



How to Submit a New Study for Ethical Review

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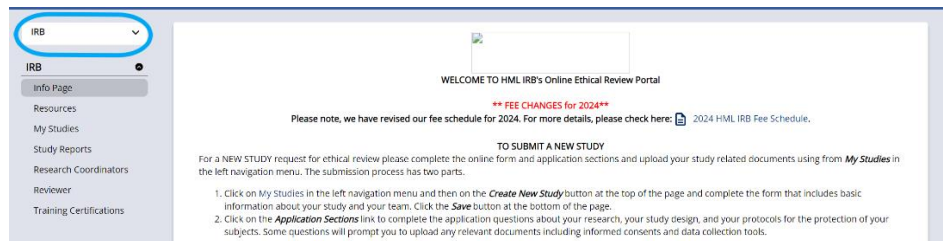
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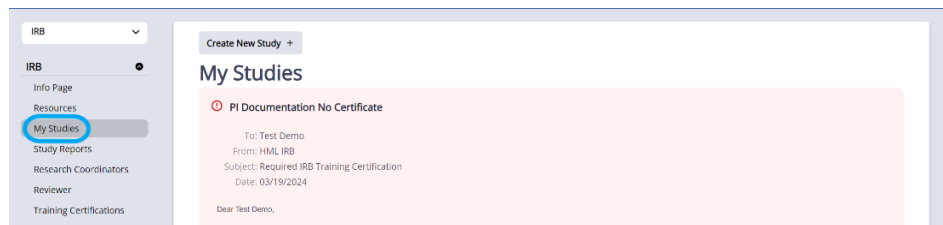
Submit a New Study for Ethical Review in the HML IRB Portal

To submit a new protocol:

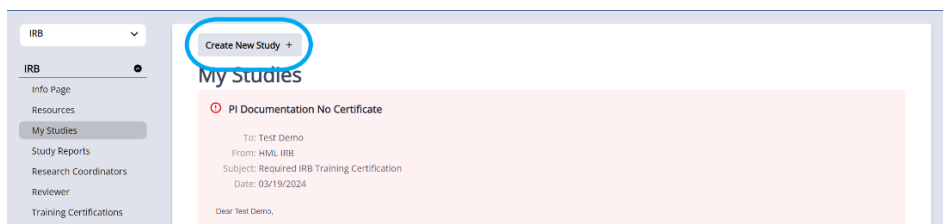
1. Login to the IRB portal. The link can be found from our website (www.hmlirb.com) or at: <https://www.axiommentor.com/login/axlogin.cfm?i=hmlirb>. Once logged in, from the drop down on the left click on the **IRB** tab.



2. Click on **My Studies** on the left navigation menu.¹



3. Then click the **Create New Study** button:



¹ If you have not uploaded certification of your training, the top of the *My Studies* page will show a notification: **“Required IRB Training Certification.”** Before submitting your study for review, please upload certification of your training. Follow the instructions in the IRB Portal or refer to *Uploading Training Certification* herein.



4. You must select one Principal Investigator (PI) from a list of pre-populated names. This list of names will be the user you are logged in as and any other users for whom you have been designated a Research Coordinator. If you are submitting the request for ethical review on behalf of the PI, and are not designated as a Research Coordinator for that person, see ***Designating Research Coordinators in the HML IRB Portal*** below before completing the application for ethical review.

Create IRB Study

Cancel

Add User

To submit a study for ethical review please complete the information sheet and the click **Save** button at the bottom. After clicking **Save**, complete the **Application Sections** by clicking on the link. Your study will not be submitted until after all application sections have been completed and you click the **Submit Study for Review** button. For details on how to complete this form and the application sections, refer to the document [How to Submit a New Study](#) located in the Guidance Documents folder within **Resources** in the left navigation menu of the IRB Portal. To create the initial study record you must complete this form and click the **Save** button. After that you can save your work on the **Application Sections** in the event you cannot complete the application all at once.

PLEASE NOTE: Our fees have changed effective January 1, 2024. For more details please see: [2024 HML IRB Fees](#).

* PI

-Select-

* Study Title

5. Complete all of the application fields. The start and end dates should be for the entire study not just data collection with human subjects.

Create IRB Study

Cancel

* Study Title

* Proposed Start Date

* Proposed End Date

* Risk Category

-Select-

* Study Country

* Data Collection Types

☐ Survey questionnaire

☐ Subject interview

☐ Key informant interview (KII)

☐ Focus/small group interview or discussion (FGD)

☐ Document review

☐ Case study

☐ Secondary data

☐ Physical (body) measurements

☐ Biological samples or specimens

☐ Other

* US Federally Funded?

-Select-

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6. When selecting *Risk Category*, choose between **Minimal Risk** or **Greater Than Minimal Risk**. If you select *Greater Than Minimal Risk*, you must select **Full Review** as your review type.
7. For **Study Country**, type the first letters of the country name and select the desired country from the list that populates. You can repeat as necessary to list all the countries where the study is being conducted. If you accidentally choose the wrong one, click on the “x” to the left of the country and it will be removed.

① ★ Study Country

☒ United States

8. Please provide the source of funding for your project. This should be completed for all studies even if the project is internally or self-funded.

Create IRB Study		Cancel ×
① Funding Source	① Billing Number/Code	
<input type="text"/>	<input type="text"/>	
Billing Name/Email		
<input type="text"/>		

9. Many of our clients require that we include a billing code or purchase order on invoices. Or that the invoice be sent to a particular person or department. Please provide that information. If there is none, please indicate by entering *NA* or *None*.
- 10.

Create IRB Study		Cancel ×
① Funding Source	① Billing Number/Code	
<input type="text"/>	<input type="text"/>	
Billing Name/Email		
<input type="text"/>		

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11. For **Review Type**, if you choose **Expedited Review** or **Exempt Determination**, you will be prompted to choose a category. You may also choose more than one and you may be prompted to answer additional questions about your choice. Scroll over each item to get a detailed description of what it includes.

★ Review Type

Expedited Review ▼

Please choose the option that you think best fits your project:

- ☐ (2) Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows
- ☐ (3) Prospective collection of biological specimens for research purposes by noninvasive means
- ☐ (4) Collection of data through noninvasive procedures
- ☐ (5) Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for nonresearch purposes
- ☐ (6) Collection of data from voice, video, digital, or image recordings made for research purposes
- ☐ (7) Research on individual or group characteristics or behavior

12. Please enter the total number of subjects you will have. This can be an estimate but should reflect all types of data collection.

Create IRB Study

★ Total Number of Subjects

13. Select any special or vulnerable subject types. We consider children to be anyone less than 18 years of age. You must select *Children* as a subject type if any subjects will be under age 18 even if you consider them to be emancipated.

Create IRB Study

Cancel

★ Vulnerable Subjects

☐ Children
☐ Prisoners
☐ Refugees
☐ Pregnant Women & Fetuses
☐ Have Health Risks
☐ At Risk of Violence
☐ At Risk of Exploitation
☐ Impacted by Disasters
☐ Involved in Illegal Activities
☐ At Risk of Human Trafficking
☐ Disadvantaged
☐ None of the Above

Other Subjects Type



14. When you have completed the form to create a new study, click *Save* at the bottom of the screen. When you click on the *Save* button, the initial record for your study will be created.
15. Once the initial application is completed you are directed to a page containing your application and further required steps. Here additional personnel can be added to the study. It is preferable that all members of the study team have user accounts and be assigned a role as Personnel. Click on **Add/Edit personnel**.

A screenshot of the "Application Sections" page. At the top, there's a header bar with "Application Sections" on the left and "Required Questions Unanswered: 37" on the right. Below this is a section titled "Personnel" with a dropdown arrow. Under "Personnel", there is a button labeled "Add/Edit personnel" with a pencil icon, which is circled in blue. Below the button, there is a table with three columns: "Name", "CITI Status", and "Date Added". The table contains one row with the values "Test Demo", "(Training)", and "03/19/2024".

16. A new screen will open where personnel information can be entered into fields. Fields that have the **Add** button are used to find the names of other system users who will be working on your study. To use these fields to add users, type in the first letters of the person's last name, or select the name from the drop down menu. As you type, a list will populate below the text input box. Continue typing to narrow the list down. Then, select the desired name from the list.

A screenshot of the "Edit Personnel: Study #2544" screen. At the top, there's a header bar with "Edit Personnel: Study #2544" on the left and "Cancel x" on the right. Below this, there are several sections for adding personnel. The first section is "PI" with the name "Test Demo" listed. Below that are three sections: "Co-PI's", "Research Assistants", and "Research Coordinators". Each of these sections has a text input box and an "Add +" button, which are circled in blue. The "Research Coordinators" section also has a dropdown menu with "-Select-" and an "Add +" button. At the bottom, there is a section for "Other Staff" with a text input box.

17. You must select the name from the list. Typing the name in the text box will not work. After selecting the name, click the *Add* button. The name will appear below the box, and you can add additional names as needed. If you select the wrong name, just click the "x" to the left of the name and the name will be removed.



PI
Test Demo

Co-PI's
 Add +

⊗ Penelope Lantz ☐ Allow Edit

Research Assistants
 Add +

⊗ Penelope Lantz

Research Coordinators
-Select- Add +

⊗ Penelope Lantz ☐ Primary

18. There are five types of study staff. There must be one PI. There are also Research Coordinators, Co-PIs, Research Assistants, and Other Staff, all of which are optional. For a detailed description of each role, please refer to ***Staff Roles and Designations in the HML IRB Portal*** below.
19. Persons designated as Other Staff can be added to the study without having 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. This is a plain text field and you may add names and other information in this box.

Research Coordinators
-Select- Add +

ⓘ Other Staff

Save ✓ Cancel ⓘ

20. If you have study staff who need to be added to the portal as Research Coordinators², Co-PIs or Research Assistants but do not have user accounts in the system, you can add them as part of creating the new study submission. To do this you will need their name and email address. Each user must have a unique email address. You add a user by clicking on ***Add User*** in top right.

² If creating user accounts for Research Coordinators, consult *Designating Research Coordinators* below for instructions on how to designate the new user as a Research Coordinator after creating the new user account.

A screenshot of a web form titled "Edit Personnel: Study #2617". At the top right is a "Cancel X" button. Below the title, there is a section for "PI" with the name "John Doe". To the right of this section is a blue arrow pointing to an "Add User" button. Below the "PI" section are two input fields: "Co-PI's" and "Research Assistants", each followed by an "Add +" button. At the bottom, there is a label for "Research Coordinators".

21. A new screen will pop up. Enter first name, last name, the email address in **both the username and email fields** and a valid phone number then click the **Save** button at the bottom of the screen. If you add users to the system this way and they subsequently want to login to the system, they will need to follow the instructions below about **Accessing My Account** to login.

A screenshot of a web form titled "Add User". It contains several input fields with labels: "★ First Name" (containing "John"), "★ Last Name" (containing "Smith"), "★ UserName" (containing "jsmith@hmlirb.com"), "★ Email" (containing "jsmith@hmlirb.com"), and "Work Phone" (containing "2022468504").

22. If the *Research Coordinators* field does not appear on the personnel page, it means that the current PI does not have any research coordinators assigned to them in the system. To add research coordinators, refer to **Designating Research Coordinators** below.
23. When you have added all of the staff to the study record, please click **Save**.

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Edit Personnel: Study #2617

-Select- ▼ **Add +**

⊗ **Penelope Lantz** ☐ Primary

① **Other Staff**

Save ✓ **Cancel ⊗**

24. You will be directed back to the study page. If you need to go back and edit any of the information on the *Create Study* page, click on the **Edit** button at the top of the study page.

Submit Study for Review ⓘ **Edit ✎** More ⋮

Demo Study

2544

25. Next, complete the required application sections and upload your files. You do not need to complete the application all at once. If you would like a copy of your application as you are completing the sections, you can obtain one by clicking on the **More** button at the top of the *View Study* page, leading to the **Print/Zip** button (this button is not available when the application sections are expanded). This will create a PDF of the application as it looks at that moment in time. Since some of the questions are conditional, the application may change, and new questions may be added as you complete each section.

Submit Study for Review ⓘ **Edit ✎** **More ⋮**

Demo Study



26. To access the application sections, click on the **Application Sections** on the study page.

Application Sections

Personnel

Add/Edit personnel

27. The application will open, and you will need to complete the questions in each section.

Section	Required Questions Unanswered
Research Design	4
Personnel	4
Sites, Dates & Risk	9
Data Collection	6
Subject Recruitment	7
Informed Consent	1
Subject Protections	1
Data Protections	5

28. Click on the arrow next to each section of the application to expand the section. Answer all the questions and upload any documents.

Research Design

Answer

* 1. Please provide a summary of your research design: Abstract plus 1000 to 1500 words.
(describe your study's background, rationale, & methodology)

Answer Required

Answer

* 2. Briefly describe how data collection will generate evidence necessary to support this study.

Answer Required



29. Click on the **Answer** button to answer the questions.

▼ Research Design

Answer ✎

★ 1. Please provide a summary of your research design: Abstract plus 1000 to 1500 words.
(describe your study's background, rationale, & methodology)

Answer Required

30. Click on the **Save Answers** button when you have answered all of the questions. Some of the questions are conditional, so your answer may prompt subsequent questions. Make sure to answer all of the questions.

★5. Does this study involve intervention, treatment, comparison or control groups? Please check all that apply:

☐ None
☐ Intervention
☐ Treatment
☐ Comparison
☐ Control
☐ Other

Save Answers ▼ **Save Answers & Close** ▼ Cancel ✕

31. If you do not answer all of the required questions, you will not be able to submit the study for review. In the image below, for example, the sections for *Personnel* and *Research Design* have been completed, but the section, *Sites, Dates & Risk*, still has unanswered questions.

> Research Design 03/19/2024 1:37 PM EDT

> Personnel 03/19/2024 1:38 PM EDT

> Sites, Dates & Risk **Required Questions Unanswered: 9**

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32. If after completing the application sections you have additional files you would like to upload, you may do that on the study page by clicking on **Upload** at the top or bottom of the page.

33. You will need to select the type of file (protocol, consent, data collection tool, etc.) and choose a file to upload. You also have the option of renaming the file. If you have several files, you may click on **Upload Multiple Files** to select multiple files to upload at once. You will then need to select an appropriate file type for each document.

34. When the application sections have been completed and the documents uploaded your study is ready to submit. The **Submit Study for Review** button will turn from light to dark gray. Click on this to formally submit your study to HML IRB and notify the IRB administrator.
35. At this point you will no longer be able to edit or modify the study while it is under review. We will begin reviewing your study within 24 hours and let you know if we need any additional information or documentation. Please feel free to contact us if you have questions about the process.

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Withdraw a Study Prior to Approval

36. At any time prior to approval, you can withdraw your study from the ethical review and approval process. To do this, simply access your study in the online portal, and click on the ***Withdraw Study From Review*** button. A new screen will open asking you to confirm the withdrawal. If you click the **Yes** button, your study will be withdrawn.

⚠ Required Questions Not Answered

PI	Approval Status	Created	03/19/2024	Approved	Set Date
Test Demo	Expedited Review	Received		Final Approval	Set Date
General User	Expedited Requested	Date of Completion	Set Date	Date Closed	Set Date
	(7) Research on individual or group characteristics or behavior				
	Withdraw Study from Review				

Staff Roles and Designations

37. 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 the other positions are optional.
38. **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.
39. **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.

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Co-PI's

Add +

☒ Penelope Lantz ☐ Allow Edit

40. **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*.
41. **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.
42. **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

43. 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.
44. 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.

A screenshot of the HML IRB Portal interface. On the left is a navigation menu with the "IRB" tab selected. Under the "IRB" tab, the "Research Coordinators" option is highlighted with a blue circle. The main content area shows a "Designate A New Research Coordinator + " button at the top. Below it is a table titled "Research Coordinators". The table has three columns: "Name", "Designated by", and "On". There are two rows of data. The first row shows "John Doe" designated by "Test Demo" on "03/19/2024". The second row shows "Penelope Lantz" designated by "Test Demo" on "03/19/2024". To the right of each row is a button labeled "Limited to Assign".

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45. 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.

Research Coordinators

Name	Designated by	On	
⋮ John Doe	Test Demo	03/19/2024	Limited to Assigned St... ▼
⋮ Penelope Lantz	Test Demo	03/19/2024	Limited to Assigned St... ▼

46. To add a new Research Coordinator, click on *Designate A New Research Coordinator*.

A screenshot of the "Research Coordinators" screen. At the top, there is a button labeled "Designate A New Research Coordinator +" which is circled in blue. Below the button, the title "Research Coordinators" is displayed. Underneath the title is a table with two columns: "Name" and "Designated by". The table contains two rows: "John Doe" and "Penelope Lantz", both designated by "Test Demo".

47. 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.

A screenshot of the "Designate A New Research Coordinator" form. The title "Designate A New Research Coordinator" is at the top. Below it is a search input field labeled "New Research Coordinator" which is circled in blue. Below the input field is a hint text: "(Type first letters of last name and select from list)". At the bottom of the form are two buttons: "Designate ✓" and "Cancel ✕".

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

A screenshot of a web interface titled "Designate A New Research Coordinator". It shows a table of "Research Coordinators" with columns for Name, Designated by, and On. Two entries are visible: John Doe and Penelope Lantz, both designated by "Test Demo" on "03/19/2024". A "My PIs" button is in the top right corner.

Name	Designated by	On
John Doe	Test Demo	03/19/2024
Penelope Lantz	Test Demo	03/19/2024

49. 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.

A screenshot of a web interface titled "Research Coordinators List of Assigned PIs". It shows a list of names, with "Camille Anderson" visible.

Name
Camille Anderson

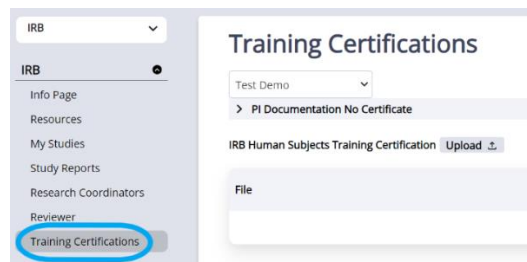
Uploading Training Certification

50. 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.
51. 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.

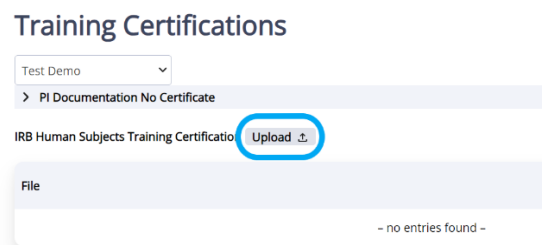
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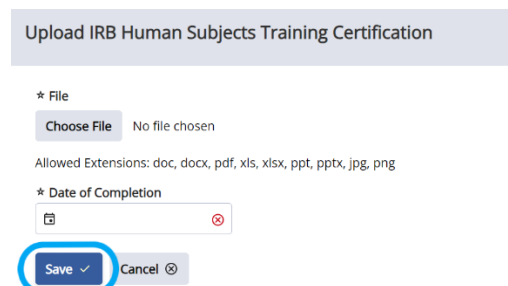
52. If you do not have a certificate of completion, please provide documentation of your training in another way. You can upload a copy of your CV or other documents that describe the training, the topics covered, the duration and date received. **Your CV must include the specifics of the training in human subjects' protections: date of course, name of course, provider, duration and topics covered.** To upload your proof of training, click on **Training Certifications** in the left navigation panel.



53. On the **Training Certifications** page, click the **Upload** button.



54. 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.





55. 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

56. 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.

57. All fields are required. For Form Code, please enter **HMLirb29**. The letters are case sensitive.



Login

Request Mentor User Account

Form Code

First Name

Last Name

Email Address


Phone Number

Degrees (MA, MPH, PhD, etc.)

Organization Name

Organization Address

Please Enter Text from the image



Submit

58. 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.

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59. After you click on the link and establish your password, HML IRB will receive notification of a new user created.
60. 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

61. 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/axlogin.cfm?i=hmlirb> and click on Forgot Password.

View Supported Browsers

Login Visit Our Website

Institution ID

☒ Remember my Institution ID

User

Password

Login

Forgot Password

Use your email address as your username.

If you have forgotten your password, click the Forgot Password link and enter your email address in the User and Email fields. The institution ID is hmlirb.

If you get locked out of your account or otherwise cannot login, please contact HML IRB at info@hmlirb.com.

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

Enter your username below to request a new password.

Institution ID

User

Email

Submit Cancel

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