How to Submit a New Study for Ethical Review

Table of Contents

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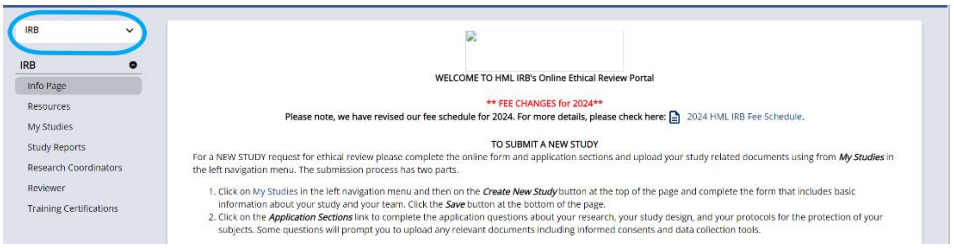
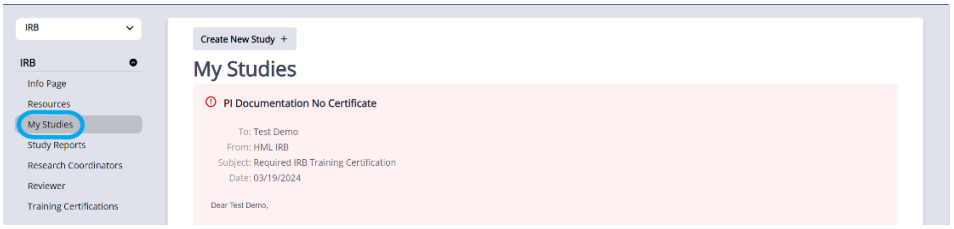
Submit a New Study for Ethical Review in the HML IRB Portal

To submit a new protocol:

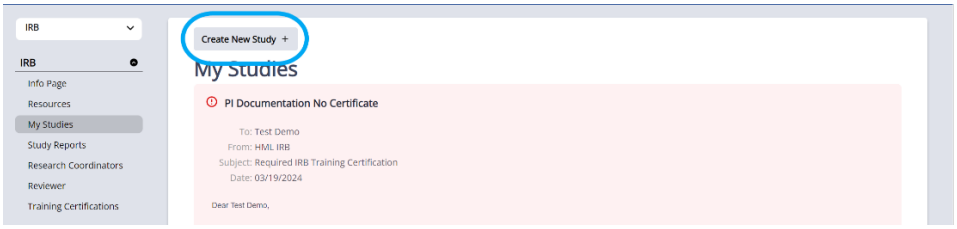
1. Login to the IRB portal. The link can be found from our website (www.hmlirb.com) or at: https://www.axiommentor.com/login/axlogin.cfm?i=hmlirb. Once logged in, from the drop down on the left click on the ***IRB*** tab.



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

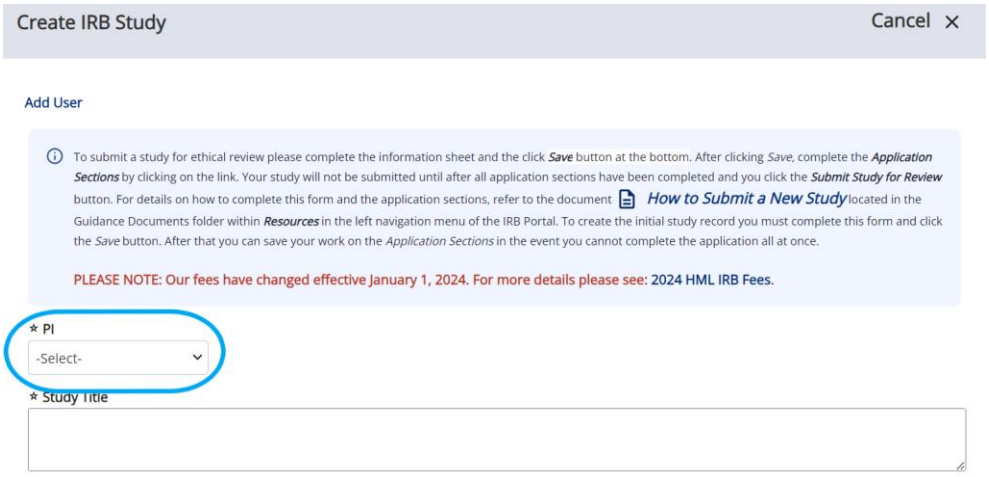


3. Then click the ***Create New Study*** button:

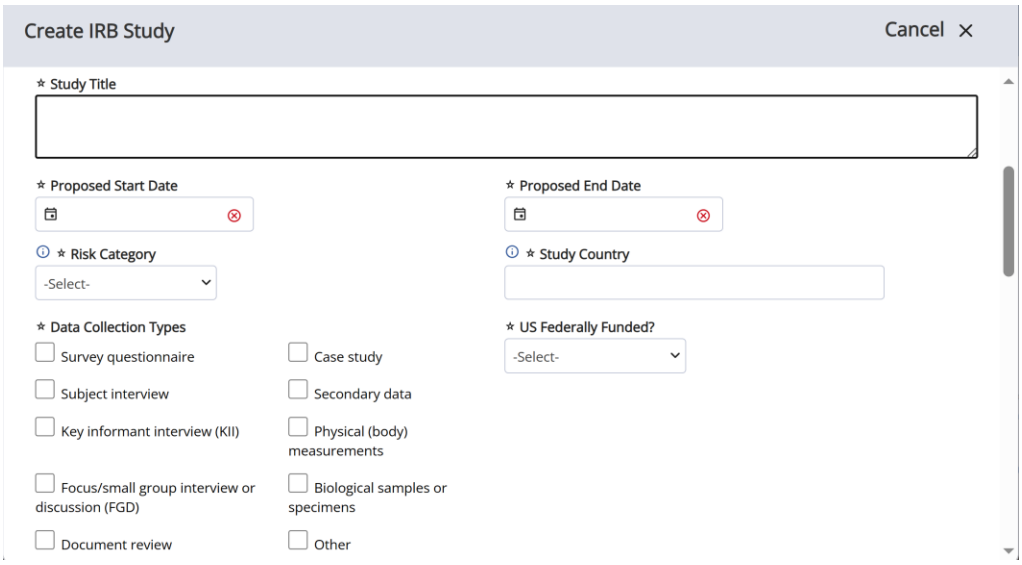


[1] If you have not uploaded certification of your training, the top of the *My Studies* page will show a notification: "*Required IRB Training Certification.*" Before submitting your study for review, please upload certification of your training. Follow the instructions in the IRB Portal or refer to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



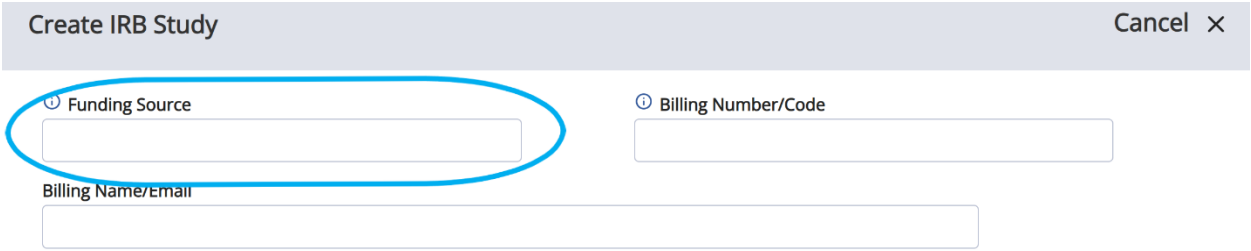
5. Complete all of the application fields. The start and end dates should be for the entire study not just data collection with human subjects.



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.

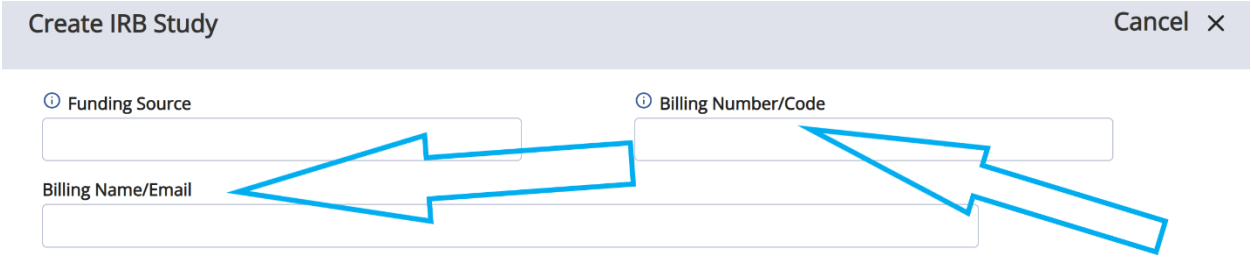
7. For ***Study Country***, type the first letters of the country name and select the desired country from the list that populates. You can repeat as necessary to list all the countries where the study is being conducted. If you accidentally choose the wrong one, click on the "x" to the left of the country and it will be removed.

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.

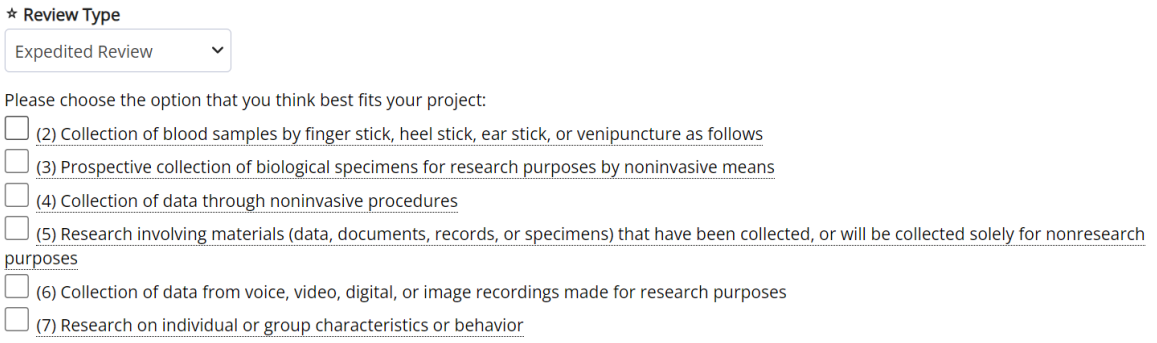


9. Many of our clients require that we include a billing code or purchase order on invoices. Or that the invoice be sent to a particular person or department. Please provide that information. If there is none, please indicate by entering *NA* or *None*.

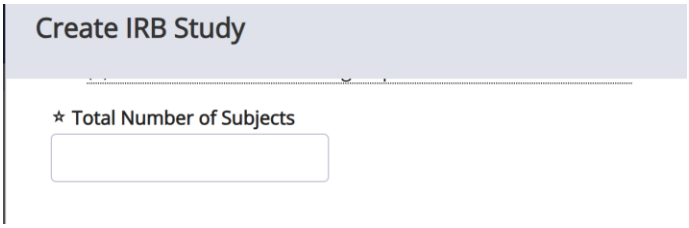
10.



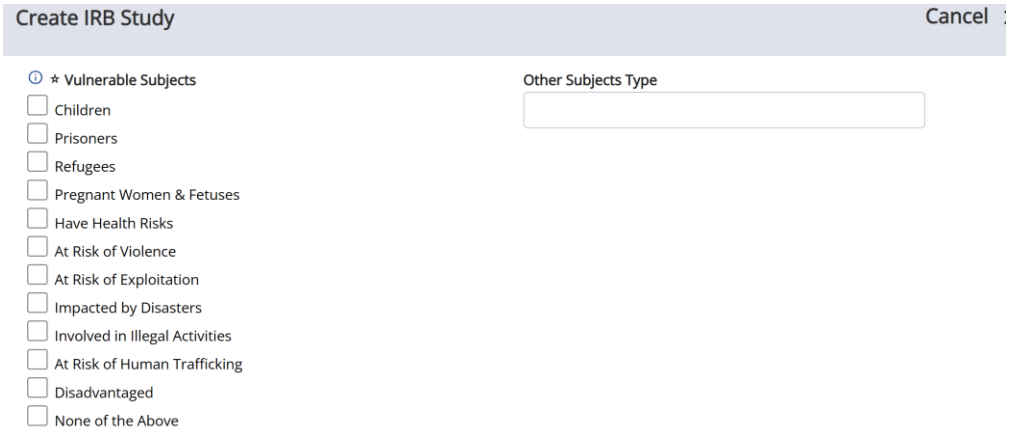
11. For ***Review Type***, if you choose ***Expedited Review*** or ***Exempt Determination***, you will be prompted to choose a category. You may also choose more than one and you may be prompted to answer additional questions about your choice. Scroll over each item to get a detailed description of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



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

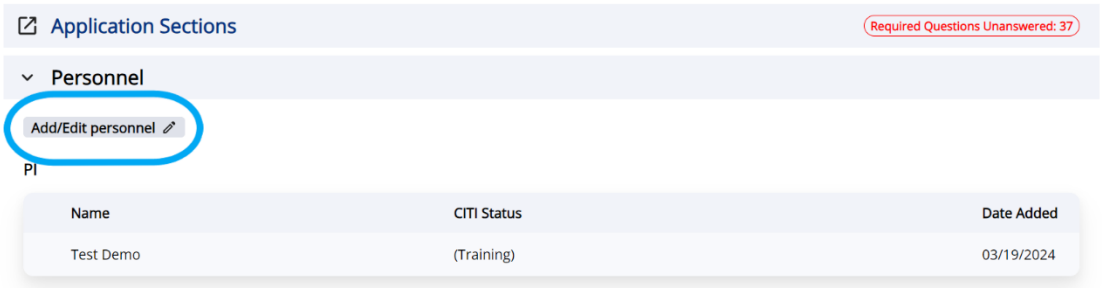


13. Select any special or vulnerable subject types. We consider children to be anyone less than 18 years of age. You must select *Children* as a subject type if any subjects will be under age 18 even if you consider them to be emancipated.

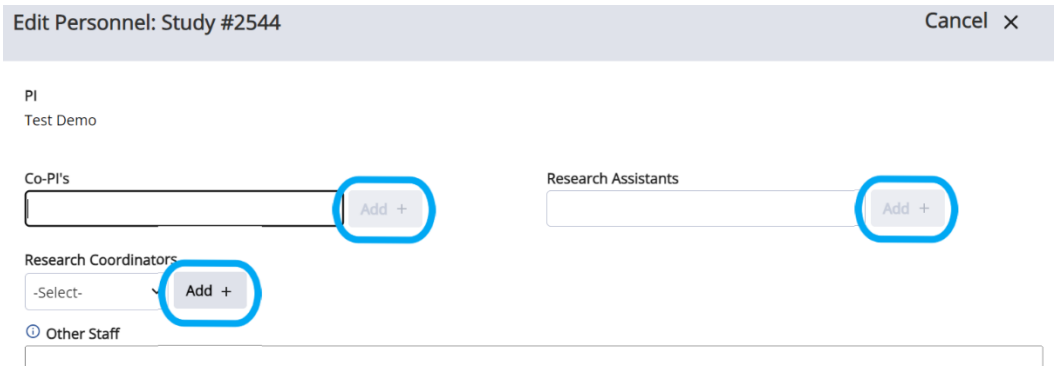


14. When you have completed the form to create a new study, click *Save* at the bottom of the screen. When you click on the *Save* button, the initial record for your study will be created.

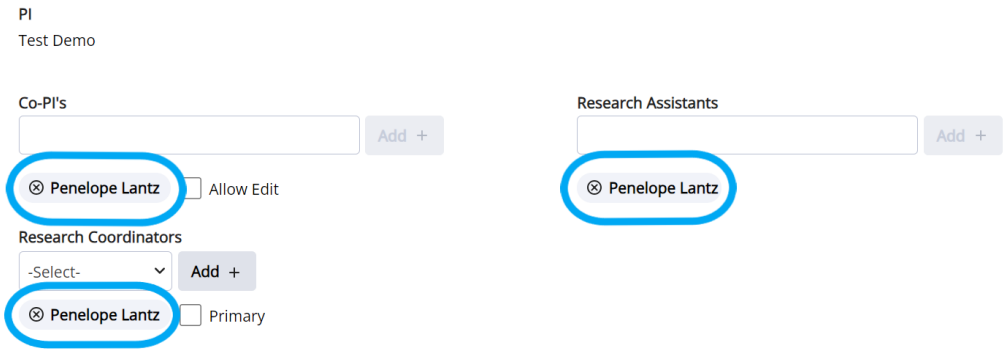
15. Once the initial application is completed you are directed to a page containing your application and further required steps. Here additional personnel can be added to the study. It is preferable that all members of the study team have user accounts and be assigned a role as Personnel. Click on **Add/Edit personnel**.



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.

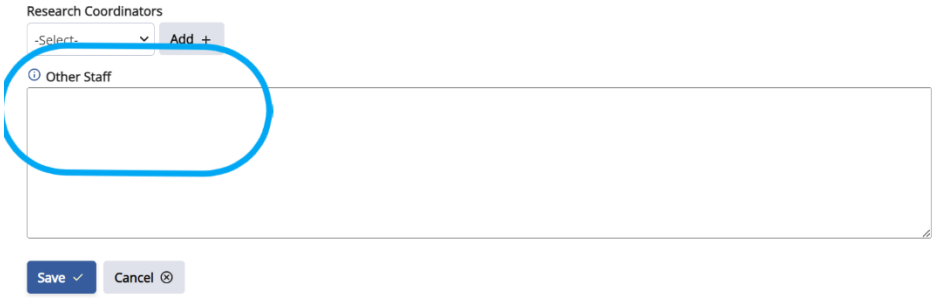


17. You must select the name from the list. Typing the name in the text box will not work. After selecting the name, click the *Add* button. The name will appear below the box, and you can add additional names as needed. If you select the wrong name, just click the "x" to the left of the name and the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



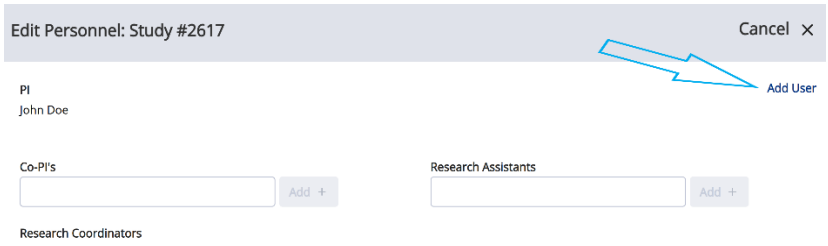
18. There are five types of study staff. There must be one PI. There are also Research Coordinators, Co-PIs, Research Assistants, and Other Staff, all of which are optional. For a detailed description of each role, please refer to ***Staff Roles and Designations in the HML IRB Portal*** below.

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.



20. If you have study staff who need to be added to the portal as Research Coordinators[2], 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.

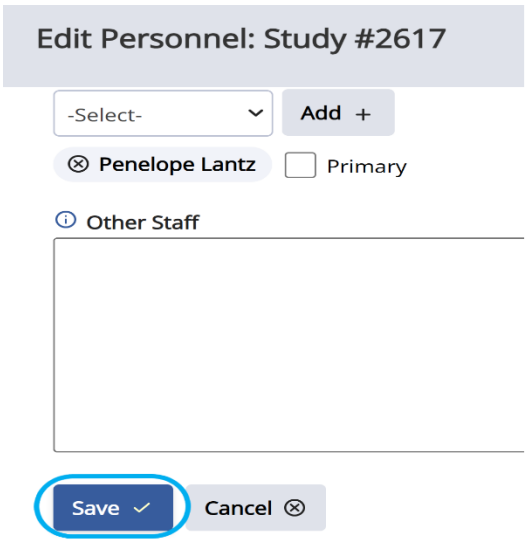
[2] If creating user accounts for Research Coordinators, consult *Designating Research Coordinators* below for instructions on how to designate the new user as a Research Coordinator after creating the new user account.



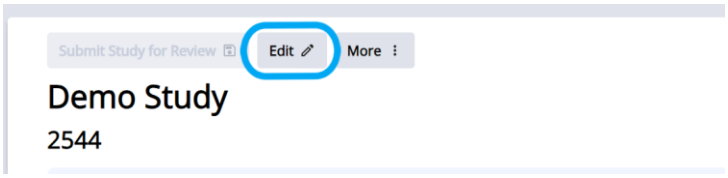
21. A new screen will pop up. Enter first name, last name, the email address in **both the username and email fields** and a valid phone number then click the ***Save*** button at the bottom of the screen. If you add users to the system this way and they subsequently want to login to the system, they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

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***.

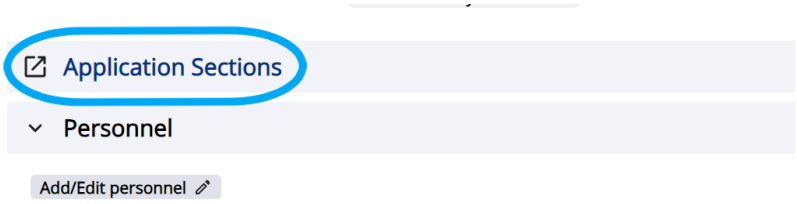


24. You will be directed back to the study page. If you need to go back and edit any of the information on the *Create Study* page, click on the ***Edit*** button at the top of the study page.



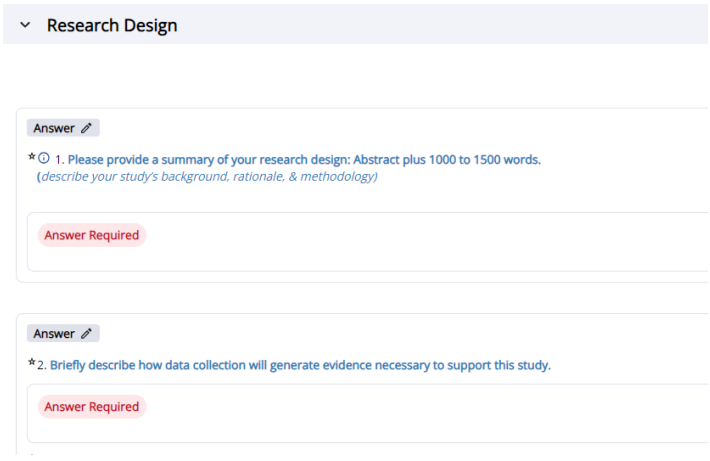
25. Next, complete the required application sections and upload your files. You do not need to complete the application all at once. If you would like a copy of your application as you are completing the sections, you can obtain one by clicking on the ***More*** button at the top of the *View Study* 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.

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



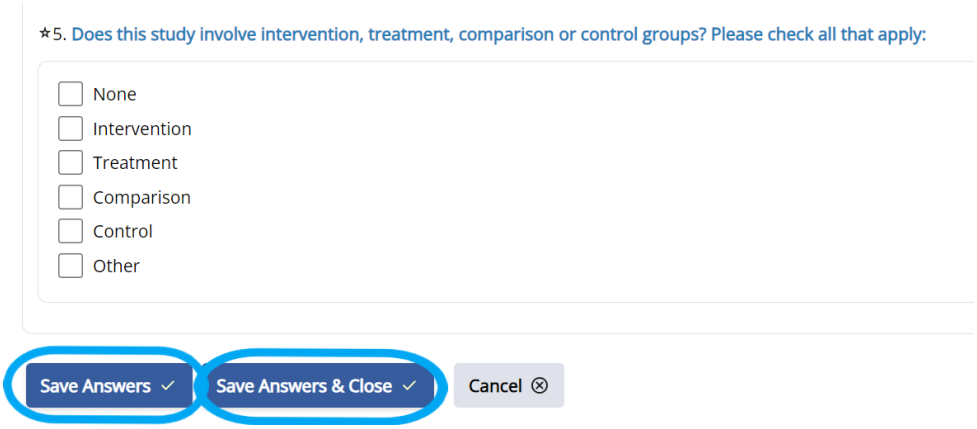
27. The application will open, and you will need to complete the questions in each section.

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

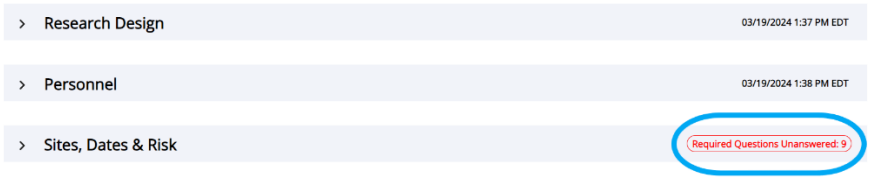


29. Click on the ***Answer*** button to answer the questions.

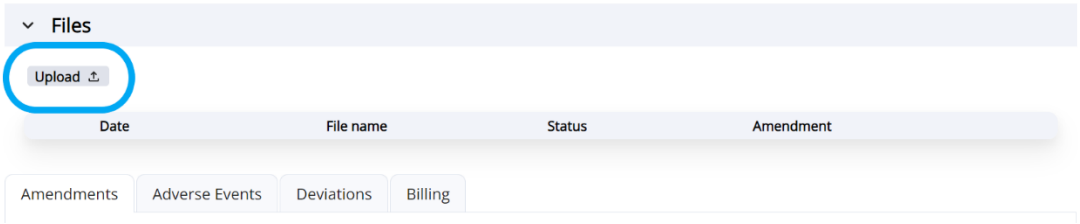
30. Click on the ***Save Answers*** button when you have answered all of the questions. Some of the questions are conditional, so your answer may prompt subsequent questions. Make sure to answer all of the questions.



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.



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. <u>At this point you will no longer be able to edit or modify the study while it is under review</u>. 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

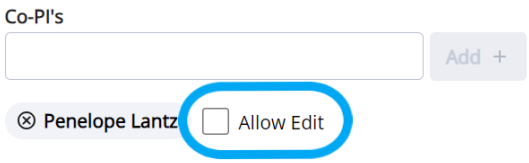
36. At any time prior to approval, you can withdraw your study from the ethical review and approval process. To do this, simply access your study in the online portal, and click on the ***Withdraw Study From Review*** button. A new screen will open asking you to confirm the withdrawal. If you click the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

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.



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*.

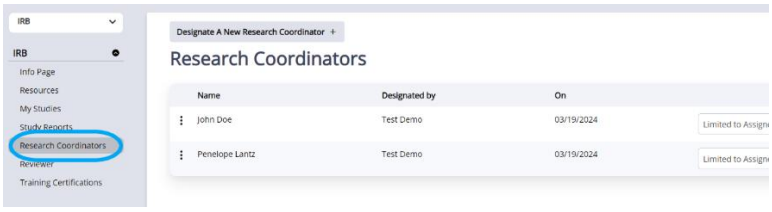
41. *Research Assistant*: A Research Assistant is a member of the study team who is integral to the project but does not require access to edit the study submission or protocols in the HML IRB Portal. These are system users who can access studies in a read only format.

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

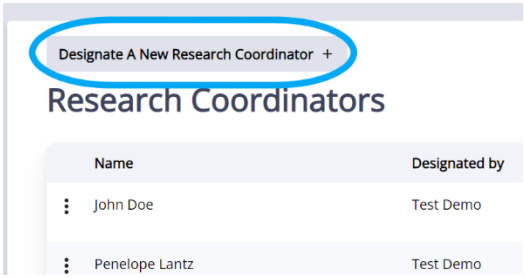
43. Each PI must designate his/her own Research Coordinators. If you have a user account, you can designate other users as your Research Coordinators or see who has designated you as their Research Coordinator. If you need to be designated as a Research Coordinator contact the PI and provide these instructions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

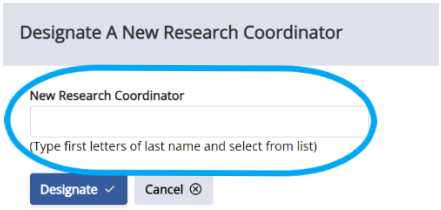


45. For Research Coordinators already associated with you, you may give them editing rights to any of your studies or limit their access to studies where they have been assigned. This is done using the drop down to the right of the person's name.

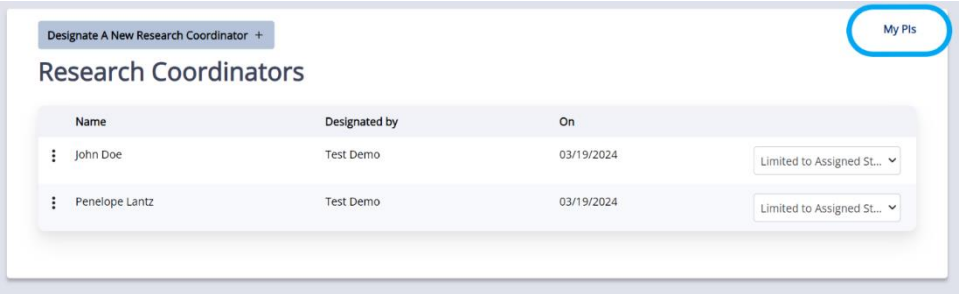
46. To add a new Research Coordinator, click on *Designate A New Research Coordinator*.



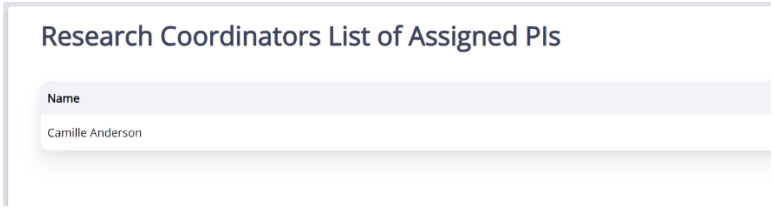
47. Begin typing the person's last name. If the individual is a user in the system, the name will appear in the drop down. Click on the name and choose Designate. If the individual does not appear, they are not yet a user in the system and you will need to have the individual create an account. Please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



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



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.

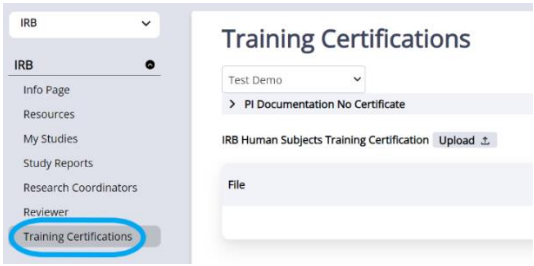


Uploading Training Certification

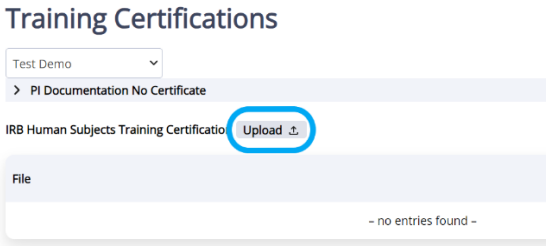
50. If you have not uploaded your training certification prior to submitting a new study, you should do it now. We previously allowed investigators and study staff to submit their certificates for ethics training or provide information about training received in the IRB application. In the new system 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.

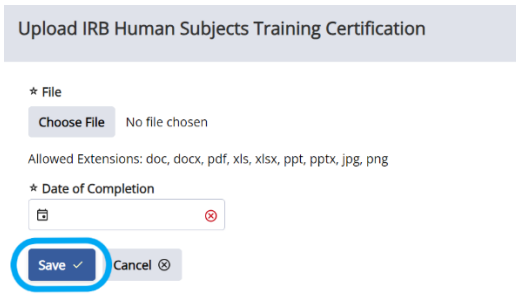
52. If you do not have a certificate of completion, please provide documentation of your training in another way. You can upload a copy of your CV or other documents that describe the training, the topics covered, the duration and date received. **Your CV must include the specifics of the training in 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.

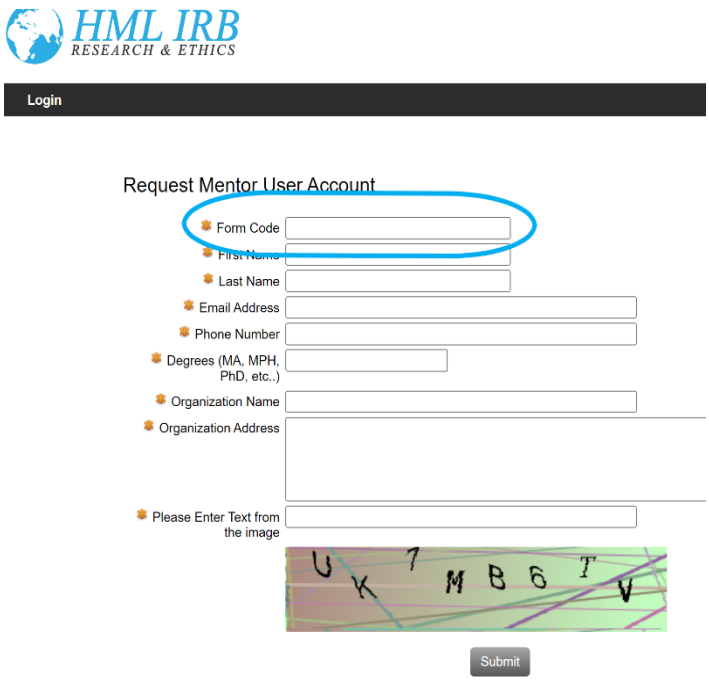


55. We will review your certifications. The system default for a certification is three years. We are aware that some of our clients receive training annually and some training certifications are active for five or more years. If we need to make any adjustments to the certification timeframe, we will.

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.



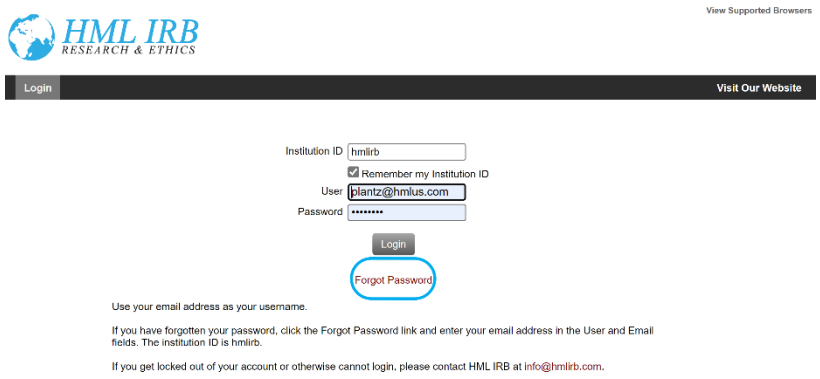
58. After you complete all fields, please click ***Submit***. After you click submit, you will receive an email at the email address you provided. It will contain a link allowing you to set a password. The link is valid for 24 hours.

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.



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.