Creating an IBC Protocol Application

Log in to Novelution:
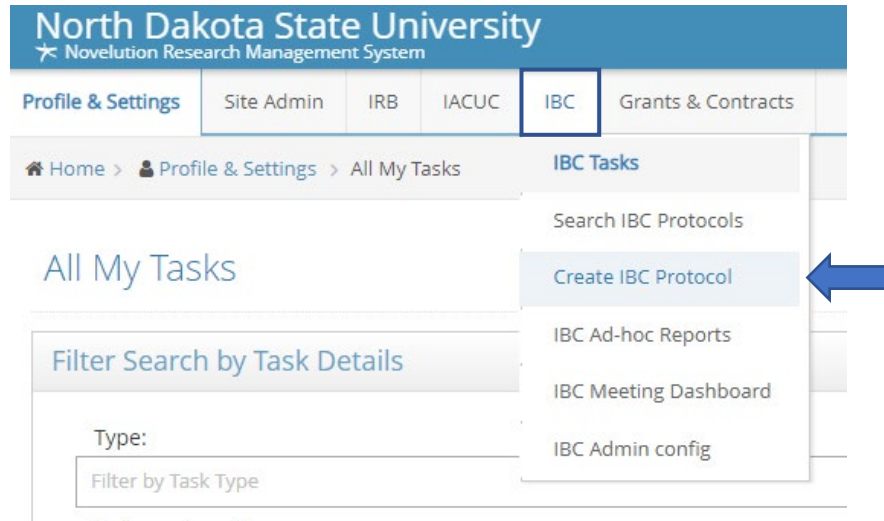
erac.ndsu.edu/login
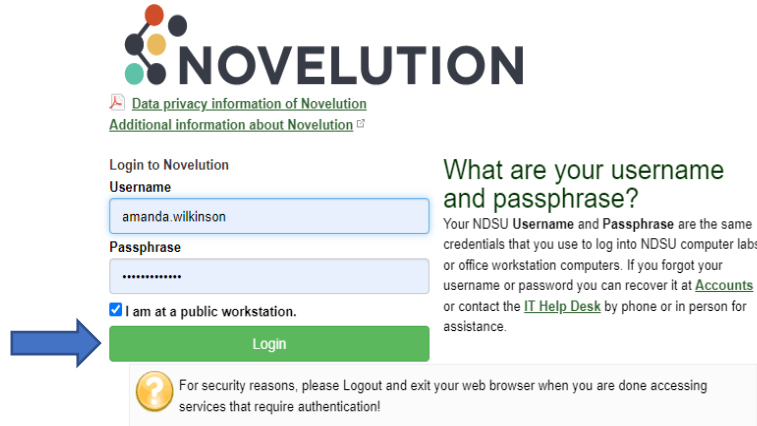

Select Create IBC Protocol:

Create IBC Protocol

Project Information

Only NDSU faculty and staff are permitted to serve as the Principal Investigator of a protocol. Students may serve as co-investigators, if needed.

PI*	Wilkinson, Amanda S

Project Department

Project Department*	VP for Research (4000)
Sub-Project Department	Select one

Office of the Provost > VP for Research

Title*	
Is this a continuation to an old protocol?	☐

CONTINUE

1. If you are not the Principal Investigator, you may select the PI from the drop-down list by typing in a few letters of their name, the person creating the application will automatically be added to the research team.

2. Once you continue from this screen, a unique protocol number will be assigned to you.

3. Any field with an asterisk (*) is required for submission.

4. If you see ❓ hover over for help text

Risks:* ❓   test

Describe risks for human, animal or plant/environmental health posed by the agents listed above and what safety measures will be taken.

Search IBC Protocol:

- Once a protocol has been assigned a number it can be found in the search IBC panel.

- You will see a list of all of your protocols in this table and their current status.

- If you stop working on a protocol prior to submission, this is the where you find it again to continue.

- Be sure to "Save" the document periodically as the program does not auto-save.

Panel shortcuts

collapse all | expand all

- ℹ️ **Review Comments**
- Admin Fields
- Project Information `<`
- Research Team
- NIH Guidelines
- Biosafety Containment
- Additional documents
- Connected Projects
- ℹ️ **IBC Correspondence**
- ℹ️ **Requirements**

- When you get to the next page you will see a panel shortcuts on the left side.

- This will change as you move through the form, adding relevant panels based on your research.

- It is important to fill the form out in order to populate the correct panels.

⌄ IBC20210000 : Amanda Wilkinson -   ☁️

⌂ Home > IBC > Edit IBC Protocol

collapse all | expand all

- There is an option to collapse all panels or expand. This image shows all panels collapsed

⌄ Review Comments

⌄ Administrative Fields & Tools

⌄ Project Information   ✓ ✎ ▯

⌄ Research Team   ✓ ✎ ▯

⌄ NIH Guidelines   ✓ ✎ ▯

⌄ Biosafety Containment   ✓ ✎ ▯

⌄ Additional documents   ✓ ✎ ▯

⌄ Connected Projects   ✓ ✎ ▯

⌄ IBC Correspondence

⌄ Requirements   ⟳

Project Information panel:

Project Category*	Select one ▼
List any literature references relevant to this application	

Protocol Type*
- ☐ Recombinant or Synthetic Nucleic Acid Molecules
- ☐ Infectious Agents
- ☐ Human Blood, Bodily Fluids, Tissues or Cell Cultures

This protocol will involve*   Select one ▼

Navigation panel:

Project Information

Research Team

→ (red arrow) NIH Guidelines

→ (yellow arrow) Infectious Agents

Human Blood, Bodily Fluids, Tissues or Cell Cultures ← (green arrow)

Biosafety Containment

Additional documents

Connected Projects

This section will create the most changes by adding additional panels base on protocol type selections

- If you select rDNA you will see the added panel with the red arrow. (See next pages for additional panels for rDNA)

- If you select Infectious agents you will see the panel with the yellow arrow. This is the only additional panel for IA.

- If you select Human blood you will see the panel with the green arrow. This is the only additional panel for HB.

- *Biosafety containment will be added for all projects

There are 4 options for rDNA use.

This protocol will involve:

1 Creating Transgenic Animals
2 Crossing and/or Using Transgenic Animals
3 Generating and/or Using rsNA Materials
4 Generating and/or Using Transgenic Plants

1

Protocol Type*
- ☑ Recombinant or Synthetic Nucleic Acid Molecules
- ☐ Infectious Agents
- ☐ Human Blood, Bodily Fluids, Tissues or Cell Cultures

This protocol will involve*
Creating Transgenic Animals

Project Information
Research Team
NIH Guidelines
Genome Editing ←
Creating Animals ←
Biosafety Containment
Additional documents
Connected Projects

2

Protocol Type*
- ☑ Recombinant or Synthetic Nucleic Acid Molecules
- ☐ Infectious Agents
- ☐ Human Blood, Bodily Fluids, Tissues or Cell Cultures

This protocol will involve*
Crossing and/or Using Transgenic Animals

Project Information
Research Team
NIH Guidelines
Transgenic Animals ←
Biosafety Containment
Additional documents
Connected Projects

3

Protocol Type* ☑ Recombinant or Synthetic Nucleic Acid Molecules
☐ Infectious Agents
☐ Human Blood, Bodily Fluids, Tissues or Cell Cultures

This protocol will involve* [Generating and/or Using rsNA Materials]

↳ rsNA* [Select one]

Viral Vector

AAV

Adenovirus

Lentivirus

Retrovirus

↳ rsNA* [Select one]

Other

Naked DNA/RNA

Plasmid

Modified Microorganism

Modified Cells

Other

scription*   scription*

Project Information

Research Team

NIH Guidelines

Material ⬅

Genes ⬅

Genome Editing ⬅

Target Recipients ⬅

Biosafety Containment

Additional documents

Connected Projects

4

Protocol Type* ☑ Recombinant or Synthetic Nucleic Acid Molecules
☐ Infectious Agents
☐ Human Blood, Bodily Fluids, Tissues or Cell Cultures

This protocol will involve* [Generating and/or Using Transgenic Plants]

Project Information

Research Team

NIH Guidelines

Genome Editing ⬅

Plants ⬅

Biosafety Containment

Additional documents

Connected Projects

Modals:

⊕ Add Lab Location

A modal will pop up allowing you to enter lab locations. All modals contain required questions. These can be used multiple times and will create a table within the protocol.

Lab Location   ✕

Building* | Select one   ▼ |

Activity description | |
                             | |

Date/Year of last laboratory safety audit | | 🗓

Have all the corrective actions required by the Office of Safety been   ○ Yes ○ No
implemented by the laboratory?

                                                          ✕ Cancel   **⊕ Save**

⊕ Add Lab Location

collapse rows ➖ | expand rows ➕

Building	Room#	Activity description	Lab safety audit	Corrective actions implemented	Action
Sudro Hall	3598				✏ 🗑

To edit this addition:
Select this blue icon

Research team panel:

Add Researcher

collapse rows ⊟ | expand rows ⊞

Name	Role	Lead Unit/Department	Business title	Contact details	Edit Permission	Responsibilities	CITI Training	Action
Wilkinson, Amanda S	Principal Investigator	VP for Research	ResIntegrity&ComplAdm-IBC&COIC	👁	YES		Completed	✎

- The PI will automatically be added as part of the research team.

- To add personnel – click the blue box by the arrow above.

- If the researcher is NDSU – they should be found in the personnel pulldown.

Add Researcher   ✕

Cannot find a researcher! Do you want to add a student or an external user?	☐
Personnel name*	Start typing... ▾
Project Role*	Select one ▾
Edit permission	☐
Responsibilities (select all that apply)	Select some ▾
Highest Earned Degree	
Prior Experience or Training Related to Responsibilities	
Hepatitis B vaccine series offered?	○ Yes ○ No ⬅ Only asked if Human blood is selected as project type

✖ Cancel   ⊕ Save

External users:

- If the researcher is not found – check the box at the top and enter the name and email

- The researcher will receive and email on how to long in and create/activate their account

Add Researcher   ✕

Cannot find a researcher! Do you want to add a student or an external   ☑
user?

Email*   [   ]

First Name*   [   ]

Last Name*   [   ]

Project Role*   [Select one   ▼]

Edit permission   ☐

Responsibilities (select all that apply)   [Select some   ▼]

Highest Earned Degree   [   ]

Prior Experience or Training Related to Responsibilities   [   ]
                                [   ]

Hepatitis B vaccine series offered?   ○ Yes ○ No
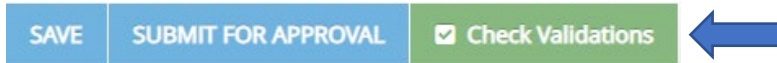
                                                                          ✖ Cancel   ⊕ Save

Protocol Submission:

You may check the completeness of the application at any time by clicking "Check Validations." (at the bottom of the screen)

This will tell you if there are any required sections that have been missed. You can click in the red box and it will take you to the section that needs correction or additional information.

✔ Application saved: 05/24/2022 10:33 AM

✘ 'Title' is required
✘ 'Non-Technical Synopsis:' is required
✘ 'Project Category' is required
✘ Detailed Project Description required.
✘ Missing Materials for rsNA: Adenovirus
✘ Enter at least 1 Gene in the table or upload the genes file
✘ 'This project will be conducted at Biosafety Level (BSL)' is required
✘ 'Specify activity that create aerosols.' is required
✘ 'Describe mitigation measures to be used.' is required
✘ 'PPE required for the biohazard agent manipulation (check all that apply):' is required
✘ 'Select all used:' is required

You will see this box if complete and ready for submission.
"Submit for Approval" will take you to the PI attestation and final submission.

✔ Application saved: 05/24/2022 10:35 AM
✔ All data field validation requirements are currently being met.

<u>Requirements Panel:</u>

1. Once the study has been submitted, you can view the "next steps" in the review process via the Requirements Panel

Status	Requirement	Completion State
Draft Submission Pending	Submit Protocol	Ready
PI Certification Pending	Certify Protocol (PI)	Not ready
Pre-submission Requirements	Approval by VP: Colleen M Fitzgerald	Not ready
	Complete training on Citi: Amanda S Wilkinson	✔Completed
IBC Review Pending	IBC Admin Processing	Not ready

2. Training for all members of the research team must be completed before the study can be reviewed. You can see the status of Team members training in the Requirements panel. If the panel states "Completed" in the Completion State column, the training is current/complete. If it states "Ready" the individual has not completed the training requirement OR the training could not be matched because two different email addresses are used in the Novelution and the CITI training systems. To correct this individual may either:

   a. Add their "CITI email address" to their Novelution profile, or
   b. Change their Primary email address in CITI (citiprogram.org) to match their Novelution email.

1. The Department Chair/Head, Dean or VP is automatically notified that a study needs their approval. Once approved, and the protocol is ready for review, the IBC Review Pending requirement will show as "Ready."

IBC Review Pending ❓	IBC Admin Processing	Ready