

1. **Who is required to be “Shared” on a project?** Maine Medical Center’s Compliance Office is requiring that a minimum of **-2-** Users be named on any project; one of the users **MUST** be the PI. A typical representation of this would be:

- PI and a CRC, or
- PI and a Sub-Investigator, or
- PI and a Mentor
- Research Navigator, if involved with proposal development

2. **I completed a CITI refresher course - but I keep getting Expiration Alerts. Why?** This is happening because there are overlapping dates for training topics. You may prevent further Expiration Alerts by modifying the expiration date of your prior training. You may accomplish this by taking the following steps:

- Select User Profile after login to IRBNet
- Select the Edit icon for the **Expired** Training
- Change the date in the Expiration field to the date that precedes the Refresher or updated/current training

3. **What are the expectations regarding “Training and Credentials” in IRBNet?** Training documents should be managed and maintained within IRBNet.

- Individual Users must upload their own CV’s, licensure, and/or other training documents in their User Profile within IRBNet. Once this step is completed, any User who compiles submissions on behalf of others (such as a CRC on behalf of a PI) are able to link the Credentials of those Users who have been “Shared” on a project
- MMCRI’s Compliance Office **requires** that Training and Credentials are linked to any Initial Submission/Project. Unless there are changes, attached credentials are not required for subsequent submissions on a given project.
- Transclerate training certificates documenting GCP training are **required** to be uploaded for Users who do not have current GCP training through CITI program.

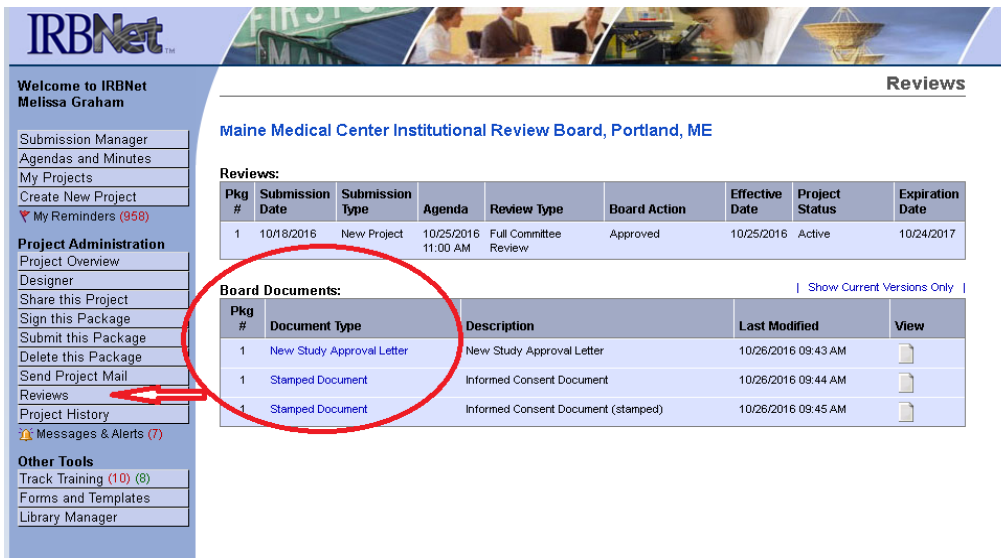
4. **Who is required to sign submissions within IRBNet?**

- PI signature is required for ALL package submissions (study team members who are shared on a project may sign a package for urgent situations – please provide the IRB staff with the reason that the PI is unable to sign at the time of submission; with approval, the PI may sign at a later date)
- A Department Chief or Practice Administrator signature is required for any, and all, departments participating in New Projects or Protocol Amendments
- Department Chiefs are required to sign Exempt applications
- Mentor signatures are required for Exempt project applications (when applicable)

5. **How do I sign a package or document in IRBNet?**

- Depending on the type of document you are submitting, either a handwritten signature or an electronic signature through IRBNet must be provided.
- Submissions that are not signed will not be reviewed.

6. Where do I find my IRB approval Letter and Board approved documents (e.g., ICF, Protocol, Patient recruitment Materials)? Click the Project Title; Click the Reviews tab (arrow below); approved documents can be found under **“Board Documents:”** as shown in red circle below:



IRBNet

Welcome to IRBNet
Melissa Graham

Submission Manager
Agendas and Minutes
My Projects
Create New Project
My Reminders (959)

Project Administration
Project Overview
Designer
Share this Project
Sign this Package
Submit this Package
Delete this Package
Send Project Mail
Reviews
Project History
Messages & Alerts (7)

Other Tools
Track Training (10) (8)
Forms and Templates
Library Manager




Reviews

Maine Medical Center Institutional Review Board, Portland, ME

Reviews:

Pkg #	Submission Date	Submission Type	Agenda	Review Type	Board Action	Effective Date	Project Status	Expiration Date
1	10/18/2016	New Project	10/25/2016 11:00 AM	Full Committee Review	Approved	10/25/2016	Active	10/24/2017

Board Documents: | Show Current Versions Only |

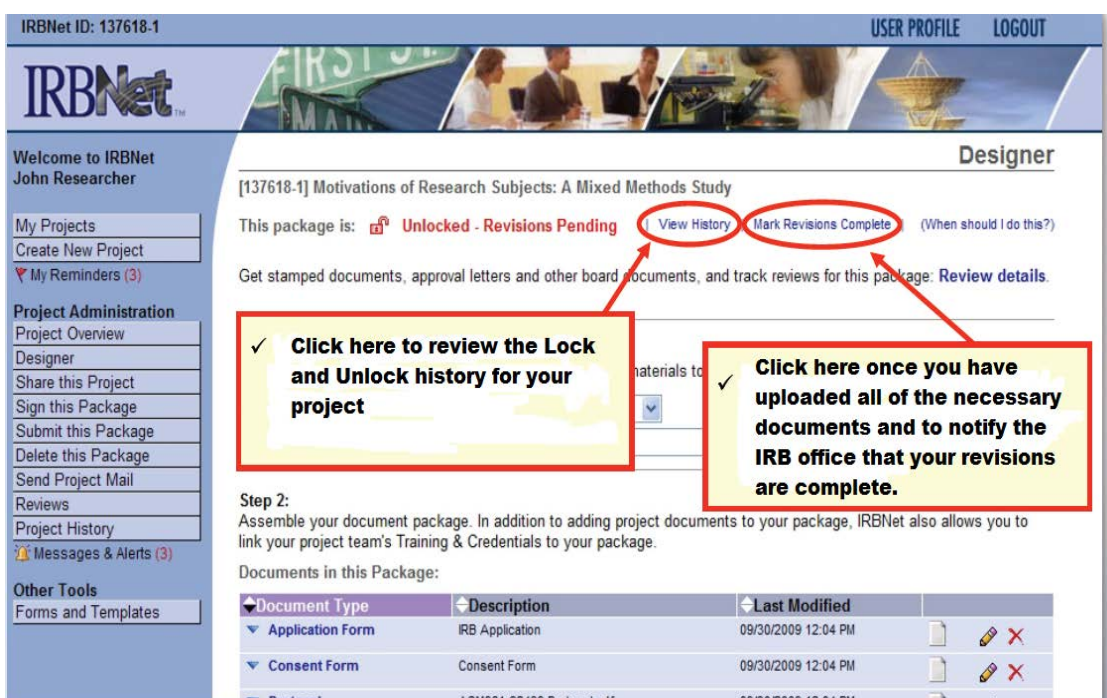
Pkg #	Document Type	Description	Last Modified	View
1	New Study Approval Letter	New Study Approval Letter	10/26/2016 09:43 AM	
1	Stamped Document	Informed Consent Document	10/26/2016 09:44 AM	
1	Stamped Document	Informed Consent Document (stamped)	10/26/2016 09:45 AM	

7. What documents should be included with an initial review submission? The list of documents will vary based on the type of project and specific protocol requirements. Please submit the following documents, with the appropriate application, as applicable:

- Protocol
- Informed Consent Form (ICF)
- Assent
- Consent/Assent Script
- Investigational Brochure (IB)
- Questionnaires
- Patient Recruitment Materials
- Data Set
- Internal Services Form
- Departmental Review Form
- Materials Management Form
- External/Outside IRB approval(s)
- Human Subject Research Protections section of approved Grant
- Scientific Review Committee Review
- FDA IND/IDE Approval Letters
- Other relevant documentation or justifications

8. How do I add documents to a package AFTER it has been submitted? First, DO NOT CREATE A NEW *PROJECT*.

- If your package was ‘submitted’, in IRBNet, and NOT yet reviewed by the review board, you will need to contact the IRB office (by Project Mail or mmcirb@mmc.org) and request that they “Unlock” the *package* to allow you to add new documents. You will then be able to upload any forgotten or accidentally missed documents. Once all documents have been uploaded, you may “Mark Revisions Complete” to proceed with the submission process.



- If your package was reviewed by the IRB and they have requested additional documents, you may add them by creating a new package, within your Project, using “Response/Follow Up” as the submission type.

9. How do I obtain more information about how to use IRBNet?

- Review the information and follow the steps provided on the MMCRI website by clicking [HERE](#).
- Contact the staff in the Research Compliance office for training:
 - mmcirb@mmc.org

10. How do I know what information is required to complete my wizard?

- Start the appropriate wizard for your submission, completing only the pages up to (and including) submission type.
- Select “Preview” and save the PDF to your desktop. You can now open the PDF to review all required elements. Sections that are not applicable will be checked “N/A” in the blue headers.
- At any time you can return to your package to complete the wizard.
- To open and edit a wizard that is in progress, select the pencil icon and continue form completion.

11. Can different wizards be submitted in the same package?

- You can submit more than **one wizard in a package ONLY if they are same submission type** (e.g. Multiple SAEs, protocol deviations, amendments).
- **Only one TYPE of submission can be included in any package.** Examples of submission types are: progress reports, amendments, new information.