



Northcentral University

IRBManager Instruction Manual

Student User Guide



Contents

1.0 IRBManager	3
1.1 IRBManager Introduction	3
1.2 IRBManager Account Creation	3
2.0 Passwords	5
2.1 First Log In	5
2.2 Forgot Password	5
2.3 After First Log In	5
3.0 Navigating the Home Page	6
3.1 Dashboard	6
3.2 Top Navigation Toolbar	6
3.3 Editing Profile Settings	6
3.3.1 Change Password	7
3.3.2 Change Your Profile	7
3.4 Left Navigation Toolbar	7
3.5 Studies	8
3.6 xForms	8
3.7 Events	9
3.8 My Studies	10
4.0 Submitting an xForm	11
4.1 Submitting an xForm for an Initial Study	11
4.2 Completing an xForm	12
4.3 Submitting an xForm	13
4.4 Submitting an xForm for an Existing Study that has Received Initial Approval	14
5.0 Navigating the Study Protocol Page	16
5.1 Study Protocol	16
5.2 Study-Site	16
5.3 Contacts	17
5.4 Events	17
5.5 Notes and Emails	18
6.0 Event Details	19
6.1 Study Site	19
6.2 Event	19
6.3 Steps	20
6.4 Actions in the Event Details	20
7.0 Returned xForms from Your Dissertation Chair or the IRB	22
7.1 Requesting Modifications to xForms Submitted Prior to IRBManager	23
8.0 IRB Dos and Don'ts – Best Practices	26

1.0 IRBManager

1.1 IRBManager Introduction

IRBManager allows users to enter IRB applications and protocol related information including forms, attachments, documents, and events which can be associated with the study.

Users have view access to the studies with which they are affiliated, as well as attachments, events, and documents generated for each study. Users do not have the authority to edit these items after the study has been submitted and approved unless the IRB returns the forms for revisions.

For studies initially approved within *IRBManager*, modification requests, requests for continuing review, and study closure notifications must be submitted via an e-Form available from the “Start xForm” on the left side menu within a study (you have to find “My Studies” on your Home page, click on your study, and then go to “Start xForm”).

Progress on all submissions, including new applications, is viewable to the Principal Investigator (PI). The Dissertation Chair assigned to the study is copied on all status update emails the PI receives via *IRBManager*.

IRBManager is a full web- based system. As long as *IRBManager* and the remote user are on the same logical network (LAN, WAN, VPN, the Internet, etc.), remote users can have access.

1.2 IRBManager Account Creation

Students can create their *IRBManager* accounts during their first dissertation course, DIS9901A. The link can be found in the course or accessed below.

1. Go to <https://ncu.my.irbmanager.com/>.
2. Create an account by clicking “Click here to register”.

NCU
Northcentral University

Login

User Name

Password

Client

Remember Client

[Forgot Password?](#)

Don't have an account?
[Click here to register.](#)

For assistance with creating an IRBManager account or resetting your IRBManager password, please contact the NCU Service Desk at 1-888-628-1567.

Copyright ©2000-2017 BEC All Rights Reserved.
Blue Oyster (2016.7.13:0/Release/65b11cc639854e553a74ae6102bb3269307092)
PRODWEB4 at 2017-03-15 17:57:44Z
Page generated in 0.007 seconds.

3. On the account registration page, select “Yes, I’m a student”.

NCU
Northcentral University

NCU Account Registration

Are you an NCU Student Yes, I'm a student
 No, I am not a student

Copyright ©2000-2017 BEC All Rights Reserved.
Blue Oyster (2016.7.13:0/Release/65b11cc639854e553a74ae6102bb3269307092)
PRODWEB4 at 2017-03-15 18:12:52Z
Page generated in 0.007 seconds.

4. Enter your NCU student email address.



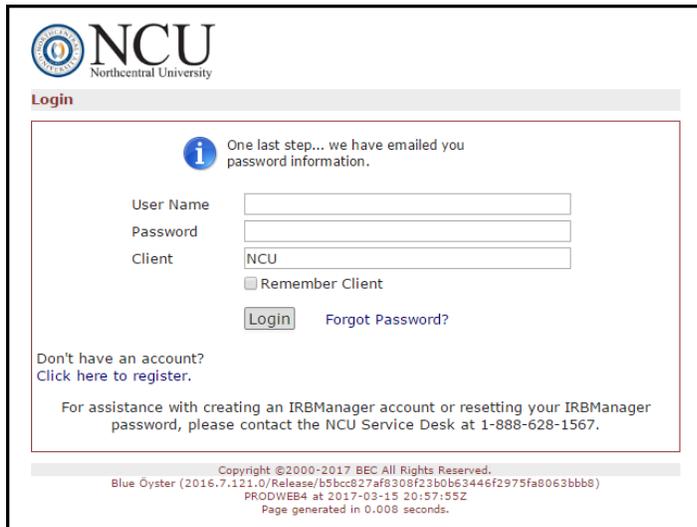
The screenshot shows the 'NCU Registration - Email' page. At the top left is the NCU logo and name. Below it is the title 'NCU Registration - Email'. The main form area has a label 'Email Address' followed by a text input field containing 'test@email.ncu.edu'. Below the input field is a note: '(must end in '@email.ncu.edu' or '@o365.ncu.edu')'. A 'Next' button is positioned below the input field. At the bottom of the page, there is a copyright notice: 'Copyright ©2000-2017 BEC All Rights Reserved. Blue Oyster (2016.7.131.0/Release/6d6e281735c383b329efaf56f547ad6483bde163) PRODWEB4 at 2017-03-15 20:59:53Z Page generated in 0.032 seconds.'

5. Enter your information.



The screenshot shows the 'NCU Registration - Details' page. At the top left is the NCU logo and name. Below it is the title 'NCU Registration - Details'. The main form area has a label 'Email' followed by a text input field containing 'test@email.ncu.edu'. Below this is a 'Prefix' label with a text input field and the text '(Mr, Ms, Dr, etc.)'. Below the prefix field are three fields for 'First Name', 'Last Name', and 'Phone', each with a text input field and a red asterisk to its right. A 'Next' button is positioned below the phone field. At the bottom of the page, there is a copyright notice: 'Copyright ©2000-2017 BEC All Rights Reserved. Blue Oyster (2016.7.121.0/Release/b5bcc827af8308f23b0b63446f2975fa8063bbb8) PRODWEB4 at 2017-03-15 20:42:29Z Page generated in 0.032 seconds.'

6. The username is your NCU email address. An email with password information will be sent to the email provided. The system will prompt users to reset the password the first time they log in.



The screenshot shows the 'Login' page. At the top left is the NCU logo and name. Below it is the title 'Login'. The main content area has an information icon (i) followed by the text 'One last step... we have emailed you password information.'. Below this is a form with three text input fields: 'User Name', 'Password', and 'Client'. The 'Client' field contains 'NCU'. Below the 'Client' field is a checkbox labeled 'Remember Client'. Below the checkbox are two buttons: 'Login' and 'Forgot Password?'. Below the form is a link: 'Don't have an account? Click here to register.'. Below the link is a paragraph: 'For assistance with creating an IRBManager account or resetting your IRBManager password, please contact the NCU Service Desk at 1-888-628-1567.'. At the bottom of the page, there is a copyright notice: 'Copyright ©2000-2017 BEC All Rights Reserved. Blue Oyster (2016.7.121.0/Release/b5bcc827af8308f23b0b63446f2975fa8063bbb8) PRODWEB4 at 2017-03-15 20:57:55Z Page generated in 0.008 seconds.'

2.0 Passwords

2.1 First Log In

The first time you log in, you will be prompted to change your password.

To change your password and proceed:

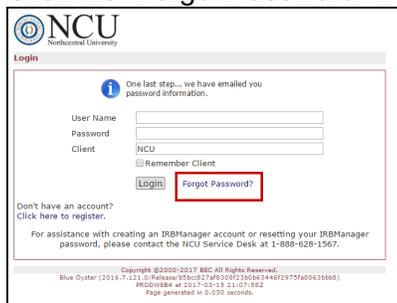
1. Enter old password.
2. Enter new password and then enter new password again to confirm.
3. Click “Update”.

If you enter the wrong username/password three times, *IRBManager* locks your account as a security precaution.

2.2 Forgot Password

In the event the password has been forgotten,

1. Click the “Forgot Password” link on the login page.



The screenshot shows the NCU login page. At the top left is the NCU logo. Below it, the text 'Login' is displayed. A message states: 'One last step... we have emailed you password information.' Below this are input fields for 'User Name', 'Password', and 'Client' (with 'NCU' entered). There is a 'Remember Client' checkbox. At the bottom of the form are 'Login' and 'Forgot Password?' buttons. The 'Forgot Password?' button is highlighted with a red rectangular box. Below the form, there is a link for users who don't have an account and a footer with copyright information and a timestamp.

2. A password reset screen will ask for your email address and Client ID. Your Client ID is NCU. Please enter the email address you used to register your account, and a new password will be sent to that email account. You will be asked to reset your password when you log in using the temporary password.



The screenshot shows the 'Forgot Password' screen. At the top left is the NCU logo. Below it, the text 'Forgot Password' is displayed. The main instruction is: 'Forgot your password? Please provide your email and client id below.' There are input fields for 'EMail' and 'Client Id' (with 'NCU' entered). Below these fields is a CAPTCHA image showing the code 'BV450'. Below the CAPTCHA is the text 'Type the code from the image above:' and a 'Retrieve' button. The 'Retrieve' button is highlighted with a red rectangular box. At the bottom, there is a footer with copyright information and a timestamp.

2.3 After First Log In

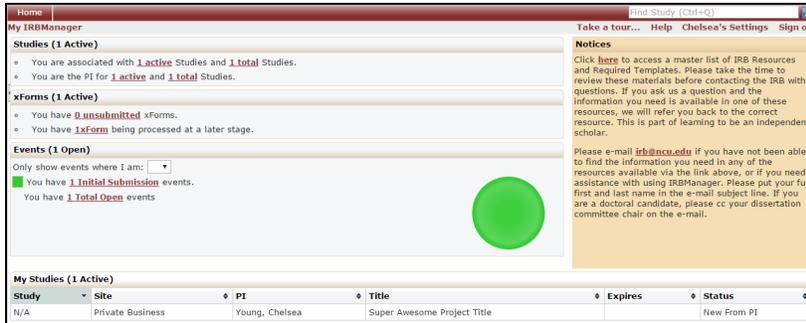
Once your password has been updated, you will be logged into the system. Your view will depend on your assigned role. If you are a researcher, your studies will appear on your Home screen, also known as the Dashboard.

Later, when asked to sign a document, you'll be able to provide a required signature electronically simply by entering your password each time.

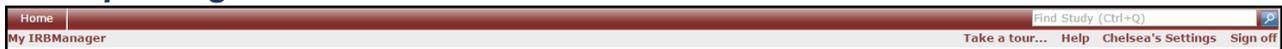
3.0 Navigating the Home Page

3.1 Dashboard

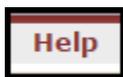
When you log in, you will arrive at the *IRBManager* home page, which is also known as the Dashboard.



3.2 Top Navigation Toolbar



The Home button takes you back to the Dashboard from any page of *IRBManager*.



The Help button directs researchers to the master list of IRB Resources and Required Templates and provides contact information for the IRB. This information can also be accessed from the Dashboard in the Notices section.



The "Take a Tour" button will take you on a tour of each section of the Dashboard. It is recommended to do this the first time you log in.



"Chelsea's Settings" allows you to edit your profile settings. "Chelsea" will be replaced with your first name

3.3 Editing Profile Settings

The following actions can take place when editing your profile settings:

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



3.3.1 Change Password

1. Click on “Change Password” link. You will then see this view:

Home Find Study (Ctrl+Q)
Change Password Help Chelsea's Settings

Valid Passwords
A valid password must be at least 6 characters long, be different from the user name, and contain characters from at least 3 of these groups: uppercase letters, lowercase letters, numbers, and special characters (e.g. !, @, #, ~).

Change Password

User
Username
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.
4. If you are trying to change your password here and you can't remember your old password, you must go to the top right of your screen, click “Sign off,” and then use the “Forgot password” link on the login page to reset your password.

3.3.2 Change Your Profile

1. Click on the “Change My Profile” link. You will then see this view:

Home Find Study (Ctrl+Q)
My Profile Help Chelsea's Settings

User Information

Prefix (Mr, Dr, etc):
Middle Name:
Suffix (Jr, III, etc):
Specialty:

First Name: Chelsea
Last Name: Young
Degree:
Email Address: cyoung@ncu.edu
From Address for Outbound Email: irb@ncu.edu

Update

2. Update your name or email address.
3. Click “Update”.

3.4 Left Navigation Toolbar

Actions

Please click here to submit a new IRB Application - Standard Version

Start xForm
Show Local Study Id

Select the link that reflects the action you want to take.

- **Submit a new IRB Application if you are submitting for the first time.**
- Click “Start xForm” if you need to submit a modification, continuing review, or closure notification **only for a study that was approved before IRBManager was implemented.**

If your study was initially approved in *IRBManager* and you need to submit a modification, continuing review, or closure notification, there is a different process for this. You have to go into your study first – more on this later.

Messages

Welcome to IRBManager
at NCU

View your active messages.

Useful Links

[IRB Resources and
Required Templates](#)

This section provides useful information such as the IRB Resources and Required Templates. The resources housed here provide important information that will provide answers to most questions that a user has. Please take the time to review these materials before completing your IRB application and before contacting the IRB with questions.

Recent Items

[2017-013-PRIB](#)

Hyperlinks will appear under this heading to show the most recent items you have accessed in *IRBManager*. Clicking on any link under “Recent Items” will take you directly to that item.

My Documents & Forms

[0 User Attachments](#)

[1 xForms](#)

View the number of attachments and xForms associated with your account.

3.5 Studies

This area shows the studies each user is associated with and the studies for which the user is the Principal Investigator (PI). Your study will only appear here after it has been sent to the IRB and the IRB has accepted it for review. If you need to view your application before that time, please go to the “xForms” section of your Dashboard and click on the link for “Unsubmitted xForms”.

Helpful Hint: By clicking on the underlined link, you will go to the studies with which you are associated. If your study shows here, you will need to click on your study to submit xForms for modifications, continuing reviews, closure notifications, or HRPO letter submissions. After you click on your study, you may click “Start xForm” on the left side menu. Different options will appear here than if you click “Start xForm” from the Dashboard.

Studies (1 Active)

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

3.6 xForms

The “xForms” tab shows the forms or applications currently being processed at this time for the user. An xForm is a document with information that is submitted to the IRB. Your study in *IRBManager* can have several xForms associated with it (initial application, modification requests, study closure notification, etc.).

xForms (2 Active)

- o You have [2 unsubmitted](#) xForms.
- o You have [0 xForms](#) being processed at a later stage.
- o There are [1 xForms](#) awaiting your attention.

In this view of the Dashboard:

- **You have 2 unsubmitted xForms.**

This line denotes xForms (submissions) started but not yet submitted. The user has clicked “Save for Later” and did not submit them to the Dissertation Chair or IRB.

Note: By clicking the underlined link, “2 unsubmitted,” the user can go directly to the unsubmitted xForms. If they appear to be the same kind of form, look at both, decide which you want to use, and then delete the other one because it’s a duplicate.

- **You have 0 xForms being processed at a later stage.**

If you have a number other than “0” here, it represents that the user has created and submitted an xForm and it is still being processed at a later stage. For example, it could be under review by the Dissertation Chair, or by the IRB. When there is something listed here, clicking on the link “1 xForms” will show what stage the submission has reached. This way you can always know the status of your submission without having to ask.

- **There are 1 xForms currently awaiting your attention.**

Your xForm has been reviewed, and there is feedback from your Dissertation Chair or the IRB and revisions that need to be made by the user. This could be a clarification regarding an answer or a condition which needs to be resolved before approval can be granted. You will always be notified via email that these submissions are awaiting your attention.

Helpful Hint: If the email says your Dissertation Chair has returned your form for revisions, this means the IRB has not yet received or reviewed the form for this particular iteration of the review process and that you will need to address your Chair’s feedback before your Chair sends it to the IRB for review.

Note: By clicking the underlined link, “[xForms](#)” the user can go directly to the xForms that need the user’s attention.

3.7 Events

The events section of the Dashboard shows all open events and the submission name, such as Renewal Request, New Submission, Closure, and Revisions.

Events (1 Open)

Only show events where I am:

■ You have [1 Initial Submission](#) events.

You have [1 Total Open](#) events



Helpful Hint: An event stays open until all actions which are part of the event have been completed. It is possible for the xForm to be complete and approved, but the event is still open until an IRB Board meeting occurs where the Board would be notified of the completion of the event.

3.8 My Studies

This is a list of all the active studies for the user. Again, your study will only appear on this list if the IRB has accepted it for review. If you are still working on your initial submission, even if your Dissertation Chair has given you feedback, your study will not appear here, and you will need to look for it under “Unsubmitted xForms” Information in this section includes:

- The study number
- The site the study is taking place
- The PI name
- The study title
- Expiration date of the study

Note: By clicking on the blue link under “Study,” the user can go directly to the study.

My Studies (1 Active)					
Study	Site	PI	Title	Expires	Status
N/A	Private Business	Young, Chelsea	Project Title		New From PI

By clicking the arrow beside the column header for Study, Site, PI, Study Title, Expiration Date and Status, you can sort the studies accordingly. For NCU doctoral candidates there will typically only be one study – the dissertation. (One exception to this is that researchers who will conduct a pilot study (not a field test – this is different) will have two studies in *IRBManager*: 1- the pilot study, and 2- the full study. These are treated as two separate and distinct studies by the IRB. Both must be approved before they can begin. The pilot study must be closed with the IRB before the IRB will initiate a review of the full study. (Please see the [IRB resource on pilot studies and field tests](#) for more information about this.)

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

4.0 Submitting an xForm

4.1 Submitting an xForm for an Initial Study

1. If you are beginning the IRB process at NCU for the first time, and you have never had an IRB application reviewed by the IRB prior to *IRBManager*, you will begin an Initial Application. Go to the “Home” page and look at the “Actions” tab in the left navigation toolbar.



2. Click on “Please click here to submit a new IRB Application – Standard Version.”
3. The application will open in a new tab. On this page, the Principal Investigator (PI) information will automatically populate, and you will be prompted to confirm whether your study is new or already existing (if it appears on the list in 1a, it is not new and is already existing).

Study-Site	Role	Title	Sponsor
------------	------	-------	---------

At the top of each page of the application, you will see a drop-down menu and the number of pages left in the application to complete. The drop-down will allow you to click to any page of the application of your choosing. To the right of the drop-down menu, you will see a tab with page numbers that will indicate what page you are as you go through the application.

4.2 Completing an xForm

Begin by completing the items on page one of the xForm for the initial submission of the NCU IRB Application – Standard Version.

1. Principal Investigator Add Note View Audit

Young, Chelsea

Email:

1e. Please choose the role in which you will be conducting this research:

NCU Graduate Student
 NCU Faculty/Staff
 NCU Undergraduate Student

If you have more than one role, please choose the primary role in which you will be conducting the research. For example, if you work at NCU and you are also working on a dissertation and this application is for your dissertation, you should choose "NCU Graduate Student," not NCU Faculty/Staff.

1f. Please choose the option to indicate the Principal Investigator's affiliation with NCU:

2. If any of your study personnel are not found within IRBManager when you enter their e-mail addresses in item 3 below, please click the "Add New Contact" link in item 2 to add them and make them available. Add Note

[Add New Contact](#)

3. Study Personnel Add Note

3a. Please enter the NCU e-mail address of your Dissertation Chair or Faculty Mentor:

If you are not yet in the dissertation phase or you are in a non-doctoral graduate program, you will need to identify an NCU Faculty mentor who will supervise your research and enter that person's NCU e-mail address here.

3c. Will you have a co-investigator(s) for this study?

Yes
 No

3d. Will you have a research assistant(s) for this study?

Yes
 No

4. Project Information Add Note

4a. Project Title:

4b. Anticipated Length of Study from Date of IRB Approval to the End of Data Collection, in days:

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 from the xForm section of the Dashboard by clicking on the "Unsubmitted xForm" link.

[Previous](#) [Next](#) [Save for Later](#) [View Questions with Notes](#) [PDF](#)

- You may have to scroll down to view and answer all the questions.
- If an item is required, an answer must be provided. If you fail to answer a required item, an error message will appear. The system will not allow you to continue until the field has been populated and red text will appear to prompt you to respond.

5. Please select the research type: (Required)

Initial Application for Approval
 Pilot Study
 Study Not Yet Approved and Previously Reviewed Outside IRBManager
 Full Board Study Not Yet Approved and Previously Reviewed Outside of IRBManager

5. Please select the research type: *(Required)*

==> Required.

==> 5a. Externally Funded - Required.

Initial Application for Approval

Pilot Study

Study Not Yet Approved and Previously Reviewed Outside IRBManager

Full Board Study Not Yet Approved and Previously Reviewed Outside of IRBManager

Attaching Documents

Site permission letter, site IRB materials and approvals, informed consent forms, readability reports, recruitment materials, etc. can all be attached within your xForm.

To attach a document:

1. Click “Add Attachment” on specified attachment items.
2. Enter a name for your attachment. If you want to use the name of the uploaded file, leave this field blank.
3. Select the type of attachment if that option is available.
4. Click the “Browse” button to locate the file on your computer.
5. Click “Attach” to finish the process.

Note: The file name will be listed in the approval letter, so please make sure the file name can identify the document.

4.3 Submitting an xForm

Be sure to review your xForm and attachments before submitting to your Dissertation Chair for review. Once you submit the xForm, it will be locked until it is returned to you for revisions, either by your Dissertation Committee Chair, who will review it before it goes to the IRB, or by the IRB.

If the xForm has not yet been submitted, you can view the xForm from the Dashboard and view any attachments in “My Documents” and “Forms” or under “Unsubmitted xForms”.

After the form has been completed and your Dissertation Chair has submitted it to the IRB, the IRB staff will load it into the system and the IRB staff will direct *IRBManager* to assign a study event on the protocol page. This might not happen immediately. The IRB processes new submissions periodically. If it takes longer than 7 business days for the study even to appear on the protocol page, please email irb@ncu.edu with your full name in the subject line to check the status. Please keep in mind that the maximum turnaround time for IRB reviews of studies that are not being reviewed at the Full Board level is 15 business days. If your study will be reviewed at the Full Board level, this usually takes longer than 15 business days and you will be notified separately. Most studies do not require review by the Full Board. When you see the study event appear on the protocol page, you can click on the event name (blue link) to track the event progress (see section on “Events”).

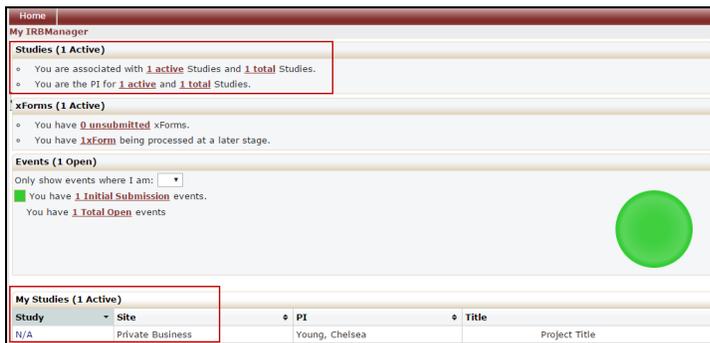
When all pages of the xForm (submission) have been completed, you will electronically sign the application using your password.

84. Please enter your password to electronically sign this form: (Required)

To sign, enter password for cyoung@ncu.edu

4.4 Submitting an xForm for an Existing Study that has Received Initial Approval

To complete an event (submission) on an active study, such as a Modification Request, Continuing Review Request or Study Closure Notification, you must first go into the study. You can access your study from the Dashboard under “Studies” or “My Studies.”



When you are in the study, click the “Start xForm” button in the “Actions” section of the left navigation toolbar.



You will then choose the appropriate form (xForm).

Select xForm to start		
Action	Form (Click to start)	Description
	Continuing Review of an Approved Study	Continuing Review of an Approved Study
	Continuing Review of an Approved Study NOT Initially Approved in IRBManager	Continuing Review of an Approved Study
	Human Research Protections Official (HRPO) Letter Submission	Human Research Protections Official (HRPO) Letter Submission
	Modification to Approved Study	Modification to Approved Study
	Modification to Approved Study NOT Initially Approved in IRBManager	Modification to Approved Study
	NCU IRB Application - Standard Version	NCU IRB Application - Standard Version
	Protocol/Study Closure Notification	Protocol/Study Closure Notification
	Protocol/Study Closure Notification of an Approved Study NOT Initially Approved in IRBManager	Protocol/Study Closure Notification of an Approved Study Not Approved in IRBManager

5.0 Navigating the Study Protocol Page

From the Dashboard, you can access a study protocol page for each of your studies. Click on the blue study code or IRB number link to access this page..

Study 2017-013-PRIB (IRB)		Help
Study		
Study:	2017-013	Sponsor(s):
Committee:	IRB	Sponsor Id:
Category:	School of Business	Grants:
Department:		
Agent Types:	Group Interview/Focus Group	CRO:
Title:	Super Awesome Project Title	Year: 2017
Comments:	To get some very important data.	
Study-Site		
Site(s):	PRIB - Private Business	PI: Young, Chelsea
Status:	New From PI	Additional: N
Approval:		Expiration:
Initial Approval:		Other Expirations:
Comments:		
▶ Contacts (1)		
▶ Attachments (1)		
▶ Events (1)		
▶ Notes (1)		
▶ Emails (1)		

5.1 Study Protocol

This section displays basic information about the study protocol, such as:

- IRB study number
- Sponsor (Funding Organization, if any)
- Sponsor ID (Funding Organization Acronym or ID, if any)
- Category of study (Will display the department of study)
- Agent Type (Interview, Online Survey, Physical Intervention, etc...)
- Study Title
- Year of initial submission
- Comments (Abstract or Purpose of the study)

You can click on any blue link in this section to view more information on the linked item. Clicking on Sponsor(s) will provide detailed information.

Study		
Study:	2017-013	Sponsor(s):
Committee:	IRB	Sponsor Id:
Category:	School of Business	Grants:
Department:		
Agent Types:	Group Interview/Focus Group	CRO:
Title:	Project Title	Year: 2017
Comments:		

5.2 Study-Site

This section displays information about the study and the study site, such as:

- Status (Active, Closed, New from PI, Withdrawn, etc.)
- Initial approval date
- PI name
- Expiration date for continuing review
- Comments

Study-Site	
Site(s):	PRIB - Private Business
Status:	New From PI
Approval:	
Initial Approval:	
Comments:	

5.3 Contacts

This section lists the contacts associated with the study.

▼ Contacts (1)	
Name	Role
Dodd, Robert	remove

All contacts involved in the study must be listed in this section. Contacts will not have access to *IRBManager*, but they still need to be added. This is done within the xForm for the standard version of the IRB application during the initial submission.

5.4 Events

This section lists all the IRB “Events” or submissions that have been or are being conducted for this protocol. The event line contains the following sections:

- Type of Event (Initial Submission, Modification Request, Continuing Review Request Form, Study Closure Notification, etc.).
- Att – number of attachments associated with that event or review.
- Instance/UDF – the material being reviewed for the submission (Change in consent form, Addition of Co-Investigator, etc.).
- Start – the date the event was started or loaded into *IRBManager* by the IRB when the IRB accepted it for review (not the date you started your xForm because your study does not exist in *IRBManager* at that point).
- Complete – the date the event was completed and reported to the IRB.
- Last Mtg – shows the last IRB Full Board meeting to which this event or review was submitted. Even if a submission is categorized as Expedited, it shows up on a convened IRB meeting agenda as an informational item.

You can click on any blue linked event in this section to view information specific to the event. After clicking on the blue link, it will take you to event details (See Section 6.0).

▼ Events (1)						
Event	Att	FE	Instance/UDF	Start	Complete	Last Mtg
Initial Submission	10			03/24/2017		

5.5 Notes and Emails

The “Notes” and “Email” sections will include any notes for the study entered by the IRB, and any emails sent to the researcher.

▼ Notes (1)

Note	Entered ▲	By	Type
<p>User submitting e-mail: Dodd, Robert From: "NCU IRB (irb@ncu.edu)" To: "Young, Chelsea" <cyoung@ncu.edu> CC: e3rqehgkaeex-hbitdwu9b-ebada@ncu.my.irbmanager.com Attachments: NHSR Determination Letter_ChelseaYoung_Test_3_24_17.pdf Subject: NHSR Determination Letter - Chelsea Young</p> <p style="text-align: center;">Body -----</p> <p>Hello, Chelsea.</p> <p>We are writing to inform you that your IRB application has been determined to be "Not Human Subjects Research." Please see the attached letter and review form for important details about the terms of this determination. We know that you will continue to follow general ethical guidelines and wish you the best as you begin your research.</p> <p>An IRB Protocol/study closure form does not need to be submitted to the IRB, but you should refer to your course syllabus for instructions on how to submit this form for the purpose of the deliverable for your course. A continuing review is also not needed the data collection and analysis extends beyond one year.</p> <p>Thank you,</p> <div style="display: flex; align-items: center; margin-top: 10px;"> <div style="font-size: 0.8em;"> <p>Institutional Review Board O: 888.327.2877 ext. 8014 E: irb@ncu.edu Twitter Facebook LinkedIn Read the latest edition of NCU's alumni publication, Higher Degrees</p> </div> </div>	03/24/2017	rdodd@ncu.edu	Email

▼ Emails (1)

Subject	Date	Del	To/From
NHSR Determination Letter - Chelsea Young	5 hours ago		e3rqehgkaeex-hbitdwu9b-ebada@ncu.my.irbmanager.com; irb@ncu.edu; cyoung@ncu.edu

6.0 Event Details

Event details are specific to the event or submission and can be located by clicking on the submission link under the event tab.

My Events		Help		Chelsea's Settings		Sign off	
Study	Event	Started	Instance	PI			
2017-013-PRIB	Initial Submission	03/24/2017		Young, Chelsea			

The event details contain the following:

Event Details: Initial Submission on 2017-013-PRIB		Help		Chelsea's Settings		Sign off	
Study-Site							
Study:	2017-013-PRIB	Site:	PRIB - Private Business				
Title:	Project Title	Committee:	IRB				
PI:	Young, Chelsea						
Event							
Type:	Initial Submission		Started:	03/24/2017			
Instance:			Completed:				
Committee:	Inherited from Study						
Acknowledge/NHSR/Exempt/Expedited Date:							
Steps (12) <input checked="" type="checkbox"/> Hide Skipped							
Step	Planned	Actual	Complete	Minutes	Micro Note		
Receive Submission	03/24/2017	03/24/2017	Yes				
Initial Screening		03/24/2017	Yes				
Assign Reviewers	03/31/2017	03/24/2017	Yes				
Under Review			No				
Notify Researcher/Dissertation Chair of Result			No				
Notify Researcher/Dissertation Chair of Result			No				

6.1 Study Site

- IRB Number (Study Number)
- Site (Location)
- PI Name

Event Details: Initial Submission on 2017-013-PRIB		Help		Chels	
Study-Site					
Study:	2017-013-PRIB	Site:	PRIB - Private Business		
Title:	Project Title	Committee:	IRB		
PI:	Young, Chelsea				

6.2 Event

The Event shows specific details about the submission you are viewing.

- Type (New Submission, Renewal Request, Revision Request Form, etc.)
- Instance (documents or information related to the event)
- Defined (the date the event first started)
- Completed (the date the event was completed)

Event			
Type:	Initial Submission	Started:	03/24/2017
Instance:		Completed:	
Committee:	Inherited from Study		
Acknowledge/NHSR/Exempt/Expedited Date:			

6.3 Steps

This shows the steps of the submission with the dates. Each event will have the steps listed with a planned date, actual date and when it will go to the Full Board for either review or notification.

Steps (12) <input checked="" type="checkbox"/> Hide Skipped					
Step	Planned	Actual	Complete	Minutes	Micro Note
Receive Submission	03/24/2017	03/24/2017	Yes		
Initial Screening		03/24/2017	Yes		
Assign Reviewers	03/31/2017	03/24/2017	Yes		
Under Review			No		
Notify Researcher/Dissertation Chair of Result			No		
Notify Researcher/Dissertation Chair of Result			No		

6.4 Actions in the Event Details

Actions in the event details screen are as follows:

Actions
Attachments (10)
Send EMail
Start xForm
xForms (1)
Done

- Attachments – shows the attachments related to the event detail. These are the attachments uploaded by the PI. This may also include site permission and IRB approval letters from other institutions, consent forms, survey instruments and all other documents provided for this submission.
 - Generated Docs – shows the approval letter and other documents associated with the study. The IRB team generates approval letters after the IRB has approved the study.

Attachments			
Help Chelsea's Settings Sign off			
Attachments on Event Initial Submission Started 03/24/2017 on 2017-013-PRIB			
Attachments (9)	Name	Attached	Type
Generated Docs (1)	A Test for UAT.docx	3/24/2017	Site Permission Letter
	Recruiting!	3/24/2017	Recruitment Materials
	Same	3/24/2017	Readability Report
	Consent	3/24/2017	Informed Consent Form
	consent more	3/24/2017	Readability Report
	A Test for UAT.docx	3/24/2017	Data Collection Instrument
	CITI	3/24/2017	CITI Completion Report-Researcher
	Test DP	3/24/2017	Misc/Other
	Test CITI	3/24/2017	CITI Completion Report-Chair

- Send Email – allows users to send an email directly from the system. The 'From' address will reflect the user's NCU email address.
- Start xForm – Allows a user to begin a new xForm.

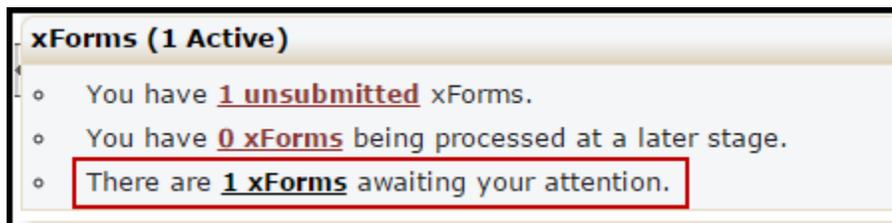
Select xForm to start		
Action	Form (Click to start)	Description
	Continuing Review of an Approved Study NOT Initially Approved in IRBManager	Continuing Review of an Approved Study
	Modification to Approved Study NOT Initially Approved in IRBManager	Modification to Approved Study
	NCU IRB Application - Standard Version	NCU IRB Application - Standard Version
	Protocol/Study Closure Notification of an Approved Study NOT Initially Approved in IRBManager	Protocol/Study Closure Notification of an Approved Study Not Approved in IRBManager

- xForms – Shows the application associated with the event. This is the application completed by the researcher.

Action	Form	Identifier	Stage/Status	Started	Submitted	By
	NCU IRB Application - Standard Version	<input type="text" value="Title"/>	Project Not Human Subjects Research	7 hours ago		Young, Chelsea

7.0 Returned xForms from Your Dissertation Chair or the IRB

If your Dissertation Chair or the IRB has reviewed your submission and has identified revisions for you to make, you will be notified under the “xForms” section of the Dashboard. You will also receive an automatically generated email from *IRBManager*, which will be sent to your NCU email account. Click the link that indicates an xForm is awaiting your attention. Your Dissertation Chair will review your re-submitted xForm and will only submit it to the IRB on your behalf if the revisions you have made are acceptable.



The next screen will list the studies that are available for you to revise. Click the link of the application you wish you revise in the “Form” section.

The screenshot shows the IRBManager dashboard with a table of forms. The table has columns for Form, Identifier, Owner, Stage, Status, Started, and Requires Approval. A search bar at the top right contains "Find Study (Ctrl+Q)".

Form	Identifier	Owner	Stage	Status	Started	Requires Approval
NCU IRB Application - Standard Version	Project Title	cyoung@ncu.edu	Standard Application Data Entry	Work in progress	02/23/2017 at 7:46 PM	No

The xForm will open up to the first page, and you can click through the application to find the questions that have comments or feedback provided.

In the example below, you will see the researcher answer of “Because I can do whatever I want” is not an acceptable response to this question. The feedback by the Dissertation Chair or IRB is posted above it, providing guidance on how to revise the response so it is more appropriate and acceptable. More information on how to respond to an item can sometimes be found by clicking the link to the right of the responses.

Helpful Hint: When you respond to feedback in IRBManager, you should revise your original response in the white text box. IRBManager will keep an audit trail of your original response and all of the changes you make to it during the review process. Please do not use “Add Note” to respond to the feedback. “Add Note” should only be used if you have a question or comment that is separate from but related to your actual response to the item.

20. Please explain why you believe site permission is not needed from the recruitment site(s): *(Required)* [Add Note](#) [View Audit](#)

Entered: 02/23/17 By: Dodd, Robert

You have stated that you will include both public and private sites. Please describe the public site and explain why it is a place where you can do whatever you want without permission.

Because I can do whatever I want.

[Click here for help understanding site permission and site IRB approval requirements.](#)

If you attempt to submit the application again without addressing all of the areas for which feedback was provided, you will be prompted to save and go back. Each area that needs attention will be listed, as seen in the example below.

Helpful Hint: If this happens, it will be helpful to copy and paste this information into a separate document or print it and then use the drop-down menu at the top of the xForm to toggle to the different pages and items that need your attention.

Your progress to this point *has been saved*, however you must address the following issues before you can submit this form. Click on a page name to go to issues on that page.

[Participants](#)

- 15. Exclusion Criteria - Change required.
- 16. Exclusion Criteria - Change required.

[Recruitment Procedures and Materials](#)

- 20. Private Site No Permission Explanation - Change required.
- 24. Locating Potential Participants - Change required.
- 27. Participant Screening - Change required.

[Informed Consent Procedure](#)

- 52. Conformed Consent Privacy - Change required.
- 53. Documentation of Informed Consent - Change required.

[Research Procedures](#)

- 60. Study Purpose - Change required.
- 61. Activities - Change required.
- 62. Meeting Frequency - Change required.

[Risk Assessment](#)

- 52. Participant Benefits - Change required.
- 53. Indirect Benefits - Change required.
- 54. Risks - Change required.

[Anonymity/Confidentiality](#)

- 70. Anonymity / Confidentiality Recruitment - Change required.
- 71. Anonymity/Confidentiality Data Collection - Change required.

[Data Security](#)

- 73. Data Security Electronic - Change required.
- 74. Data Destruction - Change required.

7.1 Requesting Modifications to xForms Submitted Prior to IRBManager

Please keep in mind that you must wait for the IRB to approve modification requests before you implement any changes to your IRB approved materials or procedures. Implementing modifications prior to IRB approval constitutes IRB noncompliance and will result in corrective and/or disciplinary actions.

If your IRB application was submitted before the implementation of *IRBManager*, you can request the IRB to approve modifications to your existing application or submit your Protocol/Study Closure Notification in *IRBManager*. In the left navigation toolbar of the Dashboard under “Actions”, select “Start xForm”.

Actions

Please click here to submit a new IRB Application - Standard Version

Start xForm

Show Local Study Id

If you need to request the IRB to approve a modification to an existing study that was approved prior to *IRBManager* Implementation, select “Modification to Approved Study NOT Initially Approved in *IRBManager*.”

Select xForm to start		
Action	Form (Click to start)	Description
	Continuing Review of an Approved Study NOT Initially Approved in IRBManager	Continuing Review of an Approved Study NOT Approved in IRBManager
	Modification to Approved Study NOT Initially Approved in IRBManager	Modification to Approved Study NOT Approved in IRBManager
	NCU IRB Application - Standard Version	NCU IRB Application - Standard Version
	Protocol/Study Closure Notification of an Approved Study NOT Initially Approved in IRBManager	Protocol/Study Closure Notification of an Approved Study Not Approved in IRBManager

Follow the steps and answer the questions, continuing through each page.

If your study appears on the 1c. Study List, and you select “Yes” your study was submitted and approved in *IRBManager*, and you can request the IRB to approve modifications to that study by following the steps below:

1c. Study List			
Study-Site	Role	Title	Sponsor
2017-013-PRIB	Investigator		
2017-018-SMM	Dissertation Committee Chair	Faculty Training	
2017-019-OTH	Dissertation Committee Chair	Testing Full Board	

1d. Does your study appear on the list above?

Yes
 No

- 1) Go to your home page to view your Dashboard.
- 2) Find your study in the "Active Study" list on the bottom of the page.
- 3) Find your study in the "My Studies" list on the bottom of the page.
- 4) Click the blue link on the left for the study number.
- 5) On the top left under "Actions," click "Start X-Form."
- 6) Choose the option for "Modification to Approved Study."

[Add Note](#)

HELP TEXT:

Please note that you should NOT choose the option for "Modification to Approved Study NOT Approved in IRBManager." This option is only for people who did not use IRBManager for their initial applications.

If your study was approved before *IRBManager* and you need to submit a Protocol/Study Closure Notification, Select Protocol/Study Closure Notification from the list.

Select xForm to start		
Action	Form (Click to start)	Description
	Continuing Review of an Approved Study NOT Initially Approved in IRBManager	Continuing Review of an Approved Study NOT Approved in IRBManager
	Modification to Approved Study NOT Initially Approved in IRBManager	Modification to Approved Study NOT Approved in IRBManager
	NCU IRB Application - Standard Version	NCU IRB Application - Standard Version
	Protocol/Study Closure Notification of an Approved Study NOT Initially Approved in IRBManager	Protocol/Study Closure Notification of an Approved Study Not Approved in IRBManager

Follow the steps and answer the questions, continuing through each page.

If your study appears on the 1c. Study List, and you select “Yes” your study was submitted and approved in *IRBManager*, and you can request the IRB to approve modifications to that study by following the steps below:

1c. Study List			
Study-Site	Role	Title	Sponsor
2017-013-PRIB	Investigator	Super Awesome Project Title	
2017-018-SMM	Dissertation Committee Chair	Faculty Training	
2017-019-OTH	Dissertation Committee Chair	Testing Full Board	

1d. Does your study appear on the list above?

Yes
 No

- 1) Go to your home page to view your Dashboard.
- 2) Find your study in the "Active Study" list on the bottom of the page.
- 3) Find your study in the "My Studies" list on the bottom of the page.
- 4) Click the blue link on the left for the study number.
- 5) On the top left under "Actions," click "Start X-Form."
- 6) Choose the option for "Protocol/Study Closure Notification."

[Add Note](#)

Please note that you should NOT choose the option for "Protocol/Study Closure Notification of an Approved Study NOT Initially Approved in IRBManager ." This option is only for people who did not use IRBManager for their initial applications.

8.0 IRB Dos and Don'ts – Best Practices

General

- **Do** use your NCU email address on all documents. **Don't** use any other email address.
- **Do** be clear about the purpose of the study in all participant materials. **Don't** use jargon. **Don't** over-simplify.
- **Do** fully disclose your title (“Northcentral University doctoral student researcher”) and any relationship you have with sites or potential participants. **Don't** use vague wording.
- **Do** align the procedures in the application with all documents. **Don't** leave it up to the IRB to reconcile inconsistent information; we will not have any way to know which information is correct, and we will need to return it to you for clarification.

Recruitment and Screening

- **Do** consider how to allow people to privately volunteer to participate. **Don't** ask people to volunteer on the spot or in front of others.
- **Do** use the master list of IRB Resources and Required Templates. These resources are available to you and should answer most, if not all, of your questions.
- **Do** plan to screen potential participants with short “yes” or “no” questions. **Don't** ask extra questions that do not directly align to eligibility or that involve data collection.

Consent

- **Do** use the current consent form template located in the IRB Resources and Required Templates. **Don't** use an old form or template.
- **Do** fill in the grey areas of the consent form template. **Don't** change any area that is not highlighted in grey.
- **Do** describe your study as minimal risk or greater than minimal risk. **Don't** describe the study as “no risk” or “no known risks.”
- **Do** accurately describe what is/is not anonymous vs. confidential. **Don't** promise anonymity or confidentiality if they cannot be secured.

Permissions

- **Do** gather site permission before you apply to the IRB and check to make sure it meets the requirements listed on the site permission help resource in IRB Resources and Required Templates. **Don't** submit blank templates or permission requests.
- **Do** go to IRB Resources and Required Templates and read the site permission handout. **Don't** forget that site permissions, DoD reviews, and dual site IRB approvals can take extra time, so make sure to plan accordingly.

CITI

- **Do** include the student's CITI certificate showing all module completion dates and quiz scores (all modules must be current and not expire within 180 days). CITI information is located in the IRB Resources and Required Templates.