

Study Status: Returned for Corrections

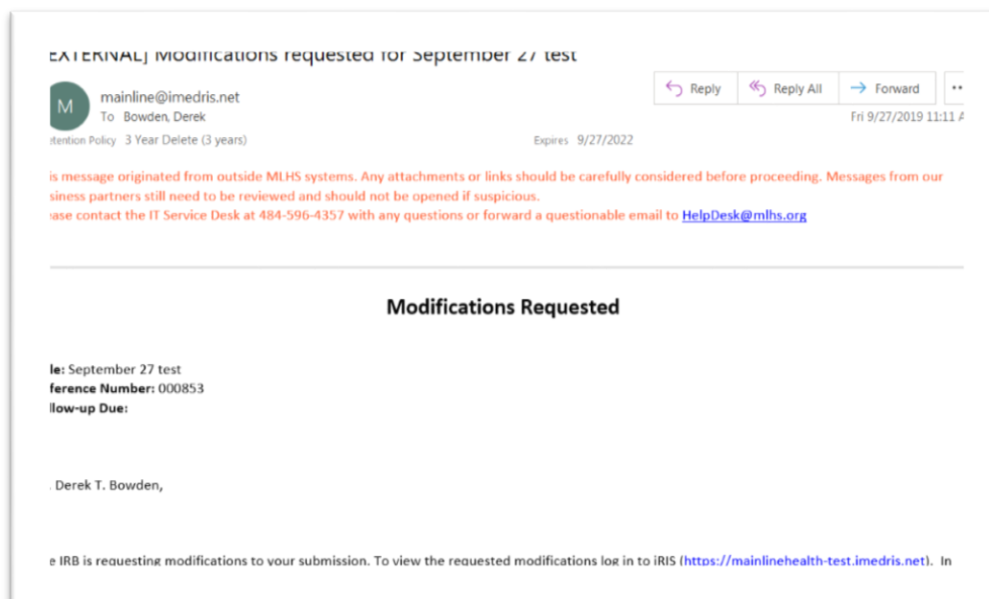


Main Line Health®

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.



MAIN LINE HEALTH OFFICE OF RESEARCH PROTECTIONS

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

The screenshot shows the iMedRIS dashboard. At the top, there's a header with the date and time (09/26/2019 02:56 PM EDT) and the user's role (Study Assistant). Below the header, there are two main sections: "Featured Study Operations" and "Tasks". The "Featured Study Operations" section includes links for "Create a New Study", "View My Studies", "Start a Study Submission Form", and "Track Approvals". The "Tasks" section includes links for "View All Tasks" and "View Study Tasks". Below these sections, there's a "All Tasks" section with tabs for "Outstanding" and "Completed". The "Outstanding" tab is selected, showing a list of tasks. A red arrow points to the first task in the list, which is a "Conflict of Interest Study Disclosure Questionnaire" due on 09/27/2019 at 11:08 AM EDT. The task description states: "Main Line Hospitals IRB returned the submission with the outcome of Requesting Modifications. Notice to complete conflict of interest study disclosure questionnaire assigned to Derek T. Bowden."

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).

The screenshot shows the "IRB - Review Response Form - (Version 1.0)". The form is titled "IRB Review Response Form" and is for the IRB Number E-19-5052, PI: Bowden, Derek T. The form is divided into two main sections: "Section view of the Form" and "Entire view of the Form". The "Entire view of the Form" section is selected, showing the IRB Title (September 27 test) and a description of the form. Below the description, there's a section for "Stipulation 1 out of 1". The stipulation is titled "Description:" and states: "There needs to be a consent form since you will have interaction with the participant, even though this is exempt." The stipulation type is "Stipulation Type: (Stipulation must be addressed)". Below the stipulation, there's a table with columns for "Operation", "Action Status", "Component Name", and "Action". The table has one row with the operation "Modify Existing Attachment", action status "Action Not Complete", component name "Initial Submission Packet (Version 1.0)", and action "Revise Existing". A red arrow points to the "Revise Existing" button. Below the table, there's a section for "Do you accept this Stipulation?" with radio buttons for "N/A", "Yes", and "No". The "Yes" button is selected. At the bottom of the form, there's a rich text editor with various formatting options.

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, there's a header with 'Main Line Health' logo, 'Department: PILT - PILT', 'Path: Home', and 'Study Assistant'. Below this, a green bar contains 'IRB - Review Response Form - (Version 1.0)'. The main content area is divided into 'Section view of the Form' and 'Entire view of the Form'. The 'Entire view of the Form' section shows a table with stipulations. The table has columns: 'Operation', 'Action Status', 'Component Name', and 'Action'. One row is highlighted with a red box and the text 'Action Not Complete'. Below the table, there's a question 'Do you accept this Stipulation?' with radio buttons for 'N/A', 'Yes', and 'No'. A red arrow points from the 'Complete Action' button in the 'Action' column to the 'Do you accept this Stipulation?' question. Another red arrow points from the 'Yes' radio button to the 'Provide an explanation on how you addressed this Stipulation:' text area.

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.

Section view of the Form | **Entire view of the Form**

3 IRB Review Response Form
3 Submission Documents

2.0 Submission Documents

2.1 The following is a list of documents associated with this application request, all of which are hyperlinks to viewable versions of these documents (click the mouse on the document name to open/view the document). Notice that this review response form is listed as "**(Incomplete)**." This should be the only incomplete document in this submission. Open and finalize any other document listed as incomplete.

The IRB Application is titled "IRB Application" followed by a version number; an Application Modification can be found under "Submission Forms." Select "**Modify**" in the upper right hand corner to see this list of documents with the option to revise your IRB Application or modification, which will be necessary to respond.

[Add New Component](#)
[Compare Item\(s\)](#)
[Create PDF Packet](#)

Compare	Include in PDF Packet	Unattach	Revises/ Attach	Revisions	All Submission Components
Submission Form(s)					
☐	☐				Main Line Hospitals IRB - Review Response Form - (Version 1.0 (Incomplete))
☐	☐				Initial Submission Packet - (Version 1.1)
Application					
☐	☐		☐		Request for Initial Review of Research Project Involving Human Subjects - (Version 1.0)
Consent Form(s)					
Category : Consent					
☐	☐	☒			Test Consent (English) - (Version 1.0)
Document(s)					
Category : Other					
☐	☐		☐		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)

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