

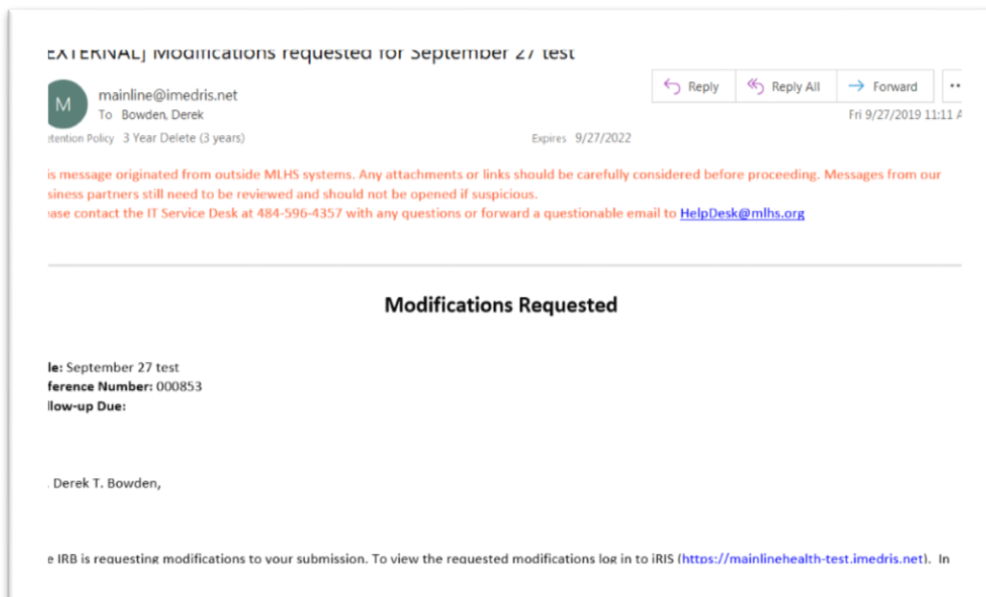
Study Status: Returned for Corrections



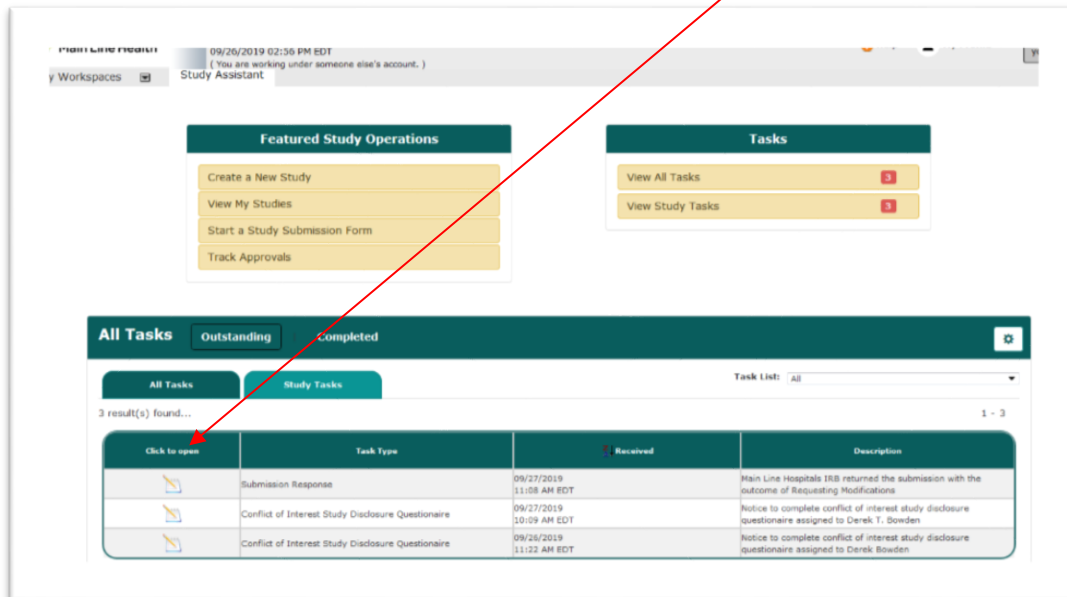
Responding to a Request for Revisions

When you submit to the MLH IRB through imedris, ORP staff and IRB reviewers have the ability to review your submission and request revisions prior to approval.

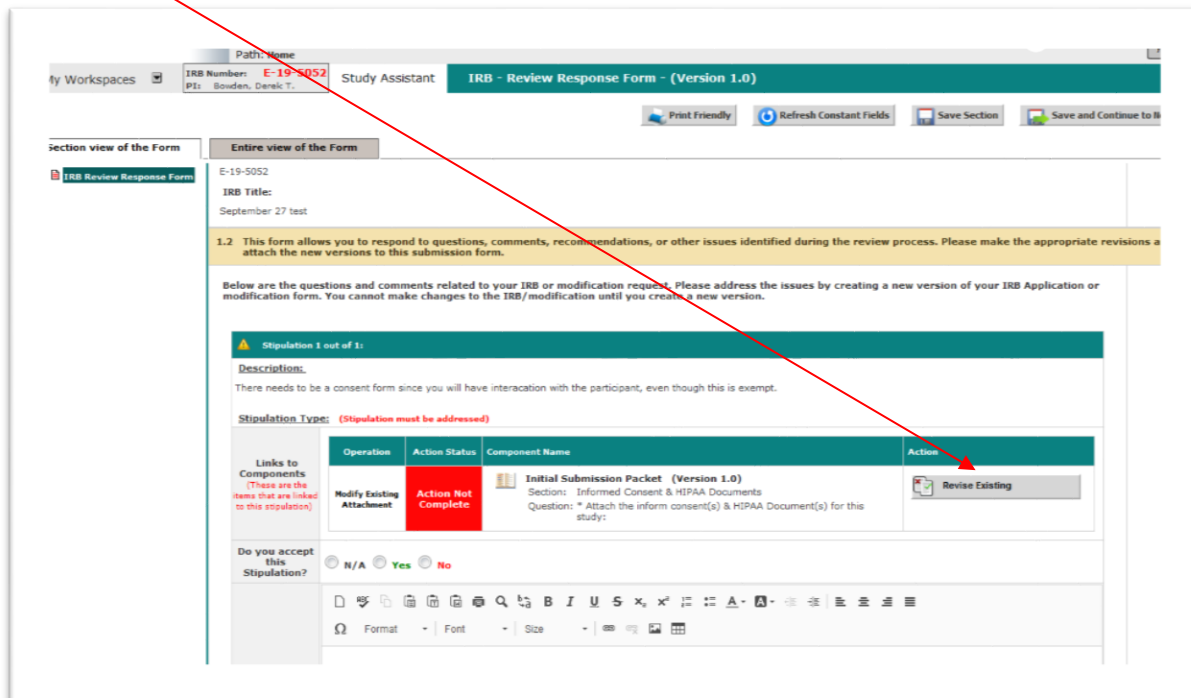
If you receive a notification from mainline@imedris.net indicating Modifications Requested, you must respond to the request in order for your submission to proceed in the review process. An email notification is generated when submission revisions are requested.



This request for changes will also appear on your dashboard as a task when you log into iMedRIS (<https://imedris.mlhs.org>)



Clicking on the notepad will take you into the Reviewer Response Form which lists the stipulations that need to be addressed in order for your submission to move forward in the approval process. Click on "Revise Existing" to respond. This action will create another version of your submission packet (1.1).



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

When you click Revise Existing, you should be taken into the revised study submission packet, directly to the section that requires the revision for that stipulation. If you have additional stipulations, you will click Revise Existing to enter the revised study submission packet to the section that corresponds to the required stipulation.

Once you complete the revision and exit the form, you will be asked to confirm the stipulation has been satisfied. Checking “Complete Action” will change the Action Status to Complete and turn **Green**.

The screenshot displays the 'IRB - Review Response Form - (Version 1.0)' interface. At the top, it shows the Main Line Health logo, department information (NHLT - NHLT), and user details (Study Assistant, IRB Number: E-19-5052, PI: Bowden, Derek T.). The main content area is titled 'IRB Review Response Form' and includes a 'Description' section stating that a consent form is needed. Below this is a table for stipulations:

Operation	Action Status	Component Name	Action
Modify Existing Attachment	Action Not Complete	Initial Submission Packet (Version 1.1)	Compare Form Version
		Initial Submission Packet (Version 1.0) Section: Informed Consent & HIPAA Documents Question: * Attach the inform consent(s) & HIPAA Document(s) for this study.	<input type="radio"/> Complete Action <input checked="" type="radio"/> Incomplete Action

Below the table is a question: 'Do you accept this Stipulation?' with radio buttons for 'N/A', 'Yes', and 'No'. The 'Yes' button is selected. Below the question is a rich text editor with a toolbar and a text area for providing an explanation.

Click “Yes” in the “Do you accept this Stipulation” question AND provide an explanation for how the stipulation was addressed before you save and continue.

The next screen will display both the original (1.0) and revised (1.1) submission packet.

The screenshot displays the 'Submission Documents' section of the IRB Review Response Form. The interface includes a sidebar with navigation options, a main header for '2.0 Submission Documents', and a table listing various documents. The table has columns for 'Compare', 'Include in PDF Packet', 'Unattach', 'Revise/Attach', and 'Revisions'. The documents listed include 'Main Line Hospitals IRB - IRB - Review Response Form - (Version 1.0 (Incomplete))', 'Initial Submission Packet - (Version 1.1)', 'Request for Initial Review of Research Project Involving Human Subjects - (Version 1.0)', 'Test Consent (English) - (Version 1.0)', and 'MLHIRBTransmittalForm (1) - (Version 1.0)'. There are also buttons for 'Add New Component', 'Compare Item(s)', and 'Create PDF Packet'.

Compare	Include in PDF Packet	Unattach	Revise/Attach	Revisions	All Submission Components
Submission Form(s)					
<input type="checkbox"/>	<input type="checkbox"/>				Main Line Hospitals IRB - IRB - Review Response Form - (Version 1.0 (Incomplete))
<input type="checkbox"/>	<input type="checkbox"/>				Initial Submission Packet - (Version 1.1)
Application					
<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>		Request for Initial Review of Research Project Involving Human Subjects - (Version 1.0)
Consent Form(s)					
Category : Consent					
<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>			Test Consent (English) - (Version 1.0)
Document(s)					
Category : Other					
<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>		MLHIRBTransmittalForm (1) - (Version 1.0)

Save and Continue until you reach the signoff page. Enter your credentials to sign and submit the response.

You will be taken back to your dashboard. Once the task has been removed from your task list, the response submission has been communicated to ORP staff. (If the task still appears on your task list, you did not complete the response submission process)