Maine Medical Center
MaineHealth

IRBNet FAQs

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

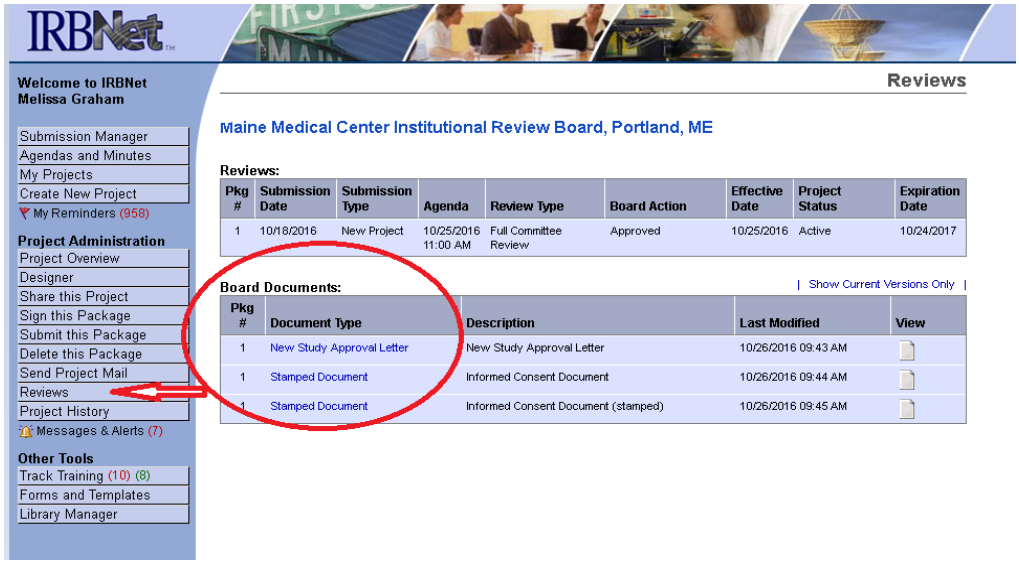
2. **I completed a CITI refresher course - but I keep getting Expiration Alerts. Why?** This is happening because there are overlapping dates for training topics. You may prevent further Expiration Alerts by modifying the expiration date of your prior training. You may accomplish this by taking the following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

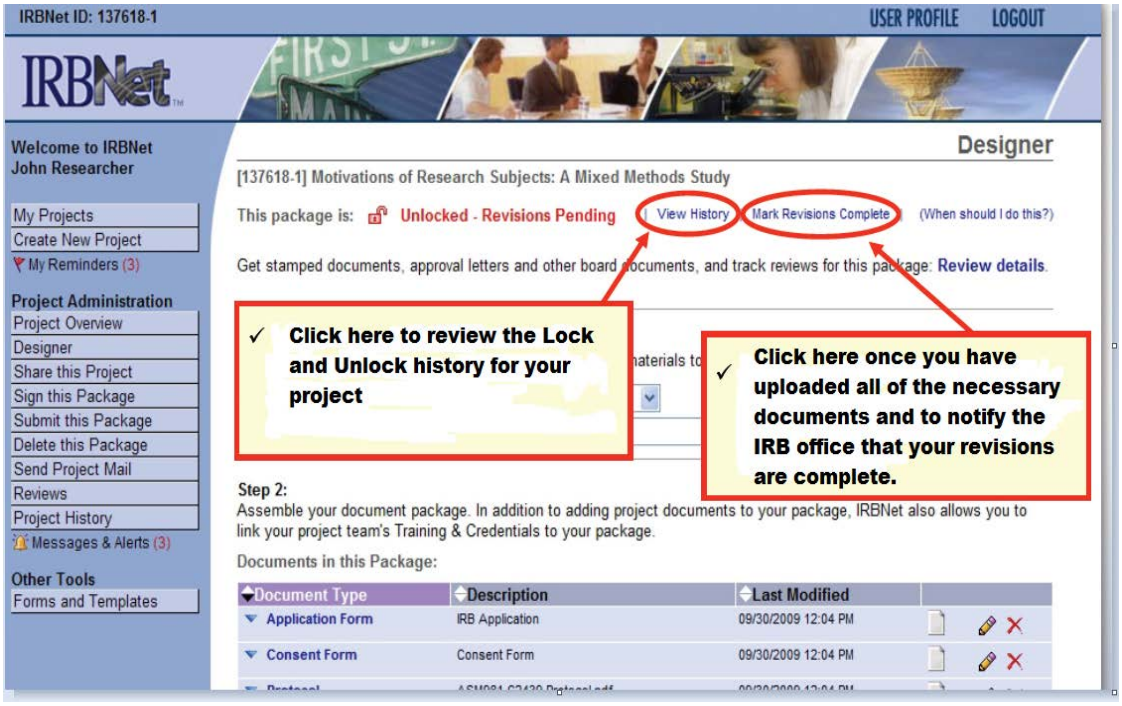


7. What documents should be included with an initial review submission? The list of documents will vary based on the type of project and specific protocol requirements. Please submit the following documents, with the appropriate application, as applicable:

- 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 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.
- If you plan to revise previously submitted documents for review, please see **Post Submission Training Energizer – Step 5 -** "Revise or Submit a Previously Submitted Documents for Review" (http://mmcri.org/ns/?page_id=15716).

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