

Training for Researchers and Staff
at the
National Marrow Donor Program
in the Use of
IRBManager

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1.0 IRBManager

1.1 What is IRBManager?

IRBManager is an online submission, workflow, and data management system for the National Marrow Donor Program (NMDP) Institutional Review Board. The electronic forms provided within this system will allow users to submit new studies for review as well as submit other forms for continuing review, amendments, unanticipated problems or adverse events, and final reports. These forms are then used to electronically route the study through the required review process.

Through IRBManager, investigators and study personnel have access to see the projects they are investigating as well as any separate study-sites. Each study will have a list of events. Events can be viewed as folders for the separate submission events required for each study such as the initial submission, amendments, and continuing reviews. Each event will contain all associated forms, documents, and letters along with a listing of review steps, which are updated to notify the investigators where the submission is within the review process. Study personnel indicated on the study application will have access to IRBManager.

IRBManager is a fully web-based system, which means that users can log in anywhere they have internet access.

2.0 Login

2.1 Non-NMDP employees:

If you had an approved (and not closed) study with NMDP IRB, your contact has been created within IRBManager. In order to activate that account, do the following:

1. Go to <https://nmdp.my.irbmanager.com/>
2. Click on 'forgot password'
3. Enter the email address on file with NMDP IRB
4. You will receive an email with a link to reset your password
5. Note if you do not use the email address on file with NMDP IRB, 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 tied to migrated studies. If you need to update your email address on file, contact IRBStaff@nmdp.org

If you are a new researcher/research staff submitting to the NMDP IRB for the first time, you will need to register for IRBManager at: <https://nmdp.my.irbmanager.com/> by clicking on 'Click here to register'

6. Enter your email address on the first screen
7. You will be required to answer all the questions in the registration form

8. 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 Julia Tkachenko, Senior Human Research Protection Program Specialist at jtkachen@nmdp.org or (763) 406-5890.

2.3 How do I reset my password?

Click on the '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 the 'forgot password' to reset your password and unlock your account.

Note: the system will also automatically log you out after 30 minutes of inactivity.

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 xForms.

The screenshot shows the Home/Dashboard interface. On the left, there are three main menu sections: **Actions** (with links for starting new Human Subjects Research Determination Forms, Biomedical Studies, Social and Behavioral Sciences Studies, and xForms, plus a link to show sponsor IDs), **Recent Items** (showing '2018-077-517'), and **My Docs & xForms** (showing '0 Attachments' and '4 xForms'). The main content area is titled 'My Studies' and features a 'Take' button. It contains three summary boxes: 'Studies (1 Active)' with two bullet points about active and total studies; 'xForms (2 Active)' with three bullet points about unsubmitted, in-progress, and awaiting attention xForms; and 'Events (7 Open)' with a dropdown menu, a pie chart (yellow and green), and three bullet points about Continuing Review, Request for Amendment, and Total Open events. At the bottom, there is a table for '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

The screenshot shows the 'My Studies' section. It has a header 'My Studies' and a sub-header 'Studies (1 Active)'. Below this, there are two bullet points: 'You are associated with **1 active** Studies and **1 total** Studies.' and 'You are the Coordinator for **1 active** and **1 total** Studies.'

This area shows any studies with which the user is associated as Principal Investigator, Coordinator, Sub-Investigator, Administrative Contact, or other research staff.

Note: By clicking on the underlined link, you will be able to view the details of the studies with which you are associated.

3.4 xForms

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.

The xForms section shows the forms or applications currently being processed at this time for the user. Note that an xForm is an electronic form (web-based).

In this view of the DASHBOARD:

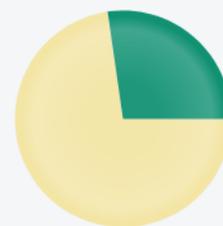
- You have 2 unsubmitted xForms.
 - The user currently started 2 xForms (submissions) but clicked "Save for Later" or closed out of the form without submitting the form.
 - Note: By clicking the underline link, 2 unsubmitted the user can go straight to the unsubmitted xForms.
- You have 3 xForms being 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 stages of the xForms
- 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 underline 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 underline link, "xForms" the user can go straight to the xForms that need the user's attention.

3.5 Events

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



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, 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.

3.5.1 Event Detail

Event Details: Request for Amendment on 2018-077-517					Help	Submitter's S
Study-Site						
Study:	2018-077-517		Site:	517 - Children's Hospital of Philadelphia		
Title:	July Test Study		Committee:	IRB		
PI:	Tkachenko, Julia		Sponsor Id			
Event						
Type:	Request for Amendment		Started:	09/16/2019		
Instance:	No		Completed:			
Committee:	Inherited from Study					
Review Type:	Expedited					
Action Date:	9/16/2019		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 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 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, Withdrawn.
- Reference Doc(s): will display documents that have been approved by the IRB.

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

By clicking on the blue link under "Study" the user can go straight to the study.

Study: 54321Test	Sponsor(s): NIH (Primary)
Committee: IRB	Sponsor Id: 1234
Category:	Grants:
Department:	CRO:
Agent Types:	Year: 2020
Title: Test Study	FDA Regulated: No
FDA Expedited Categories:	Minor Participants: N/A
Legally Authorized Representative: Adults with impaired decision-making capacity are allowed to be enrolled on this protocol.	Number of Participants Approved:
NMDP IRB Review Responsibility: All Subjects	Protocol Version: 2.0
Protocol ID: 123	
Research Category: Blood for Lab Research	

Study-Site	Site(s): 916 - 916Test	PI: Tkachenko, Julia
	Status: Active	Additional: N
	Approval: June 6, 2022	Expiration: N/A
	Initial Approval: June 6, 2022	Other Expirations:
	Is Primary Site?:	
	Comments: Example site	

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

3.6.2 Study-Site Contacts

This section lists the contacts associated with the study.

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

To add or remove study-site contacts, submit **Add/Remove Study-Site Contacts** xForm. You can find this form by clicking on 'Start xForm' on the left hand-side under the Actions.

Note: if the new contact's email is not populating, add a new contact to the IRBManager first. To do so, use the **Add New Contact to IRBManager** xForm.

3.7 Find Study

User 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	<input type="password"/>
New Password	<input type="password"/>
New Password Confirm	<input type="password"/>

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	<input type="text" value="Test Generic"/>
Last Name	<input type="text" value="Coordinator Login"/>
Degree	<input type="text"/>
Specialty	<input type="text"/>
Email Address	<input type="text"/>

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
 	<input checked="" type="checkbox"/>	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: Test Generic Coordinator Login

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
 	<input checked="" type="checkbox"/>	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: <input checked="" type="checkbox"/>	
<input type="button" value="Update Address"/> <input type="button" value="Reset"/> <input type="button" value="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)

IRBManager uses web-based forms called xForms for Initial Applications, Continuing Reviews, Amendments, etc. This section allows ways to begin an application/form for NMDP IRB review. Users submitting to the NMDP IRB will submit the xForm appropriate to the type of request (e.g., new study, amendment, continuing review)

There are two places where an xForm can be started:

1. The following xForms are started from your Dashboard:

- Add New Contact to IRBManager
- Human Subjects Research Determination Form
- Initial Application for Biomedical Studies
- Initial Application for Social and Behavioral Sciences
- NMDP sIRB Study-Specific Local Context Worksheet
- Single IRB Signatory Institution Enrollment and Local Context Form

2. The following study-specific xForms are started from your study-site:

- Add New Contact to IRBManager
- Add/Remove Study-Site Contacts
- Major Protocol Exception Request form
- Notification of Study Closure
- Reportable Event Form
- Study Site Closure Form
- Temporary Variance Request Form

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."

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.

n for Biomedical Studies -- Study Information

NMDP IRB Study Number	N/A
------------------------------	-----

The jurisdiction of the NMDP IRB for this study is solely for the protection of the rights and welfare of unrelated donors. Be The Match Registry as research subjects. The protection of any other subject population on this study (e.g. transplant related donors) is the jurisdiction of the transplant center's IRB.

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:

Please enter the email address of the Principal Investigator. *(Required)* [Add Note](#) [View Audit](#)

If the Principal Investigator has not been entered as a contact, please use the link below to enter a new contact.
[Click here to add a new 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 Attaching a Document

To attach a document:

1. Click "Add Attachment" on specified attachment questions.
2. You can enter a name for your attachment. However, the name of the attachment will appear on the IRB approval letter, so it is recommended that you leave the name field blank, so that the file name of the document appears on the approval letter.
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:	<input type="text"/>	(leave blank to use name of uploaded file)
Type:	Assent	<input type="button" value="Select"/>
File:	<input type="text"/>	<input type="button" value="Select"/>
<input type="button" value="Attach"/> <input type="button" value="Cancel"/>		

Note: a document 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.
 - c.

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 and a link that will take them to the form. If 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)

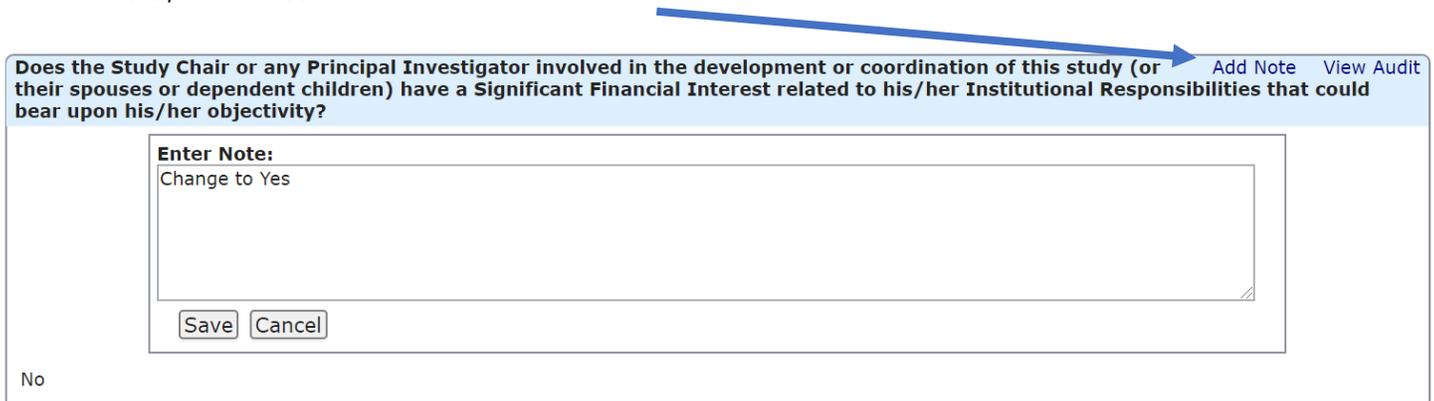
- o You have **1 unsubmitted** xForms.
- o You have **1 xForm** being processed at a later stage.
- o There are **1 xForms** awaiting your attention.

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:

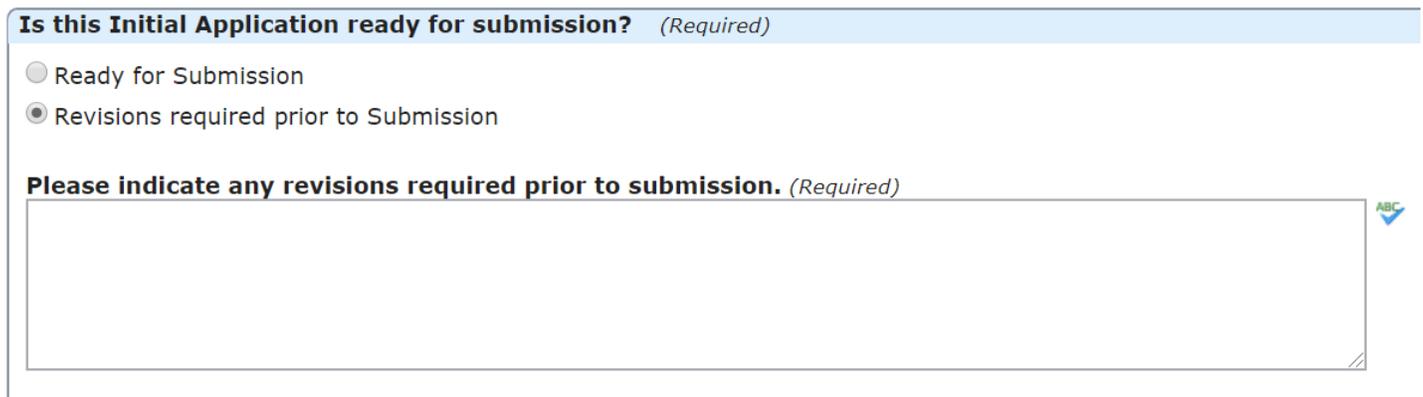


Does the Study Chair or any Principal Investigator involved in the development or coordination of this study (or their spouses or dependent children) have a Significant Financial Interest related to his/her Institutional Responsibilities that could bear upon his/her objectivity? [Add Note](#) [View Audit](#)

Enter Note:
Change to Yes

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

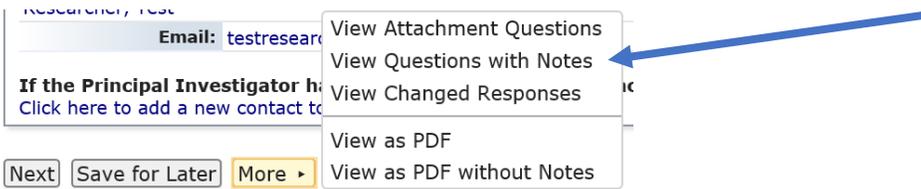
Please indicate any revisions required prior to submission. (Required)

They will click and then

4.3.1 Making requested revisions to the xForm

If the PI has indicated that revisions are required, the form will go back into 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'



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

To sign, enter password for TestResearcher

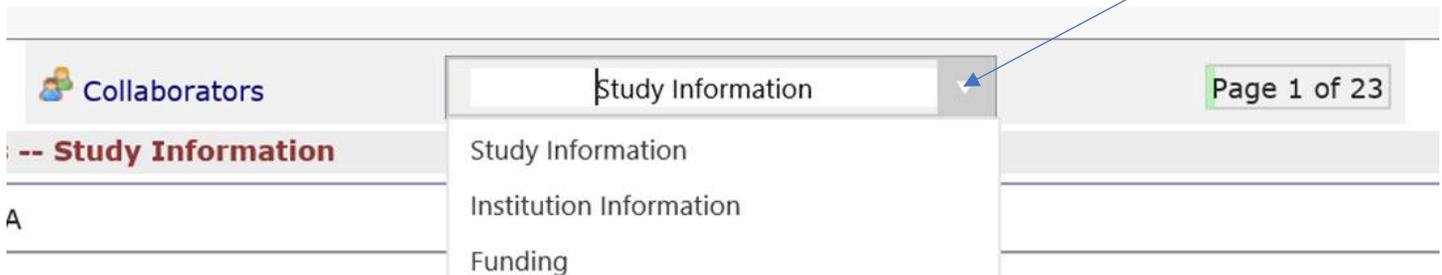
[Previous](#)
[Next](#)
[Save for Later](#)
[More ▾](#)

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:



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 National Marrow Donor Program website interface. At the top left, there are logos for 'NATIONAL MARROW DONOR PROGRAM' and 'BE THE MATCH'. A blue navigation bar contains a 'Home' link. Below this, the page title is 'Study 2018-077-517 (IRB)'. On the left side, there is a sidebar with three sections: 'Actions', 'Recent Items', and 'Useful Links'. A blue arrow points to the 'Start xForm' link in the 'Actions' section. The 'Recent Items' section lists '2018-077-517' and 'IRB-2020-0016-506'. The 'Useful Links' section is partially visible. The main content area shows a 'Study' section with a dropdown arrow. Below it, a table-like structure displays study details: 'Study: 2018-077', 'Committee: IRB', 'Category:', 'Department:', 'Agent Types:', 'Title: July Test Study', 'Coordinating Centers:', and '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 '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:

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 form
- **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
 - 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/determinaton 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 Using the NMDP IRB as a Single IRB

The NMDP IRB serves as the single IRB (sIRB) for the NIH-funded Blood and Marrow Transplant Clinical Trials Network® (BMT CTN). Centers participating in BMT CTN studies are required to use the NMDP IRB as their IRB of record. The NMDP IRB also serves as a sIRB for some multi-site CIBMTR® (Center for International Blood and Marrow Transplant Research®) and NMDP/Be The Match research. If the study is federally funded, centers are required to use the NMDP IRB. If the study is not federally funded, centers may still choose to rely on the NMDP IRB as their IRB of record. The NMDP IRB may agree to serve as a single IRB for other studies on a case-by-case basis.

Below are the xForms pertinent to the Single IRB Submissions:

- **Single IRB Signatory Institution Enrollment and Local Context Form** - use this form when your institution is first enrolling in the NMDP sIRB to provide contact and local context information for your institution.
- **NMDP sIRB Study-Specific Local Context Worksheet**- use this form to open a study using the NMDP sIRB. Note: confirmation of Signatory Institution's enrollment in the NMDP sIRB is required.
- **Revised NMDP sIRB Study-Specific Local Context Worksheet** – use this form to make any changes to the previously submitted information on the form, including a change in your study-site PI.
- **Site-specific Documents Submission** - use this form to submit your site-specific documents that are not specific to a study (e.g., Short Form templates, COVID-19 information sheets, boilerplate language template, and other research participant-facing documents that can be used for any study).
- **Study Site Closure Form**- use this form to close your site on a study only if you are closing the study before the study is completed. Otherwise, the study-level closure with the NMDP IRB will also apply to all sites relying on the NMDP IRB for the study.
- * **IRB Request for Study Amendment** - can be used for study-wide or study-site amendments. Use this form for study-site consent revisions, translations, and other study-site specific study materials, excluding short forms.
- **Add/Remove sIRB Site Contacts** – use this form to update Signatory Officials and Primary Contacts with your institution's IRB office.

6.1 Enrolling in the NMDP sIRB

Enrollment in the NMDP sIRB occurs once per institution. To enroll in the NMDP sIRB, institutions must submit the Single IRB Signatory Institution Enrollment and Local Context Form.

- From your Home/Dashboard click on Start xForm under Actions on the left-hand side and click on the **Single IRB Signatory Institution Enrollment and Local Context Form** to begin the xForm.
- After completing the xForm and attaching all the necessary documents, click 'Submit'

- The NMDP IRB staff will conduct the pre-review and inform you of any further Clarifications and when enrollment is complete.
- After the enrollment is complete, the form will appear as a Reference xForm on your NMDP sIRB Site Management page, specific to your site without study information.

6.1.1 Annual Review of NMDP sIRB Forms

All institutions enrolled in the NMDP sIRB are asked to review the information they provided to the NMDP sIRB annually. An automatic Notification from IRBManager will be sent to the institution's Primary Contacts the day before your renewal date. The notification will include a link to the xForm, which should be reviewed within a month.

6.2 Opening a Study using the NMDP sIRB

Confirmation of a Signatory Institution's enrollment in the NMDP sIRB is required prior to opening a new study.

- From your Home/Dashboard click on Start xForm under Actions on the left-hand side and click on the **NMDP sIRB Study-Specific Local Context Worksheet** to begin the xForm.
- After completing the xForm and attaching all the necessary documents, click 'Submit'
- The NMDP IRB staff will conduct the pre-review and inform you of any further Clarifications.
- After the IRB review, you will receive an email from the NMDP IRB with documentation of NMDP IRB approval for your site on the study. Approved/finalized consent/assent form(s) will also be attached.

6.2.1 Revisions to NMDP sIRB Study-Specific Local Context Worksheet

The NMDP Single IRB Study-Specific Local Context Worksheet should be updated on an ongoing basis if there are changes such as change in PI, Subject Recruitment or Population, Compensation to Study Subjects, Informed Consent Process, Pharmacy or Emergency Resources information.

- Under 'My Studies' click into the study requiring a change.
- Click on Start xForm and select the **Revised NMDP sIRB Study-Specific Local Context Worksheet**.
- After completing the xForm and attaching all the necessary documents, click 'Submit'
- The NMDP IRB staff will conduct the pre-review and inform you of any further Clarifications.
- After the IRB review, you will receive an email from the NMDP IRB with review determination.

6.3 Site-specific Document(s) Submission

Locally developed materials, not specific to a study, may include translated Short Forms, COVID-19 information sheets, boilerplate language template, and other research participant-facing documents that can be used for any study. To request the NMDP IRB review of these documents:

- Click into your Site Management page under 'My Studies' (e.g., Site Management-308)
- Click on Start xForm on the left-hand side and select the **Site-specific Documents Submission**
- After completing the xForm and attaching all the necessary documents, click 'Submit'
- The NMDP IRB staff will conduct the pre-review and inform you of any further Clarifications.
- After the IRB review, you will receive an email from the NMDP IRB with review determination.

6.4 Consent Form Revisions

When study-wide consent form revisions have been approved by the NMDP IRB, study sites that have already had their institutional study consent form approved by the NMDP IRB should incorporate the revisions and submit to the NMDP IRB for approval.

- Find the study requiring consent form submission under 'My Studies'
- Click on Start xForm and start the **IRB Request for Study Amendment**
- After completing the xForm and attaching all the necessary documents, click 'Submit'. The form will be sent to the PI for signature via email.
- Once the xForm is received by the IRB office, the NMDP IRB staff will conduct the pre-review and inform you of any further Clarifications.
- After the IRB review, you will receive an email from the NMDP IRB with review determination.

6.5 Add/Remove sIRB Site Contacts

To add or remove institutional primary contacts, submit a **Add/Remove sIRB Site Contacts** xForm from your Site Management page. You can start this form by clicking on 'Start xForm' on the left-hand side under the Actions.

6.6 Study Site Closure

To close a study at a local institution with the NMDP IRB prior to the study's completion, submit the **Study Site Closure Form**.

- Click into the study under 'My Studies'
- Click on Start xForm and start the **Study Site Closure Form**.
- After completing the xForm and attaching all the necessary documents, click 'Submit'
- The NMDP IRB staff will conduct the pre-review and inform you of any further Clarifications.
- After the IRB review, you will receive a Study Closure Acceptance email.

Further Questions

If you have further questions regarding your study status or using IRBManager, contact the NMDP IRB Staff at IRBStaff@nmdp.org or contact Julia Tkachenko, Senior Human Research Protection Program Specialist by phone at [\(763\) 406-5890](tel:7634065890).