



How to Submit a New Study for Ethical Review

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

To submit a new protocol:

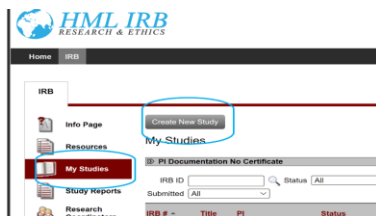
1. Login to the IRB portal. The link can be found from our website (www.hmlirb.com) or at: <https://www.axiommentor.com/login/axlogin.cfm?i=hmlirb>. Once logged in, if you are not automatically directed to the IRB page of the portal, click on the **IRB** tab or the access IRB button.



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.

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4. Complete the IRB Study submission form. The yellow starred items are required, but please complete all items relevant to your study. You can edit your submission form later, if needed.
5. 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.

6. 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. 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.

7. 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

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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.

A screenshot of the HML IRB portal's staff selection interface. It includes a dropdown menu for "PI" with "John Doe" selected, a dropdown for "Research Coordinators" with "-Select-" chosen, and a text input field for "Co-PI's". Below these is a list of names with checkboxes; "camille jones" is checked and circled in blue. An "Add" button is next to the "Co-PI's" field, and an "Allow Edit" link is next to the "camille jones" entry.

- 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.

Create IRB Study

To submit a study for ethical review please complete the information sheet below and click Save. After clicking Save, complete the Application Sections and upload any documents related to the study including your data collection tools and informed consent and submit your study for review. You study will not be submitted until after all application sections have been completed and the required documents uploaded.

A screenshot of the "Create IRB Study" form. It contains fields for "PI" (John Doe), "Research Coordinators" (-Select-), "Co-PI's", "Other Staff", "Research Assistants", and "Study title". The "Other Staff" section is circled in blue. An "Add User" button is circled in blue in the top right corner. Instructions for the "Co-PI's" and "Research Assistants" fields are provided: "(Type first letters of last name and select from popup list, then click 'Add')".

- 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.
- 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

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.



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.

Create IRB Study

To submit a study for ethical review please complete the information sheet below and click Save. After clicking Save, complete the Application Sections and upload any documents related to the study including your data collection tools and informed consent and submit your study for review. Your study will not be submitted until after all application sections have been completed and the required documents uploaded.

PI Select

Add User

11. Enter first and last name and the email address in both the username and email fields and click the **Add User** button. 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.

Add User

First Name	<input type="text" value="John"/>
Last Name	<input type="text" value="Doe"/>
UserName	<input type="text" value="jdoe@gmail.com"/>
Email	<input type="text" value="jdoe@gmail.com"/>
Work Phone	<input type="text"/>
Cell Phone	<input type="text"/>

12. If the *Research Coordinators* field does not appear on the **Create Study** 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.
13. 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.
14. 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.

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🌟 Study Country

☒ United States

15. 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

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

- ☐ (1) Educational Research
- ☐ (2) Tests, Surveys, Interviews
- ☐ (3) Benign Behavioral Interventions - Adults
- ☐ (4) Secondary Research Uses of Data or Specimens
- ☐ (5) Evaluation of Public Benefits & Service Programs

16. 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.
17. 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.

IRB

RB

Info Page Research Coordinators Upload Docs Print / Zip

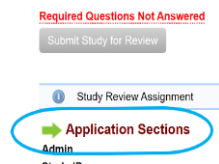
Messages (0) | Back

18. 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 **Print/Zip** button at the top of the *View Study* page (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.

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19. To access the application sections, click on the **Application Sections** link at the top or bottom of the study page.



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

A screenshot of the "Application Sections" page. At the top, there is a navigation bar with "IRB Admin", "IRB Setup", and "IRB User Management". Below the navigation bar, the page title is "Application Sections". Underneath, it says "demo 2" and "PI: Penelope Lantz". A blue box contains instructions: "Click on the double arrow at the left of each application section to expand the section and may also have some additional optional questions as well as a prompt to upload documents to complete the questions. Additionally some sections may be subdivided. Depending upon your answers you may be prompted to answer some additional questions. Save Answers at the bottom of each section." Below this is a checkbox labeled "Show Hidden Sections". A list of sections follows, each with a double arrow icon on the left and a red text label indicating the number of required questions unanswered: "Personnel Required Questions Unanswered: 2", "Research Design", "Sites, Dates & Risk Required Questions Unanswered: 4", "Subject Recruitment Required Questions Unanswered: 7", "Children Required Questions Unanswered: 6", "Survey Subjects Required Questions Unanswered: 6", "Biological Samples Required Questions Unanswered: 4", and "Informed Consent Required Questions Unanswered: 1".

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

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Personnel Required Questions Unanswered: 2

P1
Penelope Lantz, ID: (09/15/2021)

There are still questions without an answer.

Add/Edit Answers

* Is the study team comprised of staff from multiple organizations or entities?
Options: Yes
No
Answer Required

* Are you aware of any potential conflicts of interest, financial or otherwise, for any study staff on this project?
Options: Yes
No
Answer Required

22. Click on the **Add/Edit Answers** button to answer the questions.

Add/Edit Answers

* Is the study team comprised of staff from multiple organizations or entities?
Options: Yes
No
Answer Required

* Are you aware of any potential conflicts of interest, financial or otherwise, for any study staff on this project?
Options: Yes
No
Answer Required

23. 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.

* Is the study team comprised of staff from multiple organizations or entities?
Options: ☐ Yes
☐ No

* Are you aware of any potential conflicts of interest, financial or otherwise, for any study staff on this project?
Options: ☐ Yes
☐ No

* By whom will the data be collected for this study (select all that apply)?
Options: ☐ 1. The study team will conduct data collection themselves
☒ 2. The study team will contract with another entity for the supervision of data collectors
☐ 3. The study team will directly hire and supervise data collectors

Save Answers Save Answers & Close Cancel

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24. 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.

A horizontal progress bar with three sections. The first section is labeled "Personnel" and is filled with a light blue color. The second section is labeled "Research Design" and is also filled with a light blue color. The third section is labeled "Sites, Dates & Risk" and is outlined in blue, with a red text label "Required Questions Unanswered: 7" next to it.

25. 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 Docs** at the top or bottom of the page.

A screenshot of the study page. At the top, there is a navigation bar with buttons for "Edit", "Research Coordinator", "Upload Docs", and "Print / Zip". The "Upload Docs" button is highlighted with a red circle. Below the navigation bar, there is a section titled "Testing" with a description of the application sections and a "Submit Study for Review" button. Below this, there is a section titled "Application Sections" with a red arrow pointing to it.

26. 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.

A screenshot of the "Upload Documents" form. It has a title "Upload Documents" and a subtitle "Upload Multiple Files". There is a "File type" dropdown menu with "Research Protocol Description" selected. Below this, there is a "File" section with a "Choose File" button and a "No file chosen" status. Below that, there is a "Rename File to" text input field with a placeholder "Leave blank to use original file name". At the bottom, there are "Save" and "Cancel" buttons.

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27. 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.
28. 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.

Withdraw a Study Prior to Approval

29. 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.

➡ Application Sections	
Admin	
Study ID	18
Panel	No Panel Assigned
PI	John Doe (Training) Inactive On: 04/22/2022
PI Type	General User
Department	
PI Institution	
Research Coordinators	camille jones (Training) 01/31/2022 Inactive On: 04/22/2022
Other Staff	
Review Type	Expedited Review
Approval Status	Expedited Requested Withdraw Study from Review
	(6) Collection of data from voice, video, digital, or image recording purposes.
Submitted By	camille jones
Date Received	
Date of Completion	
Date Approved	
Final Approval Date	
Proposed Start Date	02/01/2021
Proposed End Date	05/20/2022
Date Closed	

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Staff Roles and Designations

30. 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.
31. *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.
32. *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.

A screenshot of the HML IRB Portal interface. It shows a section for adding Co-PIs. There is a text input field for the Co-PI's name, followed by an "Add" button. Below this, there is a list of existing Co-PIs. One entry, "John Doe", is shown with a checkbox next to it labeled "Allow Edit". This checkbox is highlighted with a red circle. Below the Co-PIs section, there is a section for "Other Staff" with a text input field and an "Add" button.

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

A screenshot of the HML IRB Portal interface. It shows the PI field with the name "Penelope Lantz" and a blue arrow pointing to it. Below the PI field, there is a section for Co-PIs with a text input field and an "Add" button. Below the Co-PIs section, there is a section for "Other Staff" with a text input field and an "Add" button. Below the "Other Staff" section, there is a section for "Assistants" with a text input field and an "Add" button. Below the "Assistants" section, there is a section for "Study Title" with a text input field.

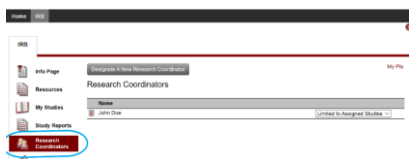
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34. **Research Assistant:** A Research Assistant is a member of the study team who is integral to the project but does not require access to edit the study submission or protocols in the HML IRB Portal. These are system users who can access studies in a read only format.
35. **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

36. 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.
37. 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.



38. 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.



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39. 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.

Commented [1]:
pronouns.

A screenshot of the "Designate A New Research Coordinator" form. The title "Designate A New Research Coordinator" is at the top. Below it, the label "New Research Coordinator" is followed by a text input field. Inside the input field, there is a placeholder text "Type first letters of last name and select from list". Below the input field are two buttons: "Designate" and "Cancel".

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

A screenshot of the Research Coordinator screen. The top navigation bar includes "IRB Admin", "IRB Setup", and "IRB User Management". Below this, there is a sidebar with icons for "Info Page", "Resources", "My Studies", "Study Reports", and "Research Coordinators". The main content area is titled "Research Coordinators" and contains a table with columns "Name" and "John Doe". A button labeled "My PIs" is located in the top right corner of the main content area.

41. 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 the "Research Coordinators List of Assigned PIs" screen. The title "Research Coordinators List of Assigned PIs" is at the top. Below it, there is a table with columns "Name" and "camille jones". The sidebar on the left includes "Info Page", "Resources", "My Studies", "Study Reports", and "Research".

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Uploading Training Certification

42. 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.
43. 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.
44. 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.



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



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46. 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.

Upload IRB Human Subjects Training Certification

Upload IRB Human Subjects Training Certification

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

Date of Completion

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

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Creating a New User Account

48. 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.
49. All fields are required. For Form Code, please enter **HMLirb29**. The letters are case sensitive.

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

50. 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.
51. After you click on the link and establish your password, HML IRB will receive notification of a new user created.
52. HML IRB will review your request and activate your user account. You will receive an email confirmation with login instructions when your account has been approved. If your organization is not an existing HML IRB client, we may reach out to you for additional information.

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Accessing My Account

53. 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.

The screenshot shows the HML IRB Research & Ethics login page. At the top is the logo and a navigation bar with 'Login' and 'Visit Our Website' buttons. Below the logo is a 'View Supported Browsers' link. The main form contains fields for 'Institution ID' (pre-filled with 'hmlirb'), a 'Remember my institution ID' checkbox, 'User' (pre-filled with 'plantz@hmlus.com'), and 'Password' (masked with asterisks). A 'Login' button is below these fields. A red circle highlights the 'Forgot Password' link. Below the form, there is instructional text: 'Use your email address as your username.', 'If you have forgotten your password(s), click the Forgot Password link and enter your email address in the User and Email fields. The Institution ID is hmlirb.', and 'If you get locked out of your account or otherwise cannot login, please contact HML IRB at info@hmlirb.com.'

54. 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.

The screenshot shows the 'Forgot Password' form on the HML IRB Research & Ethics website. It includes the logo and a 'Login' button. The main instruction is 'Enter your username below to request a new password.' The form has fields for 'Institution ID' (pre-filled with 'hmlirb'), 'User', and 'Email'. A red circle highlights the 'User' and 'Email' fields. Below these fields are 'Submit' and 'Cancel' buttons.

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