Welcome to the Research Navigator Institutional Biosafety Committee (IBC) Learning Module - Creation and Submission of Amendments

Updated 11/2015
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.
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 Navigator/IBC.

Refer to the “Welcome to Research Navigator Institutional Biosafety Committee (IBC) Learning Module – Access from outside of the NYU Langone Medical Center” training PowerPoint Presentation for specific instructions on how to obtain a KID.
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 - 2015” is located on iDevelop.

*** Washington Square/Dental School Users should contact Kechia.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.
After reviewing this PowerPoint Presentation, you will be able to:
Create and submit an Amendment to an IBC-approved registration for research involving:
– rDNA
– Human Gene Transfer
Enter your Kerberos ID and Password
Go to the IBC Module

Select View My IBC Registrations
The name of the person logged in to Research Navigator IBC

The Inbox lists items that require your action, all registrations and their submission status

All IBC registrations are stored here

Your Research Navigator IBC institutional profile

Select to create a new registration

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

Select to logoff
Finding registration to amend

Select “IBC” to reveal approved registrations.

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

Select link to amend IBC14-000020
Please note that you MUST select the “parent” registration (IBC14-000020) and not an amended version (IBC14-000020-01 or – A01)
Select the “New Amendment” button to create an amendment to the IBC-approved registration currently displayed.
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 that a new registration be created and submitted separately from this submission.*
Registration Document for Recombinant DNA Experiments (Including Transgenic Animals)

1.0 * Project Title:

Enter the title of this experiment. The title may be different from the title of the grant funding this project.

2.0 Sponsors/Agency:

Select the sponsor/agency that is funding the project.

Name | Type
--- | ---

There are no items to display

Text designed to assist in your response to most questions is found on the right.
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.

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

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.
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.

<table>
<thead>
<tr>
<th>Person</th>
<th>Organization</th>
</tr>
</thead>
<tbody>
<tr>
<td>Kristen Johnson</td>
<td>Pathology</td>
</tr>
<tr>
<td>Cory NOTINGRANTSMitchell</td>
<td>NOTINGRANTSOFFICE OF RESEARCH</td>
</tr>
<tr>
<td>Genevieve Szablya</td>
<td>Ehrman Medical Library</td>
</tr>
</tbody>
</table>

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.
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 PowerPoint training presentation 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.
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.

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