




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

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.”

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.

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.

The screenshot shows the application interface for 'Request for Initial Review of Research Project Involving Human Subjects (Version 1.0)'. The user is logged in as 'Study Assistant' for 'August 23 Test' (PI: Bowden, Derek). The left sidebar shows a navigation menu with '1.0 General Information' selected. The main content area is titled '1.0 General Information' and contains two input fields: 'Please enter the full title of your study:' (with 'August 23 Test' entered) and 'Please enter an abbreviated title that you would like to use to reference the study:' (with 'August 23 Test' entered). The top right navigation bar includes buttons for 'Print Friendly', 'Save Section', and 'Save and Continue to Next Section'. A red arrow points to the 'Save and Continue to Next Section' button.

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).

The screenshot shows the application interface for '2.0 Add Department(s)'. A search window titled 'Adding Department - Search Window' is open. The search window contains input fields for 'Institution Name', 'Department Name', and 'Dept Code', along with a 'Search' button. Below the search fields, a table displays 71 results found. The table has columns for 'Select', 'Institution', 'Department Name', and 'Department Code'. The results list various departments under the 'Mainline Health' institution, including Anesthesiology-Bryn Mawr, Anesthesiology-Lankenau, Anesthesiology-MLH Centers, Anesthesiology-Paoli, Anesthesiology-Riddle, Bryn Mawr Hospital, Bryn Mawr Rehab, Cardiology-Bryn Mawr, Cardiology-Lankenau, and Cardiology-MLH Centers. The search window also includes 'Cancel' and 'Save' buttons.

Select	Institution	Department Name	Department Code
<input type="checkbox"/>	Mainline Health	Anesthesiology-Bryn Mawr	
<input type="checkbox"/>	Mainline Health	Anesthesiology-Lankenau	
<input type="checkbox"/>	Mainline Health	Anesthesiology-MLH Centers	
<input type="checkbox"/>	Mainline Health	Anesthesiology-Paoli	
<input type="checkbox"/>	Mainline Health	Anesthesiology-Riddle	
<input type="checkbox"/>	Mainline Health	Bryn Mawr Hospital	
<input type="checkbox"/>	Mainline Health	Bryn Mawr Rehab	
<input type="checkbox"/>	Mainline Health	Cardiology-Bryn Mawr	
<input type="checkbox"/>	Mainline Health	Cardiology-Lankenau	
<input type="checkbox"/>	Mainline Health	Cardiology-MLH Centers	

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		
<input checked="" type="checkbox"/>	<input checked="" type="radio"/> Main Line HealthCare - Main Line HealthCare	<input type="checkbox"/>	<input type="button" value="+ Add"/>
<input type="checkbox"/>	<input type="radio"/> MLH - Lankenau Institute of Medical Research	<input type="checkbox"/>	<input type="button" value="✖ 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.

Section view of Application | Entire view of the Application

Print Friendly | Save Section | Save and Continue to Next Section

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 displays the 'Request for Initial Review of Research Project Involving Human Subjects (Version 1.0)' form. The user is logged in as Spider Man, M.D., MBA. The form is currently on section 5.0, 'Main Line Hospitals Institutional Review Board Request for Initial review of Research Project Involving Human Subjects'. The left sidebar shows a navigation menu with sections 1.0 through 5.0. The main content area contains the following questions:

- 5.1 Duration of Entire Study (form IRB approval to final report):** Includes two input fields labeled '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?** Includes radio buttons for 'Yes' and 'No'.
- 5.3 Are you applying for an Exemption?** Includes radio buttons for '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:** Includes a rich text editor with a 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.

Section view of the Form | Entire view of the Form

1.0 Submission Packet to the Review Board

2.0 Application

3.0 Protocol and Study Documents

1.0 Submission Packet to the Review Board

1.1 Protocol Information

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

*For investigator-initiated clinical trials study that prospectively assigns subjects to one or more health-related interventions to evaluate the effects on health outcomes must be updated on www.clinicaltrials.gov as required. See the Office of Research Protections (ORP) website for additional information.

1.2 Sponsor Information

Study Sponsor:
Boehringer-Ingelheim()

Study Sponsor Identification #:

1.3 Reviewed by Pharmacy: (Protocol and Pharmacy Fee Schedule)

Yes
 No
 N/A

1.4 Number of Subjects to be enrolled locally (indicate N/A if retrospective):

1.5 This is a medical records, retrospective chart review or database research project:
 Yes 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.

Section view of the Form | Entire view of the Form

1.0 Submission Packet to the Review Board

2.0 Application

3.0 Protocol and Study Documents

2.0 Application

2.1 * Attach/Review your completed application for this study:

Print Friendly | Refresh Constant Fields | Save Section | Save and Continue to Next Section

Unattach	Review/Attach	Edit/View	Title
<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	Request for Initial Review of Research Project Involving Human Subjects (Version 1.0)

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 '3.0 Protocol and Study Documents' section. On the left is a navigation menu with items 1.0 through 4.0. The main content area has a header '3.0 Protocol and Study Documents' and a sub-header '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 are two buttons: 'Add a New Document' and 'Add Multiple Documents'. A table with columns: Detach, Version, Title, Category, Expiration Date, Document Outcome, Checked Out, and View Document is shown. Below the table, it says 'No Document(s) have been attached to this 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.

The screenshot shows the '4.0 Informed Consent' section. At the top right are buttons: 'Print Friendly', 'Refresh Constant Fields', 'Save Section', 'Save and Continue to Next Section', and 'Signoff and Submit'. The left navigation menu is visible. The main content area has a header '4.0 Informed Consent' and a sub-header '4.1 Attach the inform consent(s) for this study:'. Below this is a note '(Click below to access the informed consent documents)'. There is an 'Add a New Consent' button and a table with columns: Detach, Version, Title, Category, Language, Expiration Date, Consent Outcome, Checked Out, and View Document. Below the table, it says 'No Consent(s) have been attached to this form.'

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 'Form has been Completed!' screen. The left navigation menu is visible. The main content area has a large green header with the text 'Form has been Completed!' and 'Instruction of Form has Been Completed Screen'. At the bottom center are two buttons: 'Exit Form' (with a red X icon) and 'Signoff and Submit'.

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.

The screenshot shows the 'Setup Signoff Submission Routing' screen. At the top, the user's account information is displayed: 'Main Line Health', 'Account: Spider Man, M.D., MBA', 'Department: MLH - MLH', and 'Path: Home > study mgmt. > track submission'. There are links for 'Help', 'My Profile', and 'Log out'. The page title is 'Setup Signoff Submission Routing' with a 'Back' button. Below the title, there are buttons for 'Return to Previous Screen' and 'Save and Continue'. The main content area is titled 'Select the Key Personnel required for routing and signoff' and includes a sub-instruction: 'Check the boxes next to the names of the personnel required for routing and signoff.' A table lists personnel with checkboxes in the 'Include in signoff' column:

Include in signoff	Approved	Name	Role
<input checked="" type="checkbox"/>		Spider Man, M.D., MBA	Study Author
<input checked="" type="checkbox"/>		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.

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.

The screenshot shows the 'Setup Signoff Submission Routing' screen. At the top, the user's account information is displayed: 'Main Line Health', 'Account: Spider Man, M.D., MBA', 'Department: MLH - MLH', and 'Path: Home > study mgmt. > track submission'. There are links for 'Help', 'My Profile', and 'Log out'. The page title is 'Setup Signoff Submission Routing' with a 'Back' button. Below the title, there are buttons for 'Return to Previous Screen', 'Add signoff', and 'Save and Continue'. The main content area is titled 'Select the additional personnel required for routing and signoff' and includes a sub-instruction: 'Check the boxes next to the names of the personnel required for routing and signoff.' A table with columns 'Include in signoff', 'Order', 'Approved', and 'Name/Role' is shown. Below the table, it states: '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:

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.

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
	 Routing Assignment List	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.

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 09/03/2019 02:35 PM EDT	Send Email with Merge Code
		09/03/2019 02:35 PM EDT 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 09/03/2019 02:35 PM EDT	Main Line Hospitals IRB assigned with the IRB Number of E-19-5041
		09/03/2019 02:25 PM EDT 09/03/2019 02:25 PM EDT	Derek Bowden as Principal Investigator review and apply 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 05:08 PM EDT 09/03/2019 02:35 PM EDT	Assign Department Personnel for Signoff
		08/30/2019 05:08 PM EDT 08/30/2019 05:08 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.

Click to open	Study Status	Review Board	RB Number	RB Expiration	Study Title	Principal Investigator	Actions
	Pending - Submitted for Initial Review	Main Line Hospitals IRB	E-19-5041		August 23 Test	Bowden, Derek	History Items Forms Hide Copy Delete

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.

Track Location	Ref Number	Request Type	Process Submission
	00028	Click on the hyperlink to edit/view the submission. Initial Submission Packet	Retract Submission