

Welcome to the Research Navigator Institutional Biosafety Committee (IBC) Learning Module - **Creation and Submission of Modifications Required for IBC approval**

Welcome to the Research Navigator IBC learning module for NYULMC users

In this module, you will learn how to create and submit IBC required modifications to secure approval in order to conduct research involving:

- recombinant DNA (rDNA),
- infectious agents,
- non-human primate materials (including established cell lines),
- select agents or human gene transfer studies conducted at New York University and within the NYU Langone Medical Center.

This request is known as a “registration.” Registrations are reviewed by the New York University Institutional Biosafety Committee. The IBC is responsible for providing review and oversight of these studies to ensure compliance with the [NIH Guidelines](#) and all of the Institution's policies. Registrations are submitted to the IBC through the online [Research Navigator IBC module](#).

Washington Square/Dental School Users

Please note that in addition to your NYU NET ID, a NYU Langone Medical Center Kerberos ID (KID) and password is required to login to @NYULMC/Research Navigator/IBC.

Refer to the [“Welcome to Research Navigator Institutional Biosafety Committee \(IBC\) Learning Module – Access from outside of the NYU Langone Medical Center”](#) training PowerPoint Presentation for specific instructions on how to obtain a KID.

Required training for IBC submissions

Environmental Health and Safety has developed a training course required for anyone submitting or participating in studies registered with the NYULMC IBC including those involving human gene transfer. This course entitled “EH&S – Recombinant DNA: Use and Safe Handling - 2015” is located on iDevelop.

***** Washington Square/Dental School Users should contact Kechia.hester@nyu.edu for access to the rDNA training course.**

The NIH’s Office of Biotechnology Affairs (OBA) has issued citations to many institutions for insufficient training of rDNA users on the NIH’s rDNA Guidelines. To satisfy this requirement, training is required **once every three years**.

If you plan to submit a registration to the IBC, you are advised to take this short 10 minute course prior to submission. If you or your study staff have not successfully completed the course at the time of IBC submission, you will be reminded of the requirement prior to IBC approval. Contact mark.olmsted@nyumc.org in Environmental Health & Safety if you have any questions related to the training course.

Objectives

After reviewing this PowerPoint Presentation, you will be able to:

Create and submit IBC required modifications to a registration for research involving :

- rDNA
- Other non-human gene transfer (HGT) studies

Log on to Research Navigator via @NYULMC

Enter your credentials

Kerberos ID/NetID:

Password:

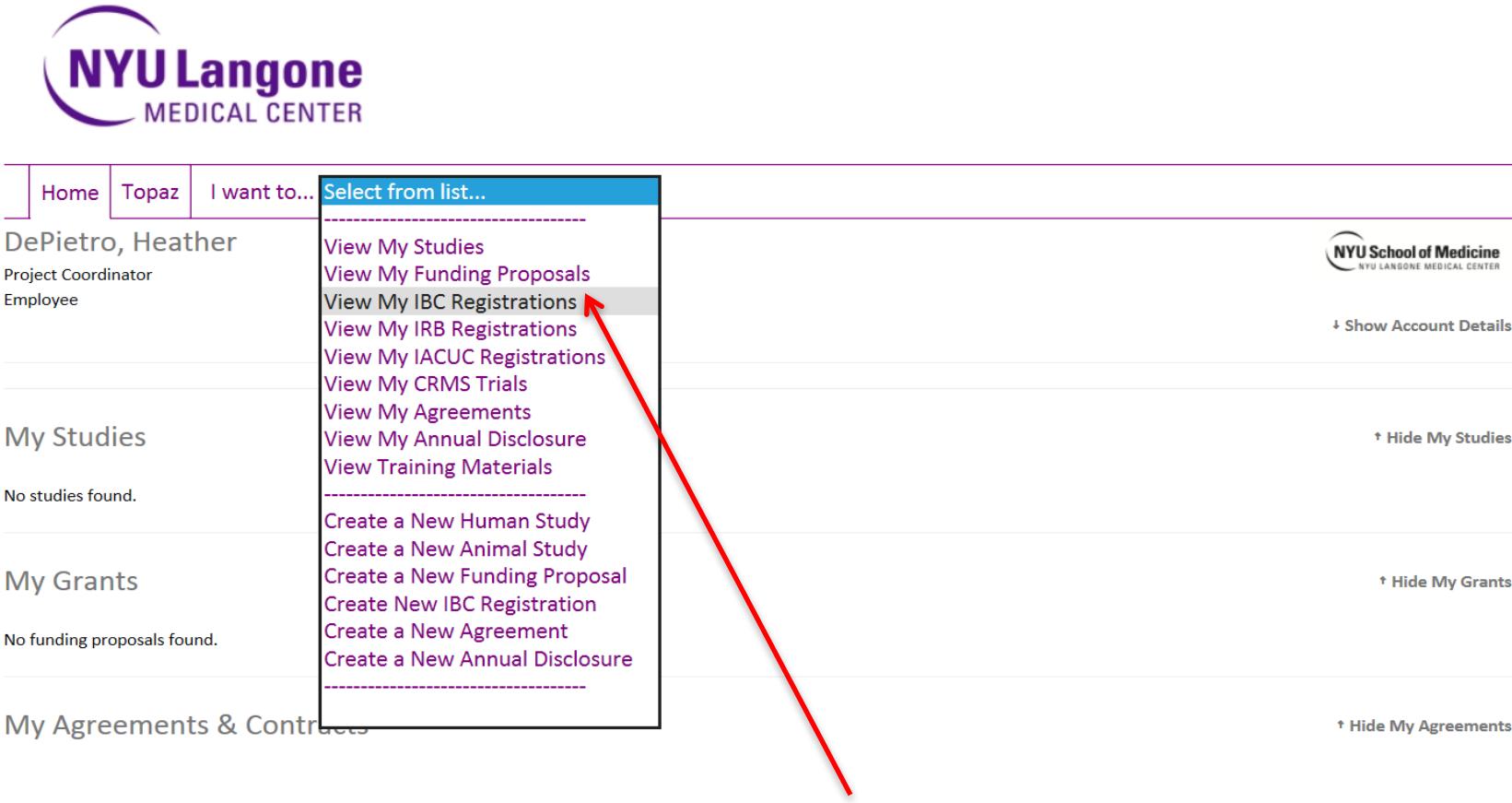
Warn me before logging me into other sites.

LOGIN | clear

[Trouble logging in?](#)

Enter your Kerberos ID and Password

Go to the IBC Module



NYU Langone MEDICAL CENTER

Home Topaz I want to... Select from list...

DePietro, Heather
Project Coordinator
Employee

NYU School of Medicine
NYU LANGONE MEDICAL CENTER

View My Studies
View My Funding Proposals
View My IBC Registrations (arrow)
View My IRB Registrations
View My IACUC Registrations
View My CRMS Trials
View My Agreements
View My Annual Disclosure
View Training Materials

My Studies
No studies found. ↑ Hide My Studies

My Grants
No funding proposals found. ↑ Hide My Grants

My Agreements & Contracts ↑ Hide My Agreements

Create a New Human Study
Create a New Animal Study
Create a New Funding Proposal
Create New IBC Registration
Create a New Agreement
Create a New Annual Disclosure

Select View My IBC Registrations

PI's Inbox

Folder for Rebecca Simms (PI)

Welcome to your Personal Page, the starting point for all interactions with this site. Note the following:

- **Inbox** - Items appearing here required immediate action by you to speed your submission through the review process. Click on link to process an item.
- **Monitor** - the progress of your submissions using the other tabs. Items on these tabs do not require any action by you.

Submitted registration that requires modification

Notice that the “state” is “modifications pending”

The screenshot shows a web-based application interface for managing registrations. At the top, there are tabs: 'Inbox' (which is selected and highlighted in blue), 'IBC Applications', and 'Audits'. Below the tabs, there is a message: 'Inbox displays all items which require action by the study team. Click on links for more information.' Underneath this message is a search/filter bar with the text 'Filter by ID' and a dropdown menu. To the right of the search bar are buttons for 'Go', 'Clear', and 'Advanced'. The main content area is a table with the following columns: ID, Name, Date Modified, Type, and State. A single row is visible in the table, showing the following data: ID 'IBC12-000006', Name 'Title-3/15/2012', Date Modified '5/8/2012 11:16 AM', Type 'IBC', and State 'Modifications Pending'. A large blue callout box with the text 'Submitted registration that requires modification' points to the 'Inbox' tab. Another blue callout box with the text 'Notice that the “state” is “modifications pending”' points to the 'State' column in the table.

ID	Name	Date Modified	Type	State
IBC12-000006	Title-3/15/2012	5/8/2012 11:16 AM	IBC	Modifications Pending

After logging in to Research Navigator IBC, select the registration in your Inbox that requires modification.

Selecting the registration link

The screenshot shows a software interface for managing IBC applications. On the left, a sidebar titled 'Current Status' shows 'Modifications Pending' with three buttons: 'Edit IBC Application', 'Printer Version', and 'View Differences'. Below this is a section titled 'My Activities...' with buttons for 'Log Public Comment', 'Send Email to IBC Administrator', 'Add Supporting Documents', 'Withdraw', 'Submit Changes', and 'Copy Registration Document'. A large red callout box points to the 'Submit Changes' button with the text: 'Select to submit changes to IBC after modifications have been made.' On the right, the main application area shows the title 'IBC: Title-3/15/2012 (IBC12-000006)'. It includes fields for 'IBC Application Type: New', 'Description', 'Principal Investigator', 'Submission Department', 'Involves Human Genome Tra...', 'Include Attempts to Obtain E...', 'Special Medical Surveillance Practices Recommended', and 'Gene:'. A light blue callout box points to the 'Description' field with the text: 'Select to edit registration'. Another light blue callout box points to the 'Principal Investigator' field with the text: 'Select to attach documents such as rDNA training certificate'. A light blue callout box points to the 'Review Notes' tab with the text: 'Select to view correspondence from IBC'. At the bottom, a 'History' tab is selected, showing a list of actions: 'Correspondence Letter Sent' and 'View Correspondence Letter'.

Current Status
Modifications Pending

Edit IBC Application
Printer Version
View Differences

My Activities...

Log Public Comment
Send Email to IBC Administrator
Add Supporting Documents
Withdraw
Submit Changes
Copy Registration Document

IBC: Title-3/15/2012 (IBC12-000006)

IBC Application Type: New

Description: Select to edit registration

Principal Investigator: Select to attach documents such as rDNA training certificate

Submission Department: Select to email IBC

Involves Human Genome Tra...
Include Attempts to Obtain E...
Special Medical Surveillance Practices Recommended:

Gene: Select to view correspondence from IBC

History

Correspondence Letter Sent

View Correspondence Letter

Viewing the correspondence letter

History Documents Review

Activity

 Correspondence Letter Sent

 View Correspondence Letter

Select this link to view letter from IBC.

To: [Rebecca NOTINGRANTSSimms \(PI\)](#)

From: Institutional Biosafety Committee

Subject: Institutional Biosafety Committee Protocol #: [IBC12-000006](#)

Title: Title-3/15/2012

Status: Modifications Required for Approval

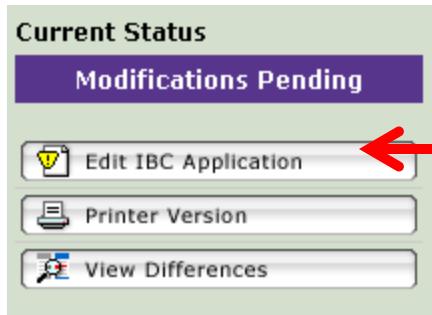
Discussion: Please complete rDNA training and attach certificate of completion.



The letter lists the modifications required

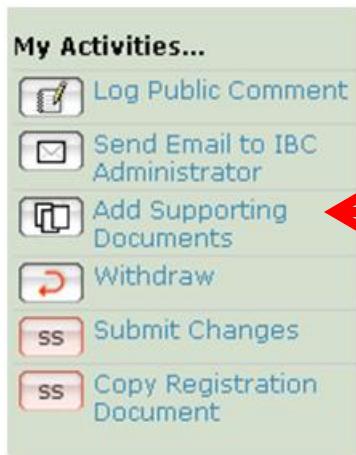


Editing the registration form

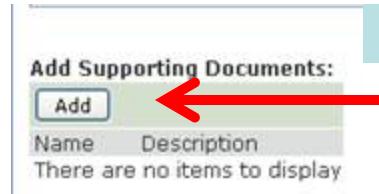


Select to edit the registration form and make any modifications that the IBC requires. After you have made the required modifications, be sure to select "Finish" at the bottom right corner of the registration form.

Finish



Select the appropriate link to "add supporting documents" if required. Another box will open.



Select the "add" button.

Select the file on your computer then select "ok" to add.

The form has fields for 'Title' (with a note: 'If not provided, the name of the file will be used') and 'File' (with a 'Browse...' button). Below the fields are buttons for 'Show Advanced Options', 'OK', 'OK and Add Another', and 'Cancel'. A note at the bottom says '* Required'.

Submitting the changes



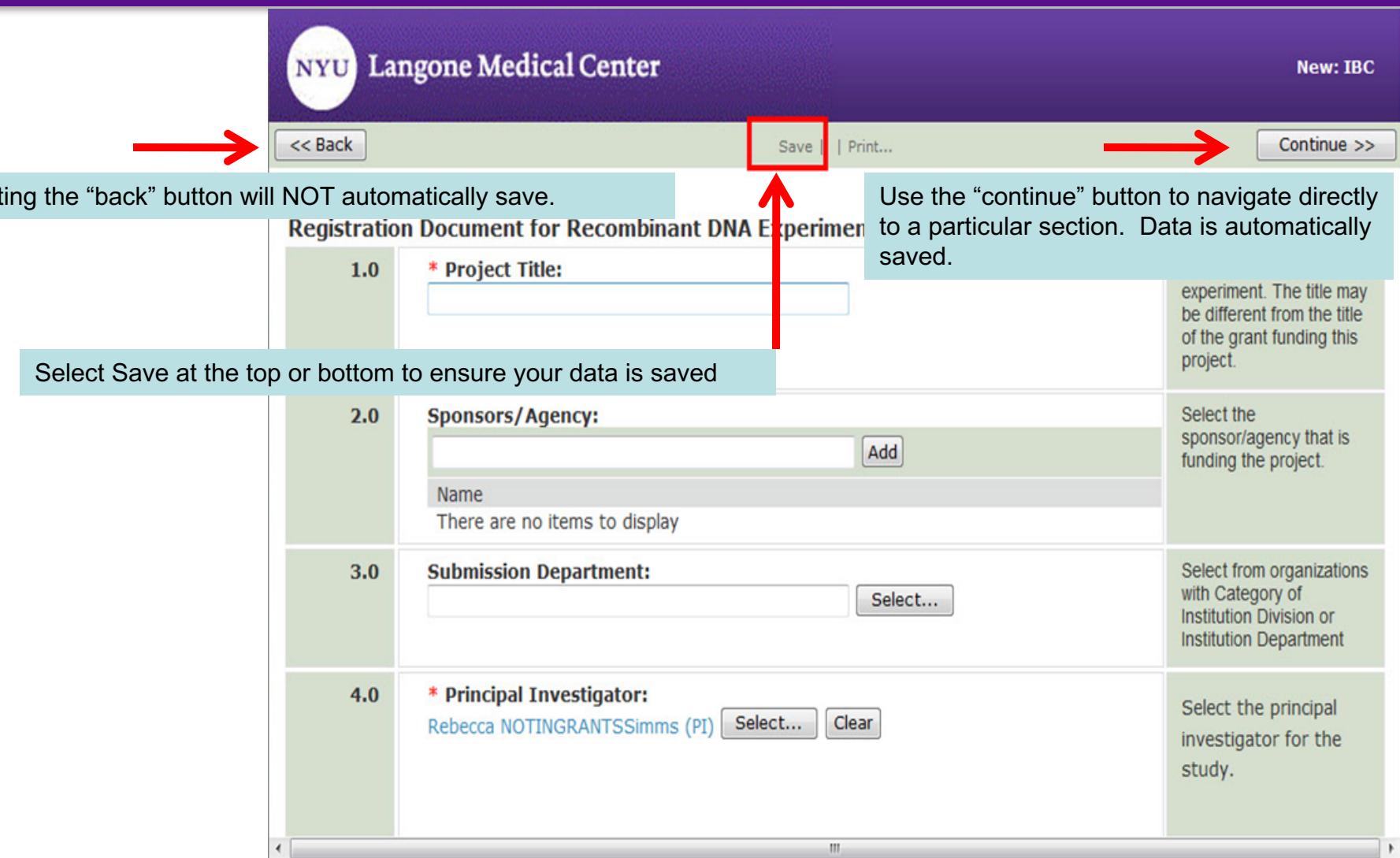
If you need to send an email to the IBC Administrator, select this link.

Once you've completed all changes to the registration form, it is time to resubmit to the IBC. Be sure to select "Submit Changes" so the registration will be returned to the IBC. If any additional information is required, you will be notified. Be sure to check your Research Navigator IBC Inbox.

Saving your information

- As you create the new registration, use the Continue button to navigate directly to a particular section
- Selecting the Continue button automatically saves
- Selecting the Back button will NOT automatically save
- Select Save at the top or bottom of the form to ensure your data is saved

Saving your information



IBC registration submission process – PI Assurance

Submit Application

Assurance

I attest that the information in this Registration Form is accurate and complete. I am familiar with and agree to abide by the provisions of the current NIH Guidelines and other specific NIH and New York University School of Medicine instructions pertaining to the proposed project, as well as any modifications subsequently issued by the Federal Government.

As the Principal Investigator, I agree to accept responsibility for training all personnel involved in the proposed project so they are familiar with and understand the potential biohazards, relevant biosafety practices, techniques, and emergency procedures. I will submit written reports to the Institutional Biosafety Committee and the NIH's Office of Recombinant DNA Activities (if applicable) concerning any research related accident, exposure incident or release of rDNA materials to the environment, or problems pertaining to the implementation of containment procedures.

If you have finished filling out your application, then click OK. After you click OK you will no longer be able to edit the application. You will receive email when your approval is granted or refused.

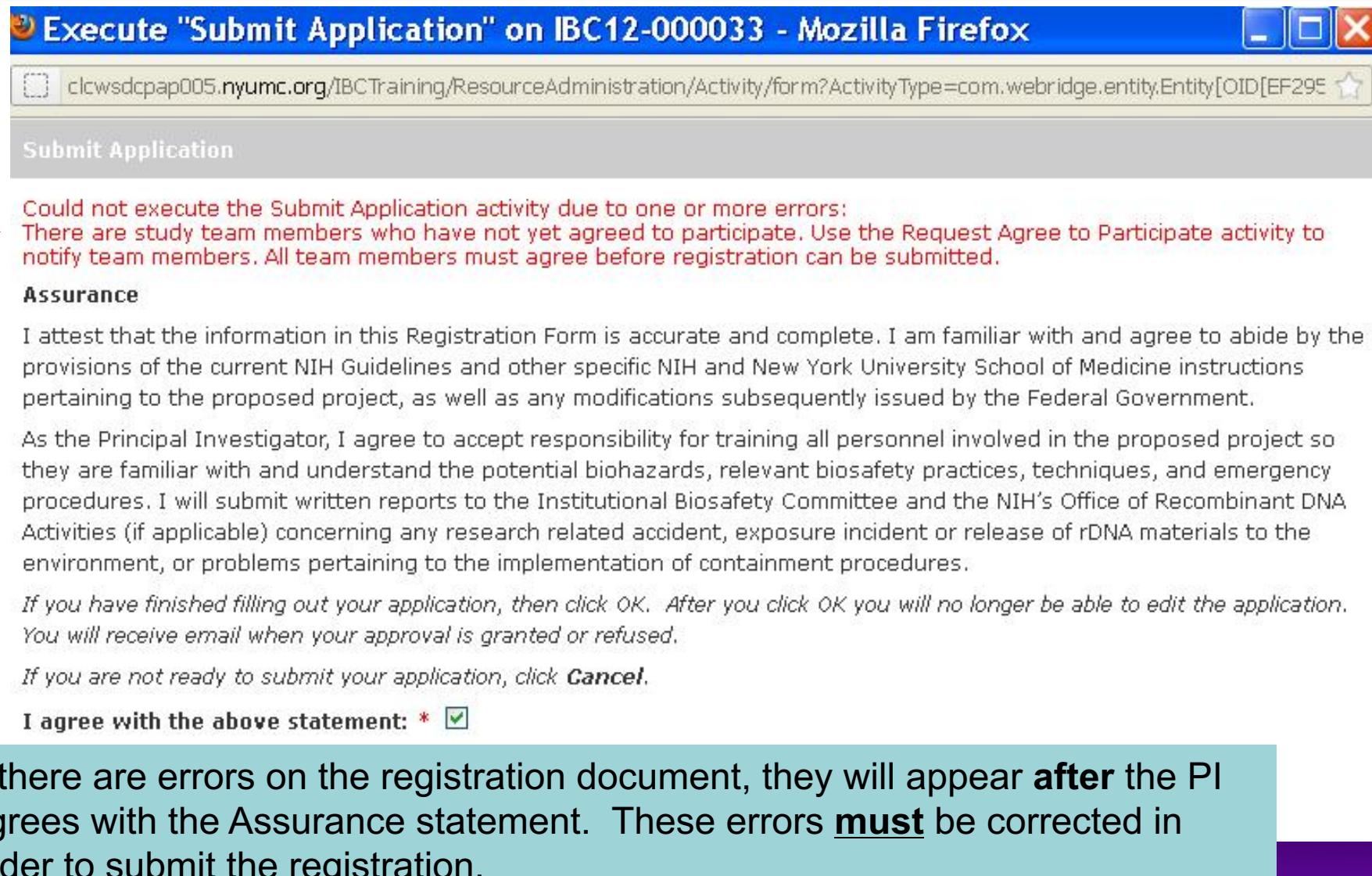
If you are not ready to submit your application, click Cancel.

I agree with the above statement: *



After the PI selects “submit application”, a window will appear requiring the PI to attest the information submitted is accurate and complete. *If you’ve added personnel, they will be required to “Agree to Participate” and you must attach their rDNA course completion certificates (see Creating and Submitting PowerPoint training presentation available on the [IBC website](#))*

IBC registration submission process – Errors

Execute "Submit Application" on IBC12-000033 - Mozilla Firefox

clcwsdcap005.nyumc.org/IBCTraining/ResourceAdministration/Activity/form?ActivityType=com.webridge.entity.Entity[OID[EF295]

Submit Application

Could not execute the Submit Application activity due to one or more errors:
There are study team members who have not yet agreed to participate. Use the Request Agree to Participate activity to notify team members. All team members must agree before registration can be submitted.

Assurance

I attest that the information in this Registration Form is accurate and complete. I am familiar with and agree to abide by the provisions of the current NIH Guidelines and other specific NIH and New York University School of Medicine instructions pertaining to the proposed project, as well as any modifications subsequently issued by the Federal Government.

As the Principal Investigator, I agree to accept responsibility for training all personnel involved in the proposed project so they are familiar with and understand the potential biohazards, relevant biosafety practices, techniques, and emergency procedures. I will submit written reports to the Institutional Biosafety Committee and the NIH's Office of Recombinant DNA Activities (if applicable) concerning any research related accident, exposure incident or release of rDNA materials to the environment, or problems pertaining to the implementation of containment procedures.

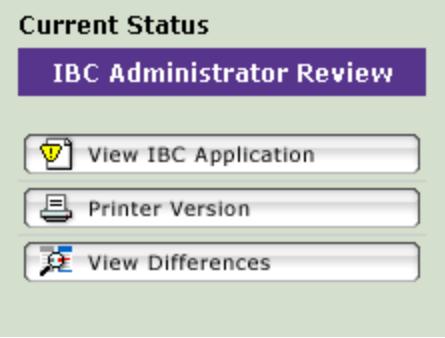
If you have finished filling out your application, then click OK. After you click OK you will no longer be able to edit the application. You will receive email when your approval is granted or refused.

If you are not ready to submit your application, click Cancel.

I agree with the above statement: *

If there are errors on the registration document, they will appear **after** the PI agrees with the Assurance statement. These errors **must** be corrected in order to submit the registration.

After submission to the IBC



After submission, the status changes to “IBC Administrator Review.” If there are any modifications needed, you will receive an email from the IBC Administrator.

IBC registration submission process – Successful Submission

Compliance Submissions

My Roles

IBC Submission

New IBC Application

Page for PI Mays

Welcome to your Personal Page, the starting point for all interactions with this system.

The PI will receive an automatic email from IBC@nyumc.org indicating successful submission.

- **Inbox** - Items appearing here required immediate action by you to speed your submission through the review process. Click on link to process an item.
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Inbox	IBC Applications	Profile	Audits
ID	Name	Date Modified	State
IBC12-000033	IBC registration project-3/1/2012	3/1/2012 2:29 PM	IBC Administrator Review

After the registration has been submitted, information on the review status is located under the “IBC Applications” tab on your Home Folder page. Refer to this section frequently for information and any actions that you may be required to take to complete the review process.

As you can see from this example, the registration is in the “IBC Administrator Review” state.

After review by the IBC, registrations are either:

- Approved or
- Modifications are required to the registration before approval
 - If the modifications are satisfactory to the IBC, the registration is approved.

Keys to Success

- Complete the IBC registration accurately and completely.
- Be sure to attach any documents as indicated on the registration.
- Ensure all study staff “agree to participate” and the rDNA course completion certificates for the PI and study staff are attached.
- Submit the IBC registration prior to the submission deadlines posted on the IBC website.
- Frequently monitor your Research Navigator IBC inbox

IBC Contact information

IBC website: <http://ibc.med.nyu.edu/>

IBC email address: ibc@nyumc.org

IBC Director

Natalie L. Mays

Natalie.Mays@nyumc.org

646-754-5258

Research Navigator information

Research Navigator IBC module: <http://era.med.nyu.edu/IBC>

If you experience any problems using Research Navigator IBC, please report the issue by opening a ticket online using [MCIT Support & Services](#) or by contacting the MCIT Help Desk at 212-263-6868 (x36868 Internal) or 866-276-1892 (toll free).