

IRBManager User Guide for Researchers and Research Staff

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1.0 IRBManager

1.1 What is IRBManager?

IRBManager is an online submission, workflow, and data management system for the NMDP Institutional Review Board.

2.0 Login

2.1 Non-NMDP employees:

Existing user:

1. Go to <https://nmdp.my.irbmanager.com/>
2. Your User Name is your email address
3. Click on 'Forgot Password' if you need to reset your password
 - 3.1 You will receive an email with a link to reset your password

Note: If you do not use the email address associated with your account in IRBManager, you will not be able to reset the password. Should this occur, contact IRBStaff@nmdp.org in order to verify the email address on file. Do not create a new account. Duplicate accounts will not be merged. If you need to update your email address on file, contact IRBStaff@nmdp.org

New user:

Go to <https://nmdp.my.irbmanager.com/>

4. Click 'Click here to register'
5. Enter your email address on the first screen
6. You will be required to answer all the questions in the registration form
7. Once you register, you will receive an email with a link to reset your password. You must use this link within 24 hours. If you do not change your password within 24 hours, you will need to click on 'Forgot Password?' to have a new link sent.

2.2 NMDP employees:

1. If you are logging in to IRBManager for the first time, contact IRBStaff@nmdp.org to ensure you have access to the IRBManager Okta account.
2. Upon confirming access with IRB staff, go to <https://nmdp.my.irbmanager.com/>
3. Use your Okta login by clicking on the link next to Okta login

NMDP Users:
To use your Okta login [click here](#)

For Help with Login please contact IRBStaff@nmdp.org.

2.3 How do I reset my password?

Click on 'Forgot Password?' to reset your password. You will receive an email with a link to reset your password. This link will expire within 24 hours. If you do not receive this email, check your spam/junk folder.

As a security precaution, IRBManager locks your account after three incorrect password attempts. It is recommended that you reset your password after two incorrect attempts. If your account is locked, use 'Forgot Password?' to reset your password and unlock your account.

If you do not use your account for over a year, it will be deactivated. To reactivate your account, please email IRBStaff@nmdp.org.

3.0 Navigating the Home Page (also known as the DASHBOARD)

3.1 Actions

This is your Home/Dashboard screen. Use left-hand side Actions to start new xForms. For studies with which you are already associated, start a new xForm by first clicking on the study link under 'My Studies' (see section 3.6).



Actions
Start a new Human Subjects Research Determination Form
Start Initial Application for Biomedical Study
Start Initial Application for Social and Behavioral Sciences Study
Start xForm
Show Sponsor Ids

Recent Items
[2018-077-517](#)

My Docs & xForms
0 Attachments
4 xForms

Home

My Studies

Take :

Studies (1 Active)

- You are associated with **1 active** Studies and **1 total** Studies.
- You are the Coordinator for **1 active** and **1 total** Studies.

xForms (2 Active)

- You have **1 unsubmitted** xForms.
- You have **1 xForm** being processed at a later stage.
- There are **1 xForms** awaiting your attention.

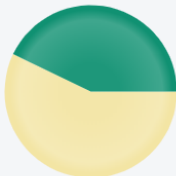
Events (7 Open)

Only show events where I am:

You have **4 Continuing Review** events.

You have **3 Request for Amendment** events.

You have **7 Total Open** events



My Studies (1 Active)

Study	Site	PI	Title	Expires
2018-077-517	Children's Hospital of Philadelphia	Tkachenko, Julia	July Test Study	08/29/2020

3.2 Messages

This heading is an area that the IRB will use for general communication to all the users within the system. Only displayed when there are current messages.

3.3 Studies

This area shows any studies with which the user is associated as Principal Investigator, Coordinator, Sub-Investigator, Administrative Contact, or other research staff. Click on the underlined link to view the details of the studies with which you are associated.

My Studies

Studies (1 Active)

- You are associated with **1 active** Studies and **1 total** Studies.
- You are the Coordinator for **1 active** and **1 total** Studies.

3.4 xForms

IRBManager uses web-based forms called xForms. The xForms section shows the forms currently being processed at this time for the user.

xForms (5 Active)

- You have [2 unsubmitted](#) xForms.
- You have [3 xForms](#) being processed at a later stage.
- There are [1 xForms](#) awaiting your attention.

In the above view of the DASHBOARD:

- You have 2 unsubmitted xForms.
 - The user currently started 2 xForms (submissions) but clicked “Save for Later” or closed out of the form without submitting the form.
 - Note: By clicking the link, ‘2 unsubmitted’, the user can go straight to the unsubmitted xForms.
- You have 3 xForms being processed at a later stage.
 - The user has submitted 3 forms that are currently awaiting review and signature by the PI or are being processed by the IRB.
 - Click on the ‘3 xForms’ link to see the current stage of each xForm
- You have xForms in error (not shown in screenshot).
 - The user has some forms that have errors. This is a software issue, and the user must notify the IRB office if they receive this notification.
 - Note: If the user has an xForm in error, the user can click the underlined link and go straight to the xForm in error.
- There are 1 xForms awaiting your attention.
 - The user has 1 xForms that currently need action by the user (e.g., review and signature required, revisions requested by the IRB).
 - Note: By clicking the link, ‘1 xForms’ the user can go straight to the xForms that need the user’s attention.

3.5 Events

The events section of the DASHBOARD shows the total number of open events and the number of events categorized by name, such as Continuing Review, Initial Submission, or Amendment. The drop-down following ‘Only show events where I am:’ will allow you to show the events according to your role in the associated study.

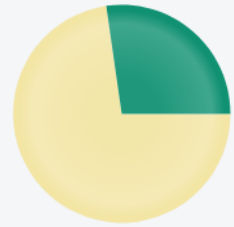
Events (11 Open)

Only show events where I am:

 You have **8 Continuing Review** events.

 You have **3 Request for Amendment** events.

You have **11 Total Open** events



3.5.1 Event Detail

Event Details: Request for Amendment on 2018-077-517

[Help](#) [Submitter's S](#)

Study-Site	
Study:	2018-077-517
Title:	July Test Study
PI:	Tkachenko, Julia
Site:	517 - Children's Hospital of Philadelphia
Committee:	IRB
Sponsor Id	

Event	
Type:	Request for Amendment
Instance:	No
Committee:	Inherited from Study
Review Type:	Expedited
Action Date:	9/16/2019
Started:	09/16/2019
Completed:	
Additional IRB NoA Comments:	

Steps (9)				
Step	Planned	Actual	Complete	Minutes
Receive Request for Amendment		09/16/2019	Yes	
Staff Review		09/16/2019	Yes	
Administrative Review		09/16/2019	Yes	
Place Expedited Approval on FBA	09/30/2019	12/28/2019	Yes	12/28/2019
Notify PI of Outcome			No	

By clicking into the event, you can view event details:

- **Study:** Study IRB number
- **Site:** NMDP Network Number (if available) and the name of the institution
- **PI:** Principal investigator's name
- **Type:** the type of event, which could include Initial Submission, Continuing Review, Adverse Event/Unanticipated, etc.
- **Started:** the date the event first started
- **Steps:** each event will have the steps listed. When the NMDP IRB has completed these actions, the complete column will be marked 'yes'.

3.5.2 Event Actions

Actions in the event details screen on the left-hand side are as follows:

- **Attachments:** shows the attachments related to the event detail
 - Generated Docs – shows the approval documents associated with the study
- **xForms:** shows the form used to create the event.

- **Done:** returns the user to the next most logical page depending on previous actions.

3.6 My Studies

My Studies (1 Active)						
Study	Site	PI	Title	Expires	Status	Reference Doc(s)
2018-077-517	Children's Hospital of Philadelphia	Tkachenko, Julia	July Test Study	08/29/2020	Open to accrual	

This is a list of all the active studies and site(s) with which the user is associated. Note: A study is not created under My Studies when a user submits an xForm. A study is created when the IRB determines that the study is ready for review. From your DASHBOARD, you can view the following information regarding your studies:

- The study number.
- The site where the project is taking place.
- The PI name.
- The study title.
- Expiration date of the project (if blank study has not yet been approved).
- Status: This will depend on whether the study is still under initial review or if elsewhere within the project's lifecycle. Statuses can include Active, Closed to enrollment, Data analysis, Data collection, Disapproved, On hold, Open to accrual, Pending Approval, Study Completed, Terminated, or Withdrawn.
- Reference Doc(s): will display documents that have been approved by the IRB. Note: this field will likely be blank as Reference Doc(s) are not being populated on the study-sites. Approved study-site documents will be displayed under Attachments (see section 3.6.2.1).

By clicking the small arrow to the right of Project, Site, PI, Title, Expires, and Status, you can sort the studies accordingly.

- Study can be sorted by Project Number
- Site can be sorted alphabetically
- PI is sorted alphabetically
- Title is sorted alphabetically
- Expiration dates are sorted by numerical date
- Status is grouped and sorted alphabetically

3.6.1 Study-Sites

Click on the blue link under "Study" (see 'My Studies') to view study-site information and make submissions associated with that study-site.

Home

Study 54321Test-916 (IRB)

Study: 54321Test

Committee: IRB

Category:

Department:

Agent Types:

Title: Test Study

FDA Expedited Categories:

Legally Authorized Representative: Adults with impaired decision-making capacity are allowed to be enrolled on this protocol.

NMDP IRB Review Responsibility: All Subjects

Protocol ID: 123

Research Category: Blood for Lab Research

Sponsor(s): NIH (Primary)

Sponsor Id: 1234

Grants:

CRO:

Year: 2020

FDA Regulated: No

Minor Participants: N/A

Number of Participants Approved:

Protocol Version: 2.0

Study-Site

Site(s): 916 - 916Test

Status: Active

Approval: June 6, 2022

Initial Approval: June 6, 2022

Is Primary Site?:

Comments: Example site

PI: Tkachenko, Julia

Additional: N

Expiration: N/A

Other Expirations:

The main/study-level IRB approval information is listed under a MASTER site. All other study-site information is listed under study-site section. This section notes information about the study and the study-site, such as:

- Site(s): NMDP Network Number (if available) and the name of the institution
- PI: Principal Investigator of the study at the site
- Status
- Approval
- Initial Approval
- Expiration
- Comments

3.6.1.1 Attachments

Beginning June 27, 2023, final documents approved by the NMDP IRB for study-site submissions will be added as attachments to the study-site under study-site attachments.

Study-Site Attachments (3)				
Action	Name	Type	Date	By
                                                				

▼ Study-Site Contacts (2)	
Name	Role
Jobe, Christina	Principal Investigator
Test, Submitter	Coordinator

Current study-site contacts can add or remove other study-site contacts:

- Select a study under 'My Studies' on the homepage.
- Click on 'Start xForm' on the left hand-side under the Actions and select the **Add/Remove Study-Site Contacts** xForm. If the new contact's email is not populating, the xForm will have an option to click on a link to add a new contact to the system.

3.6.3 Study Contacts

Study Contacts are comprised of the central study-level protocol team and can be listed under the main study details (separate from being listed as a study-site contact under the MASTER study-site). Study Contacts have access to the IRB-approved study sites and can view existing Events and submissions for approved participating sites. They can also see pending xForms, what stage they are in, and who started them for already approved study-sites.

Study Contacts can see all the study-sites they are associated with under 'Studies':

Studies (16 Active)	
○	You are associated with 16 active Studies and 17 total Studies.
○	You are the Primary Contact for 1 active and 1 total Studies.
○	You are the Research Staff for 1 active and 1 total Studies.
○	You are the Study Contact for 15 active and 16 total Studies.

*active means approved by the NMDP IRB

For study-sites that are **approved** (active) by the NMDP IRB:

- To view study-site activities, select the site from the list of 'My Studies'. Pending xForms will appear under the left-hand side Actions menu or under the corresponding Event. Note: an Event is created when IRB Pre-Review is completed and the xForm has moved to the next stage (see section 5.1)

For study-sites that are **pending** NMDP IRB approval:

- The study-site is created when the IRB Pre-Review is completed and will appear under 'Studies'. Note: 'My Studies' only shows sites that have already been approved.
- To view the site's Initial Submission prior to the IRB Pre-Review, the study contact will need to ask the submitter to add them as a collaborator on the **NMDP sIRB Study-Specific Local Context Worksheet** xForm (see section 4.1.2).
- After the IRB Pre-Review is completed, the xForm can be viewed under the Site Initial Submission Event.

To add or remove a study contact, contact IRBStaff@nmdp.org

3.7 Find Study

Users can search by PI name or complete NMDP IRB study number (e.g., IRB-1991-0002) to find a study with which the user is associated. Note: A study is not created when a user submits an xForm. A study is created when the IRB determines that the study is ready for review.



3.8 Help

Under **Help** you can contact the NMDP IRB Staff by choosing 'Contact Administrator'. Page help is currently disabled. Use this manual for assistance with using IRBManager.

3.9 User's Settings

Allows the user to edit their profile settings. By clicking on your Settings, you will access My Settings.

Under My Settings you can:

1. Change your password
2. Change your profile
3. Change your phone number
4. Change your address
5. View last 25 logins
6. Create an email signature

3.9.1 Change My Password

1. Step 1: Click on "Change My Password" link.
You will then see this view:

Change Password	
User	Test Generic Coordinator Login
Username	Coordinator
Old Password	
New Password	
New Password Confirm	
Update	

2. Enter old password.
3. Enter new password that meets requirements and then enter new password again to confirm.

Your password must meet the following requirements:

1. Be 6 or more characters
2. Be different from the username
3. Contain characters from at least 3 of the following: upper case letter(s), lower case letter(s), number(s), and special characters (e.g. !, @, #)

4. Click "Update".

3.9.2 Change My Profile

1. Click on "Change My Profile" link.
You will then see this view:

My Profile

Change User Information

First Name	Test Generic
Last Name	Coordinator Login
Degree	
Specialty	
Email Address	

2. Update your name, degree, specialty or email address.
3. Click "Update."

3.9.3 My Phone Number(s)

1. Click on "My Phone Number(s)" link. You will then see this view:

My Phone Numbers

Numbers			
Action	Primary	Type	Number
 	☒	Business	3-2693

2. Click the icon that appears to be a hand holding a piece of paper.
You will then see this view:

Contact Name

Full Name:

Phone Book

Phone Type: 

Primary Number: ☒

3. Update or add your phone number.
4. Click "Update Phone." Or "Add Phone".

3.9.4 My Address(es)

1. Click on "My Address(es)" link.

You will then see this view:

Address Book (1)

Action	Primary	Type ▾	Street ⇅	City ⇅	State ⇅	Zip ⇅	Country
 	✓	Business	10 Anywhere St	Anywhere	California	11111	United States

2. Click the “hand holding a piece of paper.”

You will then see this view:

Contact Name	
Full Name: Investigator, Test MSc	Email: test@oshpd.ca.gov
Address Book	
Address Type: Business ▾	Country: United States ▾
Street: 10 Anywhere St	
Line 2:	
Line 3:	
City: Anywhere	
State/Province: CA - California ▾	Zip/Postal Code: 11111
Primary Address: ☒	
Update Address Reset Cancel	

3. Update your address.

4. Click “Update Address.”

3.9.5 Last 25 Logins

Clicking on this link will provide a list of the time and date of the last 25 times you logged into IRBManager.

4.0 Managing forms in IRBManager (xForms)

Users submitting to the NMDP IRB will submit the xForm appropriate to the type of request (e.g., new study, amendment, continuing review). xForms are started under the action 'Start xForm' from either your Dashboard or a specific study or site. Read the description next to each xForm to determine which one to use.

1. The xForms below are started from your Dashboard. On your home/dashboard, click 'Start xForm' on the left and then choose the appropriate xForm.

- Application for Multi-Site Coordinating Center Activities
 - To be completed along with the Initial Application for federally funded multi-site studies if the Coordinating Center is not already approved by the NMDP IRB.
- Human Subjects Research Determination Form
 - This form should be completed when the investigator is uncertain whether the study is human subjects research needing NMDP IRB review.
- Initial Application for Biomedical Studies
 - This application should be used for new bio-medical studies.
- Initial Application for Social and Behavioral Sciences
 - This application should be used for new social and behavioral sciences studies.
- NMDP sIRB Study-Specific Local Context Worksheet
 - This application should be used for study sites needing to open a study using NMDP single IRB.
- Request to Rely on an External IRB
 - Use this form to request that an NMDP-initiated study relies on an external IRB. NMDP will only rely on an external IRB that is accredited by the Association for the Accreditation of Human Research Protection Programs (AAHRPP).
- Single IRB Signatory Institution Enrollment and Local Context Form
 - Use this form when your institution is enrolling in the NMDP single IRB to provide contact and local context information for your institution. This form is completed once by the institution's IRB/HRPP staff.

2. The study-specific xForms below are started from your study-site. First click the link for the study under 'My Studies'; then click 'Start xForm' on the left and then choose the appropriate xForm.

- Add/Remove Study-Site Contacts
 - Use this form to add or remove any study-site contacts, other than the Principal Investigator.
- IRB Request for Study Amendment
 - Relying institutions should use this form to submit revised consent/assent forms, translations, and other participating site study specific materials. Main study level teams (not site specific) should use this form for changes to the protocol and other study-level materials, as well as translations and overall/main PI changes.
- Major Protocol Exception Request form

- A one-time, temporary departure from the IRB-approved protocol procedures that is identified before it occurs, intended for one specific study subject, and may adversely affect the safety, rights, or welfare of the subject(s) and/or the scientific validity of the research.
- Notification of Study Closure
 - Notification of Study Closure form for the Study-Wide closure at the study level (not site specific).
- Reportable Event Form
 - For reporting potential unanticipated problems involving risks to subjects or others and potential serious or continuing non-compliance to the NMDP IRB for review.
- Revised NMDP sIRB Study-Specific Local Context Worksheet
 - Relying institutions should use this form to make any changes to the previously submitted information on the NMDP sIRB Study-Specific Local Context Worksheet including study-site PI.
- Study Site Closure Form
 - Relying institutions should use this form to close a study at their site prior to the study closing as a whole.

3. The NMDP sIRB Site Management xForms below are started from your Site Management page (see section 6.0).

- Add/Remove sIRB Site Contacts
 - Use this form to add or remove any contacts on your sIRB Site Management.
- Annual Renewal or Updates to sIRB Enrollment and Local Context Instructions
 - Instructions for completing annual renewal or updates to the sIRB Enrollment and Local Context Form.
- Site-specific Documents Submission
 - Use this form to submit your site-specific documents that are not specific to a study (e.g., Short Form English templates not previously reviewed by the NMDP IRB and boilerplate template language.)

4.1 Completing an xForm

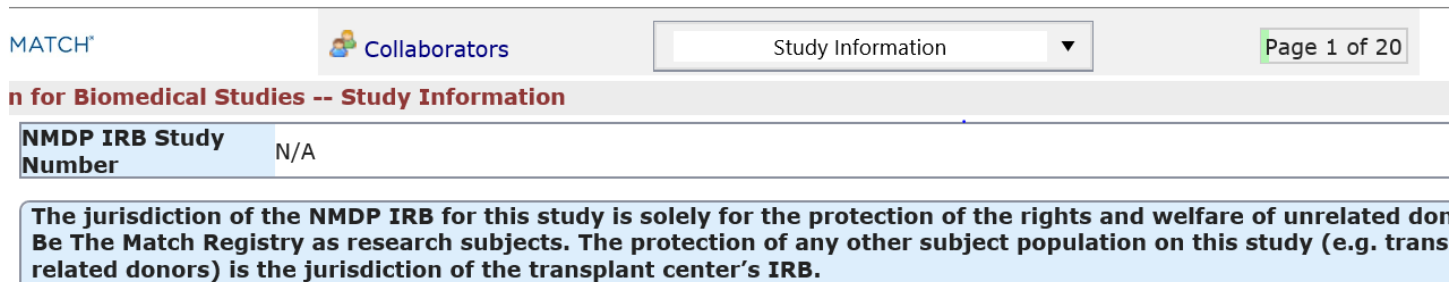
The questions in the xForms are directed by the answers given. For example, if you mark that the study does not involve NMDP donors, the form will not ask subsequent questions about NMDP donors. Changing responses on the form will enable subsequent questions that were hidden or hide questions that are no longer applicable.

To navigate an xForm, click “Next” to move on to the next page of the xForm. Click “Save for Later” to stop working on the form. The xForm can then be reopened by going to the xForm link under “Actions.”

[Previous](#)
[Next](#)
[Save for Later](#)
[More ►](#)

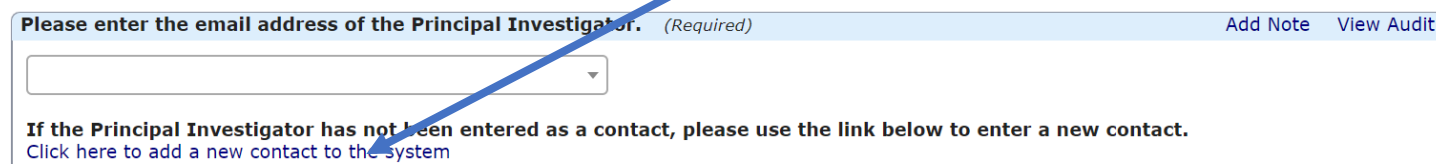
Most questions on the form are required (the question will be labelled “Required”). All required questions on the form must be completed before submitting. If they are not, a red error message will appear. The system will not allow you to continue until the field has been populated.

All required questions on a page must be completed before clicking ‘Next’. To skip to another page on the form without answering all questions on the page at that time, use the navigation drop-down at the top of the page.



4.1.1 Adding Contacts

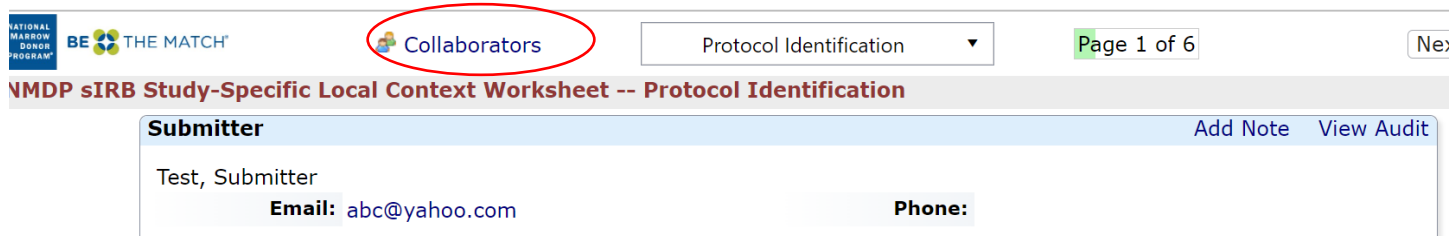
Some questions ask for a study contact. Type in the name or email address of the contact and choose the appropriate contact from the list that appears. If the contact does not appear, they are not included in the system. Click on the link provided to add a contact to the system:



A new tab will open. Enter the required information for the new contact. Click ‘Submit’ to activate the new contact. Note: this action only pertains to the Contact Form. You may click ‘Submit’ or ‘Save for Later’ to continue working on the main application. In a moment, you should be able to select the new contact from the drop-down list.

4.1.2 Adding Collaborators

Collaborators can be added to an xForm to view, edit, manage, or submit the form. To add a collaborator, click on the ‘Collaborators’ link on the top of the page:



4.1.3 Attaching a Document

To attach a document:

1. Click “Add Attachment” on specified attachment questions.
2. Do not change the name of the document. The NMDP IRB Notice of Action will display the file name of the documents as the name of the attachments.

3. Select the type of attachment if that option is available. On some questions, only a certain type of document is intended to be attached, and the type is pre-set.
4. Click the "Select" button to locate the file on your computer (files can also be attached from Dropbox or Box)
5. Click "Attach" to finish the process.

Add Attachment	
Name:	 (leave blank to use name of uploaded file)
Type:	Assent v
File:	Select
Attach Cancel	

Note: additional documents can be attached to any question. Click 'add note', save, then click on attachment icon to add attachments.

4.2 New study applications

From your Dashboard, under the action menu on the far-left side, select one of the following:

1. Start an Initial Application for Biomedical Study **or** Start Initial Application for Social and Behavioral Sciences Study (These applications should be used for new studies.)
2. Start xForm
 - a. Gives the option to start one of the above forms or to start the 'Add New Contact to IRBManager' form, which is used to create a username and login for a contact not in the IRBManager system.
 - b. Click on the name of the form to start the form.

4.2.1 Submitting an xForm

Before submitting an xForm, review the form completely. Changes cannot be made once an xForm is submitted, unless the IRB or PI requests changes.

After all pages on the form have been completed, the submission screen will appear. "Submit" will need to be clicked to complete the submission.

Form Completed	
You've completed the form. You can now either save the form for later revision, or submit it.	
Go Back Save for Later Print Submit	

If you are not the PI, the form will go to the PI for signature. They will receive an email from IRBManager indicating their review and signature is required; the email will contain a link that will take them to the form. If the PI wants to return the form to the submitter, they will have the opportunity; otherwise, the PI signs and submits the form.

Note: If the PI does not see the email from IRBManager, they should check their Spam/Junk folder and make sure to mark emails from IRBManager as safe.

The PI can also access the form from their Dashboard. Under the xForms section of their Dashboard, they will see an xForm awaiting attention:

xForms (2 Active)

- You have **1 unsubmitted** xForms.
- You have **1 xForm** being processed at a later stage.
- There are **1 xForms** awaiting your attention.

By clicking on the hyperlink to the xForms, the study PI is able to see the forms, click on the study hyperlink, and review/sign the form.

Form	Identifier	Owner	Stage	Status	Started	Requires Approval
Initial Application for Biomedical Studies	Christmas Study	Tkachenko, Julia (jtkachen@nmdp.org)	PI Signature for Research Staff Submission	Work in progress	10 minutes ago	No

4.3 Requesting PI Signature (not required for some xForms)

To request a change, the PI can click on 'Add Note' next to the question, enter comments, and save:

Does the Study Chair or any Principal Investigator involved in the development or coordination of this study (or their spouses or dependent children) have a Significant Financial Interest related to his/her Institutional Responsibilities that could bear upon his/her objectivity?[Add Note](#)[View Audit](#)

Enter Note:

Change to Yes

SaveCancel

No

The PI will select either 'Ready for Submission' or 'Revisions required prior to Submission.' If Revisions are required, the PI will be prompted to indicate revisions:

Is this Initial Application ready for submission? (Required)

- ☐ Ready for Submission
- ☒ Revisions required prior to Submission

Please indicate any revisions required prior to submission. (Required)



They will click **Next** and then **Submit**

4.3.1 Making requested revisions to the xForm

If the PI has indicated that revisions are required, the form will go back into the Data Entry stage. The submitter will receive an email with revisions required. Click on the link in the email or access the xForm from your dashboard.

To view PI notes, click on 'More' button and select 'View Questions with Notes'

Researcher, Test
Email: testresearcher@nmdp.org

If the Principal Investigator has indicated that revisions are required, click here to add a new contact to the application.

Next **Save for Later** **More ▾**

View Attachment Questions

View Questions with Notes

View Changed Responses

View as PDF

View as PDF without Notes

After making changes, click Submit. The form will go back to PI for signature. If the form is Ready for Submission, the PI will sign the form by entering their IRBManager password:

Is this Initial Application ready for submission? (Required)

[Add Note](#) [View Audit](#)

- ☒ Ready for Submission
- ☐ Revisions required prior to Submission

As Principal Investigator of this study, I assure the NMDP IRB that all statements included in this application are true. Furthermore, I acknowledge that I am responsible for reporting proposed modifications to the research study to the NMDP IRB prior to implementing those modifications except where necessary to eliminate any immediate harm to the subjects. I agree to report any unanticipated problems involving risks to subjects or others promptly to the NMDP IRB, to comply with all NMDP IRB requests to report on the status of this study, and to comply with all federal, state, and local regulations for the protection of human subjects. I assure the NMDP IRB that resources necessary to protect study participants are in place. I agree that I will not initiate this research study until I have received written approval to do so from the NMDP IRB. (Required)

To sign, enter password for TestResearcher

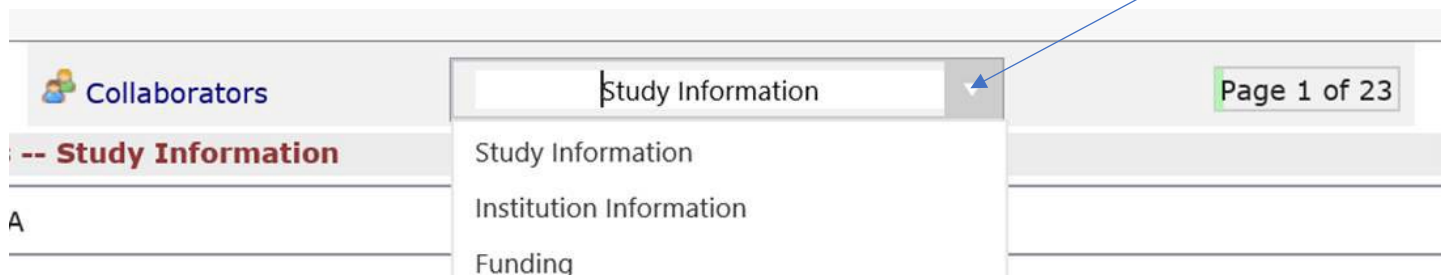
Previous **Next** **Save for Later** **More ▾**

The form will now be submitted to the NMDP IRB office for review and will move into the 'IRB Pre-Review' stage.

4.3.2 Clarifications required by the IRB Staff

If IRB Staff requires clarifications, you will receive an email with Clarifications Required. Click on the link in the email or access the xForm from your dashboard to respond to the clarifications.

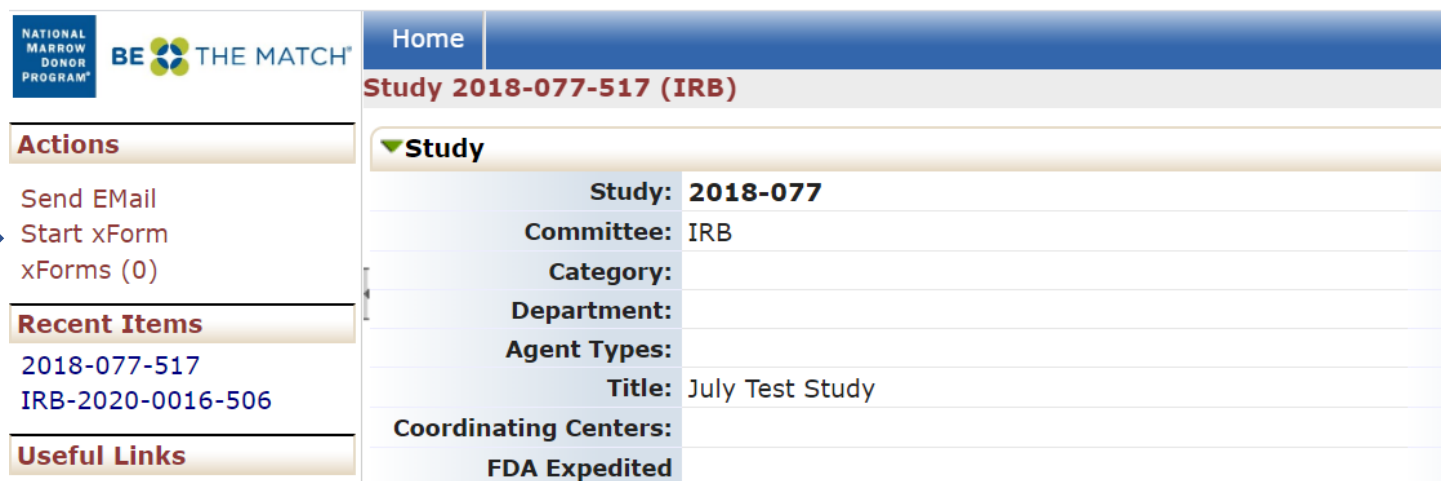
If there are any specific questions requiring clarifications, click on 'More' button at the bottom of the form and select 'View Questions with Notes.' Otherwise, navigate to 'Respond to IRB Questions' to provide a response:



The screenshot shows a dashboard with a 'Collaborators' tab and a 'Study Information' dropdown menu. The dropdown menu is open, showing options: 'Study Information', 'Institution Information', and 'Funding'. A blue arrow points to the 'Study Information' option. The page number 'Page 1 of 23' is visible in the top right corner.

4.4 Study Submissions

Study specific forms such as Request for Amendment and Notification of Study Closure, must be started from within the study. Navigate to the study. On the left-hand side under Actions, select Start xForm:



The screenshot shows the dashboard for 'Study 2018-077-517 (IRB)'. On the left-hand side, under the 'Actions' section, the 'Start xForm' button is highlighted with a blue arrow. The main content area shows the study details:

Study	
Study:	2018-077
Committee:	IRB
Category:	
Department:	
Agent Types:	
Title:	July Test Study
Coordinating Centers:	
FDA Expedited	

Click on the Form you wish to submit and begin completing the form.

After all pages on the form have been completed, the submission screen will appear. "Submit" will need to be clicked to complete the submission.

If you are not the PI, the form will go to the PI for signature. They will receive an email indicating their review and signature is required. If PI wants to return the form to the submitter, they will have the opportunity; otherwise, the PI signs and submits the form.

If IRB Staff requires clarifications, you will receive an email with Clarifications Required. Follow instructions above.

5.0 IRB Determinations

The IRB has completed the review, and the IRB Office is preparing the decision notification to the research team.

5.1 Checking the status of an xForm

Click on xForms under your Home screen or 'xForms' under 'My Documents & Forms' on the left-hand side of the screen to see a list of all xForms with which you are associated (either as a PI, administrative contact, coordinator, etc.).

Home

Find Study (Ctrl+Q)

My Forms

Help Submitter's Settings Sign off

Filter:

What's this?

This table shows xForms associated with you as a user of IRBManager across the entire system.

Status: All

Action	Form	Identifier	Owner	Stage	As Of
✖	Human Subjects Research Determination Form	sdf	Test, Submitter (testsubmitter)	Human Subjects Research Determination Data Entry (2nd time)	12/27/2019 at 5:24 PM
📄	Initial Application for Biomedical Studies	asd	Test, Submitter (testsubmitter)	IRB Pre-Review	12/17/2019 at 7:26 PM
✖	Human Subjects Research Determination Form		Test, Submitter (testsubmitter)	Human Subjects Research Determination Data Entry	12/12/2019 at 4:47 PM

1 completed xForms are Hidden.

- **Action:** If a form can be deleted or copied for an amendment, those options will display in this column. Note that an xForm can only be deleted when in the Data Entry stage.
- **Form:** Name of the xForm
- **Identifier:** This is generally the PI associated with the project
- **Owner:** The owner of the form will be the user who started the xForm until a project is created (a project will be created within IRBManager after the IRB has sent the project for review), and then the form is owned by the project
- **Stage:** This is the current stage that the form is in. Stages will vary by form, but in general will be the following:
 - Data Entry: Form is currently with the user/submitter either to complete or make changes.
 - PI Signature for Research Staff Submission: If the PI is not the submitter, this is the stage where the PI reviews and submits the form.
 - IRB Pre-Review: Stage that the IRB Office will screen the application for completeness and either request further information/documentation (clarifications) or assign for review. Note: this stage may include Administrative review and approval, if applicable.

- Expedited Review: The project is being reviewed at the expedited level.
- Full Board Review: The project is being reviewed by the convened board.
- Final Processing: The IRB has completed the review, and the IRB Office is preparing the decision notification to the research team.

You can also check the status of the xForm from within the event (see 3.2 for finding an xForm on an event). Note: the xForm will be 'owned' by the type of event with which it is associated (i.e. initial submission, continuing review, amendment [once the amendment is submitted]).

5.2 IRB Decision Notification

Once the IRB Office or the IRB reviewer(s) have completed their review, the research team will receive an email detailing the IRB decision. The appropriate approval/determination letter will be attached.

- **Approved:** No changes are requested by the IRB; the investigator may initiate the study or continue the study, or may implement the changes to the protocol.
- **Approved with Stipulations:** Study may not be initiated until Stipulations are met.
 - The form will go to the Data Entry stage. If changes are requested to specific documents, please replace current documents with red-lined copies. Click on the green arrows to replace a document, rather than deleting the document and adding the new one. State your response in the following question of the xForm 'Please use this box to respond to any IRB questions, if needed'. Alternatively you may attach a formal response letter with any additional attachments under 'Add additional attachments, if needed'. Once the revisions are submitted, the form will either go back to the primary and secondary reviewers or back to the Full Board. If additional changes are requested, the form will return to Data Entry for revisions and be routed back for review as many times as necessary until stipulations are met.
- **Disapproved:** The research is not approved.
- **Deferred:** Substantive clarifications or modifications are required by the IRB before the research may be initiated or continued beyond the current approval period, or before the protocol change may be implemented. The convened IRB must review the response to the deferral.
 - Form will go back to data entry and be routed back through the IRB Office and to the full board for review.
- **Tabled:** If the convened IRB is unable to adequately review a study due to lack of time or loss of quorum, the study will be reviewed at the next full board meeting

6.0 Locating Historical Documents and Submissions

Study contacts and study-site contacts can view historical submissions at the study or site level, respectively. Follow the steps below to access these submissions:

1. Select a Study
 - Go to the dashboard/homepage and select a study under 'My Studies'.
2. View Event Submissions
 - Click on the specific Event under the Events section.
3. Navigate to Actions
 - On the left-hand side, locate Actions section.
4. View Submitted xForms
 - Click on xForms to view the submitted xForm.
 - To view, save, or print xForm as PDF, click on 'More' at the bottom of the xForm.
 - Note: Some forms submitted prior to 2021 may not be available in IRBManager. Please contact IRBStaff@nmdp.org
5. View Attachments
 - Click on Attachments to view all the attachments for the Event, including the IRB determination letter under Generated Docs.
 - Note: Final IRB-approved study-site consent forms are included in the Notification on NMDP IRB Approval email under Emails and also under Study-Site Attachments.

7.0 Using the NMDP IRB as a Single IRB

Signatory Institutions relying on the NMDP IRB have a Site Management page in IRBManager. This page is created when a site enrolls in the NMDP single IRB (sIRB). Primary contacts associated with a Signatory Institution have access to their site under 'My Studies':

My Studies							Help	Submitter's Settings	Sign off
My Studies (97 Active)									
Study	Site	PI	Title	Expires	Status	Reference Doc(s)			
Site Management-Test Site	Test	Tkachenko, Julia	sIRB Site Management	Annual Renewal Required	Enrolled	Boilerplate -- ICF ACH Template I			

Click on the blue link under "Study" to view site information and make submissions associated with the site.

Home
Find Study (Ctrl+Q)
NMDP sIRB Site Management-Test Site (Single IRB Institutions)
Help Submitter's Settings Sign off

NMDP sIRB
collapse

NMDP sIRB: Site Management
Title: sIRB Site Management

NMDP sIRB-Site

Site(s): Test Site - Test
Location(s):
Status: Enrolled
Approval: September 14, 2021
Initial Approval: September 14, 2021
Affiliate Institutions: Affiliate 1 FWA#1234567
Comments: September 2021

Signatory Official: Heinen, Miranda
Additional: N
Expiration: Annual Renewal Required
Other Expirations: sIRB Enrollment Renewal Date - 09/20/2021
Component Institutions: Component 1

Site Contacts (3)
collapse

Name	Role
Jobe, Christina	Primary Contact
Test, Submitter	Primary Contact
Tkachenko, Julia	Primary Contact

NMDP sIRB-Site Reference Documents (1)
collapse

Name	Type	Active	Inactivated
10-CBA Recipient Consent v5.0_rev 091321_FINAL 09-13-2021.docx	Boilerplate Consent Language	09/21/2021	

Reference xForms (1)
collapse

Action	Form	Stage	As Of	Ref Active	Inactivated
	Single IRB Signatory Institution Enrollment and Local Context Form	Complete	09/21/2021	09/21/2021	

Events (3)
collapse

Event	Att	Instance/UDF	Start	Complete
Study-Site Personnel Change	0	Replace Signatory Official Add new Primary Contact	06/06/2023	06/06/2023
sIRB Renewal	1		09/21/2021	

Contacts listed under Site Contacts act as the point of contact for their institution. They can submit annual sIRB review, update their boilerplate template language, and request other site documents to be approved (see section 4.0).

For further information about sIRB, reference **NMDP Single IRB Manual for Local Institutions** found on the NMDP IRB website
<https://network.nmdp.org/research/institutional-review-board/relying-on-the-nmdp-sirb>

Further Questions

If you have further questions regarding your study status or using IRBManager, contact the NMDP IRB Staff at IRBStaff@nmdp.org.