



How to Manage An Approved Study

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Once your study has been approved by HML IRB, you and your project staff remain responsible for ensuring compliance with HML IRB's determinations. Those responsibilities include, but are not limited to:

- ensuring prompt reporting to HML IRB of proposed changes in this study's design, risks, consent, or other human protection protocols, and providing copies of any revised materials;
- conducting the research activity in accordance with the terms of the IRB approval until any proposed changes have been reviewed and approved by the IRB, except when necessary to mitigate hazards to subjects;
- promptly reporting any unanticipated problems involving risks to subjects or others in the course of this study;
- notifying HML IRB when your study is completed.

Use this document as a guide for how to access your study through the IRB Portal to ensure compliance.

If at any time you need a copy of the ethical review application and current approved documents, you can obtain it by logging into the online portal and clicking on the Print/Zip button at the top of the study page.

Submit an Amendment

Amendment Process for Studies Reviewed and Approved through the Online Portal

1. Once your study has been approved, any proposed amendment, change or alteration to the protocol approved by HML IRB must be reviewed and approved by the IRB prior to implementation, except where an immediate change is necessary to eliminate hazard to the participant. To submit an amendment to your study for review, please follow the steps below.

Health Media Lab, Inc.
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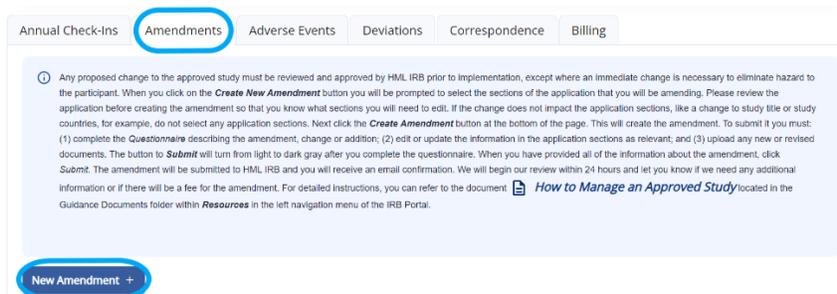
- If you are not already logged in, go to <https://www.axiommentor.com/login/axlogin.cfm?i=hmlirb> and login to the HML IRB Online Portal. See *Resetting my Password* below if you do not know your login credentials.
- Click on **My Studies** on the left navigation menu on the IRB tab.



- Then, click on the title of the study you want to amend.

IRB # -	Title	PI	Status	Approved	Review Due	Tracking Status
12	Sitan in Morocco	Nancy Westwood	Exempt Determination Approved	04/06/2022	03/27/2024	Completed
2544	Demo Study	Test Demo	Expedited Requested			Pending Initial Submission
2545	Test Demo	Test Demo	Expedited Approved	03/25/2024	04/22/2024	Completed

- Scroll to the bottom of the study page and click on the **Amendment** Tab and the **Create New Amendment** button.



- Scroll to the bottom of the screen, check the boxes next to the sections that you want to make amendments to and click **Create Amendment**. If you are not sure what sections will require changes,



go back to the *Study* page and review the application sections. If none of the application sections are impacted (a change in study title for example), leave all of the sections unchecked.

A screenshot of a web form titled "Create New Amendment". Below the title is a section labeled "Select Application Sections you wish to revise". This section contains a list of eleven checkboxes, each followed by a label: Research Design, Personnel, Sites, Dates & Risk, Subject Recruitment, Data Collection, Child Subjects, Informed Consent, Parental Consent, Child Assent, Subject Protections, and Data Protections. All checkboxes are currently unchecked.

7. When you click on the *Create Amendment* button, it will create the amendment and direct you back to the *Study* page.

A screenshot of the same "Create New Amendment" form. In this version, the checkboxes for "Informed Consent", "Child Assent", and "Data Protections" are checked. The "Create Amendment" button at the bottom left is highlighted with a red circle, and the "Cancel" button at the bottom right is also visible.

8. If you are adding data collection types or vulnerable subjects types (like prisoners, children or pregnant women), please reach out to the IRB Administrator at admin@hmlirb.com prior to submitting the amendment as we will need to modify the fields selected on the *Study* page to reflect the changes. This will add additional questions to the application to reflect the changes.

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9. Next complete the Questionnaire describing the amendment, change or addition. Click on the *Answer* button to open it.

2545. Test Demo Print to PDF | Back

Amendment Form

Answer

Select as many as apply. You will be given an opportunity to explain your changes in greater detail. Please remember to modify the original application sections as necessary to reflect these amendments.

* Please select the category(ies) that best describe the changes, modifications and/or additions being submitted in this Amendment.

- New procedures
- Study title change
- Change in study personnel
- Change in location
- Change in subjects/study participants
- Change in enrollment (total number of participants)
- Change in consent form or process
- Recruitment Materials
- Data collection tools (surveys, questionnaires, interviews, etc.)
- Other

Answer Required

10. Check the boxes which best describe your amendment and provide a brief description in the box provided. And click on *Save Answers*.

Amendment Form Cancel X

- Change in study personnel
- Change in location
- Change in subjects/study participants
- Change in enrollment (total number of participants)
- Change in consent form or process
- Recruitment Materials
- Data collection tools (surveys, questionnaires, interviews, etc.)
- Other

* Please provide a brief summary of the changes, modifications and/or additions being submitted.
(You can describe them in greater detail as needed in the relevant application sections)

Test

body Words: 1

Save Answers **Save Answers & Close** **Skip Question** **Cancel**

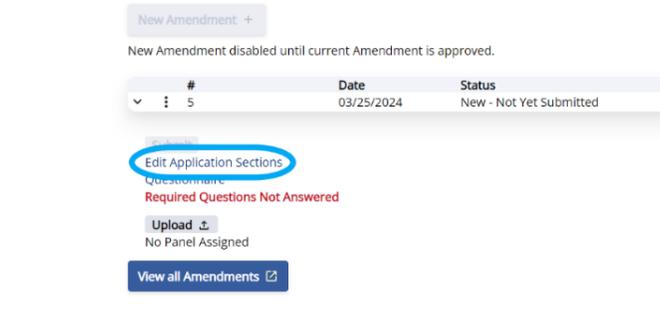
11. Unless you need to review your answers, on the next screen click on the *Return to Study Page* button.

Amendment Form

How do you wish to proceed?

Return to Study Page **Review Answers**

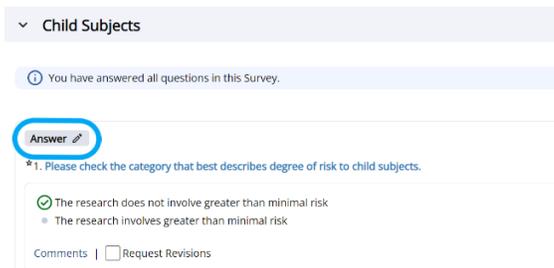
12. You need to complete all of the components of the amendment in order to submit it for review. First, if you checked any of the sections as requiring revision, click on the **Edit Application Sections** link to access those sections.



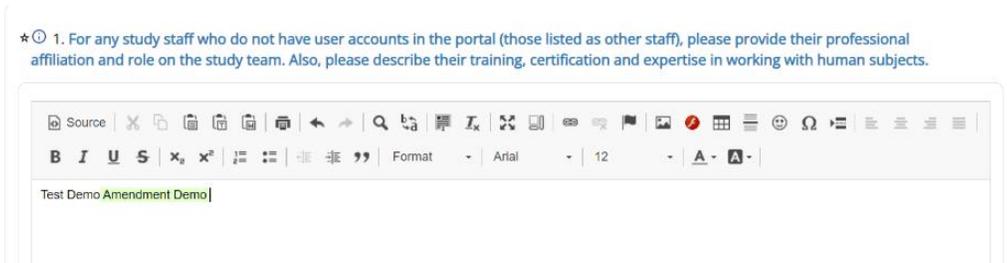
13. Open each section to edit your original answers to the application questions to reflect any changes to be made to the study.



14. Click on *Answers* to revise the application text. Do not submit your changes as *Reader Comments*.



15. All edits will be shown in mark-up for easy reference. Please do NOT remove the coloring on the background. We need to be able to easily review the changes to the approved application.



16. When you are done editing, click on *Save Answers and Close*.

*3. Are you aware of any potential conflicts of interest, financial or otherwise, for any study staff on this project?

Yes
 No

*4. By whom will the data be collected for this study (select all that apply)?

1. The study team will conduct data collection themselves
 2. The study team will contract with another entity for the supervision of data collectors
 3. The study team will directly hire (or partner with) and supervise data collectors
 4. Not applicable, the study uses only existing secondary data.

Save Answers ▾ **Save Answers & Close** ▾ Cancel ⊗

17. When you are done revising your application, click on *View Study Page*.



18. Next, you can upload any new or revised documents relevant to the amendment. Click on the three dots to upload additional documents. To upload more than one document, select **Upload Multiple Docs**. You can select the files to upload and then assign them to document types.



19. A new window will open that will allow you to upload a file. It will also allow you to link it to an existing approved file. For example, **if you have revised an approved informed consent document, choose the existing informed consent file to link to as the new one will override it when approved.** If it is an entirely new file, a new type of data collection, or if you cannot find the appropriate file to link, just leave it as the default “Do Not Link” and click the *Save* button.

Upload Amendment Document

New or Revised Additional Documentation

Choose File No file chosen

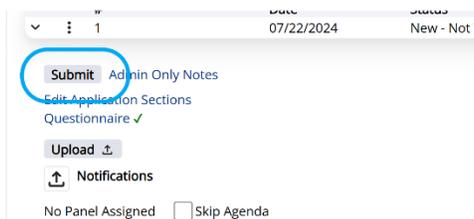
Allowed Extensions: doc, docx, pdf, rtf, xls, xlsx

Rename File to

Leave blank to use original file name

Link File to Existing Protocol File Do Not Link

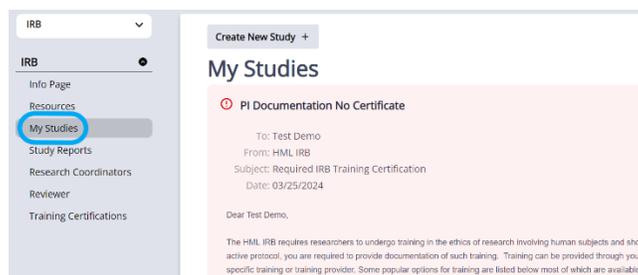
20. You will be directed back to the *Study* page. Under the *Amendment* tab, the *Submit* button will turn from light to dark gray. When you have provided all of the information about the amendment, click *Submit*. The amendment will be submitted to HML IRB. You will no longer be able to edit or modify the study while it is under review. We will begin our review within 24 hours and let you know if we need any additional information, or if there will be a fee for the amendment.





Process for Legacy Studies Imported into the Online Portal

21. All post-approval monitoring and modification of approved studies will be done through the HML IRB Portal. The process to amend studies that were imported into the portal is different from the process to amend studies submitted and approved through the IRB Portal. Use these instructions as a guide for modifying imported approved studies only.
22. Any proposed amendment, change or alteration to the protocol approved by HML IRB must be reviewed and approved by the IRB prior to implementation, except where an immediate change is necessary to eliminate hazard to the participant. To submit an amendment to your imported study please follow the steps below.
23. Using the Word document you submitted to request ethical review¹ (our filename: *HML IRB Request for Approval of Research*), make any changes to the protocol on that document showing markup. You will need to upload it to the IRB Portal when you request the amendment.
24. If you are not already logged in, Go to <https://www.axiommentor.com/login/axlogin.cfm?i=hmlirb> and login to the HML IRB online submission system for ethical review. See *Resetting my Password* below if you do not know your login credentials.
25. Click on the ***My Studies*** on the left navigation menu on the IRB tab.

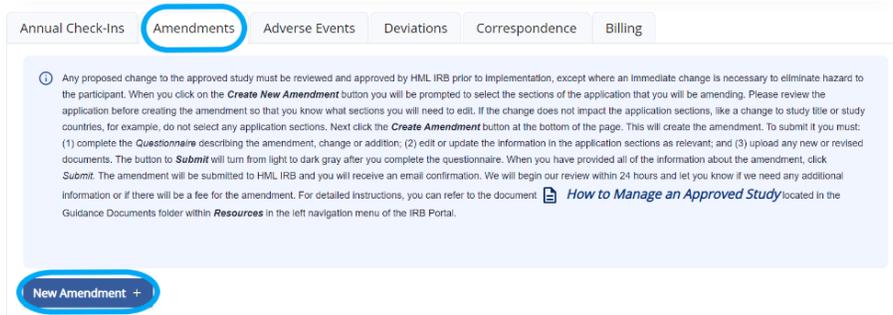


¹ If you cannot find your initial application for ethical review, please email us and ask for a copy. We will send you the latest version we have on record for your study.

26. Then click on the title of the study you want to amend.

IRB # -	Title	PI	Status	Approved	Review Due	Tracking Status
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2544	Demo Study	Test Demo	Expedited Requested			Pending Initial Submission
2545	Test Demo	Test Demo	Expedited Approved	03/25/2024	04/22/2024	Completed

27. Scroll to the bottom of the study page and click on the **Amendment** Tab and the **Create New Amendment** Button.



Annual Check-Ins **Amendments** Adverse Events Deviations Correspondence Billing

Any proposed change to the approved study must be reviewed and approved by HML IRB prior to implementation, except where an immediate change is necessary to eliminate hazard to the participant. When you click on the **Create New Amendment** button you will be prompted to select the sections of the application that you will be amending. Please review the application before creating the amendment so that you know what sections you will need to edit. If the change does not impact the application sections, like a change to study title or study countries, for example, do not select any application sections. Next click the **Create Amendment** button at the bottom of the page. This will create the amendment. To submit it you must: (1) complete the **Questionnaire** describing the amendment, change or addition; (2) edit or update the information in the application sections as relevant; and (3) upload any new or revised documents. The button to **Submit** will turn from light to dark gray after you complete the questionnaire. When you have provided all of the information about the amendment, click **Submit**. The amendment will be submitted to HML IRB and you will receive an email confirmation. We will begin our review within 24 hours and let you know if we need any additional information or if there will be a fee for the amendment. For detailed instructions, you can refer to the document: [How to Manage an Approved Study](#) located in the Guidance Documents folder within **Resources** in the left navigation menu of the IRB Portal.

New Amendment +

28. If you have any additions to personnel (with user accounts in the system) as part of your modification, check the box by *Personnel*; if not, leave unchecked. If your personnel changes are limited to “other staff”, leave this box blank. You can address changes in other staff on the amendment questionnaire. Next, click the **Create Amendment** button. This will create the amendment and direct you back to the study page.

Select Application Sections you wish to revise

Personnel

Create Amendment ✓ Cancel ⊗

29. Next complete the Questionnaire describing the amendment, change or addition. Click on the **Answer** button to open it.

2545. Test Demo

[Print to PDF](#) | [Back](#)

Amendment Form

Answer 

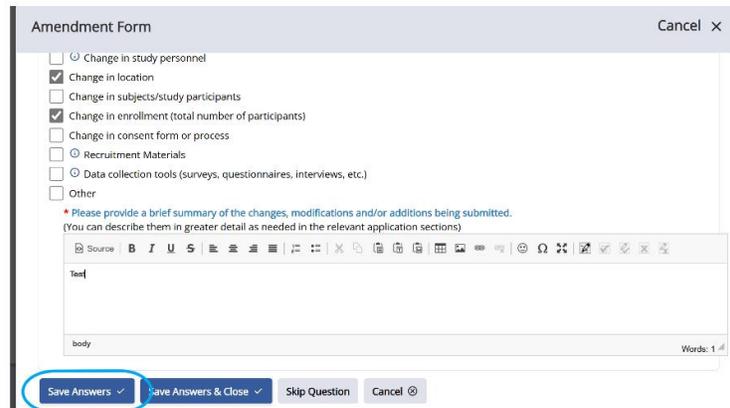
Select as many as apply. You will be given an opportunity to explain your changes in greater detail. Please remember to modify the original application sections as necessary to reflect these amendments.

* Please select the category(ies) that best describe the changes, modifications and/or additions being submitted in this Amendment.

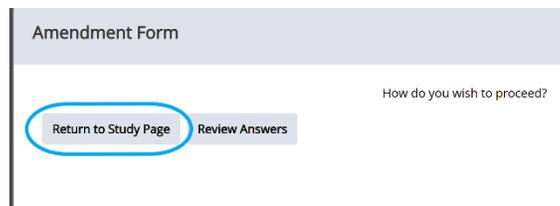
- New procedures
- Study title change
- Change in study personnel
- Change in location
- Change in subjects/study participants
- Change in enrollment (total number of participants)
- Change in consent form or process
- Recruitment Materials
- Data collection tools (surveys, questionnaires, interviews, etc.)
- Other

Answer Required

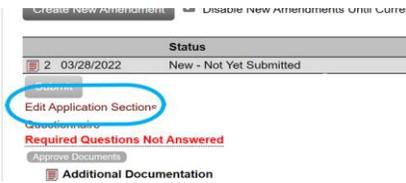
30. Check the boxes which best describe your amendment and provide a brief description in the box provided. And click on *Save Answers*.



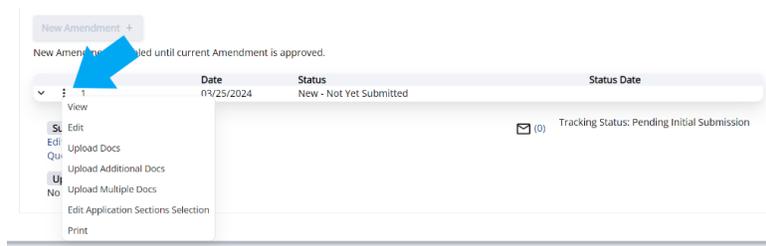
31. Unless you need to review your answers, on the next screen click on the *Return to Study Page* button.



32. Next if you check *Personnel*, click on the **Edit Application Sections** link to add staff to the study.



33. Next, upload the revised HML IRB Request for Approval of Research showing markup, along with any other new or revised documents relevant to the amendment. Click on the three dots on the left-hand side of the screen to upload files. To upload more than one file select **Upload Multiple Docs** from the drop-down menu. You can select the files to upload and then assign them to document types.



34. A new window will open that will allow you to upload a file. It will also allow you to link it to an existing approved file. For example, **if you have revised an approved informed consent document, choose the existing informed consent file to link to as the new one will override it when approved.** If it is an entirely new file, a new type of data collection, or if you cannot find the appropriate file to link, just leave it as the default “Do Not Link” and click the *Save* button.

Upload Amendment Document

New or Revised Additional Documentation

No file chosen

Allowed Extensions: doc, docx, pdf, rtf, xls, xlsx

Rename File to

Leave blank to use original file name

Link File to Existing Protocol File:

35. You must also complete the Questionnaire describing the amendment, change or addition. Click on the link, *Questionnaire*, to open it.



New Amendment +

New Amendment disabled until current Amendment is approved.

#	Date	Status
1	03/25/2024	New - Not Yet Submitted

Submit

Edit Application Sections

Questionnaire

Upload

No Panel Assigned

36. You will be directed back to the *Study* page. Under the *Amendment* tab, the *Submit* button will turn from light to dark gray. When you have provided all of the information about the amendment, click *Submit*. The amendment will be submitted to HML IRB. You will no longer be able to edit or modify the study while it is under review. We will begin our review within 24 hours and let you know if we need any additional information, or if there will be a fee for the amendment.

#	Date	Status
1	07/22/2024	New - Not Y

Submit Admin Only Notes

Edit Application Sections

Questionnaire ✓

Upload

Notifications

No Panel Assigned Skip Agenda

Submit a Deviation

37. Any alterations or deviations from the approved study protocols should be submitted to the IRB as soon as possible after the deviation occurred. Please complete the form under the ***Deviations*** tab in the IRB Portal to notify us. If this deviation from the protocol will cause you to make changes to the study or study related materials, please also complete a request for an amendment using the ***Amendment*** tab.

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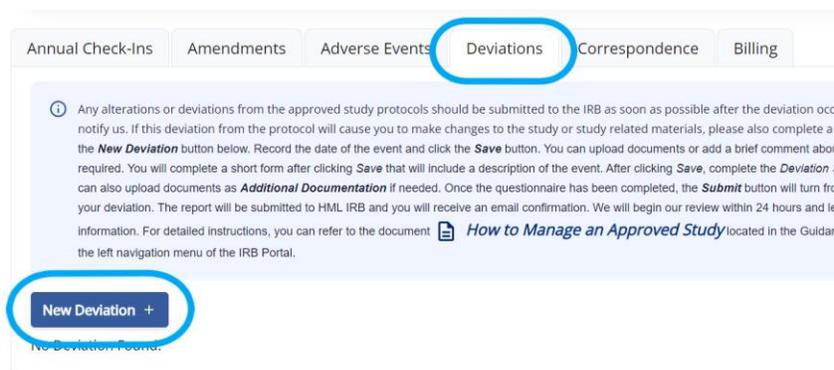
- 38. If you are not already logged in, go to <https://www.axiommentor.com/login/axlogin.cfm?i=hmlirb> and login to the HML IRB Online Portal. See Resetting my Password below if you do not know your login credentials.
- 39. Click on *My Studies* on the left navigation menu on the IRB tab.



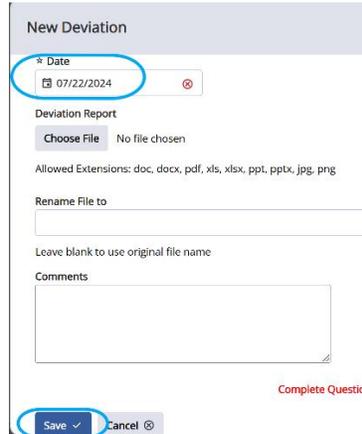
- 40. Then click on the title of the study for which you want to report a deviation.

IRB #	Title	PI	Status	Approved	Review Due	Tracking Status
12	Sitan in Morocco	Nancy Westwood	Exempt Determination Approved	04/06/2022	03/27/2024	Completed
2544	Demo Study	Test Demo	Expedited Requested			Pending Initial Submission
2545	Test Demo	Test Demo	Expedited Approved	03/25/2024	04/22/2024	Completed

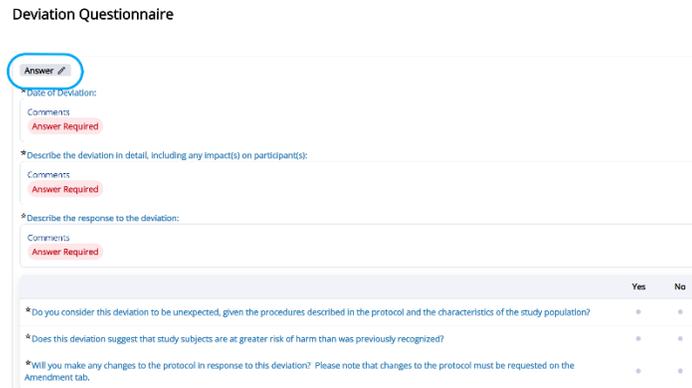
- 41. Scroll to the bottom of the study page and click on the **Deviation** Tab and the **New Deviation** button.



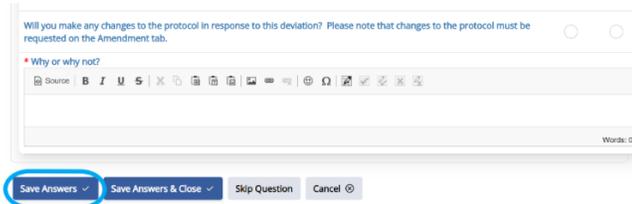
42. Record the date of the event and click the *Save* button. You can upload documents or add a brief comment about the nature of the event but it is not required. You will complete a short form after clicking *Save* that will include a description of the event.



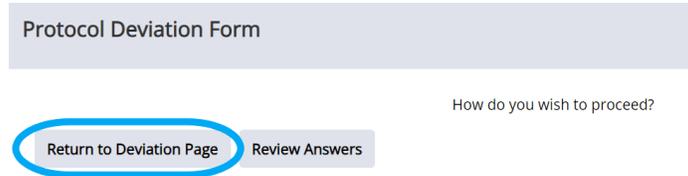
43. After clicking *Save*, complete the *Deviation Survey*. Click the *Answer* button to answer the questions about the deviation.



44. Click the *Save Answers* button when you are done filling out the form.



45. Unless you need to review your answers, click on the *Return to Deviation Page* button.

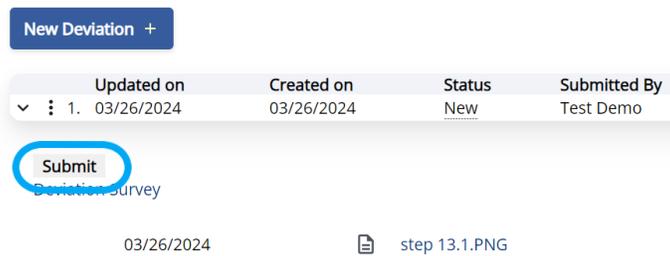


Protocol Deviation Form

How do you wish to proceed?

Return to Deviation Page Review Answers

46. Once the questionnaire has been completed, the *Submit* button will turn from light to dark gray. Otherwise, click *Submit* to report your deviation. The report will be submitted to HML IRB. We will begin our review within 24 hours and let you know if we need any additional information.



New Deviation +

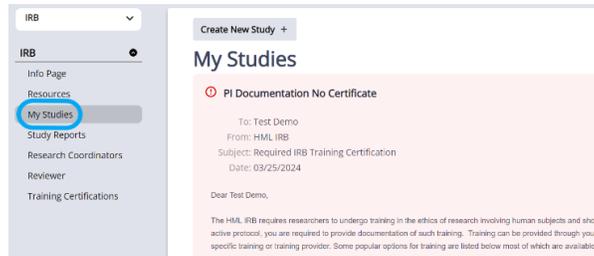
	Updated on	Created on	Status	Submitted By
1.	03/26/2024	03/26/2024	New	Test Demo

Submit

03/26/2024 step 13.1.PNG

Report an Adverse Event

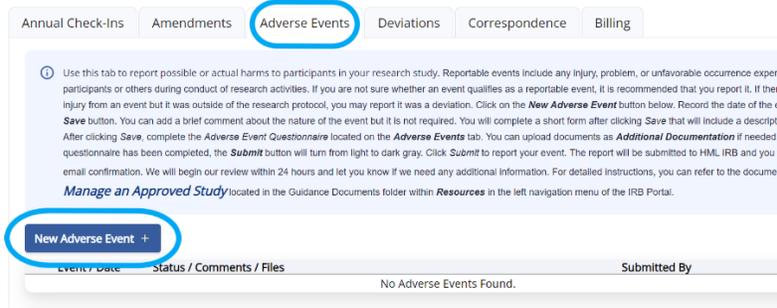
47. Use the **Adverse Events** tab to report possible or actual harms to participants in your research study. Reportable events include any injury, problem, or unfavorable occurrence experienced by human participants or others during conduct of research activities. If you are not sure whether an event qualifies as a reportable event, it is recommended that you report it. If there was no harm or injury from an event but it was outside of the research protocol, you may report it was a deviation.
48. If you are not already logged in, go to <https://www.axiommentor.com/login/axlogin.cfm?i=hmlirb> and login to the HML IRB Online Portal. See Resetting my Password below if you do not know your login credentials.
49. Click on *My Studies* on the left navigation menu on the IRB tab.



50. Then click on the title of the study for which you want to report an adverse event.

IRB #	Title	PI	Status	Approved	Review Due	Tracking Status
12	Sitan in Morocco	Nancy Westwood	Exempt Determination Approved	04/06/2022	03/27/2024	Completed
2544	Demo Study	Test Demo	Expedited Requested			Pending Initial Submission
2545	Test Demo	Test Demo	Expedited Approved	03/25/2024	04/22/2024	Completed

51. Go to the **Adverse Events** tab and click on the **New Adverse Event** button.



52. Record the date of the event and click the **Save** button. You can add a brief comment about the nature of the event but it is not required. You will complete a short form after clicking **Save** that will include a description of the event.

Adverse Event

Use this tool to report possible or actual harms to participants in your research study. Reportable events include any injury, problem, or experienced by human participants or others during conduct of research activities. If you are not sure whether an event qualifies as a reportable event, you may report it as a deviation. Click on the **New Adverse Event** button below. Record the date of the event and click the **Save** button. You can add a brief comment about the nature of the event to complete a short form after clicking **Save** that will include a description of the event. After clicking **Save**, complete the **Adverse Event Questionnaire** tab. You can upload documents as **Additional Documentation** if needed. Once the questionnaire has been completed, the **Submit** button will turn from light to dark gray. Click **Submit** to report your event. This report will be submitted to HML IRB and you will receive an email confirmation. We will begin our review within 24 hours and let you know if we need any additional information. For detailed instructions, you can refer to the document [How to Manage an Approved Study](#) located in the Guidance Documents folder within **Resources** in the left navigation menu of the IRB Portal.

Event Date: 03/25/2024

Comments:

Complete Questionnaire After Saving This Form.

Save Cancel



53. After clicking Save, complete the *Adverse Event Questionnaire*. Click the answer button to answer the questions.

54. When you have answered all the questions, click the *Save Answers* button at the bottom.

55. Unless you need to review your answers, click on the *Return to Adverse Event Page* button.

56. Once the questionnaire has been completed, the *Submit* button will turn from light to dark gray. If you need to add any files as part of reporting the deviation, upload them by clicking on the *Additional Documentation* button. Otherwise, click *Submit* to report your deviation. The report will be submitted to HML IRB, and you will receive an email confirmation. We will begin our review within 24 hours and let you know if we need any additional information.

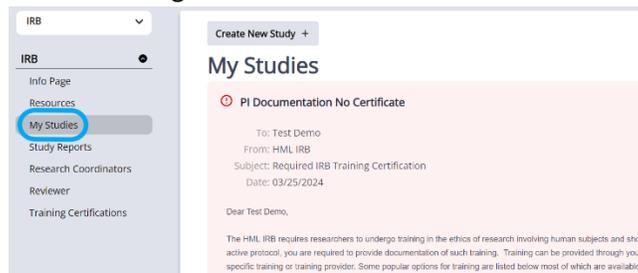


Ongoing Review

57. All studies reviewed by the Full IRB require an annual continuing review. Studies approved using an expedited review mechanism require an annual check-in. More details on both processes can be found below. All studies approved as exempt are valid for the duration of the study, provided you report any changes, modifications, deviations or adverse events to us in a timely fashion.

Submit a Continuing Review

58. Your study approval is valid for one year from the date of approval. To renew the approval for another year, complete the continuing review request prior to the study expiration. You will begin receiving email notifications to the email address we have on record in your user account six weeks before the expiration of the study. If you need to close your study, you can do so on the form by requesting to close the study from the drop down under *Continuation Status*. If there have been any amendments, deviations or adverse events that you need to make us aware of, please do so separately. You can click on the appropriate tab at the bottom of the *Study* page.
59. To complete the continuing review process, If you are not already logged in, go to <https://www.axiommentor.com/login/axlogin.cfm?i=hmlirb> and login to the HML IRB Online Portal. See Resetting my Password below if you do not know your login credentials.
60. Click on *My Studies* on the left navigation menu on the IRB tab.



61. Then click on the title of the study for which you want to submit a request for continuing review.

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2545	Test Demo	Test Demo	Expedited Approved	03/25/2024	04/22/2024	Completed

62. Scroll down to the **Cont Reviews** tab and click on the **Continuation Form** button.

The screenshot shows a navigation bar with tabs: Cont Reviews, Amendments, Adverse Events, Deviations, and Correspondence. Below the tabs is a table with columns: Year, Due Date, Date Received, and Date Approved. The Year is set to 1 and the Due Date is 05/03/2024. At the bottom, there are two buttons: 'Continuation Form' (circled in blue) and 'Submit'.

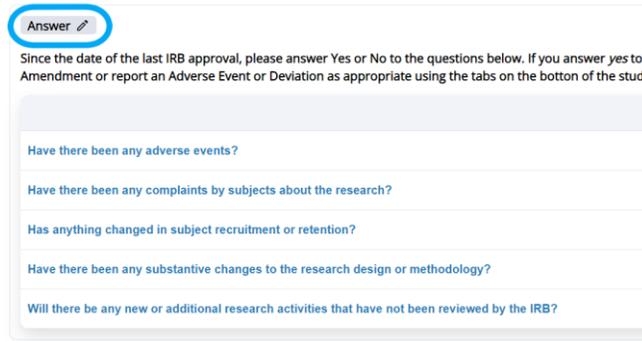
63. Complete the form and click the **Save** button. You can add a brief message about the status of the study, but it is not required. You will complete a short form after clicking **Save** that will allow for greater description.

The screenshot shows a form with the following fields: 'Total # Subjects Who Have Completed Study' (0), 'Total # Subjects Still Active' (0), and a dropdown menu for '* Continuation Status' (set to '- Select Continuation ...'). Below this is a text box for a message. At the bottom, there are two buttons: 'Save' (circled in blue) and 'Cancel'.

64. After clicking **Save**, under **Cont Reviews** click on the link to the **Continuing Review Checklist**.

The screenshot shows the same navigation bar as in step 62. Below the tabs is a table with columns: Year, Due Date, and Date Received. The Year is set to 1 and the Due Date is 05/03/2024. At the bottom, there are two buttons: 'Continuation Form' and 'Submit'. Below these buttons, there is a red text label 'Missing: Answers' and a blue link 'Continuing Review Checklist' (circled in blue). Below the link, it says 'No Panel Assigned'.

65. Click on *Add/Edit Answers* to complete the checklist.



Answer 

Since the date of the last IRB approval, please answer Yes or No to the questions below. If you answer yes to a Amendment or report an Adverse Event or Deviation as appropriate using the tabs on the bottom of the study

Have there been any adverse events?

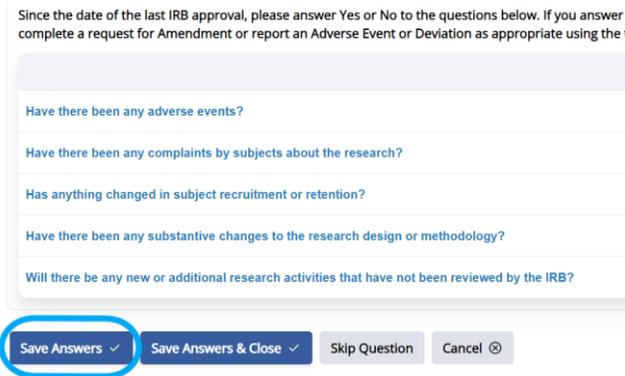
Have there been any complaints by subjects about the research?

Has anything changed in subject recruitment or retention?

Have there been any substantive changes to the research design or methodology?

Will there be any new or additional research activities that have not been reviewed by the IRB?

66. When you have answered all of the questions, click the *Save Answers* button at the bottom.



Since the date of the last IRB approval, please answer Yes or No to the questions below. If you answer yes to a complete a request for Amendment or report an Adverse Event or Deviation as appropriate using the t

Have there been any adverse events?

Have there been any complaints by subjects about the research?

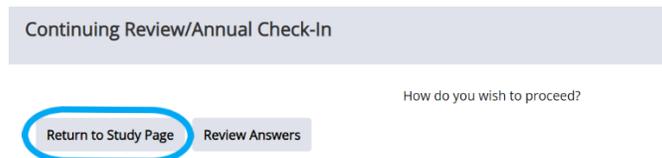
Has anything changed in subject recruitment or retention?

Have there been any substantive changes to the research design or methodology?

Will there be any new or additional research activities that have not been reviewed by the IRB?

Save Answers ✓ Save Answers & Close ✓ Skip Question Cancel ☒

67. Unless you need to review your answers, click on the *Return to Study Page* button.



Continuing Review/Annual Check-In

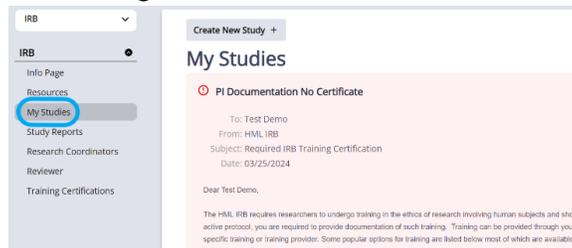
How do you wish to proceed?

Return to Study Page Review Answers

68. After you complete the questionnaire, click on the *Submit* button to submit your request for continuing review. The report will be submitted to HML IRB. We will begin our review within 24 hours and let you know if we need any additional information.

Submit an Annual Check-In

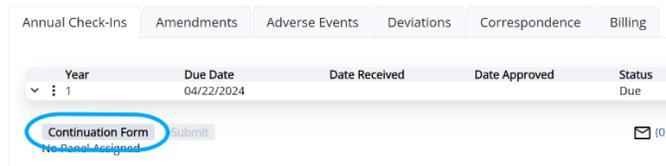
- 69. Your study approval is valid for one year from the date of approval. To renew the approval for another year, complete the annual check-in request prior to the study expiration. You will begin receiving email notifications to the email address we have on record in your user account six weeks before the expiration of the study. If you need to close your study, you can do so on the form by requesting to close the study from the drop down under *Continuation Status*. If there have been any amendments, deviations or adverse events that you need to make us aware of, please do so separately. You can click on the appropriate tab at the bottom of the *Study* page.
- 70. To complete the annual check-in process, If you are not already logged in, go to <https://www.axiommentor.com/login/axlogin.cfm?i=hmlirb> and login to the HML IRB Online Portal. See Resetting my Password below if you do not know your login credentials.
- 71. Click on *My Studies* on the left navigation menu on the IRB tab.



- 72. Then click on the title of the study for which you want to submit a request for annual check-in.

IRB # -	Title	PI	Status	Approved	Review Due	Tracking Status
12	Sitan in Morocco	Nancy Westwood	Exempt Determination Approved	04/06/2022	03/27/2024	Completed
2544	Demo Study	Test Demo	Expedited Requested			Pending Initial Submission
2545	Test Demo	Test Demo	Expedited Approved	03/25/2024	04/22/2024	Completed

- 73. Scroll down to the **Annual Check-Ins** tab and click on the **Continuation Form** button.





74. Complete the form and click the *Save* button. You can add a brief message about the status of the study, but it is not required. You will complete a short form after clicking *Save* that will allow for greater description.

Total # Subjects Enrolled in Study to Date
0

Total # Subjects Who Have Completed Study
0

Total # Subjects Still Active
0

* Continuation Status
Continue Study

An email will automatically be sent to the IRB Chair and Administrator upon successful upload of your Cont Review. If you would like to send any message along in that email, please use the text box below.

Message

75. After clicking *Save*, under *Annual Check-In* click on the link to the *Annual Check-In Checklist*.

Annual Check-Ins | Amendments | Adverse Events | Deviations

Year	Due Date	Date Received
1	04/22/2024	

Continuation Form

~~Missing: Answers~~

Annual Check-In Checklist

No Panel Assigned

76. Click on *Add/Edit Answers* to complete the checklist.

Since the date of the last IRB approval, please answer Yes or No to the questions below. If you answer yes to any of the Amendment or report an Adverse Event or Deviation as appropriate using the tabs on the bottom of the study page.

Have there been any adverse events?

Have there been any complaints by subjects about the research?

Has anything changed in subject recruitment or retention?

Have there been any substantive changes to the research design or methodology?

Will there be any new or additional research activities that have not been reviewed by the IRB?



77. When you have answered all the questions, click the *Save Answers* button at the bottom.

Since the date of the last IRB approval, please answer Yes or No to the questions below. If you a complete a request for Amendment or report an Adverse Event or Deviation as appropriate usi

Have there been any adverse events?

Have there been any complaints by subjects about the research?

Has anything changed in subject recruitment or retention?

Have there been any substantive changes to the research design or methodology?

Will there be any new or additional research activities that have not been reviewed by the IRB?

Save Answers ✓ Save Answers & Close ✓ Skip Question Cancel ⊗

78. Unless you need to review your answers, click on the *Return to Study Page* button.

Continuing Review/Annual Check-In

How do you wish to proceed?

Return to Study Page Review Answers

79. After you complete the questionnaire, click on the *Submit* button to submit your request for continuing review. The report will be submitted to HML IRB and you will receive an email confirmation. We will begin our review within 24 hours and let you know if we need any additional information.

Annual Check-Ins Amendments Adverse Events Deviations Corresp

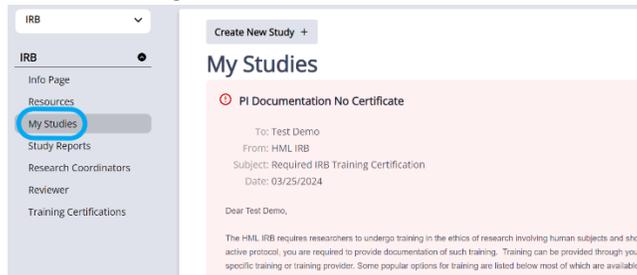
Year	Due Date	Date Received	Date Appr
1	04/22/2024		

Continuation Form Submit

Annual Check-In Check-in
No Panel Assigned

Close Out a Completed Study

- 80. If you have an active approved study in the IRB Portal that is completed and should be closed, please submit a close out request.
- 81. To complete the close out process, If you are not already logged in, go to <https://www.axiommentor.com/login/axlogin.cfm?i=hmlirb> and login to the HML IRB Online Portal. See Resetting my Password below if you do not know your login credentials.
- 82. Click on *My Studies* on the left navigation menu on the IRB tab.



- 83. Then click on the title of the study you want to close out.

IRB # -	Title	PI	Status	Approved	Review Due	Tracking Status
12	Sitan in Morocco	Nancy Westwood	Exempt Determination Approved	04/06/2022	03/27/2024	Completed
2544	Demo Study	Test Demo	Expedited Requested			Pending Initial Submission
2545	Test Demo	Test Demo	Expedited Approved	03/25/2024	04/22/2024	Completed

- 84. From the *Study* page for the study you want to close out, click on the **Close Study** button at the top of the page.



- 85. A new window will open. Please complete the enrollment numbers. If there was not a prior continuing review, leave that box blank. The date defaults to the current date, but you should set it to the date the study was actually closed. Then, click on the **Close Study** button.

Close Study

Year Number

1

Number of Subjects Approved

100

Total # Subjects Enrolled Since Last Cont Review

0

Total # Subjects Enrolled in Study to Date

0

Total # Subjects Who Have Completed Study

0

Total # Subjects Still Active

0

* Continuation Status

Close Study

* Date Study Closed

03/26/2024



86. After you click *Close Study*, the closure request will be created. To finalize and submit the closure request, scroll down to the bottom of the *Study* page and complete the *Study Closure Checklist* by clicking on the link to it.

Year	Due Date	Date Received
1	04/22/2024	

Continuation Form

~~Missing Answers~~

Study Closure Checklist

Close Study Requested

No Panel Assigned

87. Click the **Add/Edit Answers** button to complete the closure checklist.

Answer

Please answer the following questions.

Has all data collection been completed (have all subjects completed all study related activities, visits and procedures)?

Is any further contact with subjects needed for reasons related to research?

Is any further access to identifiable subject data required for research purposes (data analysis, manuscript preparations, etc.)?

Has all data been destroyed or de-identified for storage?

Has or will a de-identified data set be made available to other researchers?

Are there any other related studies or component studies still ongoing that have been reviewed by a separate HML IRB review?



88. After you answer the questions, click the **Save Answers** button.

Please answer the following questions.

Has all data collection been completed (have all subjects completed all study related activities, visits and procedures)?

Is any further contact with subjects needed for reasons related to research?

Is any further access to identifiable subject data required for research purposes (data analysis, manuscript preparations, etc)?

Has all data been destroyed or de-identified for storage?

Has or will a de-identified data set be made available to other researchers?

Are there any other related studies or component studies still ongoing that have been reviewed by a separate HML IRB review?

Save Answers ✓ Save Answers & Close ✓ Skip Question Cancel ⊗

89. Unless you need to review your answers, on the next screen click on the **Return to Study Page** button.

Study Closure

How do you wish to proceed?

Return to Study Page Review Answers

90. Scroll back down to the bottom of the *Study* page. The **Submit** button will have turned from light to dark gray. Click on the **Submit** button.

Annual Check-Ins Amendments Adverse Events Deviations

Year	Due Date	Date Received
1	04/22/2024	

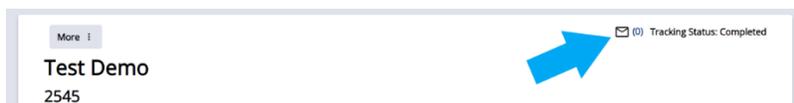
Continuation Form Study Closure Checkin
Close Study Requested
No Panel Assigned

Submit

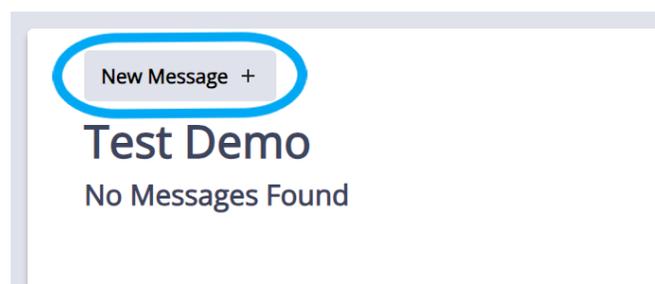
91. Your closure request will be submitted. A notification will be sent to HML IRB. You will receive a subsequent notice of closure email when the study is officially closed.

Submit a Message

92. Please feel free to reach out to us with any questions or concerns about HML IRB and the IRB process. You can reach the IRB Chair, Dr. Michael Anderson at dma@hmlirb.com or 202.549.1982. You can reach the IRB Administrator, Penelope Lantz at plantz@hmlus.com or 202.246.8504. You can also submit general inquiries to us at info@hmlirb.com.
93. For questions about studies that have been submitted for review or have been reviewed and approved, we encourage you to contact us through the IRB Portal:
<https://www.axiommentor.com/login/axlogin.cfm?i=hmlirb>.
94. You can send a *Message* on any protocol in the portal once the initial study record has been created. This includes studies that have been created but are still pending initial submission, and studies that have been requested to be closed. Go to the *Study* page for the study you want to inquire about. From that page, click on the Messages link in the top right.



95. A new window will open, click on the ***New Message*** button.



96. Compose your message in the window that opens and click the *Save* button. The default settings for Messages send a copy to the individual sending the message and also to the IRB Administrator. By checking boxes on the right, you can add members of your study to receive the message or include



the IRB Chair. There is also the option to include other members of the IRB. We do not recommend including members as all messages will be responded to by the IRB Chair or IRB Administrator.

A screenshot of a web form titled "New Study Message". The form includes a "Testing System" field, a large "Message" text area, and a list of checkboxes for "Send Notification(s) to PI(s)" and "Send Notification to IRB Member(s)". The "Save" button is circled in blue. The notification options are: John Doe (PI) [checked], camille jones (Research Coordinators (nc primary)) [unchecked], Michael Anderson (Chair) [unchecked], Penelope Lantz (Administrator) [checked], and Nancy Westwood [unchecked].

97. The IRB will respond to messages within 24 hours. A copy will be sent to your email on record in the IRB Portal and the response will be documented in the IRB Portal.

Submit Correspondence

98. You can also reach HML IRB through the ***Correspondence*** tab. This tab is available at the bottom on the *Studies* page on all approved studies.
99. Please use the *Correspondence* tab to submit materials to the IRB that do not fall into any of the standard reporting categories. Do not submit Continuing Reviews or Annual Check-Ins, Adverse Events, Amendments, or Deviations using this form. To submit correspondence, click on the ***New Item*** button. Things that could be submitted as correspondence would include reliance agreements, translated versions of approved documents, or marketing materials that have been reformatted for different mediums but do not contain any changes in the information supplied.

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Correspondence **Billing**

Please use the **Correspondence** standard reporting categories. Do Events, Amendments, or Deviation **Item** button. The submission form and a brief description of the file. |

Submit, you will receive a copy of correspondence will be submitted we need any additional information AMENDED MATERIALS. Submit to the document **How to Manage** within **Resources** in the left navig

New Item

100. The submission form defaults to the current date and allows for a single file upload and a brief description of the file. If you check the box next to *Send Receipt Confirmation On Submit*, you will receive a copy of the submission. When you click the Save button, your correspondence will be submitted to HML IRB. We will look over your document and let you know if we need any additional information. PLEASE DO NOT USE THIS FEATURE FOR ANY NEW OR AMENDED MATERIALS. Submit those as an amendment.

Date: 03/28/2022 Clear Acceptable Formats

Upload File: Choose File | No file chosen
Allowed Extensions: doc, docx, pdf, xls,xlsx, ppt, pptx, jpg, png

Description:

Send Receipt Confirmation On Submit

Include File on Agenda

Save Cancel

101. If you do reach out via email directly, please make sure you refer to the study by its Study ID (also called IRB# and IRB ID) that can be found by logging into the IRB Portal. On the *My Studies* page, all of your studies will be listed with their corresponding IDs to the left of the study title. For imported studies, it will be the same study ID that was assigned at the time of your initial review and approval. For new studies submitted into the IRB Portal, IDs will be numeric and assigned starting at the number 2000.



Resources My Studies

My Studies IRB ID [] Status [All]
 Show all PIs [v] Submitted [All]

IRB #	Title	PI
8	Sleep Habits on Trains	John
12	Sitan in Morocco	John
16	Insurance Overpayment and Claims Fraud	John
17	Jan 25	John
18	The Day before Ground Hog Day	John
19	Testing System	John
101TEST22	testing again or shall I say still	John
510	hats	John

Staff Roles and Designations in the IRB Portal

102. There are five types of study staff: Principal Investigator (PI), Co-PIs, Research Coordinators, Research Assistants, and Other Staff. There must be one designated PI to create a submission for ethical review. All of the other positions are optional.
103. *Principal Investigator:* The PI is responsible for the study, even if the application is submitted by a member of the study team on their behalf. The PI should be the same person who is listed as the PI on any grant or contract award. The PI may designate authority to submit or modify study protocols in the IRB submission and tracking system to Research Coordinators and/or Co-PIs. If you are submitting a request for ethical review on behalf of the PI, you must be designated as their Research Coordinator. Please see *Designating Research Coordinators in the IRB Portal* below.
104. *Co-Principal Investigator:* Co-PIs may be added to any protocol. By default, the role of the Co-PI is *read only* on a study, but at the time of adding the Co-PI, there is the option to check a box titled Allow Edit. This will give the Co-PI full rights and access to the study. If checked, the Co-PI will be able to edit, upload and revise the study and its materials. The Co-PI will also receive copies of all email notifications sent to the PI.

Co-PI's [] Add (Type first letters of last name and

John Doe Allow Edit

Other Staff []

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105. *Research Coordinator:* Research Coordinators are assigned to PIs. They are often tasked with project oversight and are the main point of contact between the IRB and the study. Research Coordinators have full access to the study. If you are creating a study for submission and find that the Research Coordinator field is not visible directly below PI, it means the system does not have any Research Coordinators assigned to that PI. See below for instructions on how to assign a Research Coordinator or refer to *Designating Research Coordinators in the HML IRB Portal*.

A screenshot of a web form. At the top, there is a field labeled "PI" with a dropdown arrow and the name "Penelope Lantz" next to it. Below this are three input fields: "Co-PI's" with an "Add" button to its right, "Other Staff" (an empty text area), and "Assistants" with an "Add" button to its right. At the bottom is a "Study Title" input field.

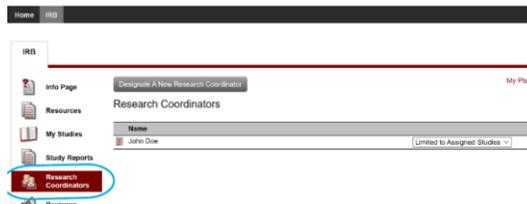
106. *Research Assistant:* A Research Assistant is a member of the study team who is integral to the project but does not require access to edit the study submission or protocols in the HML IRB Portal. These are system users who can access studies in a read only format.
107. *Other Staff:* The Other Staff field can be used to reflect study staff who will participate in the project but do not have or need user accounts in the system. This is useful for study staff who do not need to access the protocol through the HML IRB Portal or outside study staff or partners working for other organizations.

Designating Research Coordinators in the IRB Portal

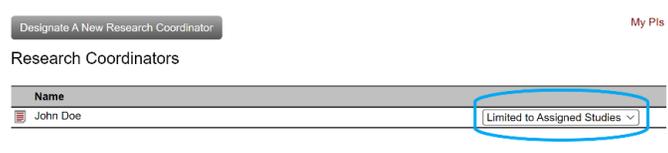
108. Each PI must designate his/her own Research Coordinators. If you have a user account, you can designate other users as your Research Coordinators or see who has designated you as their Research Coordinator. If you need to be designated as a Research Coordinator contact the PI and provide these instructions to designate you as a Research Coordinator.



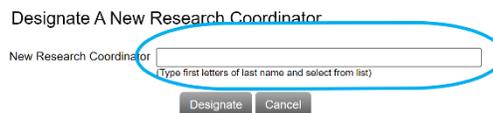
109. Click on the **Research Coordinators** item on the left navigation menu on the IRB tab. This will show you a list of all users associated with you as your Research Coordinator.



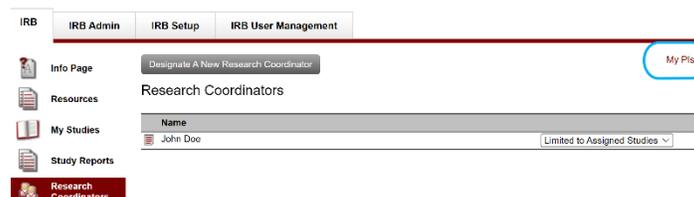
110. For Research Coordinators already associated with you, you may give them editing rights to any of your studies or limit their access to studies where they have been assigned. This is done using the drop down to the right of the person's name.



111. To add a new Research Coordinator, click on *Designate A New Research Coordinator*. Begin typing the person's last name. If the individual is a user in the system, the name will appear in the drop down. Click on the name and choose Designate. If the individual does not appear, they are not yet a user in the system and you will need to have the individual create an account. Please refer them to *Creating a New User Account* below.

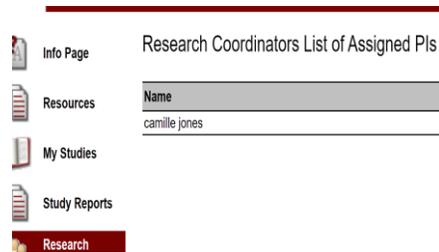


112. To see who has designated you as a Research Coordinator, from the Research Coordinator screen, click on **My PIs**.



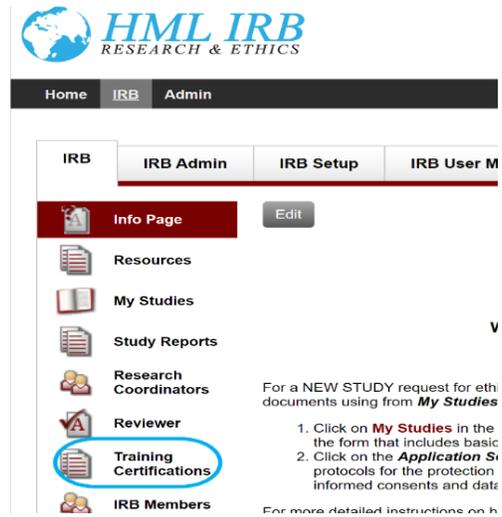


113. You will see a list of all users who have designated you as their Research Coordinator. If you need to be designated as a Research Coordinator for someone, ask them to assign you as their Research Coordinator. If you are listed incorrectly as a Research Coordinator, please contact us at info@hmlirb.com and request to be removed as a Research Coordinator for the individual.

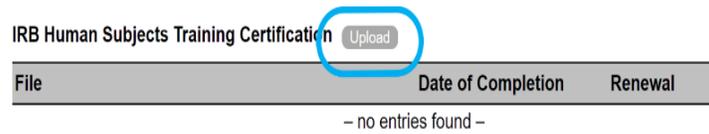


Uploading Training Certification

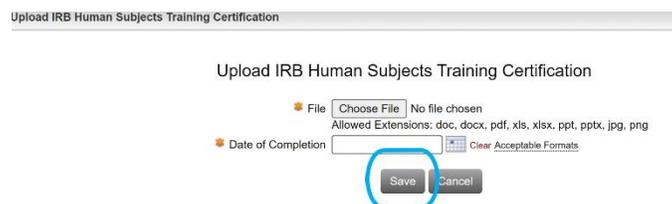
114. If you have not uploaded your training certification prior to submitting a new study, you should do it now. We previously allowed investigators and study staff to submit their certificates for ethics training or provide information about training received in the IRB application. In the new system all system users will be required to upload proof of ethical training appropriate to their position on the team and their work with human subjects. We did not import any training certifications.
115. Training can be provided through your employer or institution or a course of self-study. We do not require or endorse a specific training or training provider. If you have not already completed training through your employer or independently, there are a list of options in the online portal.
116. If you do not have a certificate of completion, please provide documentation of your training in another way. You can upload a copy of your CV or other documents that describe the training, the topics covered, the duration and date received. To upload your proof of training, click on ***Training Certifications*** in the left navigation panel.



117. On the **Training Certifications** page, scroll to the bottom and click the **Upload** button.



118. A new window will open where you can upload your certification and enter the date it was completed. Click the **Save** when you are to submit. It will upload your information.



119. We will review your certifications. The system default for a certification is three years. We are aware that some of our clients receive training annually and some training certifications are active for five or more years. If we need to make any adjustments to the certification timeframe, we will.

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Creating a New User Account

120. If you need to create a new user account for the HML IRB Portal, please go to: <https://www.axiommentor.com/hmlirb/newAccount> and complete the online request form.
121. All fields are required. For Form Code, please enter **HMLirb29**. The letters are case sensitive.

A screenshot of the "Request Mentor User Account" form. The form is titled "Request Mentor User Account" and includes a "Login" button at the top. The form fields are: Form Code (circled in blue), First Name, Last Name, Email Address, Phone Number, Degrees (MA, MPH, PhD, etc.), Organization Name, Organization Address, and a CAPTCHA field labeled "Please Enter Text from the image". The CAPTCHA image shows the letters "U K 7 M B 6 T V" on a green background. A "Submit" button is located at the bottom of the form.

122. After you complete all fields, please click **Submit**. After you click submit, you will receive an email at the email address you provided. It will contain a link allowing you to set a password. The link is valid for 24 hours.
123. After you click on the link and establish your password, HML IRB will receive notification of a new user created. HML IRB will review your request and activate your user account. You will receive an email confirmation with login instructions when your account has been approved. If your organization is not an existing HML IRB client, we may reach out to you for additional information.

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Accessing My Account or Resetting My Password

120. If you have a user account in the HML IRB Portal but are unsure how to access it, please go to <https://www.axiommentor.com/login/forgotPassword.cfm?i=hmlirb>.
121. The Institution ID should populate automatically. If it does not enter "hmlirb."

HML IRB: Penelope Lar

Home IRB

Enter your username below to request a new password.

Institution ID

User

Email

Submit Cancel

122. **Enter your email address as both your Username and your Email** and click Submit. You will be sent a link to your email address that you can use to reset your password and access the system.

HML IRB
RESEARCH & ETHICS

IRB

Enter your username below to request a new password.

Institution ID

User

Email

Submit Cancel

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