CREATION AND SUBMISSION OF AN AMENDMENT

Research Navigator Institutional Biosafety Committee (IBC)
Welcome to the Research Navigator IBC Learning Module for NYULMC 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 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 IBC.

• To obtain a KID, complete [this form](#) and email to MCITResearchIT@nyumc.org.
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).

** ****Washington Square/Dental School Users should contact Tekechia.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, 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 Kerberos ID and Password
Go to the IBC Module

Select View My IBC Registrations
**PI’s Home Screen**

- **Select to create a new registration**
- **All IBC registrations are stored here**
- **Your Research Navigator IBC institutional profile**
- **The Inbox lists items that require your action, all registrations and their submission status**
- **The name of the person logged in to Research Navigator IBC**
- **Select to logoff Research Navigator IBC**
- **You are at your Home location. Select to return “home” from anywhere in module**

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**Creation and Submission of an Amendment**

*Office of Science & Research | NYU Langone Health*
Finding Registration to Amend

Select "IBC" to reveal approved registrations.

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.

Select link to continue registration
Amendment Screen

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

IBC Application Type: New

Description: *ilddisdkj*
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

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.

<table>
<thead>
<tr>
<th>1.0</th>
<th>Amendment ID:</th>
</tr>
</thead>
<tbody>
<tr>
<td>2.0</td>
<td>Amendment Name:</td>
</tr>
<tr>
<td>3.0</td>
<td>Principal Investigator:</td>
</tr>
<tr>
<td>4.0</td>
<td>Study Co-ordinator:</td>
</tr>
<tr>
<td>5.0</td>
<td>IBC Submission ID:</td>
</tr>
<tr>
<td>6.0</td>
<td>IBC Submission Name:</td>
</tr>
<tr>
<td>7.0</td>
<td>* Reason for Amendment:</td>
</tr>
</tbody>
</table>

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.*

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.

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

Select Save at the top or bottom to ensure your data is saved.
Completing the Amendment Process

Select the “Finish” button after you’ve completed the “Amendment Form”

After you’ve finished creating the amendment, the status will change and you will see the amendment under the History tab.

Select to submit to the IBC.
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.
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.
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.

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

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

Enter messages to personnel in this section.
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’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)*
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.
Creation and Submission of an Amendment

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.

<table>
<thead>
<tr>
<th>ID</th>
<th>Name</th>
<th>Date Modified</th>
<th>State</th>
</tr>
</thead>
<tbody>
<tr>
<td>IBC12-000033</td>
<td>IBC registration project-3/1/2012</td>
<td>3/1/2012 2:29 PM</td>
<td>IBC Administrator Review</td>
</tr>
</tbody>
</table>

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.

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

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@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).