Welcome to the Research Navigator Institutional Biosafety Committee (IBC) Creation and Submission of Non-Human Gene Transfer registrations Learning Module

Updated 08/2017
In this module, you will learn how to create and submit a request to conduct research involving:

- recombinant DNA (rDNA),
- infectious agents,
- non-human primate materials (including established cell lines),
- select agent studies conducted at New York University and within the campus of NYU Langone Health.

This request is known as a “registration.” Registrations are reviewed by the New York University Institutional Biosafety Committee or the NYU Abu Dhabi 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, an NYU Health Kerberos ID (KID) and password is required to login to @NYULMC/Research Navigator/IBC.

Submit an email to IBC@nyumc.org for the applicable Sponsored Individual Kerberos ID Request Form that you will need to complete.

Refer to the IBC website for the “Welcome to Research Navigator Institutional Biosafety Committee (IBC) Learning Module – Access from outside of NYU Langone Health” training document for specific instructions on how to access Research Navigator IBC.
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 iDevelop.

*** Washington Square/Dental School and NYU Abu Dhabi Users should contact Tekechia Hester th82@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 content of the training course.
Objectives

After reviewing this module, you will be able to:

• Login to Research Navigator/IBC
• Create and submit a new non-human gene transfer registration via Research Navigator IBC
• Understand the IBC submission, review and approval process
Enter your Kerberos ID and Password
PI's Home Screen

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

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

Select to create a new registration

All IBC registrations are stored here

Your Research Navigator IBC institutional profile

Select to logoff
After logging in to Research Navigator IBC, select “New IBC Application” and complete the registration 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
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.
### Registration Document for Recombinant DNA Experiments (Including Transgenic Animals)

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>1.0</strong></td>
<td><strong>Project Title:</strong></td>
</tr>
<tr>
<td></td>
<td>[Text input field]</td>
</tr>
</tbody>
</table>

**Help text:** Enter the title of this experiment. The title may be different from the title of the grant funding this project.

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>2.0</strong></td>
<td><strong>Sponsors/Agency:</strong></td>
</tr>
<tr>
<td></td>
<td>[Text input field] [Add]</td>
</tr>
</tbody>
</table>

**Help text:** Select the sponsor/agency that is funding the project.

*Text designed to assist in your response to most questions is found on the right.*
### IBC registration creation process – initial information

**Title of IBC project**

**Agency/organization funding project**

**PI's name**

**Sponsors/Agency:**

**Submission Department:**

**Principal Investigator:**

**Study Staff:**

**Select additional team members that have EDIT rights:**

**Please select a building:**

**Please enter a room:**

**Involves Human Genome Transfer:**

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*If names are not in dropdown, email MCITResearchIT@nyumc.org.*

The person creating the registration must add themselves as an editor in order to make edits to submission.

*Answer to this question determines the type of form you will complete.*

*Personnel performing experiments described in this project* ❗

*Personnel with edit rights for this project* ❗

*Building where experiments will be conducted* ❗

*Room # where experiments will be conducted* ❗
IBC registration creation process – Non-human gene transfer (HGT) studies

If you responded “no” to this question, you will be directed to create the form for NON-HGT experiments.

* Involves Human Genome Transfer:  ○ Yes  ○ No  Clear
Activities for rDNA or HGT registrations

- Status of current registration
- Select to view "printer" version
- Select to "Submit" registration for IBC review. The PI is the ONLY person who can submit.
- Select to enter comments seen by IBC personnel
- Select to withdraw a registration
- Select to request that all study staff agree to participate in the study described in this registration document.

Current Status

<table>
<thead>
<tr>
<th>Pre Submission</th>
</tr>
</thead>
<tbody>
<tr>
<td>Edit IBC Application</td>
</tr>
<tr>
<td>Printer Version</td>
</tr>
<tr>
<td>View Differences</td>
</tr>
</tbody>
</table>

My Activities...

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

Select to edit this registration - only available in Pre Submission, Changes Requested by IBC Administrator or Changes Required by Committee.

Select to view differences between different versions of the same registration.

Select to enter comments seen by all personnel listed on registration.

Select to add additional documents such as BL2 checklist, pictures etc.

Select to copy a registration document and all attachments.
Non-HGT registration form

If you answer “Yes, K12 strain…” identify the specific strain in Section A 1.0

<table>
<thead>
<tr>
<th>Section</th>
<th>Question</th>
<th>Options</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.0</td>
<td>Will rDNA be propagated in K12 strain(s) of E.coli, or other prokaryotic host(s):</td>
<td>Yes, K12 strain of Escherichia coli, Yes, other prokaryotic hosts, No</td>
</tr>
<tr>
<td>2.0</td>
<td>Will eukaryotic cells containing rDNA be used:</td>
<td>Yes, No, Clear</td>
</tr>
<tr>
<td>3.0</td>
<td>Will animals or whole plants containing rDNA be used:</td>
<td>Yes, No, Clear</td>
</tr>
</tbody>
</table>

Answers to these questions will determine which sections of the registration document will be displayed.
### Section A – Prokaryotic Host Cells Containing Recombinant DNA

#### 1.0 Enter Host(s):
Select “Add” to enter relevant information throughout the form.

<table>
<thead>
<tr>
<th>Host Name</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>There are no items to display</td>
</tr>
</tbody>
</table>

#### 2.0 Enter Vector(s):

<table>
<thead>
<tr>
<th>Vector Name</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>There are no items to display</td>
</tr>
</tbody>
</table>

#### 3.0 Enter DNA to be inserted (include names of genes and organisms from which they were cloned):

<table>
<thead>
<tr>
<th>DNA Name</th>
<th>DNA Source</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>There are no items to display</td>
</tr>
</tbody>
</table>

#### 4.0 Will whole eukaryotic virus or provirus be cloned?

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>No</td>
</tr>
</tbody>
</table>

#### 4.1 If Yes, specify:

<p>| |</p>
<table>
<thead>
<tr>
<th></th>
</tr>
</thead>
</table>

#### 5.0 NIH Recommended Biosafety Level:

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>BL-1</td>
<td></td>
</tr>
<tr>
<td>BL-2</td>
<td></td>
</tr>
<tr>
<td>BL-2+</td>
<td></td>
</tr>
<tr>
<td>BL-3</td>
<td></td>
</tr>
<tr>
<td>BL-4</td>
<td></td>
</tr>
</tbody>
</table>

Registrations suggesting/requiring BL2 containment or greater must have prior approval from Environmental Health & Safety. If you require multiple biosafety levels select the highest level. Email Mark Olmsted to obtain approval. Once approval is obtained, attach the approval email to this registration as a "Supporting Document."
This section of the registration document (Section B) is for the propagation of recombinant DNA in eukaryotic cells.

Each Section requires you to select the highest recommended biosafety level. This selection is based on the NIH Guidelines.
This section of the registration document (Section C) is for the propagation of recombinant DNA in whole animals or plants.
If you attempt to continue to the next page without completing all required information, you will receive an error message.

**Windows Internet Explorer**

This form cannot be submitted until all required information is provided.

**4.1.1**

If yes, indicate virus type, name of the virus and fraction of viral genome contained in the vector:

<table>
<thead>
<tr>
<th>Add</th>
<th>Vector</th>
<th>Virus Type</th>
<th>Clone</th>
</tr>
</thead>
<tbody>
<tr>
<td>Update</td>
<td>Vector 8</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**5.0**

DNA to be inserted (include names of genes and organisms from which they were cloned):

**Add**

<table>
<thead>
<tr>
<th>DNA Name</th>
<th>DNA Source</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

There are no items to display.

**6.0**

*NIH Recommended Biosafety Level:*

[Note that work with fresh human blood, body fluid, or tissue, and with human and other primate cells requires BL2 containment.]

- BL-1
- BL-2
- BL-2+
- BL-3
- BL-4
Sections D, E and G are required for all experiments. Section F is required for research at Biosafety Levels 2 or 3.

<table>
<thead>
<tr>
<th>Section D 1.0</th>
<th>* Will studies include attempts to obtain expression of a foreign gene: Yes No Clear</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>If Yes, specify the protein:</td>
</tr>
<tr>
<td>Section D 1.0.1</td>
<td></td>
</tr>
<tr>
<td>Section E</td>
<td>* Description of the Proposed Experiment:</td>
</tr>
<tr>
<td></td>
<td>In lay terms, describe the proposed research. Include an outline of the methodology.</td>
</tr>
<tr>
<td></td>
<td>Include references when necessary.</td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td>Section F</td>
<td>Containment of Aerosols for Research at Biosafety Levels 2 or 3:</td>
</tr>
<tr>
<td></td>
<td>Describe the measures that will be taken to minimize potential exposure to aerosols, such as the use of NIOSH-approved respirators (if required), biological safety cabinets, centrifuge safety cups, or micro-isolator cages.</td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td>Section G 1.0</td>
<td>* Medical Surveillance: Are special medical surveillance practices recommended? Yes No Clear</td>
</tr>
<tr>
<td></td>
<td>If Yes, specify:</td>
</tr>
<tr>
<td>Section G 1.0.1</td>
<td></td>
</tr>
</tbody>
</table>
Completing registration for rDNA experiments

When information is complete, select “finish”
Prior to submission

If you couldn’t complete your registration, return to the document by selecting this button.

Select this activity to submit. The PI is the only person who can submit. This activity only appears when the PI has logged on.
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.

Enter messages to personnel in this section.

Select “OK” to have an email sent to study staff asking them to agree to participate.
The PI completes the submission process by selecting the “Submit Application” button located on the left hand column after all study staff have agreed to participate.

**Please note that the PI is the only person who can submit.**
IBC registration submission process – PI Assurance

After the PI selects “submit application”, a window will appear requiring the PI to attest the information submitted is accurate and complete.
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 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.
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.
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).