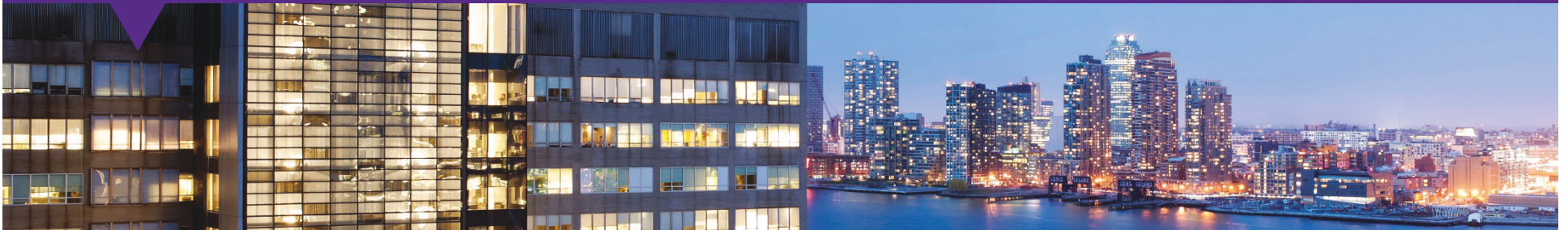




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& RESEARCH

CREATION AND SUBMISSION OF 'AGREE TO PARTICIPATE'

Welcome to the 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 **agree to participate** in an IBC submission for research involving:

- recombinant DNA (rDNA),
- infectious agents,
- non-human primate materials (including established cell lines),
- select agent studies conducted within the NYU Langone Health Medical Center.

This submission 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:

- Login to Research Navigator/IBC
- Navigate to the appropriate IBC submission which describes research that **requires your participation**
- Understand the decisions of the IBC after review

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.

Email Notification of Request to Participate

Congratulations!

- You have been named as **Study Staff** on an IBC registration. Individuals listed as Study Staff are personnel who will be performing experiments described in the submitted registration.
- You must “agree to participate” in the conduct of the experiments prior to submission of the registration to the IBC.

ID: IBC15-000005
Title: Test Study-3/25/2015
PI: Quan Tran

Hello Loredana Delucchi,

Loredana Delucchi has named you as a staff on the IBC application above.

Please log into the Click IBC system at <http://era.med.nyu.edu/IBC> and click on the "Agree To Participate" button.

Washington Square and Dental School users should access Click IBC via NYU OnsiteHealth at <http://www.nyuonsitehealth.org/>

Institutional Biosafety Committee
New York University Langone Medical Center
One Park Avenue, 6th Floor
New York, NY 10016
Phone: (646) 754-5258; Fax: (646) 754-5262

Selecting the Link to Access the Registration

Select the link to navigate to the IBC registration

ID: IBC15-000005
Title: Test Study-3/25/2015
PI: Quan Tran

Hello Loredana Delucchi,
Loredana Delucchi has named you as a staff on the IBC application above.

Please log into the Click IBC system at <http://era.med.nyu.edu/IBC> and click on the "Agree To Participate" button.

Washington Square and Dental School users should access Click IBC via NYU OnsiteHealth at <http://www.nyuonsitehealth.org/>

Institutional Biosafety Committee
New York University Langone Medical Center
One Park Avenue, 6th Floor
New York, NY 10016
Phone: (646) 754-5258; Fax: (646) 754-5262

Opening the Registration

NYU Langone Medical Center

Susan Smith | My Home | Logoff

Home IBC

Page for Susan Smith

Compliance Submissions

My Roles

IBC Submission

New IBC Application

Page for Susan Smith

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

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

Filter by ID Go Clear Advanced

ID	Name	Date Modified	Type	State	Last State Change	PI FirstName	PI LastName
IBC15-000005	Test Study-3/25/2015	3/25/2015 4:04 PM	IBC	Pre Submission	3/25/2015 3:59 PM	Quan	Tran

1 to 1 of 1 10 / page

Click on the title to access the IBC application

BEFORE You Agree To Participate

Select to open the submission.

****You must read the submission in order to understand your role and responsibilities on this submission****

The screenshot displays the 'Current Status' of an IBC application, which is 'Pre Submission'. On the left sidebar, under 'My Activities...', the 'Agree to Participate' button is highlighted with a red box. A blue circle highlights the 'Edit IBC Application' button. A callout box points to the 'Agree to Participate' button with the text 'Click on \'Agree to Participate\''. The main content area shows details for 'IBC: Test Study-3/25/2015 (IBO)'. The 'IBC Application Type' is 'New'. The 'Description' includes 'Principal Investigator:', 'Submission Department:', 'Involves Human Genome Transfer:', 'Include Attempts to Obtain Expression of a Foreign...', 'Special Medical Surveillance Practices Recommended', 'Annual Review Date:', and 'Final Expiration Date:'. The 'Facility(ies) Details' section shows 'Building: Berg Institute'. The 'EHS Audit Date:' is blank. The 'Request BL Levels' section has 'Section A:' and 'Section B:'. The 'History' tab is active, showing an activity 'Requested Agree to Participate' with a message: 'Hello Susan, please agree ASAP. Thank you!'.

Agreeing to Participate

Current Status
Pre Submission

Edit IBC Application
Printer Version
View Differences

My Activities...

Log Public Comment
Send Email to IBC Administrator
Add Supporting Documents
Withdraw
Copy Registration Document
Request Agree to Participate
Agree to Participate

IBC: Test Study-3/25/2015 (IBC)

IBC Application Type: New

Description:
Principal Investigator:
Submission Department:
Involves Human Genome Transfer:
Include Attempts to Obtain Expression of a Foreign
Special Medical Surveillance Practices Recommendation
Annual Review Date:
Final Expiration Date:

Facility(ies) Details:
Building
Berg Institute

EHS Audit Date:

Requested BL Levels
Section A: **Section B:**

History Documents Reviewer Notes

Activity
Requested Agree to Participate

Hello Susan, please agree ASAP. Thank you!.

Click on 'Agree to Participate'

Attestation Statement

Execute "Agree to Participate" on IBC15-000004 - Windows Internet Explorer

Agree to Participate

By clicking here you indicate that you understand and agree to comply with all regulations and guidelines that pertain to the performance of the herein entitled study. I understand that Hepatitis B vaccine must be offered to all personnel who have potential exposure to Hepatitis B, human blood or human cell lines.

I have read and agree to the above statement. ☒

Comments:

OK Cancel

Select to checkbox to indicate that you have read and agree to the statement.

Be sure to select "ok" to execute the agreement.

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.
- Recombinant DNA registrations are approved for 3 years with a requirement for an annual review submission in years 2 and 3.
- Human Gene Transfer registrations are approved for **one year**.
- Annual continuations and changes to an approved registration (e.g. amendments) are discussed in a separate eLearning module.

IBC Contact information

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

IBC email address: ibc@nyulangone.org

IBC Project Coordinator

Taina LoSasso

taina.losasso@nyulangone.org

646-754-4640

IBC Director

Natalie L. Mays

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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Health