Involving Human Subjects". It includes a sidebar with a list of sections: 1.0 General Information, 2.0 Setup Department(s) Access, 3.0 Grant Key Personnel access to the study, 4.0 External Personnel, and 5.0 Main Line Hospitals Institutional Review Board Request for 1... The main content area contains the following sections:

- 5.1 Duration of Entire Study (form IRB approval to final report):** This section contains two input fields: "From" and "To".
- 5.2 Are you requesting to use a non-MLH IRB as the IRB of Record? Are you requesting to use a non-MLH IRB as the IRB of Record?** This section contains two radio buttons: "Yes" and "No".
- 5.3 Are you applying for an Exemption?** This section contains two radio buttons: "Yes" and "No".
- 5.4 Provide a description of the provisions to maintain confidentiality of the data during all phases of the study include who will have access to the data, what security measures will be used, and where data will be stored:** This section contains a text area with a rich text editor toolbar.

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.

The screenshot shows the 'Submission Packet to the Review Board' form. The left sidebar indicates the current section is 1.0. The main content area is titled '1.0 Submission Packet to the Review Board' and contains several sections:

- 1.1 Protocol Information:** Includes fields for Principal Investigator (Derek Bowden), Department (MLH - Emergency Medicine-Bryn Mawr, MLH - Emergency Medicine-Lankenau, MLH - Emergency Medicine-Paoli, MLH - Emergency Medicine-Riddle), Title of study (August 23 Test), and a note about investigator-initiated clinical trials.
- 1.2 Sponsor Information:** Includes fields for Study Sponsor (Boehringer-Ingelheim()) and Study Sponsor Identification #.
- 1.3 Reviewed by Pharmacy: (Protocol and Pharmacy Fee Schedule):** Includes radio buttons for Yes, No, and N/A (selected).
- 1.4 Number of Subjects to be enrolled locally (indicate N/A if retrospective):** Includes a text input field.
- 1.5 This is a medical records, retrospective chart review or database research project:** Includes radio buttons for Yes and No.

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.

The screenshot shows the '2.0 Application' section of the form. The left sidebar indicates the current section is 2.0. The main content area is titled '2.0 Application' and contains a table with the following columns: Unattach, Review/Attach, Edit/View, and Title. The table has one row with the title 'Request for Initial Review of Research Project Involving Human Subjects (Version 1.0)'. A red arrow points to the 'Edit/View' icon in the table row. Above the table, there is a note: '2.1 * Attach/Review your completed application for this study:'. At the top right of the form, there are buttons for 'Print Friendly', 'Refresh Constant Fields', 'Save Section', and 'Save and Continue to Next Section'.

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.

The screenshot shows the 'Section view of the Form' on the left with '3.0 Protocol and Study Documents' selected. The main area is titled '3.0 Protocol and Study Documents' and contains a sub-section '3.1 * Attach the study protocol and supporting documents such as drug brochures, instructions for use, patient information, FDA letters, Sponsor contract/Grant award documents, etc. Consent and HIPAA documents will be added in the following section.' Below this is a table with columns: Detach, Version, Title, Category, Expiration Date, Document Outcome, Checked Out, and View Document. A message states 'No Document(s) have been attached to this form.' There are buttons for 'Add a New Document' and 'Add Multiple Documents'.

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.

The screenshot shows the 'Section view of the Form' on the left with '4.0 Informed Consent' selected. The main area is titled '4.0 Informed Consent' and contains a sub-section '4.1 * Attach the informed consent(s) for this study:'. Below this is a table with columns: Detach, Version, Title, Category, Language, Expiration Date, Consent Outcome, Checked Out, and View Document. A message states 'No Consent(s) have been attached to this form.' There is a button for 'Add a New Consent'. At the top right, there are buttons for 'Print Friendly', 'Refresh Constant Fields', 'Save Section', 'Save and Continue to Next Section', and 'Signoff and Submit'.

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.

The screenshot shows the 'Section view of the Form' on the left with '4.0 Informed Consent' selected. The main area is titled 'Form has been Completed!' and contains the text 'Instruction of Form has Been Completed Screen'. At the bottom, there are two buttons: 'Exit Form' (with a red X icon) and 'Signoff and Submit' (with a document icon).

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.”

The screenshot shows the 'Initial Submission Packet - (Version 1.0)' screen. The user is logged in as Derek Bowden, a Study Assistant. The left sidebar shows a list of sections: 1.0 Submission Packet to the Review Board, 2.0 Application, 3.0 Protocol and Study Documents, and 4.0 Informed Consent & HIPAA Documents. The main content area displays a large green banner that reads 'Form has been Completed!' with the subtext 'Instruction of Form has Been Completed Screen'. Below the banner are three buttons: 'Exit Form' (with a red X icon), 'Notify PI to Signoff' (with a person icon), and 'Create PDF Packet' (with a document icon). A red arrow points from the text 'Notify PI to Signoff' in the paragraph above to the 'Notify PI to Signoff' button.

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.

The screenshot shows the 'Setup Signoff Submission Routing' screen. The user is logged in as Derek Bowden, a Study Assistant. The main content area displays a question: 'Does this submission require additional routing for approval?'. There are two radio button options: 'YES - Click YES to select additional personnel for routing.' and 'NO - Click NO to bypass selecting additional personnel for routing.'. The 'NO' option is selected.

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.

Account: Spider Man, M.D., MBA
Department: MLH - MLH
Path: Home > study mgmt. > track submission

My Workspaces Study Assistant Setup Signoff Submission Routing

Select the Key Personnel required for routing and signoff
Check the boxes next to the names of the personnel required for routing and signoff.

Include in signoff	Approved	Name	Role
☒		Spider Man, M.D., MBA	Study Author
☒		Derek Bowden	Principal Investigator

Screen Instructions:
This screen enables the selection of key study personnel required to review this form.
Check the boxes next to the names of the personnel required for routing and signoff.

Return to Previous Screen Save and Continue Back

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.

Account: Spider Man, M.D., MBA
Department: MLH - MLH
Path: Home > study mgmt. > track submission

My Workspaces Study Assistant Setup Signoff Submission Routing

Select the additional personnel required for routing and signoff
Check the boxes next to the names of the personnel required for routing and signoff.

Include in signoff	Order	Approved	Name/Role
No additional personnel have been selected for signoff.			

Screen Instructions:
This screen enables the selection of personnel required to review this form and the routing order before submission.
- Person(s) designated as Department reviewers on your application are listed on the 'Select required personnel' section to the left of these instructions.
Adding Reviewers:
1. Click on the Add signoff link on the iRIS control panel.
2. On the search screen enter relevant search information and click find.
3. Select the desired reviewers by checking the box to the left of the reviewer name.
4. When all reviewers are selected click the Save and Continue button to go signoff complete screen.
The Role Column:

Return to Previous Screen Add signoff Save and Continue Back

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 submission, select which components to include in the PDF, *then* click “Create PDF Packet.”

My Workspaces ▾ Study Assistant **Submission Routing Signoff** Back

Save Signoff

Create PDF Packet

Study Title: August 23 Test
Submission Reference Number: 000828

Submission Form(s):

Include in PDF Packet	Submission Component Name
☐	Initial Submission Packet
☐	Request for Initial Review of Research Project Involving Human Subjects

Spider Man, M.D., MBA as Study Author
do you Approve or Deny this submission? ☐ Approve ☐ Deny

This form requires your electronic signature.
Please enter your User ID & Password:
User ID:
Password:

Save Signoff

View Other Comments:

Derek Bowden Principal Investigator
Comments:

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.

Main Line Health® Account: Spider Man, M.D., MBA
Department: MLH - MLH
Path: Home > study mgmt. Help My Profile Log out

My Workspaces ▾ Study Assistant **Workflow - Submission Tracking** Back

Print Friendly

Status	View Details	Date Received / Date Completed	Event Description
		09/03/2019 02:25 PM EDT	Derek Bowden as Principal Investigator review and apply signoff
		08/30/2019 05:08 PM EDT 08/30/2019 05:10 PM EDT	Assign Department Personnel for Signoff
		09/03/2019 02:25 PM EDT 09/03/2019 02:30 PM EDT	Spider Man, M.D., MBA as Study Author review and apply signoff
		08/30/2019 05:00 PM EDT 08/30/2019 05:08 PM EDT	Initial Submission Packet is waiting to be submitted

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.

Main Line Health

Account: Spider Man, M.D., MBA
Department: MLH - MLH
Path: Home > study mgmt.

My Workspaces

IRB Number: E-19-5041
PI: Bowden, Derek

Study Assistant

Workflow - Submission Tracking

Back

Print Friendly

Help

My Profile

Log out

Status	View Details	Date Received / Date Completed	Event Description
		09/03/2019 02:35 PM EDT	Main Line Hospitals IRB received the submission
		09/03/2019 02:35 PM EDT	Notice to complete conflict of interest study disclosure questionnaire assigned to Derek Bowden
		09/03/2019 02:35 PM EDT	Send Email with Merge Code
		09/03/2019 02:35 PM EDT	The following Study Personnel are not registered with up to date training records:
		09/03/2019 02:35 PM EDT	Main Line Hospitals IRB assigned with the IRB Number of E-19-5041
		09/03/2019 02:35 PM EDT	Derek Bowden as Principal Investigator review and apply signoff
		09/03/2019 02:35 PM EDT	Spider Man, M.D., MBA as Study Author review and apply signoff
		08/30/2019 05:08 PM EDT	Assign Department Personnel for Signoff
	Routing Assignment List	09/03/2019 02:35 PM EDT	
		08/30/2019 05:00 PM EDT	Initial Submission Packet is waiting to be submitted

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.

All Studies

Recently Used

Study Status

Search for IRB Number, Title, Alias

Search

All

Draft

Main Line Hospitals IRB

6 result(s) found...

1 - 6

Click to open	Study Status	Review Board	IRB Number	IRB Expiration	Study Title	Principal Investigator	Actions							
					Study abbreviated title									
	Pending - Submitted for Initial Review	Main Line Hospitals IRB	E-19-5041		August 23 Test									
					August 23 Test	Bowden, Derek								

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.

Main Line Health		Account: Spider Man, M.D., MBA Department: MLH - MLH Path: Home		Help	My Profile	Log out												
My Workspaces	IRB Number: E-19-5041 PI: Bowden, Derek	Study Assistant	Submissions															
				Back														
Study Status: Pending - Submitted for Initial Review		IRB Number: E-19-5041	Study Title: August 23 Test															
Submissions		Study Management																
Protocol Items																		
- Study Application - Informed Consent - Other Study Documents																		
- Adverse Event Reporting Form - Amendment/General Reporting Form - Initial Submission Packet - Continuing Review Submission Form																		
- Submissions History - Study Correspondence																		
Outstanding Submission(s)																		
Track Location	Ref Number	Request Type		Process Submission														
	00028	Click on the hyperlink to edit/view the submission.		Retract Submission														
Routing In Process		Initial Submission Packet																