



OSR | OFFICE OF SCIENCE  
& RESEARCH

# CREATION AND SUBMISSION OF AN AMENDMENT

Research Navigator Institutional Biosafety Committee (IBC)



# Welcome to the Research Navigator IBC Learning Module for NYULH Users

In this module, you will learn how to create and submit an amendment (changes) to an IBC-approved registration involving:

- recombinant DNA (rDNA),
- infectious agents,
- non-human primate materials (including established cell lines),
- select agents or human gene transfer studies conducted at NYU Langone Health.

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](#).

## 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”** is located on **FOCUS** (formerly iDevelop).
- 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 [biosafety@nyulangone.org](mailto:biosafety@nyulangone.org) if you have any questions related to the training course.

# Objectives

After reviewing this, you will be able to:

- Create and submit an Amendment to an IBC-approved registration for research involving:
  - rDNA
  - Human Gene Transfer (HGT)

## Log on to the Research Navigator IBC

Enter your credentials

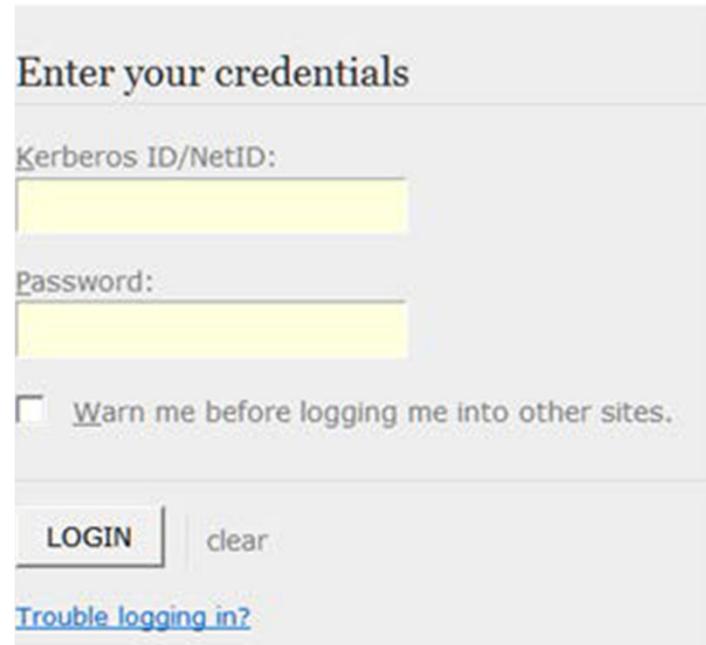
Kerberos ID/NetID:

Password:

[Warn me before logging me into other sites.](#)

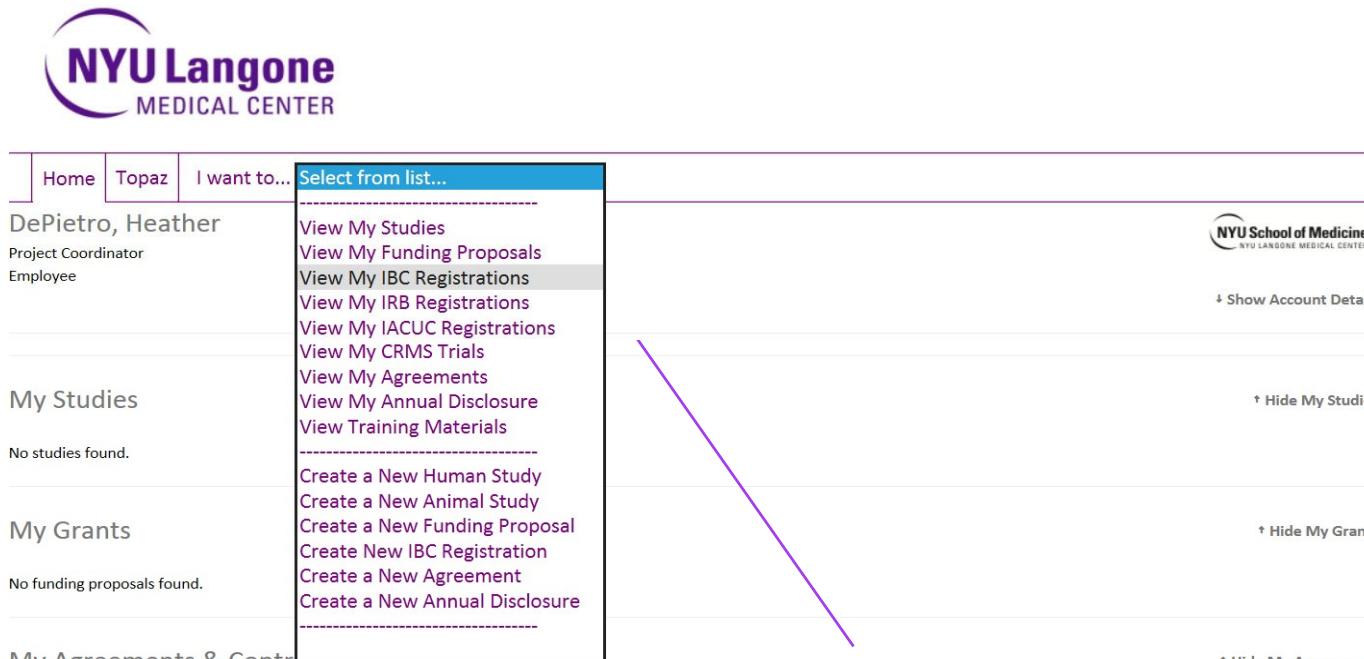
**LOGIN** [clear](#)

[Trouble logging in?](#)



Enter your Kerberos ID and Password

# Go to the IBC Module



The screenshot shows the NYU Langone Topaz software interface. At the top, there is a navigation bar with 'Home', 'Topaz', and 'I want to...' buttons. Below this, a user profile for 'DePietro, Heather' is displayed, showing 'Project Coordinator' and 'Employee' status. The main content area is titled 'My Studies' and shows 'No studies found.' A dropdown menu titled 'Select from list...' is open, listing various registration and proposal options. The 'View My IBC Registrations' option is highlighted with a blue background. To the right of the dropdown, there are buttons for 'Show Account Details', 'Hide My Studies', and 'Hide My Grants'. A purple arrow points from the text 'Select View My IBC Registrations' to the highlighted menu item.

- View My Studies
- View My Funding Proposals
- View My IBC Registrations**
- View My IRB Registrations
- View My IACUC Registrations
- View My CRMS Trials
- View My Agreements
- View My Annual Disclosure
- View Training Materials

- 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 Home Screen

NYU Langone Medical Center

Select to create a continuation

Home IBC Facilities Issues

Folder for Rebecca Simms (PI)

Compliance Submissions

My Roles

IBC Submission

New IBC Application

Inbox IBC Applications Profile Audits

Displays all items which require action by the study team. Click on links for more information.

Filter by ID Name Date Modified Type State Last State Change

ID	Name	Date Modified	Type	State	Last State Change
IBC12-000004	kkkjuiopool-3/2/2012	3/2/2012 11:01:01 AM	IBC	Pre Submission	3/2/2012 11:00:00 AM

10 / page

The name of the person logged in to Research Navigator IBC

Select to logoff Research Navigator IBC

Rebecca NOTINGRANTSSimms (PI) | My Home | Logoff

Select to create a continuation

Select to create a new registration

All IBC registrations are stored here

Your Research Navigator IBC institutional profile

You are at your Home location. Select to return "home" from anywhere in module

# Finding Registration to Amend

The screenshot shows the Click Commerce IBC Review interface for NYU Langone Medical Center. The top navigation bar includes links for Home, IBC, Facilities, Issues, and Help. The IBC link is highlighted with a purple arrow. The left sidebar shows 'Other Submission Types' with 'Amendments' and 'Continuing Review' options. A callout box with a purple border and arrow points to the 'IBC' link with the text: 'Select "IBC" to reveal approved registrations.' A red callout box with a red border and arrow points to the 'Amendments' section with the text: 'In order to make an amendment, you MUST select the "parent" registration which contains the original ID numbers. Ex: (IBC12-000003 and not an amended or version (IBC12-000003-01 or -A01)'.

Go to the "Approved" tab to view links to all of your approved registrations.

Welcome to Click Commerce IBC Review. View all safety submissions by In Progress and Approved groupings.

In Progress    **Approved**    Continuing Review    Amendments    Archived

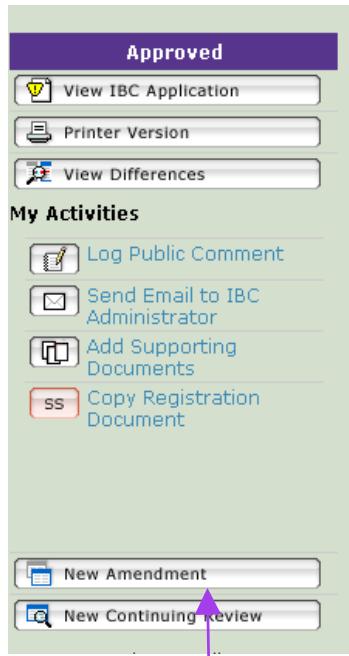
Filter by: ID    Go    Clear    Advanced

ID	Name	Date Modified	State	Priority
IBC12-000003	NLM March 2-3/2/2012	3/29/2012 11:47 AM	Approved	Rel
IBC12-000002	Amendments Demo-2/28/2012	2/28/2012 1:29 PM	Approved	Rel

Select link to continue registration

8    Creation and Submission of an Amendment

# Amendment Screen



## IBC Submission: NLM March 2-3/2/2012(IBC12-000003)

### IBC Application Type: New

Description: ilkddlsdkj  
Principal Investigator: Rebecca NOTINGRANTSSimms (PI)  
Submission Department:  
Involves Human Genome Transfer: no  
Include Attempts to Obtain Expression of a Foreign Gene: yes  
Special Medical Surveillance Practices Recommended: yes  
Date Approved: 3/2/2011  
Annual Review Date: 3/2/2012  
Final Expiration Date: 3/1/2014

### Facility Details:

Name	Room Number	Facility Class	Containment Level
There are no items to display			

### Meeting:

Institutional Biosafety Committee meeting on 4/6/2012 11:00 AM

### Approval Letter: [View](#)

### IBC Review Type and Level:

Select the “New Amendment” button to create an amendment to the IBC-approved registration currently displayed.

# Amendment Form

Some data from the original IBC-approved registration will automatically transfer to the Amendment Form. The PI will need to make any changes to this registration by modifying the information on this form.

**\*Please note that a change in PI requires a new registration to be created and submitted separately from this submission.\***

## Instructions for an amendment to an approved IBC Registration Document:

- An amendment request includes two parts: the Amendment form and modifications to the Study form.
- Only one amendment request is allowed at any given time, i.e: amendment 1 must be approved, denied or withdrawn before amendment 2 can be created.
- The original approved submission will be displayed. Only items requiring modifications need to be changed.

1.0	Amendment ID:	
2.0	Amendment Name:	
3.0	Principal Investigator:	Submit a new registration document if there is a change in PI.
4.0	Study Co-ordinator:	
5.0	IBC Submission ID:	
6.0	IBC Submission Name:	
7.0	* Reason for Amendment:	

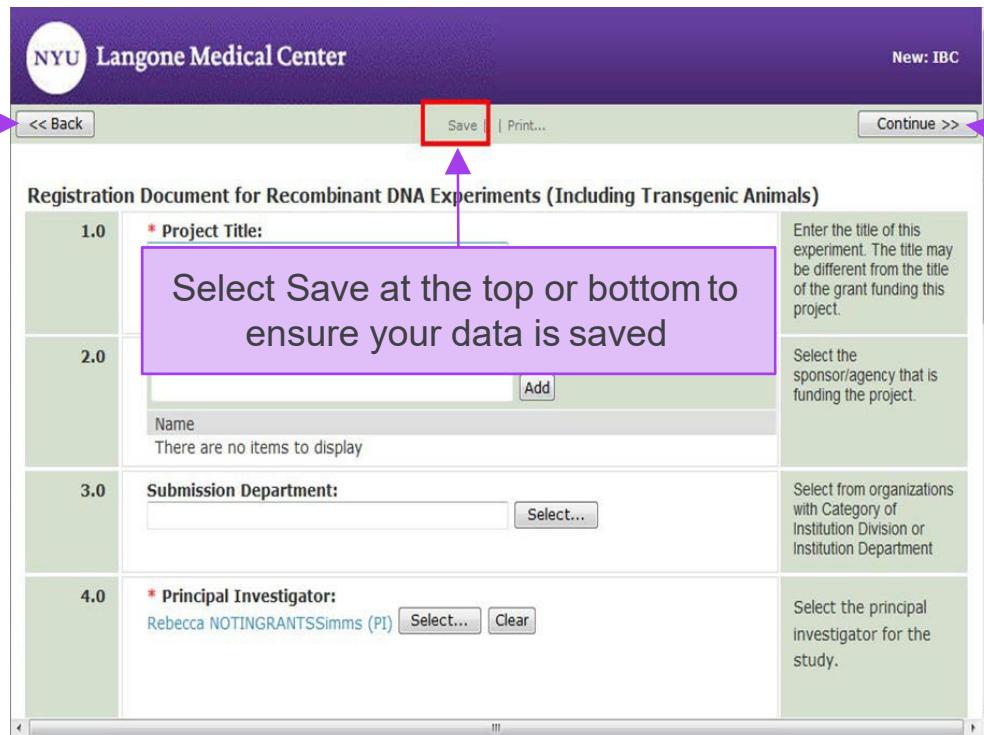
Help text designed to assist in your response to the questions will be found in this portion of the form

## 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

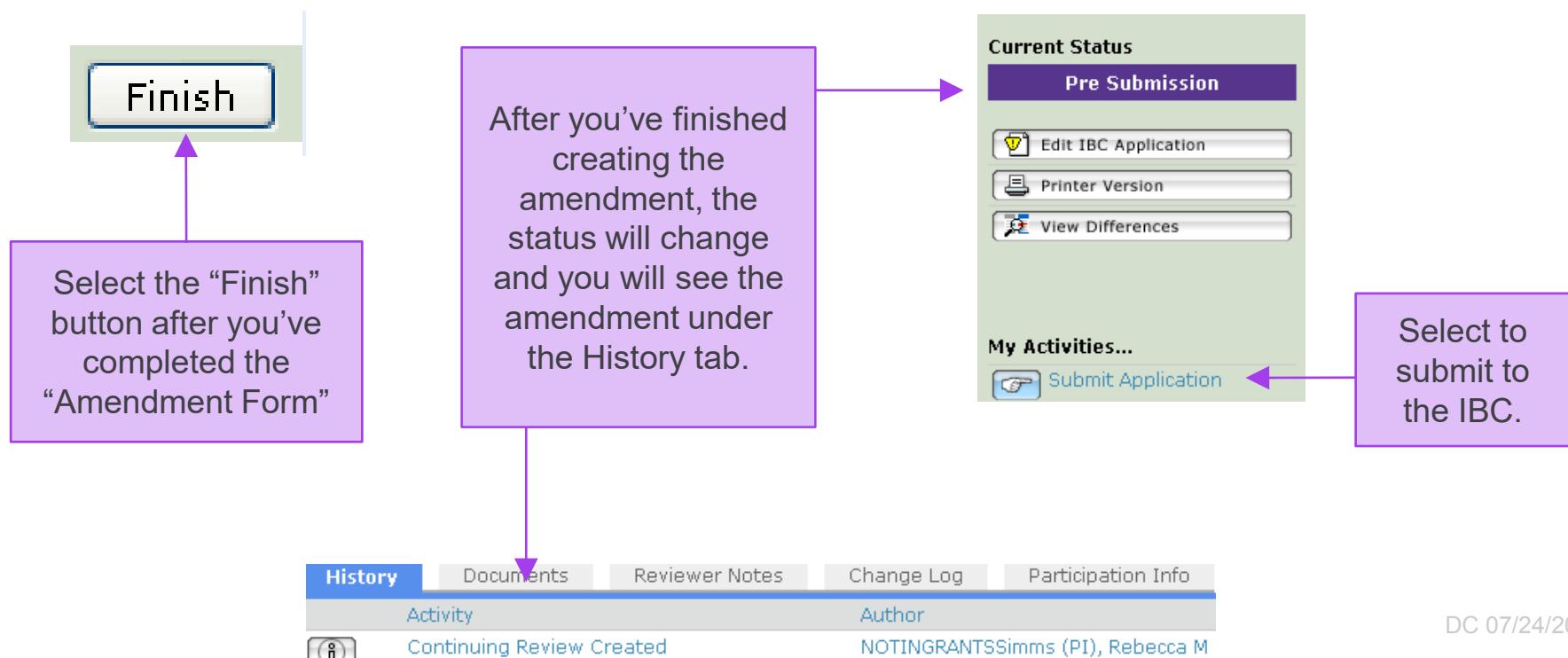
Selecting the “back” button will NOT automatically save.



The screenshot shows a registration document for Recombinant DNA Experiments (Including Transgenic Animals). The top navigation bar includes the NYU Langone Medical Center logo, a 'New: IBC' link, a 'Save' button (which is highlighted with a red box and an arrow), a 'Print...' button, and a 'Continue >>' button. The main content area is titled 'Registration Document for Recombinant DNA Experiments (Including Transgenic Animals)'. It contains four sections: 1.0 (Project Title), 2.0 (Name, with a note: 'There are no items to display'), 3.0 (Submission Department), and 4.0 (Principal Investigator, with a note: 'Rebecca NOTINGRANTSSimms (PI)'). A large callout box in the center of the form area contains the text: 'Select Save at the top or bottom to ensure your data is saved'.

Use the “continue” button to navigate directly to a particular section. Data is automatically saved.

# Completing the Amendment Process

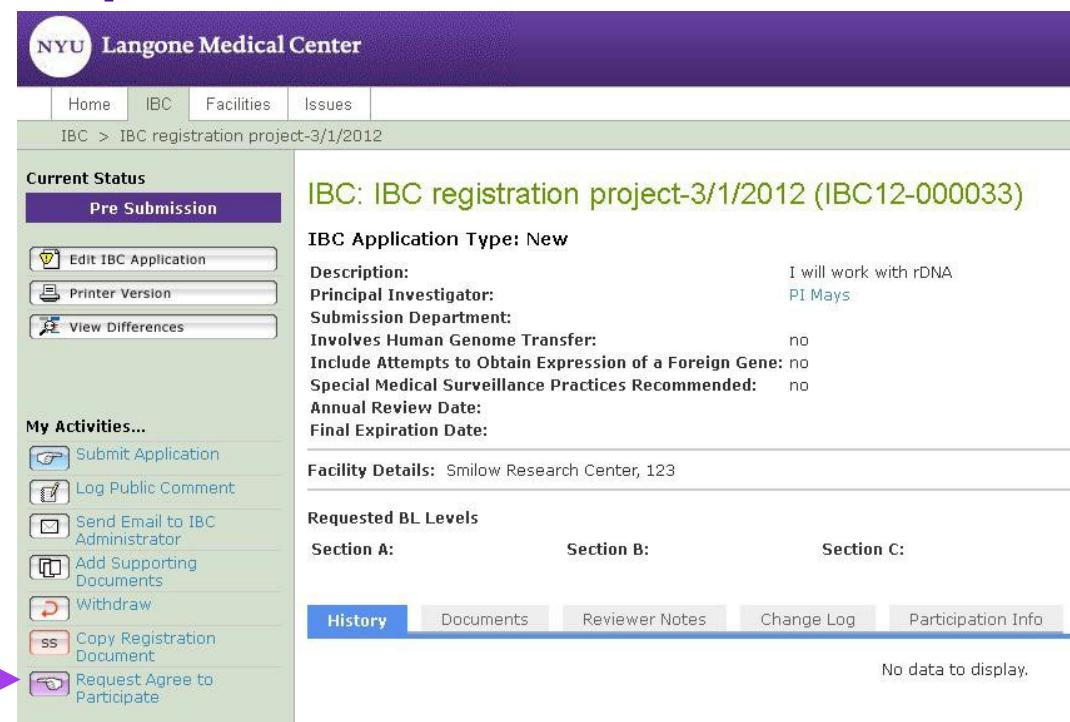


## IBC Registration Creation Process – Request Agree to Participate

- Prior to submission, **Study Staff** listed on the registration are required to verify that they have read and understood their roles and responsibilities as described in the registration document. This step is known as "agreeing to participate."
- **Study staff** will complete this action by logging in to Research Navigator IBC and selecting the participation link located in their inbox.
- The PI will not be able to submit the registration until all study staff have agreed to participate.

# IBC Registration Creation Process – Request Agree to Participate

If study staff has been added to this registration, the PI will be required to request that they agree to participate in the study described in this registration document. The request is made by selecting the “Request Agree to Participate” link.



The screenshot shows a web-based application for IBC registration. At the top, the NYU Langone Medical Center logo is visible. The main header reads "IBC: IBC registration project-3/1/2012 (IBC12-000033)". Below this, the "Current Status" section indicates "Pre Submission". A purple arrow points from the text in the purple box to the "Request Agree to Participate" link in the "My Activities..." sidebar. The sidebar also includes links for "Submit Application", "Log Public Comment", "Send Email to IBC Administrator", "Add Supporting Documents", "Withdraw", "Copy Registration Document", and "Request Agree to Participate". The main content area displays the IBC application details, facility details, and requested BL levels. A message at the bottom states "No data to display."

Execute "Request Agree to Participate" on IBC12-000004 - Mozilla Firefox Shared

Request Agree to Participate

Personnel associated with this experiment are required to agree to participate to indicate that they have read and understood the nature of the experiments described in this registration.

Person	Organization
Kristen Johnson	Pathology
Cory NOTINGRANTS Mitchell	NOTINGRANTS OFFICE OF RESEARCH
Genevieve Szablya	Ehrman Medical Library

By clicking "OK" the system will email the above study staff asking them to "agree to participate" in the study.

Comments:

Select "OK" to have an email sent to study staff asking them to agree to participate.

Enter messages to personnel in this section.

OK Cancel

# 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 training available on the IBC website)\***

**OK** **Cancel**

# IBC Registration Submission Process – Errors

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.

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

clcwsdcpap005.nyumc.org/IBCTraining/ResourceAdministration/Activity/form?ActivityType=com.webridge.entity.Entity[OID[EF29E

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.

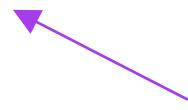
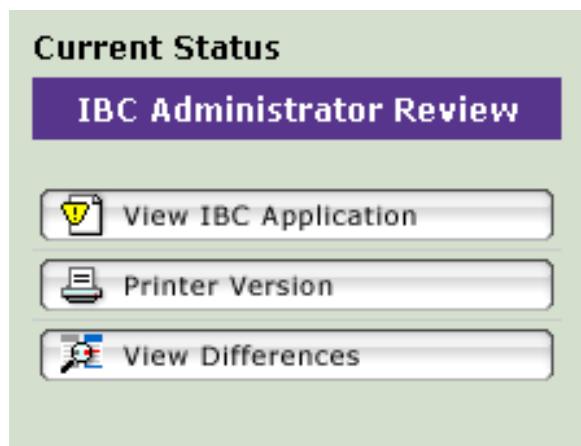
As the Principal Investigator, I agree to accept responsibility for training all personnel involved in the proposed project so they are familiar with and understand the potential biohazards, relevant biosafety practices, techniques, and emergency procedures. I will submit written reports to the Institutional 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: \*

## 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



## Page for PI Mays

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.

Inbox	IBC Applications	Profile	Audits
<input checked="" type="checkbox"/> ID IBC12-000033	Name IBC registration project-3/1/2012	Date Modified 3/1/2012 2:29 PM	State 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.

DC 07/24/2019

## IBC registration submission process – outcome of IBC review

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 then approved.
- **The expiration and annual continuation dates of the original registration do not change after an amendment has been 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@nyulangone.org](mailto:ibc@nyulangone.org)

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### IBC Project Coordinator

Taina LoSasso  
[taina.losasso@nyulangone.org](mailto:taina.losasso@nyulangone.org)  
646-754-4640

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### IBC Director

Natalie L. Mays  
[natalie.mays@nyulangone.org](mailto:natalie.mays@nyulangone.org)

## 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).



THANK YOU

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