IRBNet Submission Instructions

The purpose of this document is to provide IRBNet submission instructions for UNM researchers using IRBNet. Please contact the Office of the IRB for assistance:

irb.unm.edu | 505.277.2644 | IRBMainCampus@unm.edu

All submissions made to the UNM IRB are submitted through IRBNet. Should you need additional assistance with using IRBNet, OIRB offers workshops and consults. Please see the OIRB website for more information. For a smooth IRB review process, please also use the IRB Submission Checklist to ensure that all required documents are submitted.

<table>
<thead>
<tr>
<th>Instructions for:</th>
<th>Description</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>IRBNet New User Registration &amp; Profile</td>
<td>Create your IRBNet Account using your UNM e-mail address <a href="mailto:UNMNetID@unm.edu">UNMNetID@unm.edu</a></td>
<td>2</td>
</tr>
<tr>
<td>First IRBNet Submission</td>
<td>How to submit your first IRBNet submission for a brand new project or currently approved project</td>
<td>5</td>
</tr>
<tr>
<td>Responding to an ‘Unlocked’ IRBNet Submission Package</td>
<td>How to respond to an ‘unlocked’ package that requires clarifications as requested by the OIRB</td>
<td>12</td>
</tr>
<tr>
<td>Creating a new package for a ‘Locked’ IRBNet Project</td>
<td>How to create a new package for a ‘locked’ project that is either approved or requires a response to the IRB’s modification request</td>
<td>15</td>
</tr>
</tbody>
</table>
IRBNet New User Registration & Profile

All UNM Main and Branch Campus Investigators that need to submit an IRB application must create an IRBNet Account in order to utilize the system. IRBNet does not interface with the UNM Account System.

Instructions to complete new user registration:

1. Go to www.irbnet.org and click on the New User Registration link (upper-right of screen).

2. Follow the on-screen instructions to create a new user account and click on the Continue button.
   - In the ‘Username’ text field, enter your preferred username.
   - In the ‘Password’ text field, enter a password that is 8 characters long. You may choose to use your UNM password.

3. Read the “IRBNet: Individual User Terms of Use” and click on the Accept button.
4. Follow the on-screen instructions to add your affiliation with UNM and click on the **Continue** button.
   a. In the ‘Search for an organization’ text field, type “Mexico.”
   b. Make sure that ‘Research Institutions’ is the only box checked.
   c. Click on the **Display** button.
   d. In the ‘Your Organization’ box, select “University of New Mexico, Albuquerque NM.”

5. Follow the on-screen instructions to enter your contact information and click on the **Continue** button.
   - In the Telephone Number field, please enter a number that the IRB can use to reach you. Often times the IRB calls to address urgent concerns like “fast track” requests.
   - In the ‘Email’ text field, enter your full UNM e-mail address (**UNMNetID@unm.edu**).

6. Review your information and edit as necessary. Click on the **Register** button. IRBNet will send an e-mail to your UNM e-mail address that you provided in step 5. You will need to open this message and click on the link provided to activate your account. After you have successfully activated your IRBNet account, log into the IRBNet system to manage your user profile and submit IRB submissions.
Instructions to manage your IRBNet user profile:

1. Go to [http://www.irbnet.org](http://www.irbnet.org) and log in using your IRBNet account username and password.
2. Click on the [User Profile](http://www.irbnet.org) link (upper-right of screen).
3. Review and edit your IRBNet user account and affiliations as necessary.
4. In the ‘External Accounts’ section, click on the [Add an External Account](http://www.irbnet.org) link. You will see a pop-up window that will ask you to provide information CITI Training Program.
   a. In the ‘CITI Member ID’ text filed, enter your CITI Member ID number.
   b. Click on the [Continue](http://www.irbnet.org) button.
5. In the ‘Training & Credentials’ section, click on the [Add a New Training & Credentials Record](http://www.irbnet.org) link.
   a. In the ‘Document Type’ drop-down menu, select ‘CV/Resume’.
   b. In the ‘Effective Date’ field, click on the [Calendar](http://www.irbnet.org) icon and select the date that your CV/Resume was last updated.
   c. Click on the [Choose File](http://www.irbnet.org) button and search your computer for your current CV/Resume to upload into your user profile.
   d. When you are satisfied with the information provided, click on the [Attach](http://www.irbnet.org) button.
   e. In the ‘Document Type’ drop-down menu, select ‘CITI – Human Subjects Research’.
   f. In the ‘Effective Date’ field, click on the [Calendar](http://www.irbnet.org) icon and select the date that you passed the course.
   g. Click on the [Choose File](http://www.irbnet.org) button and search your computer for your current CITI Completion Report to upload into your user profile.
   h. When you are satisfied with the information provided, click on the [Attach](http://www.irbnet.org) button.
First IRBNet Submission

All first-time IRBNet submissions for a project will be entered into IRBNet as a new project. The UNM OIRB did not preload the system with your approved projects, therefore, it is the responsibility of the Principal Investigator to provide this information for each project upon the very first IRBNet submission. This will only need to happen once for each individual on-going project. Follow the OIRB Submission Checklist to ensure all needed documents are attached.

Instructions to submit your first IRBNet submission:

1. Go to [http://www.irbnet.org](http://www.irbnet.org) and log in using your IRBNet account username and password.
2. Click on the [Create New Project] button (left of screen) to go to the ‘Project Information’ page.
3. Follow the on-screen instructions to create a new project and click on the [Continue] button to go to the ‘Designer’ page.
   a. The ‘Research Institution’ is “University of New Mexico, Albuquerque, NM.”
   b. In the ‘Title’ text field, enter title of your project.
   c. In the ‘Local Principal Investigator’ text fields, enter the First and Last Name and degrees of the UNM Principal Investigator of Record.
   d. In the ‘Keywords’ text field, enter words that will help you quickly identify your project, if any.
   e. In the ‘Sponsor’ text field, enter the organization that is providing monetary support, if any.
   f. In the ‘Internal Reference Number’ text field, enter the number that will help you quickly identify your project, if any.

![Image of Project Information page]

1The individual that is identified as the UNM Principal Investigator must meet the criteria for PI eligibility. Please refer to the UNM Office of the IRB’s policy on Principal Investigator Eligibility.
4. In Step 1 of the “Designer” page, you can download and save copies of IRB Forms and Templates to your computer. Please note that the same forms are available in the IRB Library at irb.unm.edu. If you have completed some or all of the required forms as noted in the OIRB Submission Checklist, skip this step and go to step 6 to attach your documents.
   a. In the 'Select a Document' drop-down menu, select the “OIRB Submission Checklist.” Use this checklist as a guide to download the appropriate and required Forms and Templates for a specific submission.
   b. Click on the [Download] button to save the document to your computer.
   c. Repeat step 4 to download the appropriate documents for a specific submission.

5. On your computer, search for the documents that you have downloaded from IRBNet. Open each document and provide the appropriate information. All IRB Forms that have a signature line are required to be signed by the appropriate individual.

6. In Step 2 of the ‘Designer’ page, upload your completed IRB documents from your computer. Follow the OIRB submission checklist to upload the appropriate and required IRB forms and project documents.
   a. Click on the [Add New Document] button. This will take you to the ‘Attach Document’ page.

7. Follow the on-screen instructions to attach a document:
   a. In the 'Document Type' drop-down menu, select the appropriate document type.
   b. In the 'Description' text field, enter the name of the document.
   c. Click on the [Choose File] button and search your computer for your completed IRB Forms/Templates to upload into this project.
   d. Use the IRB Submission Checklist to help identify and label documents. When you are satisfied with the information provided, click on the [Attach] button.

8. Documents that you have attached will appear in the “Documents in this Package” section of the ‘Designer’ page. Review the documents that you have attached to this project and revise information as needed.
   - To change the ‘Document Type,’ click the arrow to the left of the document type and select the appropriate document type in the dropdown menu.
   - To update the ‘Description,’ click the text in the description column and edit as needed.
   - To download a copy of the document, click the paper icon.
   - To edit a document, click the pencil icon.
   - To remove/delete a document, click the X icon.
9. Click on the **Share this Package** button to grant permission levels to project team members that have an active IRBNet account and need to edit, review, and sign project packages. Please note that this does not replace the Project Team Form.
   - Principal Investigator of Record (UNM Faculty) – required to edit, review, and sign all IRBNet packages.
   - Project Coordinator – can edit packages for PI of Record to review.
   - Lead Student Investigator – can edit packages for PI of Record to review.
10. Click on the **Share** link (center-left of screen)
11. Follow the on-screen instructions to display the list of users affiliated with a specific organization.
   a. In the ‘Search for an organization’ text field, type “Mexico.”
   b. Make sure that ‘Research Institutions’ is the only box checked.
   c. Click on the **Display** button.
   d. In the ‘Your Organization’ box, select “University of New Mexico, Albuquerque NM.”
   e. Click on the **Select Organization** button.

12. A listing of users affiliated with the organization AND with active IRBNet accounts will appear. Follow the on-screen instructions to grant access to IRBNet users.
   a. Locate the individual user.
   b. Click on the **Radio** button next to the appropriate ‘Access Type.’
   c. In the ‘Your Comments’ text field, you may choose to include comments for the individual(s).
   d. Click on the **Save** button.
13. Click on the [Project Overview] button to review and edit this package as necessary.

- Click on the [Edit] link to edit the ‘Project Information.’
- Click on the [Designer] link (center of screen) or button (left of screen) to review and edit the ‘Documents in this Package.’
- Click on the [Shared] link (center of screen) or the [Share this Project] button (left of screen) to edit the ‘Share Project’ access types.
14. Once the Principal Investigator of Record is satisfied with the information provided in this package, the Principal Investigator of Record will need to sign this package.
   a. Click on the `Sign this Package` button (left of screen).
   b. Read the attestation and select ‘Principal Investigator’ from the drop-down menu.
   c. Click on the `Sign` button. You will see a pop-up window that will ask you to provide your IRBNet username and password.
   d. Enter your IRBNet Username and Password.
   e. Click on the `Continue` button.
15. After the package has been reviewed and signed by the Principal Investigator of Record, the package can be submitted for IRB processing. Submitting the package will lock it to any edits or additions; ensure that your submission is complete before submitting for processing. Follow the OIRB Submission Checklist to ensure all needed documents are attached.
   a. Click on the **Submit this Package** button (left of screen).

16. Follow the on-screen instructions to submit this package for IRB review.
   a. The default board in the ‘Select a Board’ field will list ‘University of New Mexico IRB, Albuquerque, NM.’
   b. Click on the **Continue** button.

   c. In the ‘Submission Type’ drop-down menu, select the appropriate submission type for this package.
   d. In the ‘Your Comments’ text field, you may specify any additional comments to be included in the notification to the Office of the IRB. Follow the guidance provided in the OIRB submission checklist.
   e. Click on the **Submit** button.
17. Click on the Project Overview link (center of screen) or button (left of screen) to review this package as necessary. At this time, this package is now 'locked' and cannot be edited. Keep the following in mind as you are reviewing the information on this page:

- Access your 'locked' project documents by going to the 'Designer' page.
- View on-demand project status updates by looking at the 'Project Status.'
- View on-demand package status updates by looking at the 'Board Action.'
Responding to an ‘Unlocked’ IRBNet Submission Package

The OIRB staff will ‘unlock’ an IRBNet package for the following situations:

- The OIRB staff has conducted a pre-review of the package and notes that items are either missing from the package or more information is needed before sending the package for IRB review.
- The Principal Investigator has contacted the OIRB Staff requesting to make changes to the package prior to pre-review.

If any of the above situations are true for your package, follow the instructions below to respond to an unlocked IRBNet submission package.

Instructions to respond to your unlocked IRBNet submission package:

1. Go to [http://www.irbnet.org](http://www.irbnet.org) and log in using your IRBNet account username and password.
2. Click on the [My Project](http://www.irbnet.org) button (left of screen) to go to the ‘My Projects’ page.
3. Locate the package that is unlocked and click on the [Red Unlocked](http://www.irbnet.org) icon (right of screen). This will take you to the ‘Designer’ page.
4. In the ‘Designer’ page, click the **View History** link (upper-center of screen). This will show you the ‘Lock history’ and contains messages related to each action.

5. Review the message to see what needs to be edited or added in the ‘Designer’ page.
   - If you need to add a new document, click the **Add New Document** button (lower-center of screen).
   - To change the ‘Document Type,’ click the arrow to the left of the document type and select the appropriate document type in the dropdown menu.
   - To update the ‘Description,’ click the text in the description column and edit as needed.
   - To download a copy of the document, click the paper icon.
   - To edit a document, click the pencil icon.
   - To remove/delete a document, click the X icon.
6. When you are satisfied with your revisions, click on the **Mark Revisions Complete** link (upper-center of screen). You will see a pop up window to continue marking revisions as complete.
   a. In the ‘Message’ text field, add your message to the OIRB.
   b. Click on the **Continue** button to ‘lock’ your package.
   
   ![Mark Revisions Complete](image)

   c. You will see that ‘This package is: Locked – Revisions Complete’ and is waiting for the OIRB staff to pre-review your revisions.

   ![Locked Package](image)
Creating a new package for a ‘Locked’ IRBNet Project

The Principal Investigator will need to create a new package for the following situations:

- The PI has received an IRB determination letter indicating that the IRB has conducted a review of the submission and
  - requires modifications or more information to secure approval; PI is submitting a modification response.
  - determines that more information is required to make a determination; PI is submitting a response.
  - disapproves the submission; the PI is submitting an appeal for IRB reconsideration.
- The expiration date is approaching for this project and continuing review is required to request continuing IRB approval.
- The project is closed or has expired and the PI wishes to reactivate this project to commence research activities.
- The PI intends to make changes to this project and needs to submit an amendment to request IRB approval.
- Something has happened with this project and the PI needs to report an event to request IRB review.

If any of the above situations are true for your project, follow the instructions below to respond to create a new package for a ‘locked’ project

**Instructions to create a new package for a ‘locked’ project:**

1. Go to [http://www.irbnet.org](http://www.irbnet.org) and log in using your IRBNet account username and password.
2. Click on the **My Projects** button (left of screen) to go to the ‘My Projects’ page.
3. Locate the project that you want to respond to IRB modifications or continue, reactivate, amend, report and click on the **Title of Project** icon (lower-right of screen). This will take you to the ‘Project Overview’ page.
4. Click on the **Project History** button (left of screen) to go to the ‘Project History’ page.
5. Click on the **Create New Package** button (center of screen) to create a new package.

6. The package that you have just created will show up in the ‘Project History’ table with the ‘Submission Type’ set to “Work in progress (Not submitted). Click on the **Work in progress (not submitted)** link (center of screen) to go to the ‘Designer’ page for this package.
7. Attach new documents to this package.
   a. If you need to complete a new IRB Form or Template, download a document from the library to your computer. For detailed instructions, go to instructions for “First IRBNet Submission, steps 4 and 5.”
   b. When you are satisfied with your new documents, attach the documents to this package by clicking on the Add New Document button. Follow the on-screen instructions to attach a document. For detailed instructions, go to instructions for “First IRBNet Submission, steps 6, 7 and 8.”

8. Attach revised documents from a previous package.
   a. If you need to revise previously approved documents, click on the Paper icon to download a copy of the currently approved version to your computer.
   b. When you are satisfied with your revised documents, click on the Pencil icon to attach the newer version. Follow the on-screen instructions to attach a revised document.
18. Click on the **Project Overview** button to review and edit this package as necessary.

- Click on the **Edit** link to edit the ‘Project Information.’
- Click on the **Designer** link (center of screen) or button (left of screen) to review and edit the ‘Documents in this Package.’
- Click on the **Shared** link (center of screen) or the **Share this Project** button (left of screen) to edit the ‘Share Project’ access types.
19. Once the Principal Investigator of Record is satisfied with the information provided in this package, the Principal Investigator of Record will need to sign this package.
   a. Click on the [Sign this Package] button (left of screen).
   b. Read the attestation and select ‘Principal Investigator’ from the drop-down menu.
   c. Click on the [Sign] button. You will see a pop-up window that will ask you to provide your IRBNet username and password.
   d. Enter your IRBNet Username and Password.
   e. Click on the [Continue] button.
20. After the package has been reviewed and signed by the Principal Investigator of Record, the package can be submitted for IRB processing.
   a. Click on the Submit this Package button (left of screen).

21. Follow the on-screen instructions to submit this package for IRB review.
   a. The default board in the ‘Select a Board’ field will list ‘University of New Mexico IRB, Albuquerque, NM.’
   b. Click on the Continue button.

c. In the ‘Submission Type’ drop-down menu, select the appropriate submission type for this package.

d. In the ‘Your Comments’ text field, you may specify any additional comments to be included in the notification to the Office of the IRB. Follow the guidance provided in the OIRB submission checklist.

e. Click on the Submit button.
22. Click on the **Project Overview** link (center of screen) or button (left of screen) to review this package as necessary. At this time, this package is now 'locked' and cannot be edited. Keep the following in mind as you are reviewing the information on this page:

- Access your 'locked' project documents by going to the 'Designer' page.
- View on-demand project status updates by looking at the 'Project Status.'
- View on-demand package status updates by looking at the 'Board Action.'