CREATION AND SUBMISSION OF HUMAN GENE TRANSFER (HGT) REGISTRATIONS

Research Navigator - Institutional Biosafety Committee (IBC)
Welcome to the Research Navigator IBC Learning Module for NYU Langone Health Users

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

• Human Gene Transfer (HGT) studies conducted at New York University and within NYU Langone Health.

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.
NYU Washington Square and Dental School Users

• 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.

• To obtain access, complete this form and send to MCITResearchIT@nyumc.org

• 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 from outside of the NYU Langone Health campus.
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 NYU 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 Kechia.hestер@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, you will be able to:

• Login to Research Navigator/IBC
• Create and submit a new Research Navigator IBC registration for research involving:
  – HGT
• Understand the IBC submission, review and approval process
Log on to Research Navigator via @NYULMC

Enter your Kerberos ID and Password
Go to the IBC Module

Select View My IBC Registrations
PI’s Home Screen

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.

The name of the person logged in to Research Navigator IBC.

Select to create a new registration.

Select to logoff.

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

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
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.
Help Text

Text designed to assist in your response to most questions is found on the right.
## IBC Registration Creation Process – Initial Information

<table>
<thead>
<tr>
<th>Registration Document for Recombinant DNA Experiments (Including Transgenic Animals)</th>
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- **Agency/organization funding project**
- **PI’s name**
- *If names are not in dropdown, email MCITResearchIT@nyumc.org*
- **Title of IBC project**
- **PI’s department associated with this project**
- **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 only**
IBC Registration Creation Process – Human Gene Transfer (HGT) Studies

If you responded “yes” to this question, you will be directed to create the form for Human Genome Transfer (HGT) experiments.

9.0  * Involves Human Genome Transfer:  Yes  No  Clear
The HGT “form” lists standard text describing the SOP for the Product. Select “Update” to modify the standard text.

This is the “standard” text that you can modify.
HGT Registration Form

Additional required information is added as attachments AFTER the Human Genome SOP has been added.
HGT Registration Form - Attachments

Add HGT IBC - Submission Attachments

<table>
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<tr>
<th>* Submission Attachments Type:</th>
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<tbody>
<tr>
<td>Title</td>
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<tr>
<td>Investigator's Brochure</td>
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<tr>
<td>Consent Form</td>
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<tr>
<td>Response letter from Recombinant DNA Advisory Committee (RAC)</td>
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<tr>
<td>Protocol</td>
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<td>NIH Guidelines Appendix M</td>
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</tbody>
</table>

* Attachment:
[None] Add

* Required

When finished adding attachments, select “Finish” located at the top and bottom right side of the screen.

Attachments must be added one at a time.

All of the attachments listed are required.
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

- Pre Submission
  - Edit IBC Application
  - Printer Version
  - View Differences

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 statuses.

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

Enter messages to personnel in this section.
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 the registration.**
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.
IBC Registration Submission Process – Successful Submission

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 – General Timeline for New Submission

1. PI Submits IBC Registration
2. IBC Administrator conducts ADMIN review and IBC Chair conducts PRE-REVIEW
3. IBC Committee Meets on a bimonthly basis to review submitted registrations
4. PI Receives Correspondence from IBC
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.
Keys to Success

• Complete the IBC registration accurately and completely and attach any documents as indicated on the registration.

• If this is an initial site study, submit to the RAC prior to submitting to the IBC

• Ensure all study staff “agree to participate” and the rDNA course completion certificates for the PI and study staff are attached and valid.

• 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

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