# eProst Frequently Asked Questions

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eProst Accounts and Access to the System

1. Do I need an eProst account?
   If you are going to be involved in the conduct of human subject research at UM/JHS, if you are an ancillary reviewer, departmental/division reviewer, or IRB member, or if you require the ability to run reports from the eProst system, you must have an eProst account.

2. How do I get an eProst account?
   Go to the eProst home page (https://eprost.med.miami.edu) and complete and submit the New Account Request Form. Account requests are normally processed within one business day.

3. I requested an eProst account but I still can’t log in. What do I do?
   New account requests are normally processed within one business day, but sometimes there can be delays, especially if you are not a UM employee/student. For non-UM employees, we may need to verify your status with your employer, with Faculty Affairs, the Volunteer Office, or with International Students and Scholars.

   Contact the eProst Help Desk for assistance (eprost@med.miami.edu or 305-243-2314).

4. I am a non-UM employee and I am requesting an account. What is a C-number?
   In order to have access to the eProst system, you must have a valid C-number. A C-number consists of the letter C followed by 8 digits and is an ID number that uniquely identifies you.

   If you do not have a Cane ID or C-number, you may request one at: https://caneid.miami.edu/edu/default.aspx?action=create. Once your Cane ID is created, please make a note of your C-number, as you will be required to enter this when requesting an eProst account.

5. I have an eProst account but I can’t log in. What do I do?
   Contact the eProst Help Desk (eprost@med.miami.edu or 305-243-2314). Your account may have been disabled (we disable accounts after one year of inactivity).

6. My Cane ID/CAS account is disabled. What do I do?
   Contact the Cane ID Help Desk (305-284-6565). Your CAS account may have been disabled.

7. I requested an eProst account but I am being asked to sign a confidentiality agreement. Why do I need to do this?
   If you require access to more than just the studies for which you are listed as a study team member, the eProst Help Desk will ask you to sign a confidentiality agreement.
For all study team members

Additional instructions on using the new IRB system are available in the IRB Study Submission Guide. This user guide is available from the eProst website, under Shortcuts.

8. When will the transition to the new IRB 7 system be complete?
In order to transition to the new eProst system, we will migrate studies from the old eProst system (eprostarchive.med.miami.edu) to the new eProst system (eprost.med.miami.edu) as they move into a “stable” state – this means that the study must be (1) active and approved by the IRB; (2) have no amendments, continuing reports, or reportable events pending submission or pending review. The migration of studies will take place on a nightly basis. The transition will be complete when all of our active studies have been moved to the new system.

9. What will happen to the old eProst system?
As studies are migrated to the new system, they will be “locked down” in the old eProst system so that no new submissions can be created there.

Once the migration of active studies is complete, the old eProst system will continue to be available for the foreseeable future, but it will serve as more of an archive than an active system. We will continue using the old system for reporting purposes and for historical records, but not for ongoing administration of studies.
10. Where is my study? It's not in my Inbox.

Not all active studies have been migrated to the new system. Studies that are not yet IRB-approved, or that are IRB-approved and active but have pending amendments, continuing reports, or reportable events, have not yet been migrated – these can be found in the old system (https://eprostarchive.med.miami.edu/eprost/). Studies will be migrated once they are in a "stable" state - IRB-approved, active, and with no pending related submissions. Studies will be migrated on a nightly basis (Monday through Friday only).

To locate your studies in the NEW system:

1. Go to https://eprost.med.miami.edu/eprost/ and log in.
2. Click on the IRB link in the top left hand corner of the page.
3. Click on the Active tab (2nd tab) to find your currently active studies, or go to the In-Review tab (first tab) to find submissions that are currently in Pre-Submission or somewhere in the review process.

To locate your studies in the OLD system (eprost Archive):

1. Go to https://eprostarchive.med.miami.edu/eprost/ and log in.
2. Click on My Home.
3. Click on the Protocols tab (next to the Inbox tab). This should show you the studies still in the old eProst system, as well as those that have been migrated. You can identify the migrated studies because the state says "(Exported)" after the name of the state.

Please refer to the decision tree below to determine whether your study is still in the old eProst system (eprostarchive.med.miami.edu) or the new eProst system (eprost.med.miami.edu). Please also remember that as with the old system, your Inbox will contain only those items that are currently in progress, not items that are already approved by the IRB.
START HERE

Was study IRB-approved prior to 12/05/2013?

Was study active as of 12/05/2013?

Did study have any pending amendments, continuing reports, or reportable events as of 12/05/2013?

PENDING = in Pre-Submission or still in review

YES

NO

Study has been migrated to new eProst system (eprost.med.miami.edu)

Migration of studies from the old system to the new system will take place on a NIGHTLY basis.

YES

NO

YES

NO

Study will remain in old eProst system until it is approved by the IRB OR withdrawn and re-created/re-submitted in the new eProst system by the PI/study team.

Study will remain in old eProst system until all amendments, continuing reports, and reportable events have been approved by the IRB OR withdrawn and re-created/re-submitted in the new eProst system by the PI/study team.

ACTIVE = Must be in the Approved, Exempt Approved, Suspended, Voluntary Suspension or Protocol at External IRB states.
11. Where are my old amendments/continuing reports/reportable events?

If your study has been migrated to the new eProst system, locate your study in the new system. There will be links from the study workspace to the amendments, continuing reports, and reportable events that were submitted in the old system:

1. Log in to the new eProst system and click on the IRB link at the top of the page.

2. From the IRB page, click on the Active tab and locate your study.

3. From the study workspace, click on the Follow-on Submissions tab. You should be able to find a link to your old amendments, continuing reports and reportable events that will take you back to the old eProst system.

If your study has not yet been migrated to the new eProst system, then please locate your study in the old system (eprostarchive.med.miami.edu):

1. Log in to the old eProst system (eprostarchive.med.miami.edu) and click on the Protocols tab.
2. Locate your study.
3. From the study workspace, click on the Amendments, Continuing Reports, or Reportable Events tab.

12. I need to submit a new amendment/continuing report/reportable event (RNI) – where do I go?

*If your study has been migrated to the new system*, please submit any new Modifications, Continuing Reviews, or RNI’s in the new system.

*If your study has not yet been migrated to the new system* because there are still pending amendments, continuing reports, or reportable events going through the review process, you may EITHER (1) submit the new amendment/continuing report/reportable event in the old eProst system, OR (2) you can wait until your study is migrated to the new system and then submit it there. However, if your study is nearing its expiration date or if you have a reportable event that requires prompt reporting to the IRB, you should go ahead and submit it in the old eProst system.

13. My study was moved from the old system to the new system. My reportable events have been moved to the new system, but my amendments and continuing reports are still in the old system. Why?

Migrating all the amendments, continuing reports, and reportable events from the old eProst to the new system would have greatly increased the cost and complexity of the IRB 7 implementation and data migration. Therefore, it was decided to limit the migration effort to the studies themselves and any internal SAEs that had been submitted in the old system.
14. Why hasn’t my study been moved to the new system?
We will only migrate a study if it is active and has no pending amendments, continuing reports, or reportable events (see question 10 above). Until a study meets these criteria, we cannot move it to the new system.

Studies that were closed, administratively closed, terminated, or withdrawn prior to the launch of the new eProst system (November 15, 2013) will NOT be migrated to the new system.

15. How do I submit my COI disclosure?
The new eProst system will not be used for submission of COI disclosures. If the study for which your COI disclosure is required is in the new eProst system, you should have received an email with a link to the Disclosure Profile System (DPS). If you cannot locate the email but you know that your COI disclosure is required for a particular study, go to https://www.miami.edu/dps and log in with your Cane ID username and password. When you log in, you should be able to locate your study in the Human Subject Research Studies tab. For complete instructions, please refer to the Help pages for the Disclosure Profile System (http://uresearch.miami.edu/?p=397).

16. How do I locate my Inbox?
Once you have logged in to eProst, you will either automatically be redirected to your Inbox page, or you can go to your inbox by clicking on the My Inbox link in the upper right hand corner of the screen. If you have studies in both the old and new systems, you should check both inboxes to make sure there is nothing pending for you.

17. There are a bunch of items in my Inbox. Do I need to do anything with them?
The Inbox contains all of the submissions that are pending some action by you or by another member of your study team (usually this would be the PI, Primary Contact, or PI Proxy).

18. What is the IRB Library?
The IRB Library is a collection of templates, SOPs, checklists, and worksheets used in the IRB submission/review process. These documents will be updated periodically, but the latest versions will always be available in the IRB Library.

19. What is the Investigator Manual?
The Investigator Manual is a document outlining the responsibilities of investigators/study teams conducting human subject research at the University of Miami. This document will be updated periodically, but the latest version will always be available in the IRB Library.

20. Where can I find copies of the new IRB Policies and Procedures?
IRB Policies and Procedures and the Investigator Manual can be found in the IRB Library on the eProst website (eprost.med.miami.edu). These documents will be updated periodically, but the latest versions will always be available in the IRB Library.
21. What is the status of my IRB submission?
Look for your submission in either your Inbox or the In-Review tab (IRB > In-Review). Open the submission and look at the current state in the orange box in the upper left hand corner of the screen. You can also refer to the graphic on your submission’s workspace. The stage that is highlighted in dark blue will indicate where your submission is in the review process. See example below:

![Diagram showing submission process]

22. My submission is in the Clarification Requested or Modifications Required state. What does this mean? Do I need to do anything?
If a submission is in the Clarifications Requested (Pre-Review), Clarification Requested (Committee Review), Clarification Requested (Designated Review), Clarifications Requested (RNI Review) Modifications Required, or Deferred state, this means that the HRSO or IRB has requested clarifications or changes. The Study Team must make the requested changes or answer the HSRO's/IRB's questions, and then execute the Submit Changes activity to send the submission back to the HSRO/IRB for review.

23. Whom can I contact at the HSRO about my submission?
Once your study/modification/continuing review/RNI has been submitted for review, it will be assigned to an IRB coordinator who will do the initial pre-review and help you prepare it for IRB review. The IRB coordinator assigned to your submission is listed in the submission’s workspace below the name of the PI, submission type, and name of the Primary Contact.

24. Where can I find the approval letter for my study/amendment/continuing report/reportable event?
If the study/amendment/continuing report/reportable event was submitted in the old eProst system, the determination letter can be found in the submission’s workspace on the eprostarchive.med.miami.edu site.

If the study/modification/continuing review/RNI was submitted in the new eProst system, the determination letter can be found in the submission’s workspace on the eprost.med.miami.edu site.

25. What is a Modification?
A Modification is equivalent to an Amendment in the old eProst system.

26. How many Modifications can I have pending IRB review at one time?
The new eProst system allows up to two modifications to be open/pending IRB review at one time. There are two types of Modifications: one for study team changes only and one for changes to any other aspect of the study. You may have no more than one modification at a
time affecting each of these two areas, or you may have just one modification if that modification affects both.

27. Where is the Change Log?
There is no longer a Change Log. It has been replaced by the View Differences feature. This feature lets you compare the current version of a submission with previous versions of the same submission, and highlights all changes. Items deleted/removed will be red-lined and items added will be highlighted in green. For instructions, please refer to the IRB Study Submission Guide available from the new eProst site.

28. What is the difference between Discard and Withdraw?
Discard a submission if you no longer intend to submit it for review. It will be moved to the Archived tab (IRB link at top of page > Archived tab).

Withdraw a submission if you want to remove it from the IRB review process, but intend to re-submit it to the IRB at a later date.

29. Why don’t I get an email notification when someone adds a comment in eProst?
In IRB 7, the system does not send an email notification to the study team or to the HSRO when the Add Comment activity is executed. These comments are visible only in the submission’s workspace.

When communicating with the HSRO while your submission is in review, we recommend that you use the Submit Changes activity to send questions/comments to the IRB coordinator, whenever this activity is available to you. This ensures that your comment is sent to the IRB coordinator via email.

30. Why are CRS staff listed as part of my study team?
If your study is being managed by CRS (the box for CRS services is checked in question 8a of your Study SmartForm), the CRS staff members will automatically be added to your study team roster whenever the submission becomes editable (in pre-submission or when the submission is returned to you by the HSRO for changes). This gives them the ability to make revisions on your behalf.

The CRS staff will automatically be removed from your study team roster when the submission becomes non-editable (when you submit it for review or when changes are submitted back to the HSRO for their review).

When your submission is approved by the IRB, the CRS staff will remain on your guest list, as long as your study is being managed by CRS.

31. What is committee review/non-committee review?
Committee review refers to an IRB review in which a submission is reviewed by the full board. Non-committee review refers to the IRB review conducted by a single IRB member, as opposed
to review by the full board. Submissions that can be approved under an expedited or exempt approval category will go through non-committee review.

32. What types of documents are watermarked by the HSRO/IRB?
Only consent forms, recruitment materials, HIPAA forms, data collection sheets, press releases and IRB determination letters will be watermarked.

33. I need to revise my study’s consent form. Where do I find a draft copy of the latest version?
All of your study documents can be found in the Documents tab of your study workspace. Locate the document you wish to revised, then right-click on the Draft version and save it to your computer. When you are finished with your revisions, upload the revised document in the appropriate section of the SmartForm.

34. I need to find a previous version of my consent form. Where do I look?
All of your study documents can be found in the Documents tab of your study workspace. Locate the document you wish to revised, then right-click on the History link for that document. This will give you links to all previous versions of the document.

35. What do you mean by “external sites”? Does this include Jackson Health Systems?
“External Sites” refers to sites where the PI is responsible for the research and would not ordinarily have privileges to conduct research. This includes research the PI conducts personally or oversees. Examples of external sites might include a local elementary school, shopping mall, nursing home, or private physician’s office.

For UM investigators, Jackson Health Systems would not be considered an external site, but you would need to include Jackson Health Systems as a research location on the Additional Study Information page of the Study SmartForm.

36. How can I get help or training for the new eProst system?
Contact the HSRO (305-243-3195) for information regarding training for eProst and human subject research. Online help is also available – look for the 💻 icons throughout the system. User guides geared toward different user groups are available from the IRB Library and from the Shortcuts links on your Inbox page. You may also contact the eProst Help Desk for technical issues related to eProst (305-243-2314 or eprost@med.miami.edu) or the HSRO (305-243-3195) for regulatory questions or non-technical questions.

37. I created a new study and the system made me the Principal Investigator but I am the study coordinator. Why is this happening?
By default, the system will set the Principal Investigator to the person who created the study. If you are not the Principal Investigator, just select the correct PI in question 4 of the Study SmartForm.
38. I am trying to submit a Continuing Review. Why am I being asked for enrollment and # charts reviewed for my UMH/JHS sites?
If your study involves either UMH and/or Jackson Health Systems sites, you will be asked to enter the number of subjects enrolled and/or the number of charts/records reviewed at UMH and JHS at the time of continuing review. To enter these numbers, look for the Update UMH and JHS Enrollment and Records Reviewed activity under My Current Actions, in the Continuing Review workspace. This information is required by the JHS Clinical Trials Office and the UMH CRRC Office.

39. Who can edit submissions in the new eProst system?
- Anyone listed on the study team may edit a submission.
- Help Desk staff in Research IT may also edit submissions.
- The CRS regulatory team can also edit submissions for studies managed by Clinical Research Services at the Sylvester Cancer Center.
- HSRO staff members no longer have the ability to edit submissions on your behalf.

40. Where do I create my Modification/Continuing Review/RNI?
Go to the study workspace. To create a Modification and/or Continuing Review, click the Create Modification/CR button. To create an RNI, click the Report New Information button.

41. How do I submit a final report to close my study?
Submit a Continuing Review. Depending on the answers to the questions in the Continuing Review form, your study will either be renewed or closed.

If your study is under the purview of an External IRB, you will not be required to submit a final report in the new eProst system. Look for the Update External IRB Status activity under My Current Actions. Select YES for the “Has the external IRB closed the study?” question. When you submit this form, your study will automatically be closed.

42. What is a follow-on submission?
“Follow-on submission” refers to modifications, continuing reviews, and reportable new information (RNIs). The follow-on submissions for your study can be found in the Follow-on Submissions tab in your study’s workspace.

43. I need to add someone to my study team but cannot find them in the system. What do I do?
Ask the person to request an eProst account. See question #2 above for instructions.

44. In the Funding Sources page of the study SmartForm, I cannot find the name of the company/organization/agency providing funding for my study. What do I do?
Notify the Research IT/eProst Help Desk (eprost@med.miami.edu or 305-243-2314). We will need the full name of the company/organization/agency. If the entity already exists in the system, we will let you know how to find it in the Funding Sources selection list. If the entity does not exist in the system, it will be added within 1 business day.
45. Why am I being asked to complete the Update Billing Information activity? What am I being billed for?
The Update Billing Information activity is required for all industry-funded studies. For each industry-funded study, the HSRO needs a valid account number in order to charge HSRO/IRB review fees and RCQA compliance fees. Please refer to the University Fees page of the HSRO website for further details.

46. I have a sponsor protocol for my study. Do I need to fill out the protocol template and upload my protocol in the Study SmartForm?
No – if you have a sponsor protocol, you do not need to complete the Word version of the protocol template. However, you may be required to complete a site-specific supplemental form giving further information to the IRB.

47. My study is investigator-initiated, so I don’t have a sponsor protocol. What do I need to do?
Download a copy of the protocol template from the eProst website (IRB > IRB Library > Templates). There are two versions of the protocol template – one with instructions and one without. The template is a Word document.

The HSRO will be developing other versions of this protocol template, specifically designed for chart review/minimal risk studies, and other types of research. As these templates become available they will be posted on the HSRO website.

48. Where can I get a consent form template?
Sample consent forms (regular and short form) can be found in the IRB Library (IRB > IRB Library > Templates).

49. Where can I find the IRB-approved, watermarked documents for my study?
From the Study workspace, go to the Documents tab. This tab lists all documents related to the study. The versions uploaded by the study team can be found under the Draft column. The IRB-approved/watermarked versions can be found under the Final column.

Please note that not all documents will be watermarked – only consent forms, HIPAA forms, and other patient/subject-facing materials will be finalized or watermarked by the HSRO staff.

Drug and Device Studies

50. In the Drugs page of the study SmartForm, I cannot find the generic or brand name of my study drug. What do I do?
Notify the Research IT/eProst Help Desk (eprost@med.miami.edu or 305-243-2314). We will need the drug’s brand name and generic name, if available. If the drug already exists in the system, we will let you know how to find it in the Drugs selection list. If the drug does not exist in the system, it will be added within 1 business day.
51. In the Devices page of the study SmartForm, I cannot find the name of my study device. What do I do?

Notify the Research IT/eProst Help Desk (eprost@med.miami.edu or 305-243-2314). We will need the device’s brand name, if available. If the device already exists in the system, we will let you know how to find it in the Devices selection list. If the device does not exist in the system, it will be added within 1 business day.

52. My study has an IND or IDE. How do I know who holds the IND/IDE?

Refer to the IND/IDE letter from the FDA. The FDA’s acknowledgement letter will be addressed to the IND/IDE holder.

53. My study has an IND or IDE held by another UM investigator. What do I select for the “who holds the IND/IDE” question?

- If the IND is held by the PI for this study OR any other UM investigator/faculty member, select Investigator
- If the IND is held by the drug manufacturer or study's sponsor (not a UM investigator), select Sponsor
- If the IND is held by a non-UM investigator, select Other and enter the name of the IND holder in the "If other, identify the IND Holder" box

Reportable New Information

54. What is an RNI?

RNI stands for Reportable New Information. This type of submission is similar to the Reportable Event/Notification submissions in the old eProst system.

55. How do I submit a follow-up Internal SAE?

(The following assumes that your study has been migrated to the new eProst system) From the Study workspace, locate the initial Internal SAE RNI in your Follow-on Submissions tab. Open the RNI and click on the Create Follow-on RNI activity under My Current Actions. By doing so, the follow-up RNI will automatically be associated with the initial RNI.

56. How do I submit an external SAE or IND Safety Report?

These do not require IRB review, so you do not need to submit them in the new eProst system.

57. How do I submit an internal SAE/Deviation/Unanticipated Problem?

Submit these types of reportable events as RNI’s, with the applicable categories selected in question 3 of the RNI form.
58. How do I submit an exception?
Submit study exceptions as Modifications. They are not to be submitted as RNI’s.

59. How do I submit an executed clinical trials agreement or Form 1572?
These are no longer required by the IRB.

External IRB studies

60. My study is at an external IRB. How do I update my study team members/funding sources/drug/device/performance sites/etc.?
Look for the Update Study Information activity under My Current Actions. This activity allows you to update your study team members, funding sources, drugs, devices, IND/IDE information, and performance sites. This activity also asks several questions related to ancillary committee reviews – these questions are used to determine which ancillary reviews are applicable to your study.

61. How do I update the expiration date for my study?
Look for the Update External IRB Status activity under My Current Actions. This activity allows you to upload the approval letter from the external IRB, enter the approval and expiration dates, and upload supporting documents.

62. How do I close my External IRB study?
Look for the Update External IRB Status activity under My Current Actions. Select YES for the “Has the external IRB closed the study?” question. When you submit this form, your study will automatically be closed.

63. How do I update the consent forms for my External IRB study?
Look for the Update Study Information activity under My Current Actions. Upload the approved consent forms which have been watermarked by the External IRB for your study, and click OK.

64. How do I update the study team members for my External IRB study?
Look for the Update Study Information activity under My Current Actions. Add/remove study team members as needed, and click OK.

65. I have uploaded a supplemental form required by one of the ancillaries reviewing my study in the External IRB page of the SmartForm. Why am I still getting an error saying that I need to upload this form?
The supporting documents section of the SmartForm is intended for documents related to your study’s review by the External IRB, as opposed to the ancillary committee reviews. Please upload the supplemental forms required by your ancillary committee reviewers via the Update Study Information activity.
66. Do I need to submit a Modification or Continuing Review for my External IRB study?
No. You must report changes to your study and submit continuing reviews to the External IRB. However, to ensure accuracy of the data in eProst, you should use the Update Study Information activity to refresh your study information as the changes are approved by the External IRB, and you should update your study’s expiration date as soon as a continuing report is approved by your study’s External IRB.

For Principal Investigators

Additional instructions on using the new IRB system are available in the IRB Study Submission Guide. This user guide is available from the eProst website, under Shortcuts.

67. How do I submit a new study?
As of November 15, 2013, all new studies must be submitted via the new eProst system. Log into the eProst system, and go to your Inbox. On the Inbox page, look for the button labeled Create New Study. Click on this button and complete all required questions in the SmartForm. Once the form is complete, click on the Submit button under My Current Actions. The system will check for errors – if any errors are found, they must be resolved before you will be allowed to submit the study. If no errors are found, your study will be submitted for review and will automatically be routed to your department approvers, applicable ancillary committees, and the HSRO.

68. What is a PI Proxy?
A PI Proxy is a person designated by the PI of a study to perform certain functions on behalf of the PI, such as submitting a study/follow-on submission or submitting changes. Only UM faculty who are members of the study team can be designated as a PI Proxy.

69. I am the PI for a study, but I will be out of the country/on leave for X months. What do I need to do?
Go to the study workspace and look for the Assign PI Proxy activity under My Current Actions. Select a UM faculty member who is on the study team to serve as your proxy during your absence.

70. What is a Primary Contact and who should I select as Primary Contact(s)?
The Primary Contact is the person who will be copied on all email notifications sent to you by the eProst system. You may designate one person as your Primary Contact. The Primary Contact does not necessarily need to be a member of the study team.
By default, the person who creates a submission is set as the Primary Contact, but as the PI, you have the ability to change the Primary Contact at any time by executing the **Assign Primary Contact** activity under My Current Actions. This can be done for any type of submission (study, modification, continuing review, RNI).

71. **What is the Guest List?**
The Guest List is a list of the individuals who have read access to your study/submission. By default, this will include all study team members and departmental/ancillary reviewers whose review is required. To view the Guest List for your study, you may go to the Project Contacts tab in your submission’s workspace, or you can click on the Manage Guest List activity.

For studies managed by Clinical Research Services at the Sylvester Cancer Center, the Guest List will also include CRS staff members.

72. **I would like to give read-only access to my study to someone from outside my study team. How can I do this?**
Go to the study workspace and execute the **Manage Guest List** activity. You may add anyone with an eProst account to your guest list.

73. **My study received multi-year approval. How do I submit my annual affirmation?**
Annual affirmations are no longer required. However, if the study protocol and/or study risk have changed, you must report the changes to the IRB via a Modification. If any serious adverse events have occurred, these must be reported to the IRB via an RNI submission.

**Ancillary Reviews**

74. **How can I tell which ancillary reviews are pending for my submission?**
Go to the submission’s workspace and click on the Reviews tab. This tab will list all applicable ancillary reviews for your submission.

A “yes” in the **Response Required** column indicates that the review is required. A “yes” in the **Accepted** column indicates that the review has been completed and the ancillary committee has granted their approval. A “no” in the **Accepted** column indicates that some further action is required before the ancillary committee can grant their approval.

75. **I am getting error messages saying I need to upload a certain form for an ancillary committee. Where do I find the forms?**
All ancillary committee supplemental forms can be found on the HSRO website (http://hsro.miami.edu).
76. Why does my study require review by the _______ ancillary committee?

The system will automatically determine which ancillary committee reviews are required, based on the answers to questions in the Additional Study Information and Clinical Research Only pages of the Study SmartForm.

<table>
<thead>
<tr>
<th>If your study involves.....</th>
<th>...review by this committee is required</th>
</tr>
</thead>
<tbody>
<tr>
<td>Facilities and/or support from the Clinical Research Center (CRC)</td>
<td>Clinical Research Center (CRC)</td>
</tr>
<tr>
<td>Study-related activities at Jackson Health Systems sites</td>
<td>Jackson Health Systems CRRC</td>
</tr>
<tr>
<td>Study-related activities at UMH</td>
<td>University of Miami Hospital (UMH)</td>
</tr>
<tr>
<td>Cancer patients, diagnosis, or therapy</td>
<td>Cancer Protocol Review Committee (PRC)</td>
</tr>
<tr>
<td>Use of CRS or the Sylvester Cancer Center’s DSMC</td>
<td>Cancer Protocol Review Committee (PRC)</td>
</tr>
<tr>
<td>Patient specimen collection at any UM patient care facility, archived tissues or slides, Department of Pathology expertise/facilities</td>
<td>Pathology Protocol Review Committee</td>
</tr>
<tr>
<td>Biological agents, Biosafety Level 2 or higher</td>
<td>Environmental Health &amp; Safety (EHS)</td>
</tr>
<tr>
<td>Radioactive materials, radioisotopes, and/or radiation-producing equipment</td>
<td>Human Use Radiation Safety Committee</td>
</tr>
<tr>
<td>Recombinant DNS and/or gene transfer</td>
<td>Institutional Biosafety Committee (IBC)</td>
</tr>
<tr>
<td>Human embryonic stem cells and/or their derivatives</td>
<td>ESCRO</td>
</tr>
<tr>
<td>An investigator-held IND or IDE</td>
<td>Clinical Research Operations and Regulatory Support Quality Control (CRORS QC)</td>
</tr>
<tr>
<td>PI on a clinical research study who has never served as PI on clinical research before</td>
<td>Clinical Research Operations and Regulatory Support (CRORS)</td>
</tr>
<tr>
<td>PI on an IND/IDE study who has never served as PI on an IND/IDE study before</td>
<td>Clinical Research Operations and Regulatory Support (CRORS)</td>
</tr>
<tr>
<td>PI or study team member who may have a financial conflict of interest for the study</td>
<td>Conflict of Interest Committee (COIC)</td>
</tr>
</tbody>
</table>

77. My study requires review by the ___ ancillary committee. Can’t I just add the committee using the Manage Ancillary Reviews activity?

Yes, both the study team and HSRO staff are able to add ancillary committees via the Manage Ancillary Reviews activity, but you run the risk of the system removing the committee as the Study SmartForm is updated. We strongly recommend that you avoid using the Manage Ancillary Reviews activity. It is best to make sure the Study SmartForm correctly identifies the characteristics of your study and the ancillary reviews required.

78. My study doesn’t require review by the ___ ancillary committee. Can’t I just remove the committee using the Manage Ancillary Reviews activity?

Yes, both the study team and HSRO staff are able to remove ancillary committees via the Manage Ancillary Reviews activity, but you run the risk of the system adding it back again the next time the Study SmartForm is updated. We strongly recommend that you avoid using the Manage Ancillary Reviews activity. It is best to make sure the Study SmartForm correctly identifies the characteristics of your study and the ancillary reviews required.
For Department/Ancillary Reviewers

**Additional instructions on using the new IRB system are available in the IRB Ancillary Reviewer’s Guide.  
This user guide is available from the eProst website, under Shortcuts.**

79. I am a department/ancillary reviewer. How do I find the submissions I need to review? 
To access the studies/submissions requiring your review, click on My Inbox in the upper right hand corner of the screen.

80. I am a department/ancillary reviewer. Why are my own studies mixed in with the ones I need to review?
If your own submissions are mixed with the ones requiring your ancillary review, contact the eProst Help Desk and ask for your personal page template to be updated. We have a special personal page template for people who are both PI’s/study team members and ancillary reviewers. This template gives you two separate inboxes – one for the items for your own studies and the other for the items requiring your review.

81. I am a department/ancillary reviewer. How do I send a submission back to the study team for changes?
Ancillary reviewers cannot send a submission back to the study team for changes. Instead, please use the Submit Ancillary Review activity to add your comments/questions/requested changes. The HSRO staff member responsible for the submission will take care of sending the submission back to the study team for changes.

82. I am a department/ancillary reviewer. How do I send a message to the study team?
You may either use the Add Comment activity or you may send a message via the Submit Ancillary Review activity. Please note that the system will not send an email notification when Add Comment activity is executed.

83. I am a department/ancillary reviewer. How do I submit a review?
Open the submission and look for the Submit Ancillary Review activity under My Current Actions. This activity lets you submit your decision, add comments, and attach documents.

84. I am a department/ancillary reviewer. How do I change a review I have already submitted?
Open the submission and look for the Submit Ancillary Review activity under My Current Actions. This activity will let you update your decision, add comments, and attach documents.

85. Why am I getting emails telling me that something is pending my ancillary review? I’m not an ancillary reviewer. Is there something I need to do?
You are listed as a “reviewer” for an organization/committee – if you are an administrator for a department or division and need access to all of the submissions for PI’s in your department/division, the only way for us to provide that access is to make you a “reviewer.”
However, it is up to the departments/divisions to determine whose review is required. For most departments it will be the department chair’s approval that is required, and for divisions it may be the division chief’s approval that is required.

If your review is not actually required, you can disregard these emails. The email notifications cannot be turned off. However, if you would like to automatically move these emails to your Trash folder in Outlook or some other folder, refer to http://office.microsoft.com/en-us/outlook-help/manage-email-messages-by-using-rules-HA010355682.aspx for instructions on creating a rule in Outlook.

Reports

86. Why doesn’t my report include all of the submissions for my school/department/division/center?
Reports will only display the studies/submissions for which you have access. If you require a report listing more than the studies for which you have access, please contact the HSRO for assistance (305-243-3195).

87. When I run a report from the new IRB system, why can I sort on some columns but not others?
This can be due to the structure of the data. If you export the report to Excel, you should be able to sort on any column from within Excel.

88. How can I export a report from the eProst system into Excel?
Run the report, then click on the Export button. The system will export the data as a .csv file, which you can then save to your computer.
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