



Transition Information for HML IRB Online Portal

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HML IRB Ethical Review Online Submission & Tracking System

We are in the process of moving to an online IRB submission and tracking system (IRB Portal). Beginning April 1, 2022, all new NON-UNICEF requests for ethical review should be submitted using the new online system. Existing approved studies have been imported into the system. Future modifications, changes, annual reviews for these studies should be conducted using the online system as well. The online system is hosted by Axiom Mentor. More information about the company and their product can be found at the end of this document.

Processes and procedures for UNICEF and their contractors will NOT change at this time. UNICEF should continue to submit requests for ethical review via email to dma@hmlirb.com and plantz@hmlus.com. Please contact us with any questions or concerns.



The Transition of Approved Study Materials¹

The transition of existing studies to the platform includes three components:

1. **APPROVED STUDIES:** Information about all approved, active studies has been imported into the system. This includes basic information including study title, funding source, approval date and study staff. It may include some studies that are no longer active, but have not yet been closed out. We will discuss that in greater detail below in *Closing an Imported Study*.
2. **FILES FOR APPROVED STUDIES:** The initial import did not include the current files associated with the study. We will import those over time. If it is particularly important to you to have the files uploaded as soon as possible, please let us know as part of your review of your records in the system. Details on how to reach out about specific studies are included below in *Updating Information or Files for an Imported Study*.
3. **PRINCIPAL INVESTIGATORS AND STUDY STAFF:** Principal Investigators (PI) and some staff (primarily the staff who requested the ethical review) will have user accounts created in the system as part of the import. Everyone who has a user account created will receive an email from the system with instructions on how to login and set their password. If you believe you should have a user account as you are a PI or have submitted a study for ethical review and approval in the last three years, and you do NOT receive an email on or before April 9, 2022 with login information, please contact us or visit our website to complete the new user form to request system access.

Reviewing Approved Studies & User Data

4. Every researcher who has a study imported into the system will receive an email with instructions on how to login to the new system and create a password. Your user ID and email are both the email address we have associated with you. The customized IRB portal for HML IRB can be found at: <https://www.axiommentor.com/login/axlogin.cfm?i=hmlirb>.
5. We encourage you to login and make sure we have correct information for you and your studies.

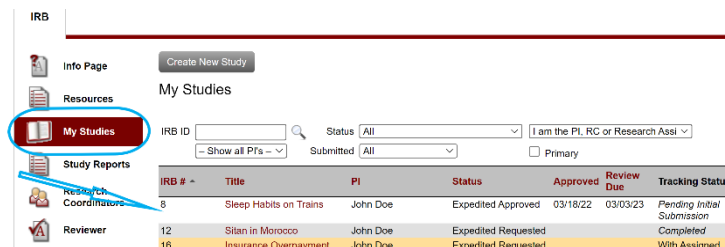
¹ If you have a study pending that was submitted prior to April 1 but is not yet approved, it will continue to be reviewed and approved via email. After approval, it will be manually entered into the system and tracked and monitored through the online platform.



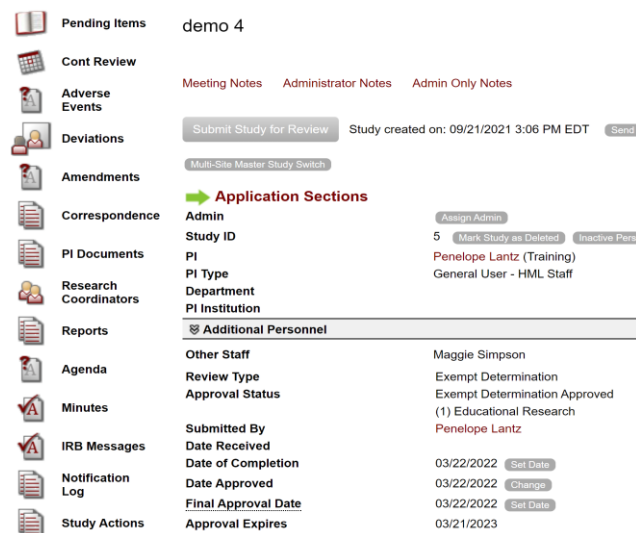
- When you login and set your password for the first time, you will be directed to the home page of the IRB Portal. To access the IRB, click on **IRB** on the black band at the top of the page or the **Access IRB** button to be directed to the IRB page.



- From the IRB Landing Page, click on My Studies to see all of the studies that are associated with you. You will need to scroll down to the bottom of the page to see the list of studies as at the top of the My Studies page will be some information about entering your training information. For additional information on each study, click on the study title.



- The study page will open with details imported about each study. This includes study title, staff, review type, funding source, and approval date.



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9. It does not include information about any renewals or modifications to the study. But it should include an expiration date. This date reflects when your continuing review or annual check-in is due. More information on that process is found in *How to Manage an Approved Study* available on our website and in the IRB Portal under **Resources**.
10. If everything looks correct, you do not need to do anything for this study until the continuing review or annual check-in, if there is one. If the information is wrong or you need to update or add additional staff, you will need to submit a request. The process to do that is described below in *Updating Information or Files for an Imported Study*.
11. If the study is no longer active but has not yet been closed out, please close it. The process to close an imported study is described below in *Closing an Imported Study*.
12. After reviewing the details of your studies, you will want to update your training information. 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.
13. 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.
14. 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 or expertise you have in working with human subjects. To upload your proof of training, click on **Training Certifications** in the left navigation panel.



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

A screenshot of the "IRB Human Subjects Training Certification" page. At the top, there is a header with the text "IRB Human Subjects Training Certification" and a blue "Upload" button. Below this is a table with three columns: "File", "Date of Completion", and "Renewal". The table is currently empty, with the text "- no entries found -" centered below the column headers.

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

A screenshot of the "Upload IRB Human Subjects Training Certification" window. It has a title bar that says "Upload IRB Human Subjects Training Certification". Inside the window, there is a section for "File" with a "Choose File" button and the text "No file chosen". Below this, it lists "Allowed Extensions: doc, docx, pdf, xls,xlsx, ppt, pptx, jpg, png". There is also a "Date of Completion" field with a calendar icon and a "Clear Acceptable Formats" link. At the bottom, there are "Save" and "Cancel" buttons. The "Save" button is circled in blue.

17. 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.

Updating Information or Files for an Imported Study

18. If you would like to update any of the information contained in the record for your study, create a list of the items that need to be updated or edited in a Word or other document file. For example:

1. Title should be revised from *A View of Birds*, to *A View of Modern Flight*
2. There should be a Co-PI added, John Smith; email: jsmith@google.com

19. Save the file. In the IRB Portal, scroll to the bottom of the study page that requires editing and use the **Correspondence** Tab to upload the document with the edits and click on **New Item**.

A screenshot of the "Correspondence" tab in the IRB Portal. The tab is highlighted in blue. Below the tab, there is a message: "Please use the correspondence tab to submit materials standard reporting categories. Do not submit Continuing Events, Amendments, or Deviations using this form." At the bottom, there is a "New Item" button, which is circled in blue. Below the button, it says "0 Items".

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20. A new window will open. Upload the file you created with the list of edits. The date defaults to the current date and you should not need to edit it. You can add a description, but you do not need to. Do not use the Description box to ask for any data edits. If you check the **Send Receipt Confirmation** box, it will send a confirmation to you. The system will notify the IRB Administrator when you click **Save** even if that box is not checked. You can only upload one file. After you click save, we will receive the request and update the data.

A screenshot of a web form titled "Submit New Item for Correspondence". The form has a header bar with the title. Below the header, there is a blue information box with a question mark icon and text: "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." Below this, there is a "Date" field with the value "03/22/2022" and a "Clear Acceptable Formats" link. There is an "Upload File" section with a "Choose File" button and the text "No file chosen". Below this, it says "Allowed Extensions: doc, docx, pdf, xls,xlsx, ppt, pptx, jpg, png". There is a "Description" text area. At the bottom, there is a checkbox labeled "Send Receipt Confirmation On Submit" which is unchecked. There are "Save" and "Cancel" buttons at the bottom right.

21. To have the files for your imported studies uploaded to the IRB portal, create a document with a list of the file names exactly as they were submitted to us.² Only include final documents. Below is a list of files submitted as part of a now approved ethical review. The assent document for children ages 13 to 17 was revised during the initial review (revised file name: *jr revised 13-17 assent*). We will only import the approved one, so the original version, shown below with a line through it, should not be included in your list. Similarly, the teacher consent form was revised through an amendment and the original version was never used. It should not be included in your list. The teacher focus group guide was revised for both 2021 and 2022. All three versions should be listed, as all three were used for data collection. We will confirm the list and add these files to the record. Submit the request for the file upload using the procedure described above in 19 and 20.

A list of files submitted for ethical review, each with a document icon. The files are: "FGD teachers fall 2021", "FGD teachers fall 2022", "FGD teachers", "survey tools", "Request for HML IRB ethical review - mo...", "jr revised 13-17 assent", "~~13-17 assent~~", "9-12 assent", "parental consent", "informed consent teachers rev2.15", and "~~informed consent teachers~~".

² We do not rename client files, so we will have them stored using the files names given to us. If you have changed those file names since submission, we will not be able to match the files.



Messages & Correspondence

22. 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.
23. 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>.
24. There are two mechanisms to use to communicate with us about your study that do not involve an action like an amendment or deviation. There are ***Messages*** and ***Correspondence***.
25. 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.



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



27. 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.

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New Study Message

New Study Message

Testing System

Message

Send Notification(s) to PI(s)

☒ John Doe (PI)

☐ Camille Jones (Research Coordinators (nc primary))

Send Notification to IRB Member(s)

☐ Michael Anderson (Chair)

☒ Penelope Lantz (Administrator)

Send Notification to Full Administrator(s)

☐ Nancy Westwood

Save Cancel

28. 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.
29. 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.
30. 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.

Correspondence Billing

Please use the **Correspondence** standard reporting categories. Do not submit Continuing Reviews, Amendments, or Deviations using this form. To submit correspondence, click on the **New 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

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31. 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

32. 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

Study Reports

Research Coordinators

Reviewer

Training Certifications

IRB ID: Status: All
Show all PI's Submitted: All

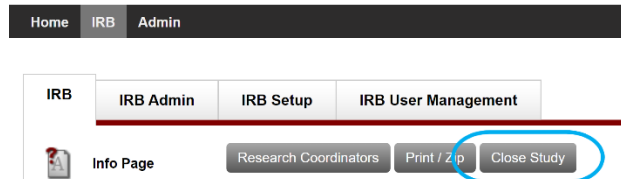
IRB #	Title	PI
8	Sleep Habits on Trains	John
12	Sitan in Morocco	John
16	Insurance Overpayment and Claims Fraud	John
17	Jan 25	John
18	The Day before Ground Hog Day	John
19	Testing System	John
101TEST22	testing again or shall I say still	John
510	hats	John

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Closing an Imported Study

33. If you have an active approved study in the IRB Portal that is completed and should be closed, please submit a close out request. From the *Study* page for the study you want to close out, click on the **Close Study** button at the top of the page.



34. A new window will open. You can leave the number of subjects boxes blank, except for the last one which should be zero in order to close out the study. 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

On the **Annual Check-Ins** tab, click on and complete the **Annual Check-In Checklist** or **Study Closure Checklist**. Then click on the **Submit** button. 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. 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.

IRB ID: 101TEST22
Study Title: testing again or shall I say still
Year Number: 1
Number of Subjects Approved: 400

Total # Subjects Enrolled Since Last Cont Review:
Total # Subjects Enrolled in Study to Date:
Total # Subjects Who Have Completed Study:
Total # Subjects Still Active:

Continuation Status:
Date Study Closed: 03/28/2022 [Click Here to Select Date](#)

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:

35. 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.

Annual Check-Ins | **Amendments** | **Adverse Events**

Year	Status	Due Date	Date Recd
1	Due	03/09/2023	

[Click Here to Submit](#)

Missing: Answers

[Study Closure Checklist](#)

Close Study Requested

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

Study Closure Checklist

Please answer the following questions to close out your study. HML IRB considers a study concluded and ready for closure when all data collection is complete and there will be no further contact with subjects; all data analysis has been completed; and data has either been stripped of all identifiers as further access to identifiable subject data is no longer required.

Add/Edit Answers

Please answer the following questions.

	Yes	No
Has all data collection been completed (have all subjects completed all study related activities, visits and procedures)?	<input type="radio"/>	<input type="radio"/>
Is any further contact with subjects needed for reasons related to research?	<input type="radio"/>	<input type="radio"/>
Is any further access to identifiable subject data required for research purposes (data analysis, manuscript preparations, etc.)?	<input type="radio"/>	<input type="radio"/>
Has all data been destroyed or de-identified for storage?	<input type="radio"/>	<input type="radio"/>
Has or will a de-identified data set be made available to other researchers?	<input type="radio"/>	<input type="radio"/>
Are there any other related studies or component studies still ongoing that have been reviewed by a separate HML IRB review?	<input type="radio"/>	<input type="radio"/>

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

Study Closure

Please answer the following questions.

	Yes	No
Has all data collection been completed (have all subjects completed all study related activities, visits and procedures)?	<input checked="" type="radio"/>	<input type="radio"/>
Is any further contact with subjects needed for reasons related to research?	<input type="radio"/>	<input checked="" type="radio"/>
Is any further access to identifiable subject data required for research purposes (data analysis, manuscript preparations, etc.)?	<input type="radio"/>	<input checked="" type="radio"/>
Has all data been destroyed or de-identified for storage?	<input checked="" type="radio"/>	<input type="radio"/>
Has or will a de-identified data set be made available to other researchers?	<input checked="" type="radio"/>	<input type="radio"/>
Are there any other related studies or component studies still ongoing that have been reviewed by a separate HML IRB review?	<input type="radio"/>	<input checked="" type="radio"/>

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

38. 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**

39. 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**

Year	Status	Due Date
1	Due	03/09/2023

Submit

Study Closure Checklist

Close Study Requested

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40. A new screen will open to confirm your request, click on the **Submit Report** button. Your closure request will be submitted. A notification will be sent to HML IRB and you will receive a confirmation email. You will receive a subsequent notice of closure email when the study is officially closed.

Submit Cont Review

IRB ID: 101TEST22
Study Title: testing again or shall I say still
Year Number: 1
Number of Subjects Approved: 400
Continuation Status: Close Study
Date Study Closed: 03/28/2022

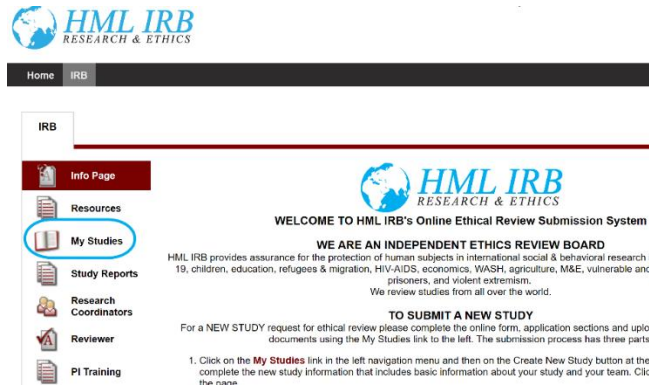
Amending an Imported Study

41. Effective April 1, 2022, 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.
42. 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.
43. Using the Word document you submitted to request ethical review³ (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.
44. 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.

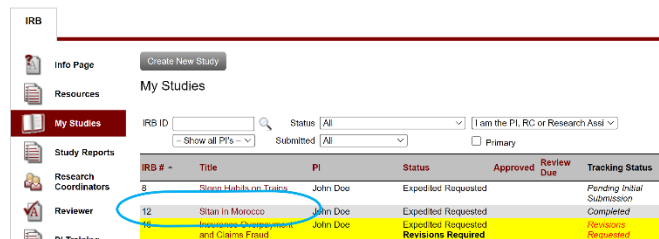
³ If you cannot find your initial application for ethical review, please email us and ask for a copy. We will send you the latest version we have on record for your study.



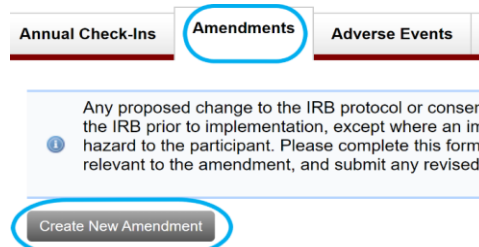
45. Click on the **My Studies** on the left navigation menu on the IRB tab.



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



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



48. If you have any additions to personnel as part of your modification, check the box by **Personnel**; if not, leave it unchecked. Next, click the **Create Amendment** button. This will create the amendment and direct you back to the study page.



Create New Amendment

Create New Amendment

1 This form will create a new Amendment. You will be prompted after the Amendment record is created to provide additional information and/or file uploads.

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. To submit an amendment, click on the **Create New Amendment** button. If you have any additions to personnel as part of your modification, check the box by Personnel; if not, leave it unchecked. Next click the **Create Amendment** button. This will create the amendment. To submit it you must: (1) complete the Questionnaire describing the amendment, change or addition; (2) add staff to Personnel if applicable; and (3) upload any new or revised documents. If the amendment results in a change to the original application for ethical review submitted via email, please revise it showing the changes in "markup" and upload it as a Revised Protocol Document. 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.

Study Title: Independent Evaluation Services for...

Select Application Sections you wish to revise

☐ Personnel

Create Amendment Cancel

49. If you check *Personnel*, click on the Edit Application Sections link to add staff to the study.

Create New Amendment Disable New Amendments Until Current

Status		
2	03/28/2022	New - Not Yet Submitted

Submit

Edit Application Sections

Questionnaire

Required Questions Not Answered

Approve Documents

Additional Documentation

50. 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 page icon (also called the context menu) to the left of the filename.

Questionnaire ✓

Documents

- New or Revised Additional Documentation
- New or Revised Assent Form
- New or Revised Consent Form
- New or Revised Data Collection Tool
- New or Revised Focus Group Data Collection Tool
- New or Revised Interview Data Collection Tool
- New or Revised Observation Checklist/Tool
- New or Revised Parental Consent Form
- New or Revised Recruitment/Marketing Materials
- New or Revised Survey Data Collection Tool
- Other New or Revised Documents
- Revised Research Protocol
- Revised Subject Protections Protocols

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51. A new window will open that will allow you to upload a file. It also will allow you to link it to an existing approved file. In studies where you are asking to revise an existing approved file, this is useful. However, most studies that were imported will not have the approved files uploaded to the IRB Portal. If the file you are asking to revise is not available, just leave it as the default “Do Not Link” and click the *Save* button.

Upload New Amendment File

Study Title Independent Evaluation Services for...

New or Revised Data Collection Tool No file chosen

Allowed Extensions: doc, docx, pdf, rtf

Link File to Existing Protocol File

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

☒ Disable New Amendments Until C...

Status	
1 03/28/2022	New - Not Yet Submitted

[Questionnaire](#) **Required Questions Not Answered**

53. The Questionnaire will open in a new window. Click on the **Answer** button to answer the questions about your amendment.

Amendment Form

1. AmendmentType Type: Multiple Select **Required**

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

Options:

- 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

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

A screenshot of a web form for submitting an amendment. At the top, there are two checkboxes: "Data collection tools (surveys, questionnaires, interviews, etc.)" and "Other". Below these is a text area with a placeholder text: "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)". The text area has a rich text editor toolbar with various icons. At the bottom of the form, there are four buttons: "Save Answers", "Save Answers & Close", "Skip Question", and "Cancel". The "Save Answers" button is highlighted with a red circle.

55. 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?

A screenshot of the "How do you wish to proceed?" section of the amendment form. It contains two buttons: "Return to Study Page" and "Review Answers". The "Return to Study Page" button is highlighted with a red circle.

56. 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 and you will receive an email confirmation. 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.

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What Has Changed & What Has Stayed the Same

57. **COSTS:** Our fees will stay the same as posted on the website and in effect since January 1, 2022. There is no cost to using the online system for submission or tracking of your studies.
58. **TIMELINE FOR REVIEW:** Our timeline for review and approval of studies will not change. You should receive an immediate confirmation from the system once you submit a new request for ethical review or make any changes to an existing study. You will receive our comments in an email format that allows you to make changes and edits in the system as well as upload any revised documents. The approval process will still result in a letter that you will receive via email, and it will be accessible in the system along with all study related materials that have been submitted and approved.
59. **IMPROVED TRACKING:** The online tracking component for studies allows both the IRB and the study team to login and see what the current and approved documents are for a study. Any modifications or amendments are tracked and everyone can see current approved materials along with previous versions.
60. **CONTACTING US:** Please feel free to reach us directly by email or phone with any questions you may have about us or the ethical review process in general prior to submitting your study for review. However, once a study has been submitted into the system, it is helpful for you to direct all study related inquiries through the system using the tabs on the study page. Information on how to do that can be found in *Messages & Correspondence* above.
61. **SUBMITTING AN APPLICATION:** The online application requests similar information to what was requested in the paper application. It uses conditional logic, so not all questions are asked for each study. The application process is tailored to your study specifics around subject and data collection types. There are additional multiple-choice questions in an effort to obtain greater detail about some study specifics and reduce the requests for additional information during the review process. If you find the application process burdensome or confusing, please let us know. It is a work in progress. For step-by-step details on how to submit a new study, please refer to *How to Submit a New Study for Ethical Review* located on the HML IRB website and in the Guidance Documents folder within *Resources* in the left navigation menu of the IRB Portal.
62. **ANNUAL CHECK-IN:** We will require an annual check-in for all studies approved under an expedited review process. This is to make sure that we are kept current on the progress of studies and to be sure they are closed out in a timely fashion. There will not be a fee for an annual check-in, and we hope to keep the process simple and non-burdensome for investigators. You will receive an email

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notice six weeks before the annual check-in to remind you that you should login and submit the annual check-in status survey. The survey will be available from the study page in the system. Any deviations, modifications or amendments should be completely separate from the annual check-in using the correct tabs in the online system. For step-by-step details on how to complete an annual check-in, please refer to *How to Manage an Approved Study* located on the HML IRB website and in the Guidance Documents folder within *Resources* in the left navigation menu of the IRB Portal.

63. There will not be a required annual check-in for studies reviewed and determined to be exempt. However, the system will send an annual email reminding the study team to close out the study once it is completed.
64. CONTINUING REVIEW: All full board approved studies will require an annual continuing review. There will not be a fee for an annual continuing review and we hope to keep the process simple and non-burdensome for investigators. You will receive an email notice six weeks before the due date to remind you that you should login and submit the continuing review status survey. The survey will be available from the study page in the system. Any deviations, modifications or amendments should be completely separate from the continuing review using the correct tabs in the online system. For step-by-step details on how to complete a continuing review, please refer to *How to Manage an Approved Study* located on the HML IRB website and in the Guidance Documents folder within *Resources* in the left navigation menu of the IRB Portal.
65. STUDY CLOSURE: We strongly encourage you to close out studies as soon as they are complete. This can be done at the time of the continuing review/annual check-in, or before it is due by logging in and requesting study closure. Details on how to do this are discussed above in *Closing an Imported Study*.
66. ADVERSE EVENTS: Adverse events still need to be reported. The form we were previously using has been updated and is now found in the online system under the **Adverse Event** tab on the bottom Study page. For step-by-step details on how to report an adverse event, please refer to *How to Manage an Approved Study* located on the HML IRB website and in the Guidance Documents folder within *Resources* in the left navigation menu of the IRB Portal.
67. DOCUMENTATION OF INVESTIGATOR AND STAFF TRAINING: We have 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. If an individual did not receive a certificate as part of their training, it is fine to



upload the information in another way like a CV or list of relevant training or expertise. Details on how to do this are located above in *Reviewing Approved Studies & User Data*.

68. CREDENTIALS & DEGREES: New Users will have the ability to enter their credentials as part of creating an account. Please be sure to type in your credentials exactly as you want them displayed (PhD, EdD, MPP, MPH, etc.). For users imported into the system, we were unable to import credentials. However, if you want to have them added to your account, please send an email to info@hmlirb.com and we will update your record in the system.

The Mentor IRB Software

69. Mentor IRB is designed specifically to help IRBs manage the review and approval of new and continuing human subjects research. Mentor is hosted in Amazon Web Services in the United States. All data is encrypted in transit and stored in an encrypted format. The Mentor system is backed-up to separate physical locations on a transactional basis and with nightly snapshots of the database. All files are encrypted and mirrored in separate physical locations as well. Mentor is available 24/7 from anywhere in the world and averages 99.95% uptime, exclusive of scheduled maintenance. Mentor stores all data securely and will not share any client data with any third parties under any conditions without the express written consent of the owner. More information about the company and their product can be found at <https://axiom-mentor.com/>.

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