CREATION AND SUBMISSION OF AN ANNUAL CONTINUATION

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 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 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 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

Enter your credentials

Kerberos ID/NetID:

Password:

Warn me before logging me into other sites.

LOGIN  clear

Trouble logging in?

Enter your Kerberos ID and Password
PI’s Home Screen

Select to create a new registration

All IBC registrations are stored here

Select to create a continuation

The name of the person logged in to Research Navigator IBC

Select to logoff Research Navigator IBC

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

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

Your Research Navigator IBC institutional profile

NYU Langone Medical Center
Finding Registration for Continuation

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

Select “IBC” to reveal approved registrations.

Select link to continue registration.
Select the “New Continuing Review” button to create a continuation to the IBC-approved registration currently displayed.
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.

<table>
<thead>
<tr>
<th>Continuation Review - Study Status</th>
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<tbody>
<tr>
<td>1.0</td>
<td><strong>Continuing Review ID:</strong> IBC12-000003-03</td>
</tr>
<tr>
<td>2.0</td>
<td><strong>Name:</strong> NLM March 2-3/2/2012</td>
</tr>
<tr>
<td>3.0</td>
<td><strong>Principal Investigator:</strong> Rebecca NOTINGRANTSSimms (PI)</td>
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<tr>
<td>4.0</td>
<td><em>Please select a study status:</em></td>
</tr>
<tr>
<td>5.0</td>
<td><strong>Reasons, summary or details:</strong></td>
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</table>

- **Active - With Changes**
- **Active - No Changes**
- **Withdrawn (give reason)**
- **Complete (provide summary of results)**
- **Other (provide details)**
  - **Clear**
### Continuation Form – Active With Changes

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.

<table>
<thead>
<tr>
<th>* Please select a study status:</th>
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<td>Complete (provide summary of results)</td>
<td></td>
</tr>
<tr>
<td>Other (provide details)</td>
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<tr>
<td>Clear</td>
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Some example of changes are: Study Staff, Location, experimental constructs, sponsor, etc.
Continuation Form – Active – No Changes

* Please select a 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:

- 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.
## Continuation Form – Complete

### Continuing Review - Study Status

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<tbody>
<tr>
<td>1.0</td>
<td><strong>Continuing Review ID:</strong> IBC12-000003-04</td>
</tr>
<tr>
<td>2.0</td>
<td><strong>Name:</strong> NLM March 2-3/2/2012</td>
</tr>
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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.
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 Continuation Process

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

After you’ve finished creating the continuation, the status will change and you will see the continuation 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.
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.
Enter messages to personnel in this section.

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

**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

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

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 require 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>
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<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.

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.
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 a continuation 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).
THANK YOU