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.

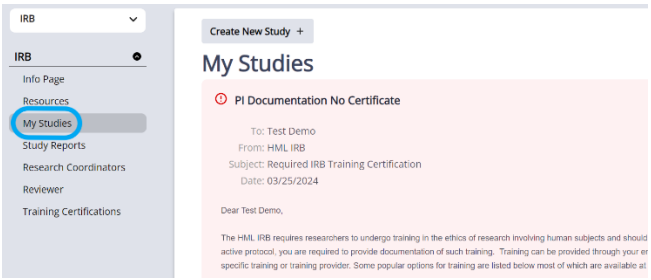
Submit an Amendment

Amendment Process for Studies Reviewed and Approved through the Online Portal

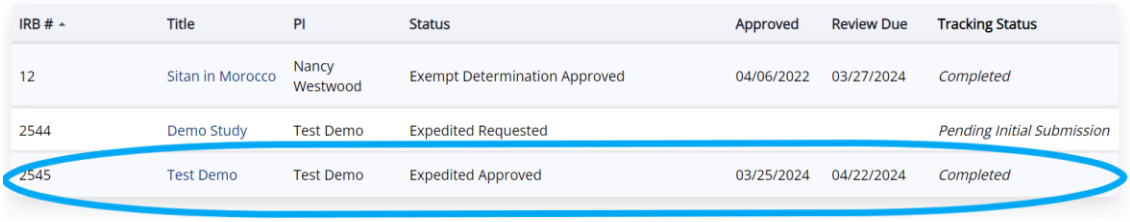
1. Once your study has been approved, any proposed amendment, change or alteration to the protocol approved by HML IRB must be reviewed and approved by the IRB prior to implementation, except where an immediate change is necessary to eliminate hazard to the participant. To submit an amendment to your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

2. 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.

3. Click on ***My Studies*** on the left navigation menu on the IRB tab.

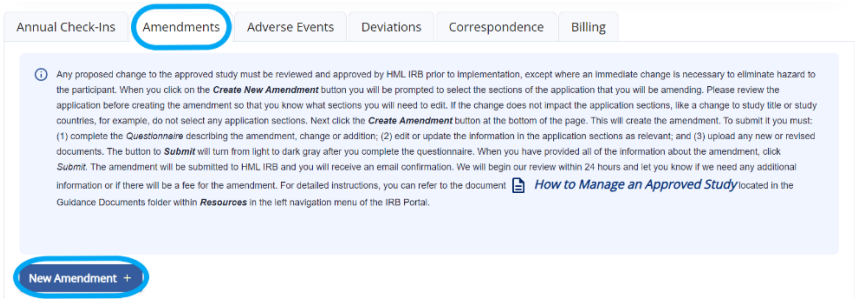


4. Then, click on the title of the study you want to amend.



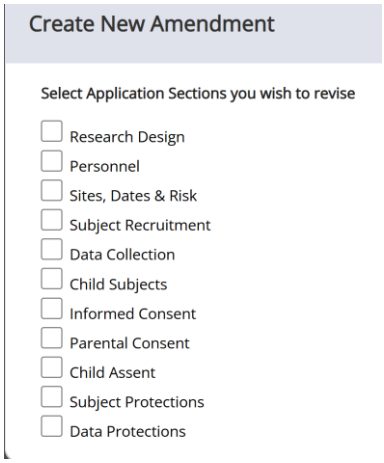
IRB #	Title	PI	Status	Approved	Review Due	Tracking Status
12	Sitan in Morocco	Nancy Westwood	Exempt Determination Approved	04/06/2022	03/27/2024	*Completed*
2544	Demo Study	Test Demo	Expedited Requested			*Pending Initial Submission*
2545	Test Demo	Test Demo	Expedited Approved	03/25/2024	04/22/2024	*Completed*

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

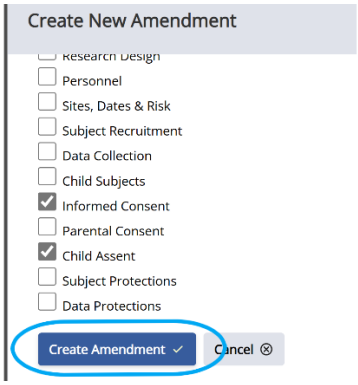


6. Scroll to the bottom of the screen, check the boxes next to the sections that you want to make amendments to and click ***Create Amendment***. If you are not sure what sections will require changes,

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.

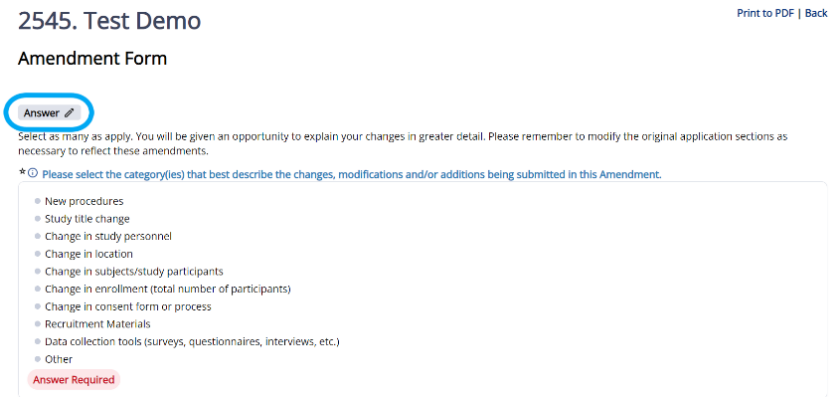


7. When you click on the *Create Amendment* button, it will create the amendment and direct you back to the *Study* page.

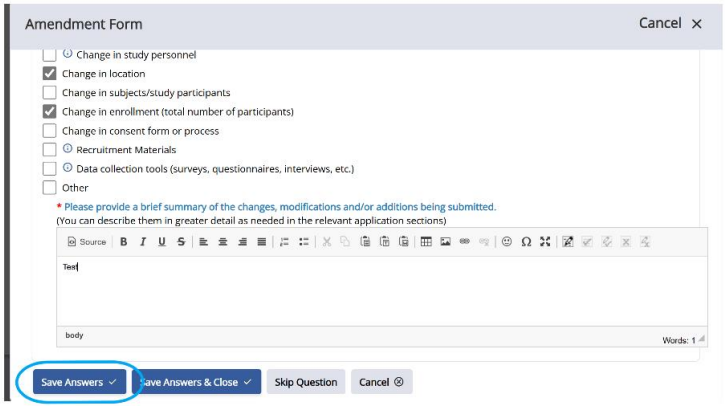


8. If you are adding data collection types or vulnerable subjects types (like prisoners, children or pregnant women), please reach out to the IRB Administrator at admin@hmlirb.com prior to submitting the amendment as we will need to modify the fields selected on the *Study* page to reflect the changes.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

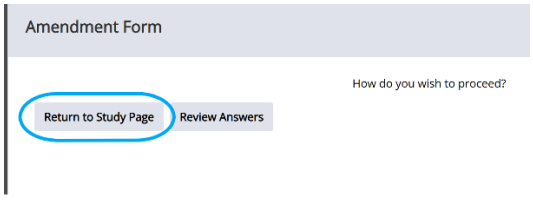
9. Next complete the Questionnaire describing the amendment, change or addition. Click on the *Answer* button to open it.



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



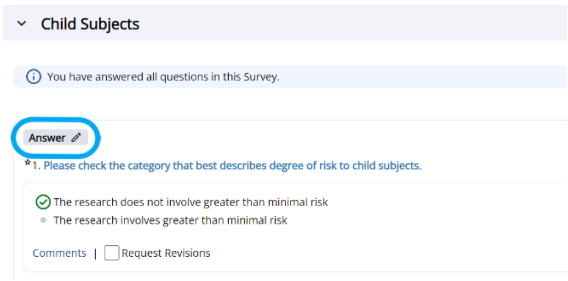
11. Unless you need to review your answers, on the next screen click on the *Return to Study Page* button.



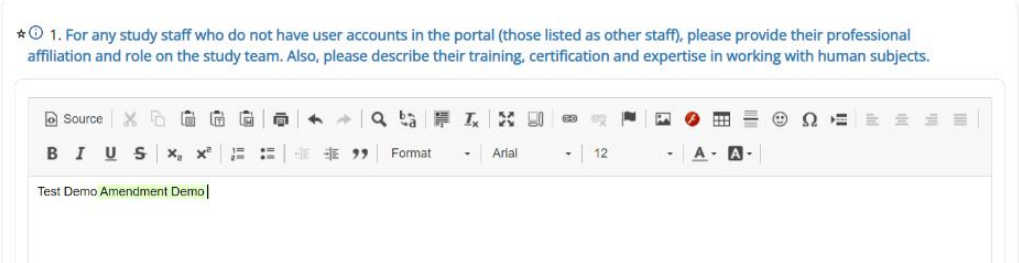
12. You need to complete all of the components of the amendment in order to submit it for review. First, if you checked any of the sections as requiring revision, click on the ***Edit Application Sections*** link to access those sections.

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

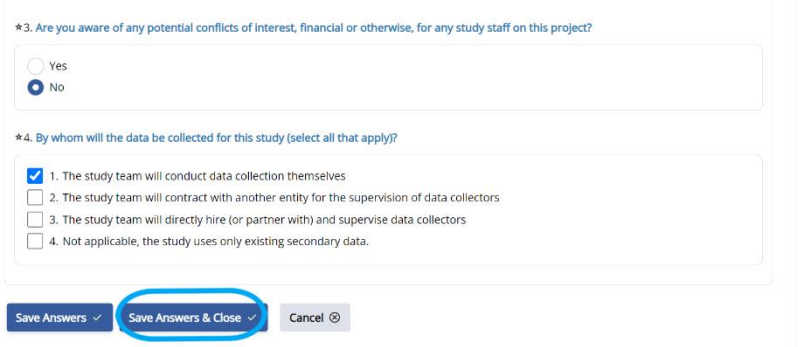
14. Click on *Answers* to revise the application text. Do not submit your changes as *Reader Comments.*



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.

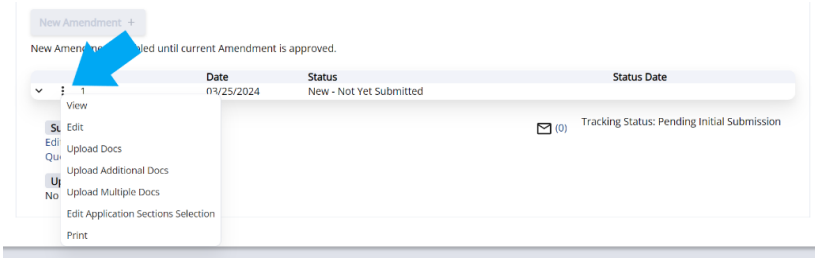


16. When you are done editing, click on *Save Answers and Close.*

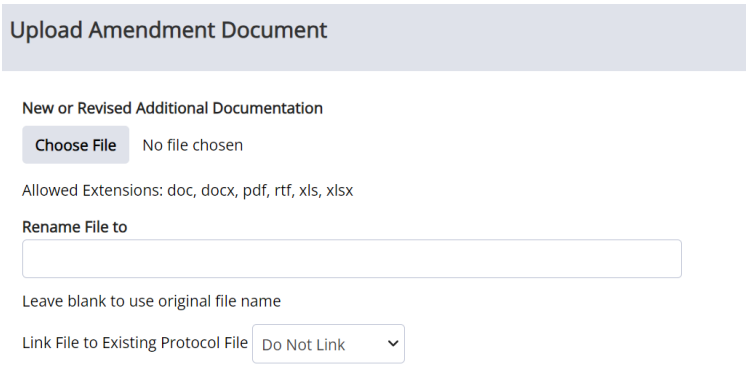


17. When you are done revising your application, click on ***View Study Page.***

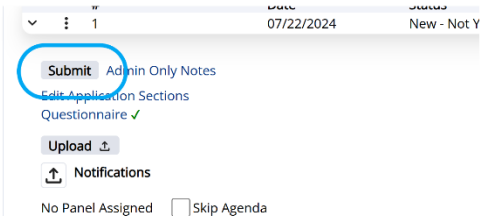
18. Next, you can upload any new or revised documents relevant to the amendment. Click on the three dots to upload additional documents. To upload more than one document, select ***Upload Multiple Docs.*** You can select the files to upload and then assign them to document types.



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.



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.

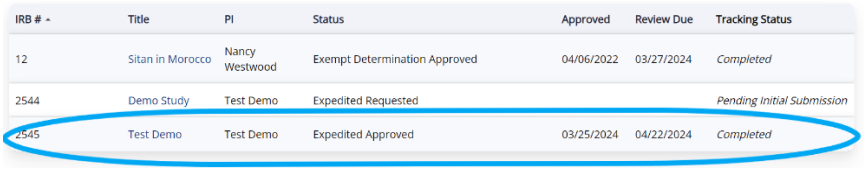
23. Using the Word document you submitted to request ethical review[1] (our filename: *HML IRB Request for Approval of Research)*, make any changes to the protocol on that document showing markup. You will need to upload it to the IRB Portal when you request the amendment.

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.



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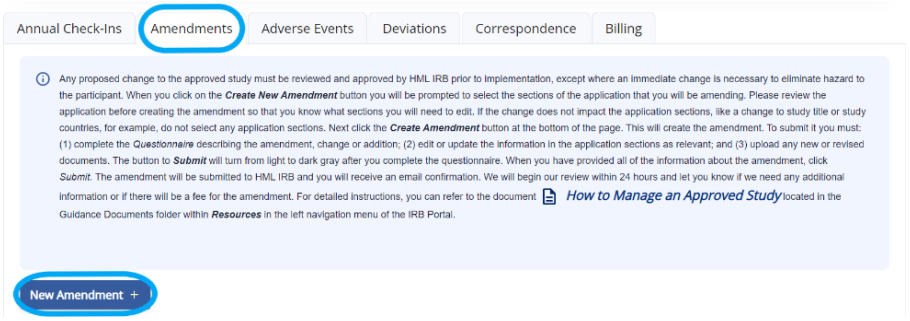
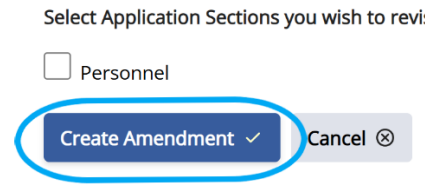
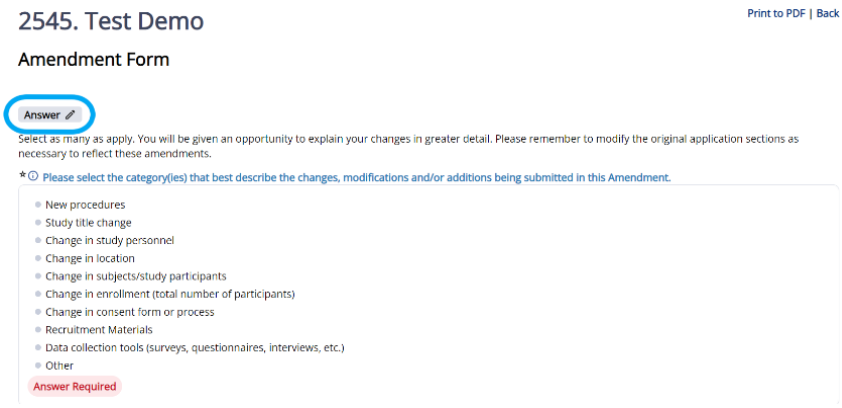
27. Scroll to the bottom of the study page and click on the ***Amendment*** Tab and the ***Create New Amendment*** Button.



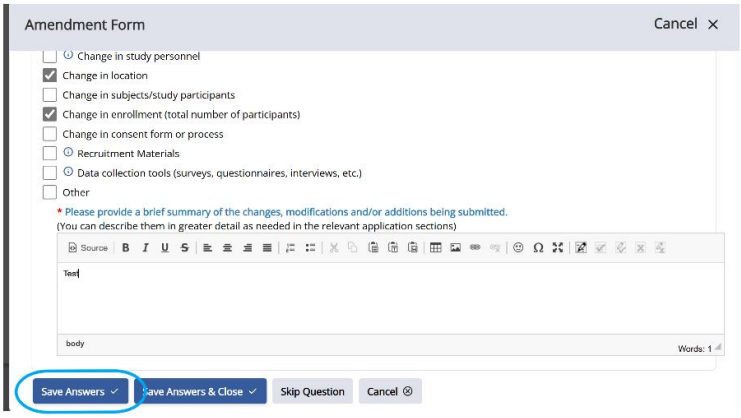
28. If you have any additions to personnel (with user accounts in the system) as part of your modification, check the box by *Personnel*; if not, leave unchecked. If your personnel changes are limited to "other staff", leave this box blank. You can address changes in other staff on the amendment questionnaire.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



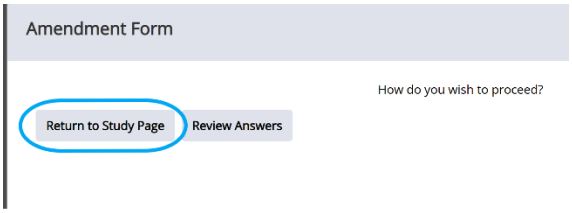
29. Next complete the Questionnaire describing the amendment, change or addition. Click on the *Answer* button to open it.



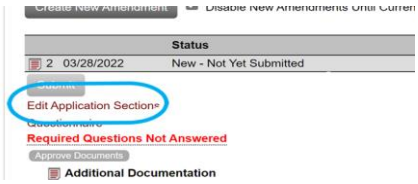
30. Check the boxes which best describe your amendment and provide a brief description in the box provided. And click on *Save Answers*.



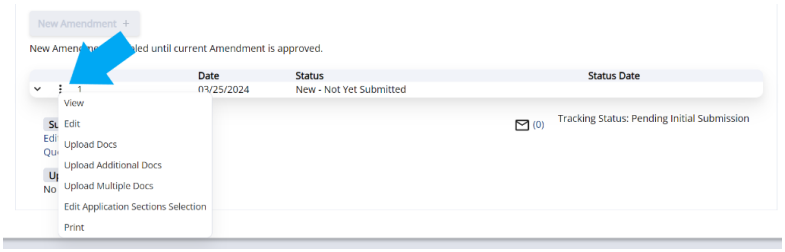
31. Unless you need to review your answers, on the next screen click on the *Return to Study Page* button.



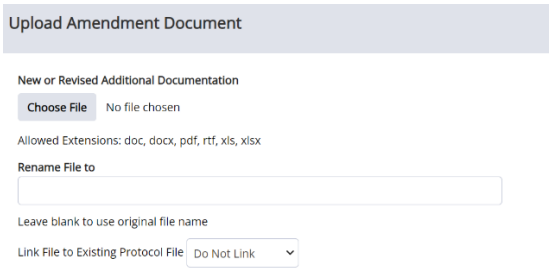
32. Next if you check *Personnel*, click on the ***Edit Application Sections*** link to add staff to the study.



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.

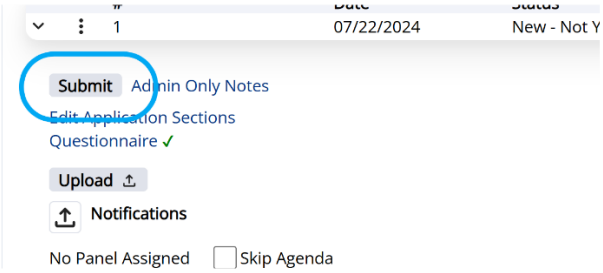


34. A new window will open that will allow you to upload a file. It will also allow you to link it to an existing approved file. For example, **if you have revised an approved informed consent document, choose the existing informed consent file to link to as the new one will override it when approved.** 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.



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

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.

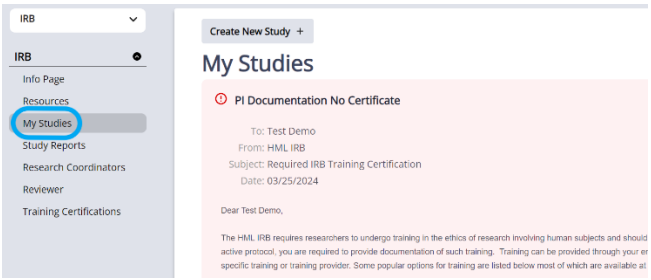


Submit a Deviation

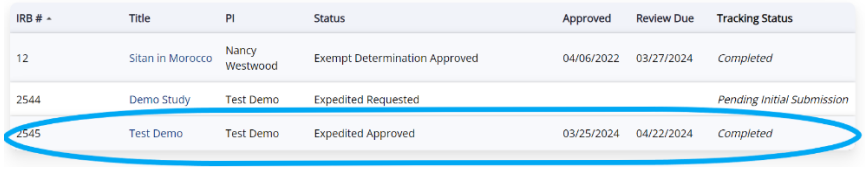
37. Any alterations or deviations from the approved study protocols should be submitted to the IRB as soon as possible after the deviation occurred. Please complete the form under the ***Deviations*** tab in the IRB Portal to notify us. If this deviation from the protocol will cause you to make changes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

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.



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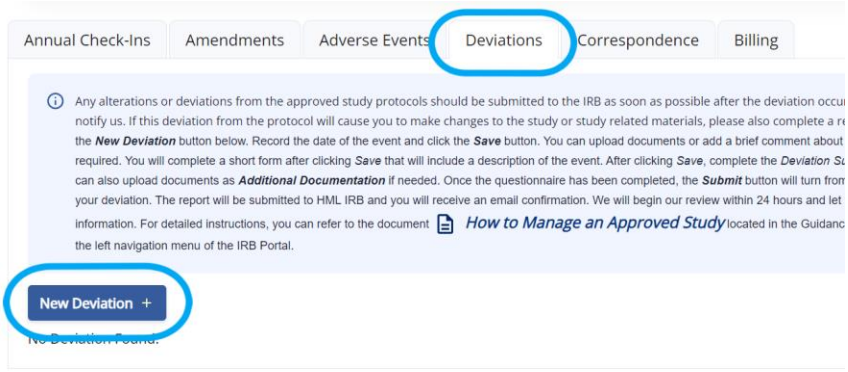
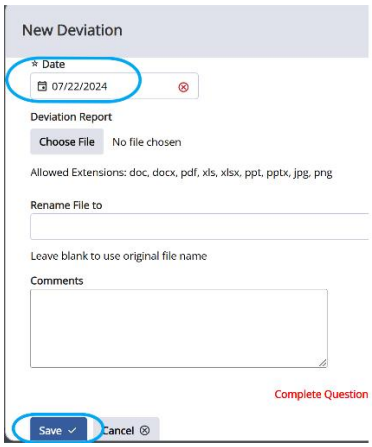
2545	Test Demo	Test Demo	Expedited Approved	03/25/2024	04/22/2024	*Completed*

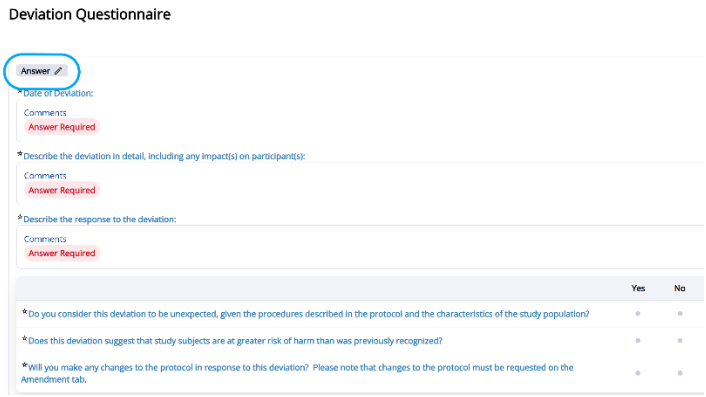
41. Scroll to the bottom of the study page and click on the ***Deviation*** Tab and the ***New Deviation*** button.



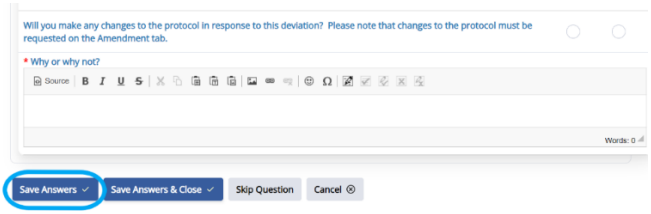
42. Record the date of the event and click the *Save* button. You can upload documents or add a brief comment about the nature of the event but it is not required. You will complete a short form after clicking *Save* that will include a description of the event.



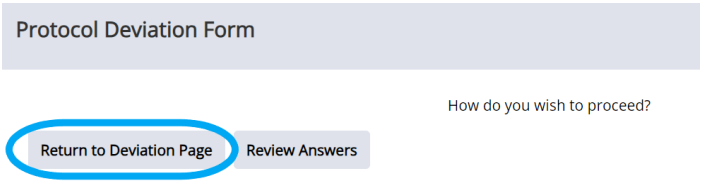
43. After clicking *Save*, complete the *Deviation Survey*. Click the *Answer* button to answer the questions about the deviation.



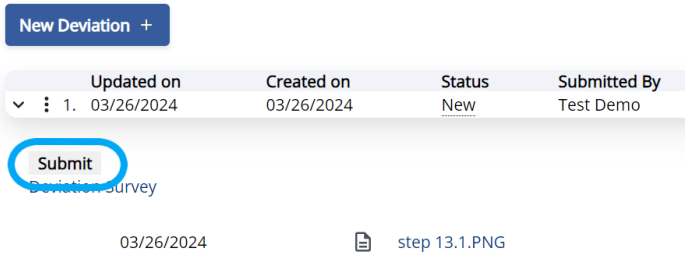
44. Click the Save Answers button when you are done filling out the form.



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



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.



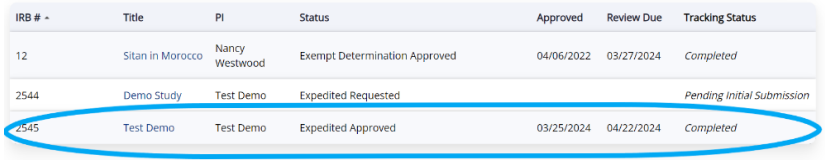
Report an Adverse Event

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.



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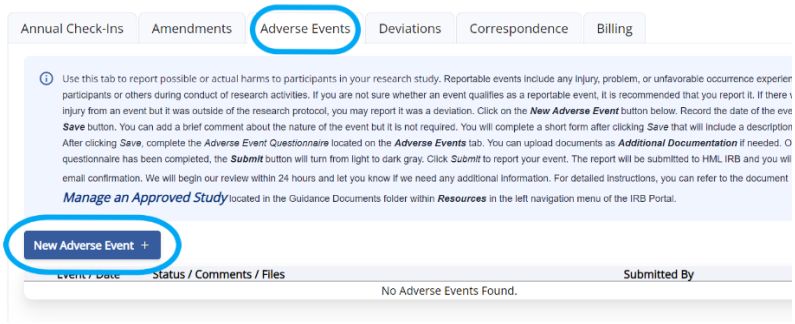
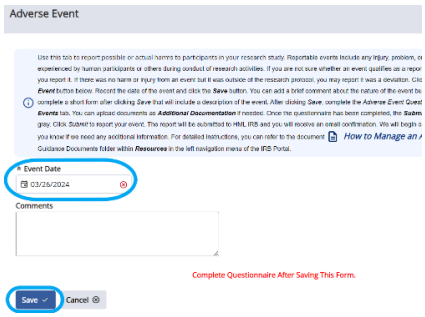
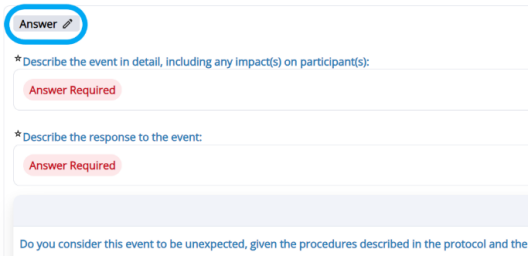
51. Go to the ***Adverse Events*** tab and click on the ***New Adverse Event*** button.



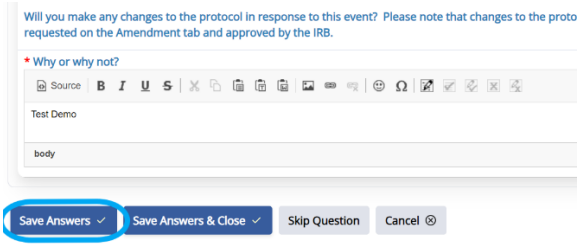
52. Record the date of the event and click the *Save* button. You can add a brief comment about the nature of the event but it is not required. You will complete a short form after clicking *Save* that will include a description of the event.



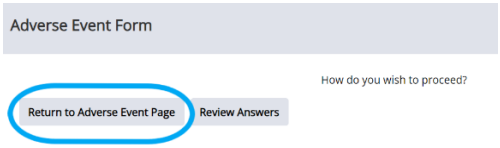
53. After clicking Save, complete the *Adverse Event Questionnaire*. Click the answer button to answer the questions.



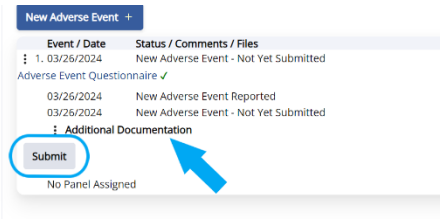
54. When you have answered all the questions, click the *Save Answers* button at the bottom.



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

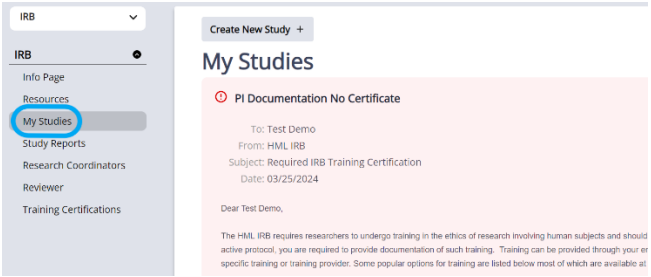
57. All studies reviewed by the Full IRB require an annual continuing review. Studies approved using an expedited review mechanism require an annual check-in. More details on both processes can be found below. All studies approved as exempt are valid for the duration of the study, provided you report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

Submit a Continuing Review

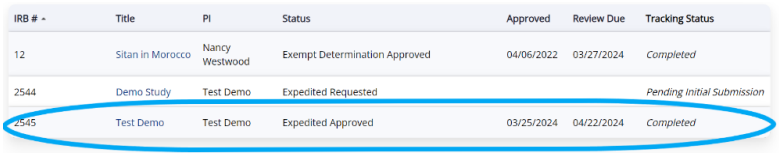
58. Your study approval is valid for one year from the date of approval. To renew the approval for another year, complete the continuing review request prior to the study expiration. You will begin receiving email notifications to the email address we have on record in your user account six weeks before 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.

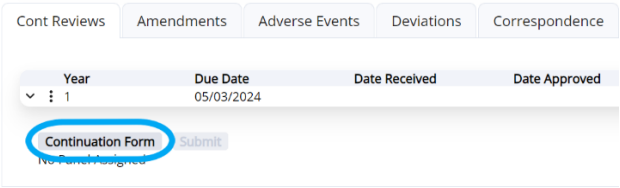
60. Click on *My Studies* on the left navigation menu on the IRB tab.



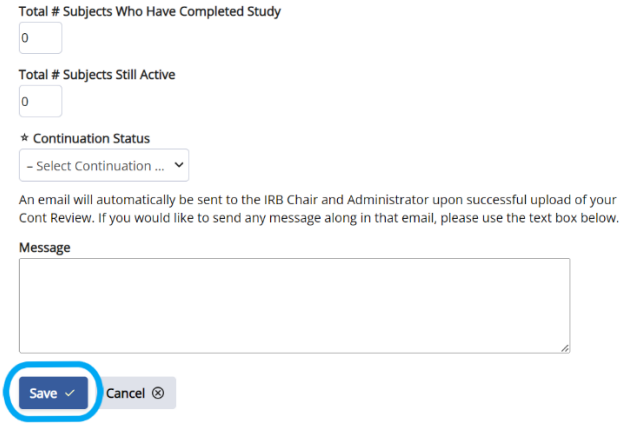
61. Then click on the title of the study for which you want to submit a request for continuing review.



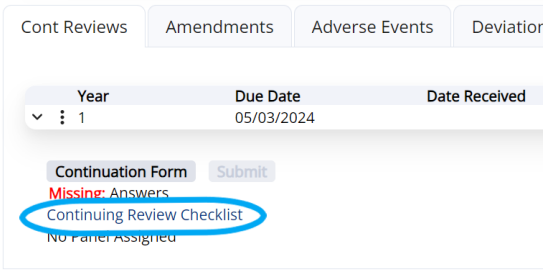
62. Scroll down to the ***Cont Reviews*** tab and click on the ***Continuation Form*** button.



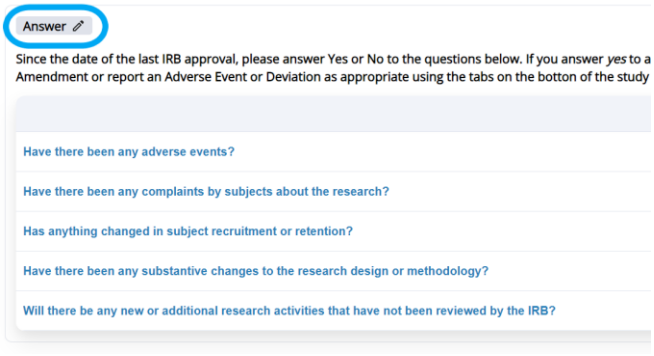
63. Complete the form and click the *Save* button. You can add a brief message about the status of the study, but it is not required. You will complete a short form after clicking *Save* that will allow for greater description.



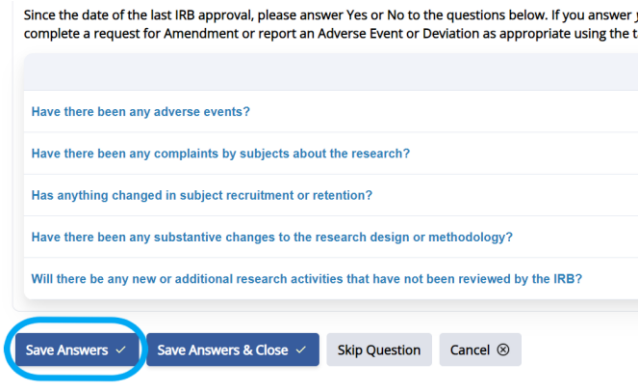
64. After clicking Save, under *Cont Reviews* click on the link to the *Continuing Review Checklist*.



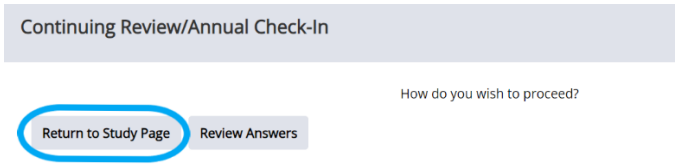
65. Click on *Add/Edit Answers* to complete the checklist.



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



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



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.

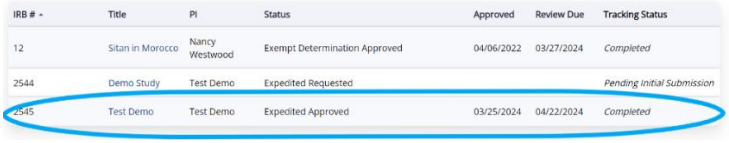
Submit an Annual Check-In

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.

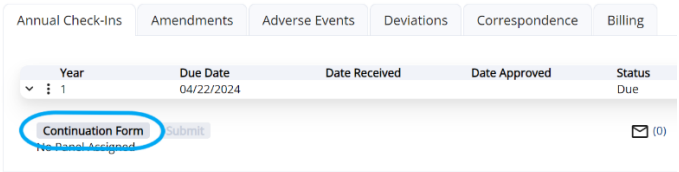
70. To complete the annual check-in process, If you are not already logged in, go to https://www.axiommentor.com/login/axlogin.cfm?i=hmlirb and login to the HML IRB Online Portal. See Resetting my Password below if you do not know your login credentials.

71. Click on *My Studies* on the left navigation menu on the IRB tab.

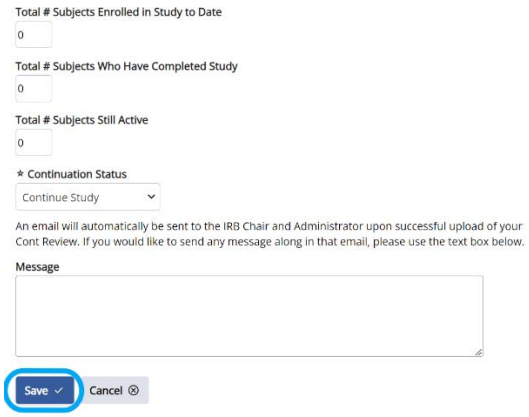
72. Then click on the title of the study for which you want to submit a request for annual check-in.



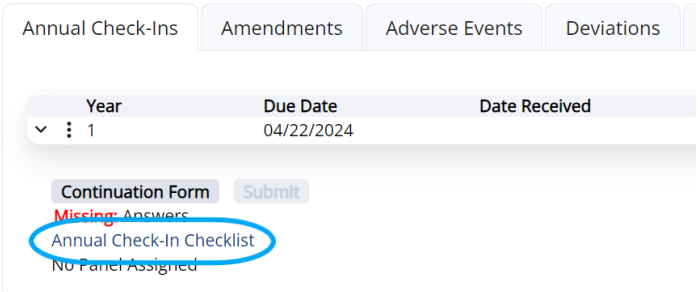
73. Scroll down to the ***Annual Check-Ins*** tab and click on the ***Continuation Form*** button.



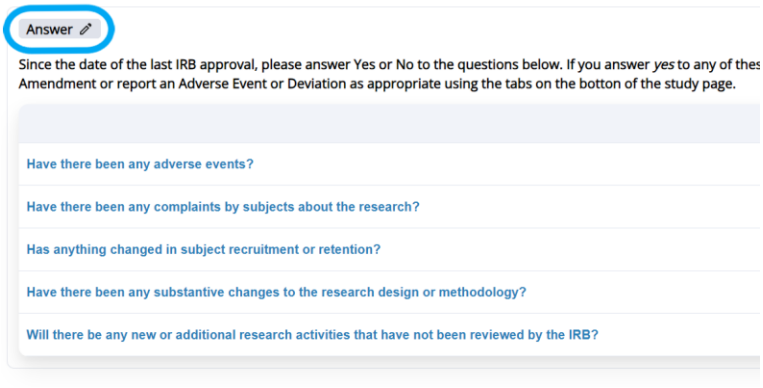
74. Complete the form and click the *Save* button. You can add a brief message about the status of the study, but it is not required. You will complete a short form after clicking *Save* that will allow for greater description.



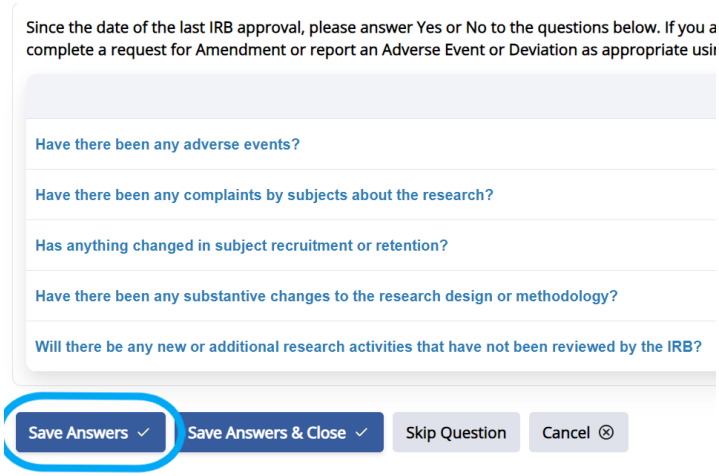
75. After clicking Save, under *Annual Check-In* click on the link to the *Annual Check-In Checklist*.



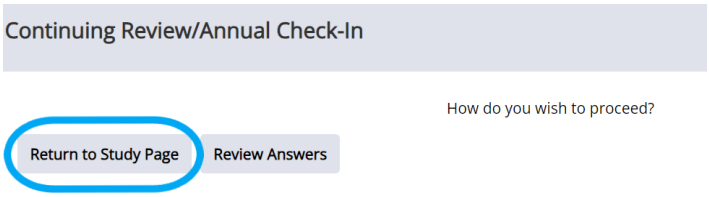
76. Click on *Add/Edit Answers* to complete the checklist.



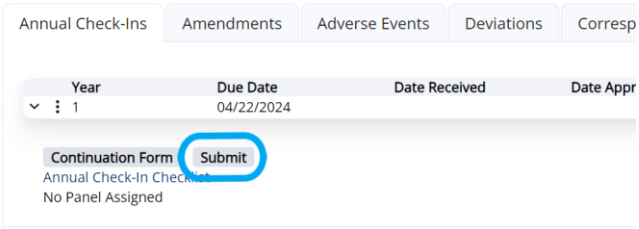
77. When you have answered all the questions, click the *Save Answers* button at the bottom.



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



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.

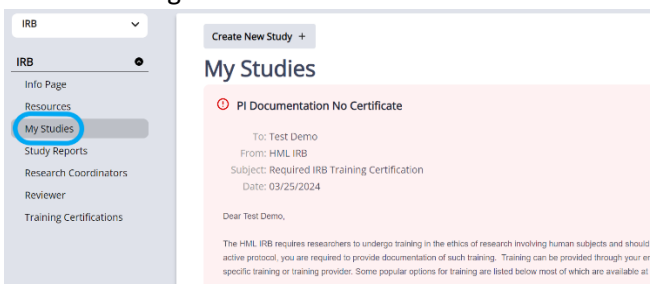


Close Out a Completed Study

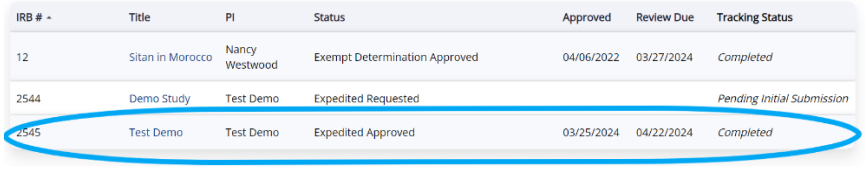
80. If you have an active approved study in the IRB Portal that is completed and should be closed, please submit a close out request.

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.

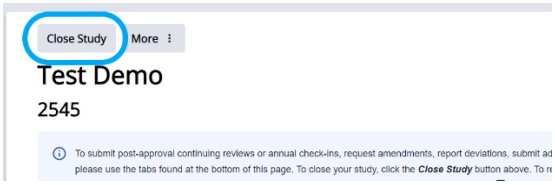


83. Then click on the title of the study you want to close out.

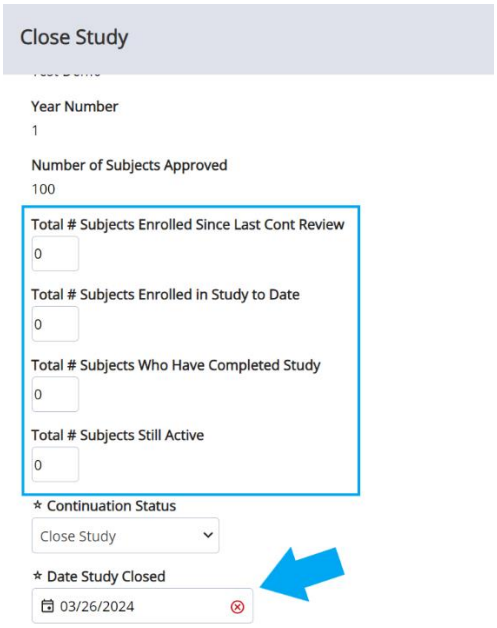


IRB #	Title	PI	Status	Approved	Review Due	Tracking Status
12	Sitan in Morocco	Nancy Westwood	Exempt Determination Approved	04/06/2022	03/27/2024	*Completed*
2544	Demo Study	Test Demo	Expedited Requested			*Pending Initial Submission*
2545	Test Demo	Test Demo	Expedited Approved	03/25/2024	04/22/2024	*Completed*

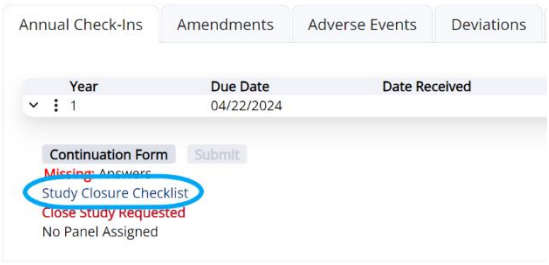
84. From the *Study* page for the study you want to close out, click on the ***Close Study*** button at the top of the page.



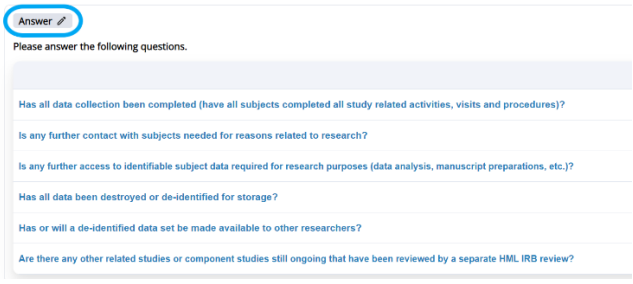
85. A new window will open. Please complete the enrollment numbers. If there was not a prior continuing review, leave that box blank. The date defaults to the current date, but you should set it to the date the study was actually closed. Then, click on the ***Close Study*** button.



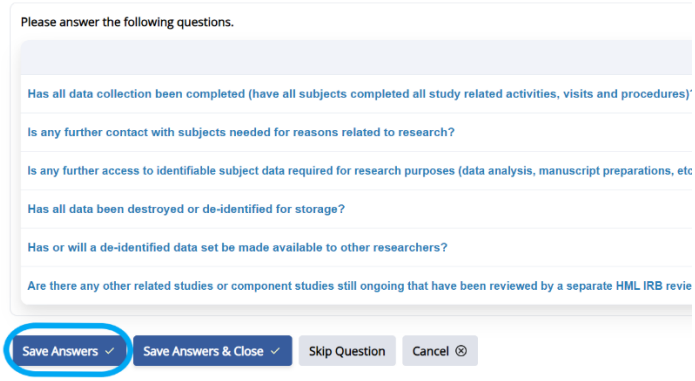
86. After you click *Close Study,* the closure request will be created. To finalize and submit the closure request, scroll down to the bottom of the *Study* page and complete the *Study Closure Checklist* by clicking on the link to it.



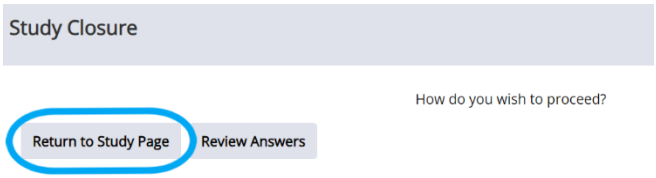
87. Click the ***Add/Edit Answers*** button to complete the closure checklist.



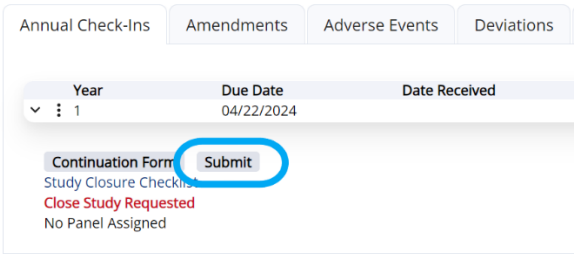
88. After you answer the questions, click the ***Save Answers*** button.



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



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.



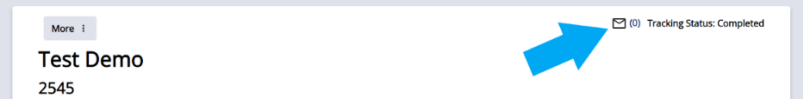
91. Your closure request will be submitted. A notification will be sent to HML IRB. You will receive a subsequent notice of closure email when the study is officially closed.

Submit a Message

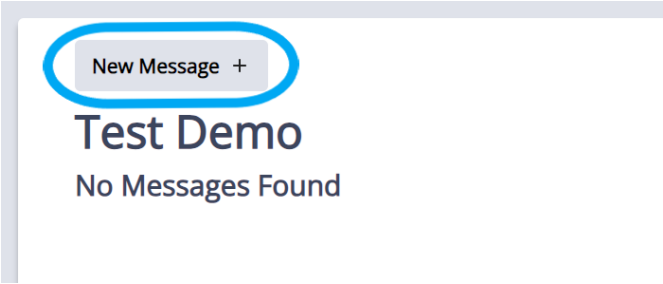
92. Please feel free to reach out to us with any questions or concerns about HML IRB and the IRB process. You can reach the IRB Chair, Dr. Michael Anderson at dma@hmlirb.com or 202.549.1982. You can reach the IRB Administrator, Penelope Lantz at plantz@hmlus.com or 202.246.8504. You can also submit general 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.

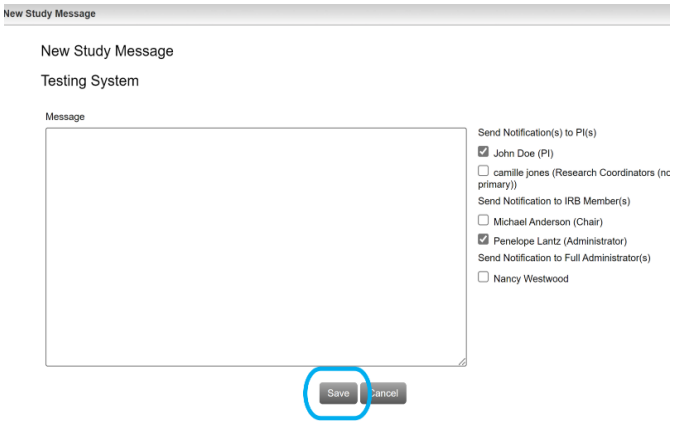


95. A new window will open, click on the ***New Message*** button.



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.

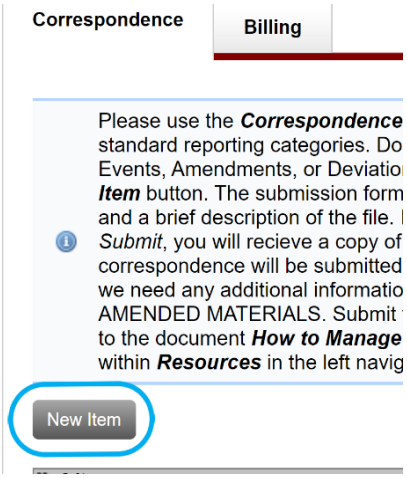


97. The IRB will respond to messages within 24 hours. A copy will be sent to your email on record in the IRB Portal and the response will be documented in the IRB Portal.

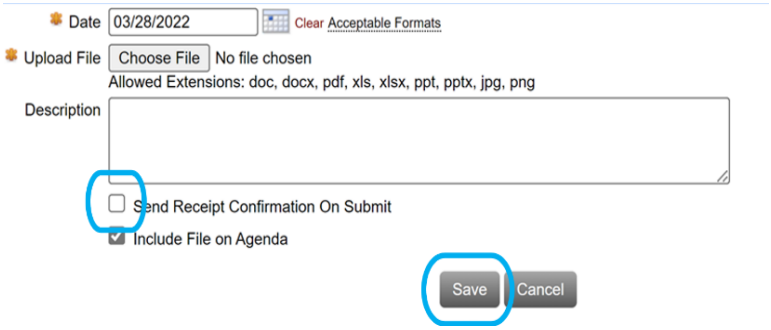
Submit Correspondence

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.

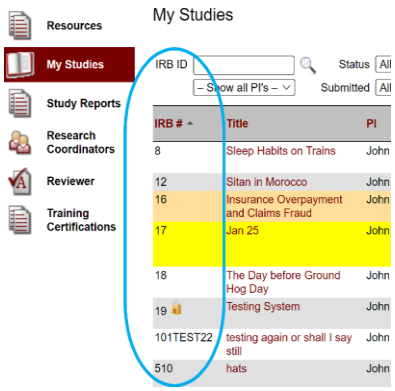
99. Please use the *Correspondence* tab to submit materials to the IRB that do not fall into any of the standard reporting categories. Do not submit Continuing Reviews or Annual Check-Ins, Adverse Events, Amendments, or Deviations using this form. To submit correspondence, click on the ***New Item*** 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.



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.



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.

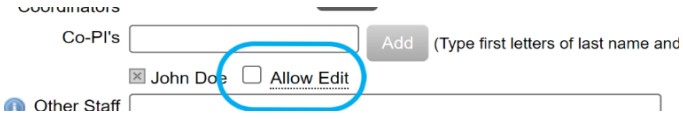


Staff Roles and Designations in the IRB Portal

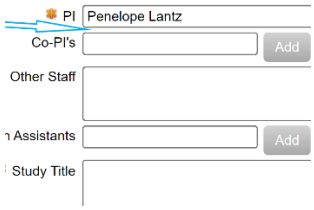
102. There are five types of study staff: Principal Investigator (PI), Co-PIs, Research Coordinators, Research Assistants, and Other Staff. There must be one designated PI to create a submission for ethical review. All of the other positions are optional.

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.



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*.



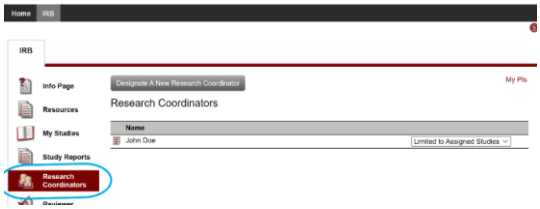
106. *Research Assistant*: A Research Assistant is a member of the study team who is integral to the project but does not require access to edit the study submission or protocols in the HML IRB Portal. These are system users who can access studies in a read only format.

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.

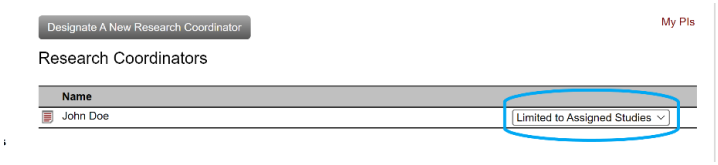
Designating Research Coordinators in the IRB Portal

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.

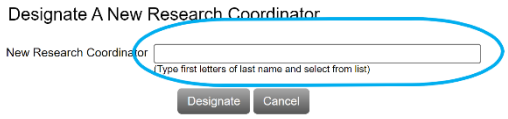
109. Click on the ***Research Coordinators*** item on the left navigation menu on the IRB tab. This will show you a list of all users associated with you as your Research Coordinator.



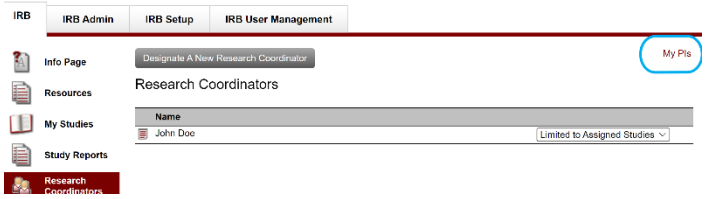
110. For Research Coordinators already associated with you, you may give them editing rights to any of your studies or limit their access to studies where they have been assigned. This is done using the drop down to the right of the person's name.



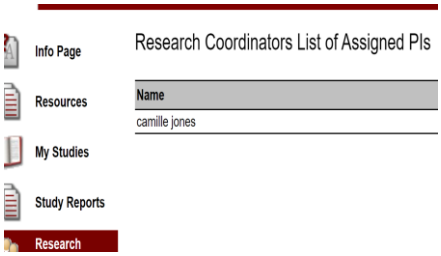
111. To add a new Research Coordinator, click on *Designate A New Research Coordinator*. Begin typing the person's last name. If the individual is a user in the system, the name will appear in the drop down. Click on the name and choose Designate. If the individual does not appear, they are not yet a 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.



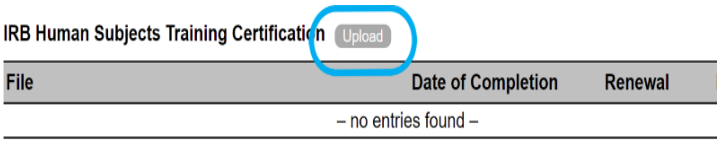
Uploading Training Certification

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.

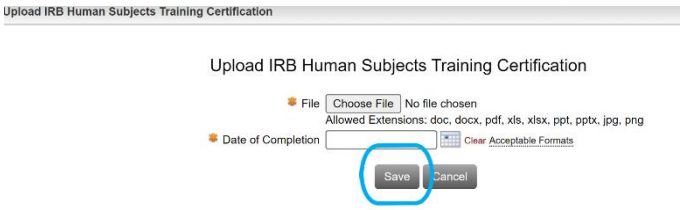
115. Training can be provided through your employer or institution or a course of self-study. We do not require or endorse a specific training or training provider. If you have not already completed training through your employer or independently, there are a list of options in the online portal.

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.

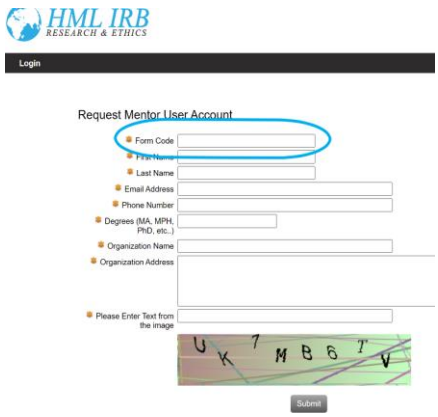


119. We will review your certifications. The system default for a certification is three years. We are aware that some of our clients receive training annually and some training certifications are active for five or more years. If we need to make any adjustments to the certification timeframe, we will.

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.



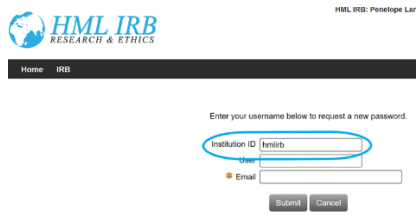
122. After you complete all fields, please click ***Submit***. After you click submit, you will receive an email at the email address you provided. It will contain a link allowing you to set a password. The link is valid for 24 hours.

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.

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."



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.