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.
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.ny onsitehealth.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

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**
Agreeing to Participate

Click on 'Agree to Participate'
Attestation Statement

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).