Training for Committee Members and Authorized Officials
at the
National Marrow Donor Program
in the Use of
IRBManager

Contents

V2.0 March 5, 2020

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

1.2 Non-NMDP users:

If you had an approved (and not closed) study with NMDP IRB, your contact has been created within IRBManger. 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 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.

1.3 NMDP users:

1.   Go to https://nmdp.my.irbmanager.com/

2.   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 by phone at jtkachen@nmdp.ort or (763) 406-5890.

1.4 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: they 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

Under actions, you can start either a Human Subjects Research Determination Form or an Initial Application for Biomedical or Social and Behavioral Studies.

Note: Request for Amendment Form, Application for Continuing Review Form, Notification of Study Closure, Reportable Event, Major Protocol Exceptions, and single IRB Forms cannot be started from this area as they must be started from within the study. See section 3.0 on how to start an xForm

3.2 Recent Items

The hyperlinks under this heading will show the most recent items you have viewed in IRBManager. You can just click on any link under "Recent Items" to go directly to that item.

3.3 Messages

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

3.4 Studies

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.

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.

3.5 xForms section of dashboard

xForms (5 Active)

- You have **2 unsubmitted** xForms.
- You have **3 xForms** being processed at a later stage.
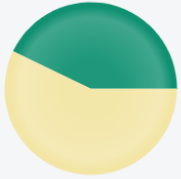- There are **1 xForms** awaiting your attention.

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 form that is currently awaiting review and signature by the PI or is being processed by the IRB.
- 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 xForms currently awaiting your attention
    - The user has 1xForms that currently need action by the user (i.e. 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.
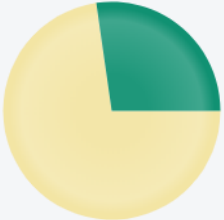
3.6 Events

Events (11 Open)

Only show events where I am: [▼]

- [yellow] You have **8 Continuing Review** events.
- [green] 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 dropdown following "Only show events where I am:" will allow you to show the events according to your role in the associated study.

3.6.1 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 availalble) 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'.

3.6.2 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.

3.7 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 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 main 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.

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

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

3.7.1 Study-Sites

The main 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 availalble) and the name of the institution
- PI: Principal Investigator of the study at the site
- Status
- Approval
- Initial Approval
- Expiration
- Comments

3.7.2 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 a "Add/Remove Study-Site Contacts" xForm. You can start this from by click on 'Start xForm' on the left hand-side under the Actions.

Note: before you add anew contact to the study-site, please ensure the contact is added to the IRBManager first. To do so, use the "Add New Contact to IRBManager" xForm.

3.8 Find Study

User can search by PI name or Study number (**complete number**) 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.

3.9 Help

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.

3.10 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

3.10.1 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 any 3 of the following: upper case letter(s), lower case letter(s), number(s), and special characters (e.g. !, @, #)
4. Click "Update".

3.10.2 Change My Profile

1. Click on "Change My Profile" link.

My Profile

Change User Information

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

[Update]

You will then see this view:

2. Update your name, degree, specialty or email address.

3. Click "Update."

3.10.3 My Phone Number(s)

1. Click on "My Phone Number(s)" link.

My Phone Numbers

Action	Primary	Type	Number
🗑️ ❌	✓	Business	3-2693

You will then see this view:

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:	☑
	Add Phone Cancel

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

3.10.4 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."

3.10.5 Last 25 Logins

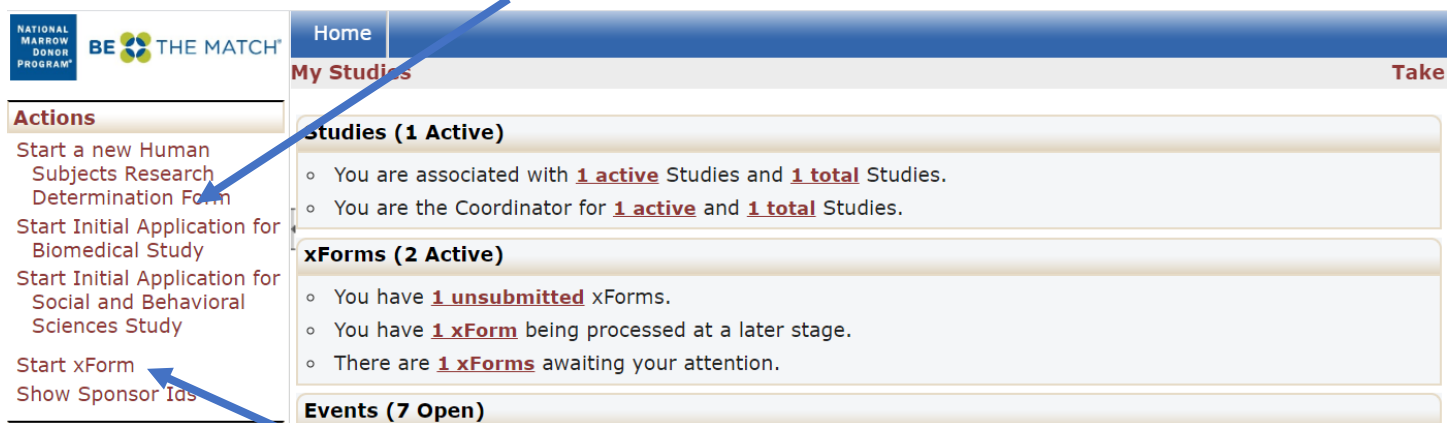Clicking on this link will provide a list of the time and date of the last 25 times you logged into IRBManager.

4.0 Managing forms in IRBManager (xForms)

IRBManager uses web-based forms called xForms. An xForm is an electronic form which is equivalent to NMDP IRB paper forms for Initial Application, Continuing Review, Amendments, etc. This section allows ways to begin an application for NMDP IRB review. Users submitting to the NMDP IRB will submit the xForm appropriate to the type of request (i.e. new study, amendment, continuing review)

4.1 Human Subjects Research Determination Form

This form should be completed when the investigator is uncertain whether the study is human subjects research. The PI or a member of the research team (called the submitter within IRBManager) will complete the form and submit. No signature is required.

1. On the home page (the view when a user logs in), under the action menu on the far-left side go to 'Start a new Human Subjects Research Determination Form'

2. Start xForm
   i. Gives the option to start other forms, such as 'Create New Contact' form, which is used to create a username and login for a contact not in the IRBManager system.

4.2 Completing an xForm

The questions in the xForms are directed by the answers given. For example, research not involving NMDP donors, will not ask 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.

4.2.1 Adding a Contact

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.

4.3 New study applications

1. On the home page (the view when a user logs in), under the action menu on the far-left side, select one of the following:
   a. Start an Initial Application for Biomedical or Social and Behavioral Sciences Forms

      i. These applications should be used for new studies.

   b. Start xForm

      i. Gives the option to start one of the above forms or to start the 'Create New Contact' form, which is used to create a username and login for a contact not in the IRBManager system.

2. Click on the name of the form to start the form.
   a. This will start the applicable form that you have requested.

4.2.1 Attaching Documents

To attach a document:

1. Click "Add Attachment" on specified attachment questions.

2. Enter name for your attachment. If you want to just use the name of the uploaded file, leave this field blank.

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 ▼	
File:		Select

[Attach] [Cancel]

4.2.2 Submitting the xForm

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

4.4 Requesting PI Signature (not required for some xForms)

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.

Under the xForms section of their Dashboard, they will see an xForm awaiting attention:
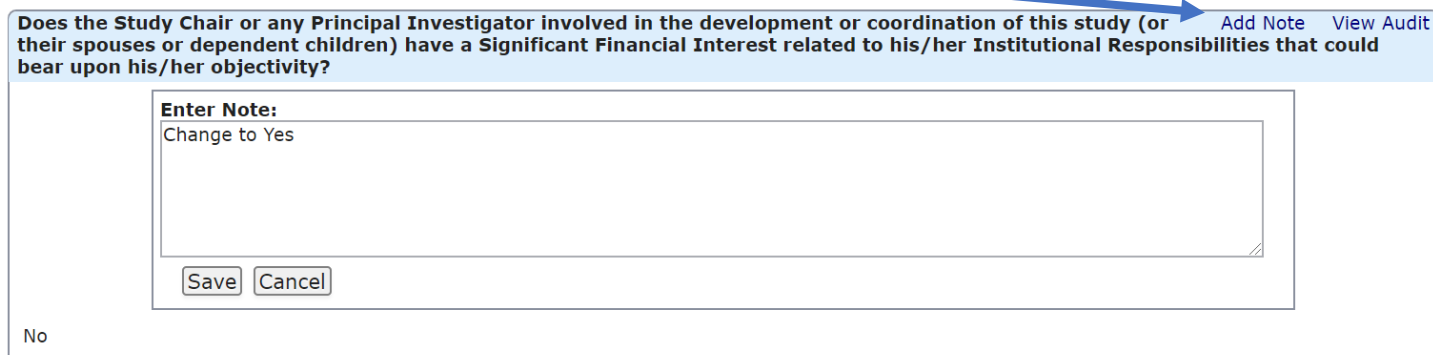
xForms (2 Active)

- 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

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

[Save] [Cancel]

No

The PI will make selected 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]

4.4.1 Making requested revisions to the xForm

If the PI has indicated the revisions are required, the form will go back into Data Entry stage. You 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:

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

4.4.2 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:

4.5 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 requiring the Submission. On the left hand-side under Actions, select Start xForm:

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, et cetera).

Find Study (Ctrl+Q)

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 data entry

- **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 have the following

  - **Data entry**—form is currently with the user either to complete or make changes

  - **PI review**—if the PI did not complete the xForm, this is the stage the PI reviews and submits the form

  - **Responsible Official Signature**—Stage that the RO will sign the form and submit to the IRB

  - **IRB Screening**—Stage that the IRB Office will screen the application for completeness and either request further information/documentation or assign for review

  - **Under Expedited Review**—the project is being reviewed at the expedited level

  - **Under Full Board Review**—the project is being reviewed by the convened board

  - **Decision 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 <u>not</u> be initiated until Stipulations are met.
  - o The form will go to data entry and, 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.

- **Dissapproved:** 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.

  - o Form will go back to data entry and be routed back through the IRB Office and to the full board for review.
  - o
- **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.

Event

Type:	Initial Submission	**Started:**	08/21/2017
Instance:		**Completed:**	
Committee:	Inherited from Study		
Review Cycle:			

▶ **Notes (1)**

Steps (10) ☑ Hide Skipped

Step	Planned	Actual	Complete	Minutes	Micro Note
Receive Submission		08/21/2017	Yes		
Review for completeness		08/21/2017	Yes		
Assign to Reviewers		08/21/2017	Yes		
Receive Expedited Reviewer Recommendation		08/23/2017	Yes		
Notify Board of Recommended Approval			No		
Notify PI of Approval			No		

5.3 Further Questions

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