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& RESEARCH

CREATION AND SUBMISSION OF AN ANNUAL CONTINUATION

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 a continuation 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 - 2017” is located on **FOCUS** (formerly known as 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 if you have any questions related to the training course.

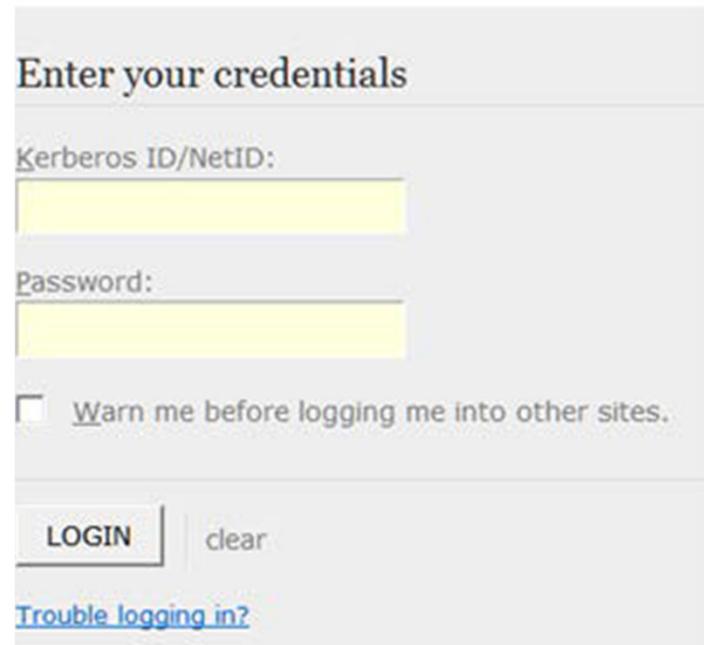
Objectives

After reviewing this, you will be able to:

- Create and submit a Continuation to an IBC-approved registration for research involving:
 - rDNA
 - Other non-human gene transfer (IBC) studies

*Please note that Continuations are for studies occurring in the 2nd and 3rd year of approval of the original registration. A new registration is required in the 4th year and the cycle resets *

Log on to the Research Navigator IBC



The screenshot shows a login form titled "Enter your credentials". It contains two input fields: "Kerberos ID/NetID:" and "Password:", both highlighted in yellow. Below the password field is a checkbox labeled "Warn me before logging me into other sites." At the bottom, there is a "LOGIN" button and a "clear" link. A blue link "Trouble logging in?" is located below the login button.

Enter your Kerberos ID and Password

PI's Home Screen

The screenshot shows the Research Navigator IBC interface. At the top, the header includes the NYU Langone Medical Center logo and navigation tabs for Home, IBC, Facilities, and Issues. The user's name, Rebecca NOTINGRANTSSimms (PI), and a My Home | Logoff link are visible in the top right.

On the left sidebar, there are sections for Compliance Submissions, My Roles (including IBC Submission), and a New IBC Application button.

The main content area is titled "Folder for Rebecca Simms (PI)" and contains a welcome message and two main sections: "Inbox" and "Monitor". The "Inbox" section is highlighted and contains a list of items requiring action. Below this is a table of IBC applications.

Callout boxes provide the following information:

- Select to create a continuation:** Points to the "Home" tab in the top navigation bar.
- The name of the person logged in to Research Navigator IBC:** Points to the user name "Rebecca NOTINGRANTSSimms (PI)" in the top right.
- Select to logoff Research Navigator IBC:** Points to the "Logoff" link in the top right.
- You are at your Home location. Select to return "home" from anywhere in module:** Points to the "Home" tab in the top navigation bar.
- The Inbox lists items that require your action, all registrations and their submission status:** Points to the "Inbox" section header.
- Select to create a new registration:** Points to the "New IBC Application" button in the left sidebar.
- All IBC registrations are stored here:** Points to the "Inbox" section.
- Your Research Navigator IBC institutional profile:** Points to the "Profile" tab in the main content area.

The table below shows the data for the IBC application:

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

Finding Registration for Continuation

The screenshot shows the NYU Langone Medical Center IBC Review system. The top navigation bar includes 'Home', 'IBC', 'Facilities', and 'Iss'. The left sidebar has 'Other Submission Types' with 'Amendments' and 'Continuing Review' options, and a 'Create...' section. The main content area is titled 'Welcome to Click Commerce IBC Review. View all safety submissions by In Progress and Approved groupings.' It features a tabbed interface with 'Approved' selected. Below the tabs is a filter section with 'Filter by ID' and a search box. A table lists submissions with columns for ID, Name, Date Modified, State, and Priority. Two rows are visible: 'NLN March 2-3/2/2012' and 'Amendments Demo-2/28/2012'. Callout boxes provide instructions: 'Select "IBC" to reveal approved registrations.' (pointing to the IBC menu item), 'Go to the "Approved" tab to view links to all of your approved registrations.' (pointing to the Approved tab), and 'Select link to continue registration' (pointing to the 'Amendments Demo-2/28/2012' link in the table).

NYU Langone Medical Center

Home IBC Facilities Iss

IBC

Other Submission Types

- Amendments
- Continuing Review

Create...

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	Pri
IBC12-000003	NLN 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

DC 07/24/2019

Continuation Screen

Approved

View IBC Application

Printer Version

View Differences

My Activities

Log Public Comment

Send Email to IBC Administrator

Add Supporting Documents

Copy Registration Document

New Amendment

New Continuing Review

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 Continuing Review" button to create a continuation to the IBC-approved registration currently displayed.

Select a Status

Select the status based on your intent to Continue or Terminate this registration. You can request to Continue with or without changes to the original IBC-approved registration or you can declare your intent to terminate by selecting Withdraw, Complete or Other.

Continuing Review - Study Status

1.0	Continuing Review ID: IBC12-000003-03
2.0	Name: NLM March 2-3/2/2012
3.0	Principal Investigator: Rebecca NOTINGRANTSSimms (PI)
4.0	<p>* Please select a study status:</p> <p>Study Status</p> <p><input type="radio"/> Active - With Changes</p> <p><input type="radio"/> Active - No Changes</p> <p><input type="radio"/> Withdrawn (give reason)</p> <p><input type="radio"/> Complete (provide summary of results)</p> <p><input type="radio"/> Other (provide details)</p> <p>Clear</p>
5.0	<p>Reasons, summary or details:</p> <div style="border: 1px solid #ccc; height: 100px;"></div>

Continuation Form – Active With Changes

* Please select a study status:

Study Status

Active - With Changes

Active - No Changes

Withdrawn (give reason)

Complete (provide summary of results)

Other (provide details)

Clear

Select the status of this registration. If you select “Active – With Changes*,” you will be required to indicate the changes in subsequent pages of the form. Remember, the form is populated with data from the original IBC-approved registration.

Some example of changes are: Study Staff, Location, experimental constructs, sponsor, etc.

Continuation Form – Active – No Changes

* Please select a study status:

Study Status

Active - With Changes

Active - No Changes

Withdrawn (give reason)

Complete (provide summary of results)

Other (provide details)

Clear

If you select “Active – No Changes,” you are not required to answer any additional questions prior to submission of this Continuation form.

Continuation Form – Withdrawn

*** Please select a study status:**

Study Status

Active - With Changes

Active - No Changes

Withdrawn (give reason)

Complete (provide summary of results)

Other (provide details)

[Clear](#)

At the time of continuation, if you choose to terminate this registration, select "Withdrawn."

You will be returned to the registration history screen. Select the Withdraw activity button to complete the withdrawal process.

Current Status

Pre Submission

[Edit IBC Application](#)

[Printer Version](#)

[View Differences](#)

Activity Activities...

[Submit Application](#)

[Log Public Comment](#)

[Send Email to IBC Administrator](#)

[Add Supporting Documents](#)

[Withdraw](#)

IBC: NLM March 2-3/2/2012 (IBC12-000003-03)

IBC Application Type: Continuing Review

Description: ikddlsdkj

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

Annual Review Date: 3/2/2012

Final Expiration Date: 3/1/2014

Facility Details: 26th Street Apartment Residence, 120

Requested BL Levels

Section A: BL-2	Section B: BL-2	Section C: BL-2
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[Withdraw](#) | [Documents](#) | [Reviewer Notes](#) | [Change Log](#) | [Participation Info](#)

Continuation Form – Complete

Continuing Review - Study Status

1.0	Continuing Review ID: IBC12-000003-04
2.0	Name: NLM March 2-3/2/2012
3.0	Principal Investigator: Rebecca NOTINGRANTSSimms (PI)
4.0	<p>* Please select a study status:</p> <p>Study Status</p> <p><input type="radio"/> Active - With Changes</p> <p><input type="radio"/> Active - No Changes</p> <p><input type="radio"/> Withdrawn (give reason)</p> <p><input checked="" type="radio"/> Complete (provide summary of results)</p> <p><input type="radio"/> Other (provide details)</p> <p>Clear</p>

If you select “Complete” you are indicating that the experiments described in this registration have come to an end.

Provide a brief summary of results in the text box below.

5.0	Reasons, summary or details: <div style="border: 1px solid #ccc; height: 60px; width: 100%;"></div>
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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

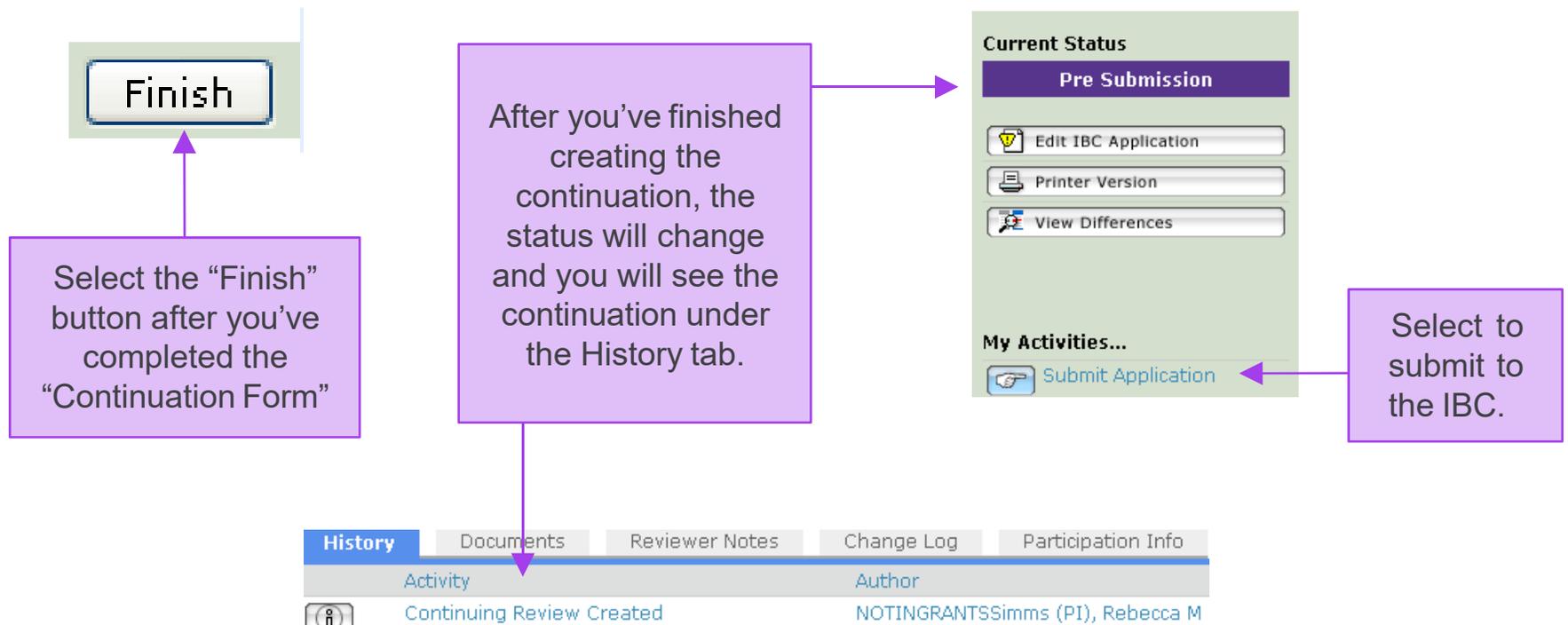
Saving Your Information

Selecting the “back” button will NOT automatically save.

The screenshot shows a web form titled "Registration Document for Recombinant DNA Experiments (Including Transgenic Animals)" from NYU Langone Medical Center. At the top, there are navigation buttons: "<< Back", "Save", "Print...", and "Continue >>". The "Save" button is highlighted with a red box. Below the navigation bar, the form is divided into sections: 1.0 Project Title, 2.0 Sponsor/Agency, 3.0 Submission Department, and 4.0 Principal Investigator. A purple callout box points to the "Save" button with 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 Continuation 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.

NYU Langone Medical Center

Home IBC Facilities Issues

IBC > IBC registration project-3/1/2012

Current Status
Pre Submission

Edit IBC Application
Printer Version
View Differences

My Activities...
Submit Application
Log Public Comment
Send Email to IBC Administrator
Add Supporting Documents
Withdraw
Copy Registration Document
Request Agree to Participate

IBC: IBC registration project-3/1/2012 (IBC12-000033)

IBC Application Type: New

Description: I will work with rDNA
Principal Investigator: PI Mays
Submission Department:
Involves Human Genome Transfer: no
Include Attempts to Obtain Expression of a Foreign Gene: no
Special Medical Surveillance Practices Recommended: no
Annual Review Date:
Final Expiration Date:

Facility Details: Smilow Research Center, 123

Requested BL Levels

Section A:	Section B:	Section C:

History Documents Reviewer Notes Change Log Participation Info

No data to display.

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

clwscdcpap005.nyumc.org/IBC/ResourceAdministration/Activity/form?ActivityType=com.webbridge.entity.Entity[OID[6EE1A2F8467]

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 NOTINGRANTSMitchell	NOTINGRANTSOFFICE 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:

OK Cancel

Enter messages to personnel in this section.

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

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

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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

clcwscpap005.nyu.edu/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.

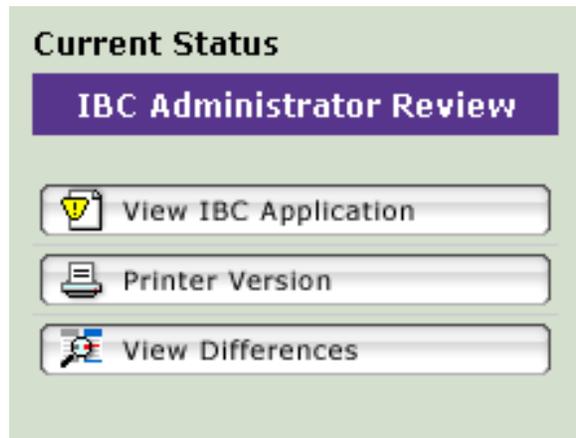
As the Principal Investigator, I agree to accept responsibility for training all personnel involved in the proposed project so they are familiar with and understand the potential biohazards, relevant biosafety practices, techniques, and emergency procedures. I will submit written reports to the Institutional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

After Submission to the IBC



Current Status

IBC Administrator Review

 View IBC Application

 Printer Version

 View Differences

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

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

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.

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

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IBC Project Coordinator

Taina LoSasso

taina.losasso@nyulangone.org

646-754-4640

IBC Director

Natalie L. Mays

natalie.mays@nyulangone.org

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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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