NUgrant IBC PROTOCOL FORM INSTRUCTIONS

(For assistance please contact EHS at (402) 472-4925 or visit our web site at http://ehs.unl.edu/)

Contents
Introduction .............................................................................................................................. 2
Requested Information Checklist ........................................................................................... 3
NUgrant Login Information ..................................................................................................... 4
IBC Protocol Approval Process ............................................................................................. 5
Logging In to NUgrant ............................................................................................................. 6
IBC Protocol Form: Page 1 ..................................................................................................... 9
  Section I: Protocol Information ............................................................................................ 10
  Section II: Research Description ....................................................................................... 12
Moving Between Form Pages ............................................................................................... 12
New Protocol Form: Page 2 .................................................................................................. 12
  Section III: Microorganism Information ............................................................................ 13
  Section IV: Organ, Tissue or Cell Cultures Information .................................................... 13
  Section V: Research Organism Information ..................................................................... 13
New Protocol Form: Page 3 .................................................................................................. 14
  Section VI: Recombinant and/or Synthetic Nucleic Acid Information .............................. 14
New Protocol Form: Page 4 .................................................................................................. 14
  Section VII: Toxin Information .......................................................................................... 14
  Section VIII: Facilities Information .................................................................................... 14
  Section IX: Specialized Equipment Information ............................................................... 14
New Protocol Form: Page 5 .................................................................................................. 15
  Section X: Risk Assessment/Safety Considerations ........................................................... 15
  Section XI: Attachments .................................................................................................... 16
Submitting the form for review ........................................................................................... 16
Navigating the IBC Protocol List and Protocol Summary Pages ...................................... 18
When Revisions are Requested ........................................................................................... 22
Electronically Signing the Form ......................................................................................... 24
Introduction

PLEASE READ ALL INSTRUCTIONS! *(Thank you!)*

In accordance with the UNL Biosafety Guidelines, a protocol must be submitted for review by the Institutional Biosafety Committee (IBC), for clinical, diagnostic, teaching, and research activities involving:

- Recombinant or synthetic nucleic acid molecules (r/sNA) (regardless of origin) and r/sNA-containing organisms or cell cultures.
- Microorganisms or agents potentially pathogenic to humans, animals, or plants.
- Human blood or other body fluids, tissues, and cell lines potentially containing bloodborne pathogens, as similarly materials derived from experimentally challenged animals.
- Select agents and toxins.
- Animals for which a reasonable potential for transmission of naturally infected zoonotic agents exists, e.g., wild-trapped animals, necropsy, etc.

The protocol is submitted for IBC review as an electronic document using the secure NUgrant system administered by the Office of Research. Once approved and assigned an IBC registration number (NUgrant ID), the protocol is valid indefinitely, contingent on the PI submitting *Annual Update Forms* and obtaining approval of amendments and minor modification forms, as applicable. An *Annual Update Form* will be requested on the anniversary of the protocol approval date or last amendment approval date. This form, submitted from within the NUgrant system, is used to inform the BSO and IBC if the research is still active as well as notify the committee of minor changes, such as additional grant applications, staffing and location changes, and/or changes in decontamination/disinfection methods. Minor changes made in between annual updates can be submitted using the Minor Modifications Form, available in NUgrant as well.

Modifications in the materials and methods used in your research are considered “Major Changes” should be submitted for IBC review by logging into the NUgrant system and submitting an *Amendment Form*. 
Requested Information Checklist

Following is a list of the information that will be needed to complete the NUgrant protocol form. Although the system will allow a form to be saved in an unfinished state, it is most efficient to gather the requested information prior to starting the electronic submission process.

- List of current personnel and collaborators/Co-PIs (Page 1, Section I)
- Research Description (in laymen’s terms) (Page 1, Section II)
- Microbes in use (Page 2, Section III)
  - Source, risk group, pathogen type (human, animal, plant), toxin production, use, recipient, antibiotic/drug resistance introduced
- Organ, Tissue, or Cell culture (OTCC) use (Page 2, Section IV)
  - Source, name, supplier, containment level, passage, use, recipient
- Research Organism (animals and plants) use (Page 2, Section V)
  - Organism name, recipient of rDNA, OTCC, microbe (route and dose), or toxin
- Recombinant or Synthetic Nucleic Acid use (Page 3, Section VI)
  - Gene name, source, type, function, use, risk assessment
  - Vector type, source, name, vendor, risk attenuation, plasmid maps
  - Viral vectors: system, plasmids used, tropism, transgenes, use
  - Viral vector packaging: system, cell line, location of production/packaging and procedures
- Toxin use (Page 4, Section VII)
  - Name, source, supplier, pathogen type (human, animal, plant), LD-50 or LDL, Target organs, use, recipient
- Facility information (Page 4, Section VIII & IX)
  - Building & room numbers
  - Room use
  - Containment Equipment
  - Sharps Use
  - Specialized Equipment
- Risk Assessment Safety Information (Page 5, Section X)
  - Proposed containment level
  - Personal Protective Equipment (PPE)
  - Medical surveillance (vaccinations & medical monitoring)
  - Disinfectant use
  - Decontamination and disposal methods
  - Autoclave (location and identification #’s)
  - Safe Operating Procedures observed (EHS or lab-specific)
  - Lab security features/practices
Sections I, II, and VIII-X are mandatory for all protocols. Sections III-VII may or may not be required, depending on the project attributes. When completing the electronic form, check the “not applicable” check box if a section does not apply to your work. This will collapse the section so no further questions need be answered for that section. Section XI allows the investigator to attach additional information to aid the IBC in the review process. Examples include: import permits, plasmid maps, lab-specific procedures, etc.

The following references are commonly used by the IBC when reviewing a protocol and may be helpful in completing the NUgrant form:


**NUgrant Login Information**

The web address for the NUgrant system is https://nugrant.unl.edu. For UNL faculty and staff your login defaults to your My.UNL (Blackboard) login and password. For instructions on how to find your username and password see the FAQs at http://my.unl.edu. If you are unable to find your login and password by completing the steps in the FAQ, please send the following information to nugrant-ibc@unl.edu:

- Name
- Email Address
- Phone Number
- Physical Address (e.g., street address or Bldg & Room #)
- University Department affiliation

An account will be set up for you within NUgrant and you will be notified of your login and password by email. The following pages contain screen shots and additional instructions.
SCREEN SHOT WALK-THROUGH

Logging In to NUgrant

Login here with your My.UNL (Blackboard) ID and password
Beneath the **IBC Protocols** header you will see a list of most recently viewed protocols, you can click on this to view the Protocol Summary page when you reenter NUgrant.

Click on the “[add new]” link to start a new protocol or click on “**IBC Protocols**” to view existing protocol.
Clicking on “IBC Protocols” link will take you to this screen. If this is your first IBC protocol submission, you won’t see any files listed under the search boxes.

There are two ways to start a New Protocol Form. You can either:
1. Click on “Add New IBC protocol” button on the screen above or;
2. Click on the “[add new]” link on the NUgrant home page as scene on the previous page.
Both options will take you to the IBC Protocol Form page.
IBC Protocol Form: Page 1

There are several elements here that display on every page of the form.

- **Protocol Workflow** – This shows the steps of the protocol approval process. Red dots 🔄 indicate incomplete steps. Green dots ✅ indicate the step has been completed.
- **Protocol Status** – This shows what step in the workflow you are working on.
- **Form Pages** – This is a clickable list of the pages of the form, when they are complete a checkmark appears next to the page title.
- **Return Button** – This will take you back to the Protocol Summary Page.

The❓ buttons found throughout the form provide additional information or explanation about the section or question on the form.
Important
If you are working with multiple model systems or microorganisms but the basic techniques and procedures are the same, you may enter all of the information in one protocol form with a generalized title. The individual projects should be clearly described and differentiated in the "Research Description" section at the bottom of Page 1.

Important
Several sections within the form are dynamically linked, meaning they are dependent on information entered in previous sections. It is highly recommended that you complete each section in sequential order to avoid having to go back and edit entries once the missing information is entered.

Section I: Protocol Information

Protocol Title:
Enter a title for your protocol. This can be as specific or generic as you desire. If your protocol will cover multiple projects, please ensure the title is descriptive enough for all projects. Try not to use grant titles as these are often too focused.

Legacy protocol #:
This field can be ignored as this field was initially added to the form to maintain continuity between the old IBC registration system and NUgrant. Export Control Compliance
All institutions of higher education and their faculty, staff, and students must comply with export controls, which are designed to ensure that sensitive information, technology, software, biological and chemical agents, equipment, and know-how are not employed for purposes other than their intended use. In case of violations, criminal sanctions – including substantial fines and even prison terms – can be applied. Refer to the Export Control page on the Office of Research’s website for more information.
**Protocol Attributes**
Enter the requested information and check the relevant boxes describing your protocol’s attributes. Some of the check boxes require additional information when checked.

**Item 13 - Recombinant or synthetic nucleic acid molecule** use requires selection of the applicable sections of the *NIH Guidelines*. More than one section of the *Guidelines* may apply. The info icon provides a link to the *Guidelines* on the NIH website. The *Guidelines* state that it is the PI’s responsibility to determine which sections apply; however, you may contact the UNL Biosafety Officer with any questions at 472-9554.

**Grant Information**
You can search for grants that you have been awarded and that are tracked through NUgrant. This is not a required field and some internal funding as well as other private organization funding will not be selectable. If you wish to list funding sources you can do this in the comments box at the end of Section I.

**Investigators**
Add your information (this may already be entered) and indicate your department. Add your department head/chair, dean or director as applicable. Finally add any co-investigators or collaborators on the project. This search is limited to personnel in the University of Nebraska system. If you have collaborators outside the university that you may be receiving research materials from, please list them and their institutions in the comments box at the end of Section I.

*NOTE: If you cannot find your Dept. Head/Chair, Dean, Director or equivalent using the search tool, please have them contact the NUgrant support staff at nugrant-ibc@unl.edu to setup an account. If information is incorrect for any of the Investigators, please enter the correct information in the comments box at the end of Section I.*

**Personnel**
Enter all of the personnel that will be working on the projects described in this protocol. The years of experience listed should be in working with the materials and/or techniques described in the protocol.

*NOTE: If you cannot find a person in the system, please provide their name, title and years of experience in the comments box at the end of Section I. Sometimes there is a delay in adding people to the directory.*
Section II: Research Description

For the research description, please provide a general overview of the project(s) and any relevant experimental details that will aid the IBC committee in assessing the risk of the proposed work. You can describe more than one project, but please delineate them with project titles.

Moving Between Form Pages

There are navigational buttons at the bottom of each page of the form. You may see “Previous”, “Save” or “Next” buttons at the bottom of the page depending on what page you are working on. When you have entered all of the information requested on a page, check the box above the navigation buttons labeled “Check if Page is Completed,” then click the “Save” button if you want to stay on the page you are on or one of the navigation buttons to move to the next page. Checking this box “validates” the page to confirm that all of the required information has been completed. If required information has been omitted, a red box will appear next to the question indicating that the question is a required field. Provide the required information and click on the “Save” button again.

Note: You can move between pages without validating the entered information, but you will not be able to submit the protocol for review without the validation check for each page. Moving between pages without validation still saves the entered information.

New Protocol Form: Page 2

There are 3 sections on this page: Microorganism information; Organ, Tissue, or Cell Culture Information; and Research Organism Information. Complete all applicable sections. If a section does not apply, click the “Not Applicable” box for that section.

For each section if there is additional information that you wish to provide that is not collected by the listed questions, please enter it in the comments box at the end of the relevant section.

In each of these sections, you add items by clicking on the “add new” button. This will open a popup window with a list of questions. In general, each organism or material should be added as a separate item. You must provide an answer for all questions in order to save the item.

Once entered and saved, you can click on the “Edit/View” button next to each item to make changes or view the information entered. Clicking on the “Remove” button will delete that entry.
Section III: Microorganism Information

In this section you will enter all microorganisms used in your research, including viral vectors, parasites, and single-celled organisms such as algae (e.g. Chlamydomonas). After entering the microbe, you will see it listed as above by the organism name. You can click on the “Edit/View” button to make changes or view the information entered. Clicking on the “Remove” button will delete that entry.

Section IV: Organ, Tissue or Cell Cultures Information

In this section you will enter all organs, tissues, cell cultures, bodily fluids, etc. that will be used in the research. Each item should be entered individually. Exceptions to this can be discussed with the IBC Administrator.

Section V: Research Organism Information

In this section you will enter research organisms that are used in your research. The information requested in this section identifies what the animals or plants will be receiving, whether, microbes, OTCC, r/sNA, or toxins. If the organisms are only used as a source of cells or research material, enter those animals or plants in this section and provide information in the comments box for this section as to the use of the organism.
New Protocol Form: Page 3

Section VI: Recombinant and/or Synthetic Nucleic Acid Information

- **Genetic Material Information**
  - In this subsection you will enter all of the “genes of interest” that will be introduced into the microbes, OTCC or organisms. It is not necessary to list every gene in a plasmid or those associated with viral vectors, just the genes or material that will be expressed in the microbe, cell or organism. Examples would be the transgene that is being investigated, siRNA or shRNA constructs that are used to silence genes.

- **Vector Information**
  - In this subsection, you will enter information about the plasmids that you are using to introduce the genes that you listed in the Genetic Material Information section. Be sure to attach plasmid maps in Section IX.

- **Viral Vector Information**
  - If you are working with viral vectors, this is where we ask specific questions about the how the vector is made and what you are doing with it.

- **Viral Vector Packaging**
  - In this section we ask about how the viral particles are generated through packaging in cells.

New Protocol Form: Page 4

Section VII: Toxin Information

If you are working with any biological toxins, please add them in this section and provide the requested information.

Section VIII: Facilities Information

In this section, you will list the facilities where work on the project(s) described in the protocol will be done. Include your main lab, common equipment rooms, collaborators labs with specialized equipment, animal holding and procedure areas, greenhouses, etc. If the room use is identical, you may list multiple rooms in one entry, otherwise each room should be entered separately.

Section IX: Specialized Equipment Information

In this section you can list pieces of equipment that are not considered standard biology lab equipment and other equipment that requires disinfection after use. There is no need to list centrifuges and biosafety cabinets here. Examples include: HPLC machines, NMR magnets, etc.
New Protocol Form: Page 5
Safety and safety-related information is entered on this page.

**Section X: Risk Assessment/Safety Considerations**

The first field in this section asks you to enter the proposed containment level for the experiments. If you conduct work at more than one biosafety containment level, enter the highest containment level.

If you are utilizing facility enhancements beyond those described for the indicated BSL, describe those in the second field. Also, indicate other practices that are beyond those required for the BSL indicated. If you are working at multiple BSLs, use this space to detail which experiments are conducted at which BSL. For example, using double gloves at BSL-2 is an added protection for workers and should be listed here.

Below you will find instructions for completing the subsections of Section X.

- **Personal Protective Equipment**
  - Indicate all PPE used in the lab. If you are conducting work with animals, you can list the specific PPE used for that work in the Additional Information box at the end of Section X.

- **Proposed Vaccination and Medical Monitoring**
  - Enter any medical surveillance procedures or vaccinations required for work with the materials in your protocol. Example: when working with bloodborne pathogens, Hepatitis B Vaccinations are required and should be entered here.

- **Disinfectants**
  - List the disinfectants used in this subsection. Please list each disinfectant separately, and provide a brief description of how the disinfectant is applied. Example: 10% bleach is sprayed on the surface and allowed to sit for 10min before being rinsed with water.

- **Decontamination and Disposal Methods**
  - Enter decontamination and disposal methods here. Be sure to check all that apply. If waste is being autoclaved, enter the location of the autoclave (bldg. and room) and the unique EHS identifier # for that autoclave (The naming convention is as follows: room number-autoclave number i.e. 217-1).

- **Standard Safety Procedures Observed**
  - Check the EHS SOPs that your lab will use and follow. Then go to the EHS website and download a copy for your lab Biosafety Manual if you do not already have a copy.

- **Lab-specific Safety Procedures**
  - If you opt to use lab-specific procedures in lieu of or in addition to EHS SOPs, please list them and upload a copy of the document in this section.

- **Security Attributes**
  - Check the security attributes that apply to your lab.
• **Additional Information**
  o Use this space to provide additional information about the procedures and practices used in your lab to mitigate the risk presented by the biological materials proposed for use in this form. This should not necessarily duplicate the information already provided in the previous questions, but rather provide context or explanation for the work described in the form as it relates to the safety of the lab workers.

**Section XI: Attachments**

In this section you may attach any materials or documents that you feel would assist the IBC in evaluating and reviewing your protocol. Examples include: plasmid/vector maps, APHIS or CDC permits, specific experimental procedures, BBP verification of lab-specific training forms, etc.

**Submitting the form for review**

Once all of the pages have been completed and validated, the status at the top of the page will change indicating the preparation task is complete. Click on the “Next” button in the green bar to move to the next step.
On the page for “Step 2,” you must click on the “Submit” button to send your protocol to the Biosafety Officer for initial review. Once you click on this button, the form will be locked from any further editing by you.

Once submitted to the Biosafety officer, you will receive email updates as to the status your protocol in the review process. Should anyone request revisions (BSO, Dept. Head/Chair, IBC committee), you will be notified and asked to login and address the issues and/or make necessary changes. The following pages illustrate what you will see when you login to do this.
Navigating the IBC Protocol List and Protocol Summary Pages

When you log back in to the system you will click on “IBC Protocols” as seen on Page 7 of these instructions. Below is the page that will be displayed. To view your protocol, click on the “View” button next to your protocol.
Below is the IBC Protocol Summary page, the ‘homepage’ for maintenance of your protocol. This gives an overview of the protocol and provides status indicators and a list of the forms you have submitted. Amendment forms, Minor Modification Forms and Annual Update forms will be listed here as well. The forms will have a code prefix indicating the form type as well as the form number. The form number is separate from your Protocol ID number. NP (New Protocol Form), AM (Amendment Form), MM (Minor Modification Form), AU (Annual Update Form).
From the Protocol Summary page, you can access attached files, messages and comments that are attached to your forms. Clicking on the “View Messages” link brings up the window below. From here you can view and print approval letters and other notifications that are sent through NUgrant regarding your protocol. Simply click on the title of a message and a preview will appear below the title with a link to a “Printer Friendly Version”. Clicking on that link will allow you to print a copy of the message.
This is an example of a Protocol Form Homepage. On this page you can navigate to the various workflow steps as well as see a snapshot of the form status including attachments, messages, history and comments. You can also print a PDF copy of the form from this page or delete the form if needed.

Additionally, you can send comments to the BSO or IBC through the “Add a Comment” link. Comments sent through this link will be attached to the specific form you are viewing.
When Revisions are Requested
After logging in to the NUgrant system, click on the "IBC protocols" header link from the main NUgrant home page. This will take you to a list of protocols to which you are attached as a PI. From here, click on the “View” button to go to the Protocol Summary page. Alternatively, you can click on the name of the protocol listed under the IBC Protocols header to navigate to your IBC Protocol Summary page.

Click on the tab at the top for your most recently submitted form, this will almost always be the one on the far left. You will see a screen like this:

![Protocol Summary Page](image)

Yellow boxes indicate that your attention is needed on this form. Read the box to see what is needed, then click on the red “Get started” button to open the form.
Revisions have been requested on your form, click on the red “View Request” button to view the letter detailing the revisions needed in the form.

When you have completed all of the requested revisions, click on the “Submit Your Revisions” button. A popup window like the one above will appear. Provide comments as to what changes were made and click the “Submit Your Revisions” button.
Electronically Signing the Form

Because this is an online system you cannot physically sign the form, but you must still “sign” the form to make it official. This done by providing your login credentials on the “Routing” page of the form. There are two instances where you will be required to electronically sign the form.

1. As the Principal Investigator on a protocol
   a. Once the Biosafety officer has reviewed and signed-off on your protocol you will be notified by email and asked to login and electronically sign your protocol.

Below is the page you will see when you navigate to view your protocol. (See instructions on p. 19 for viewing your protocol)
b. Read the statements and if you agree to follow the statements, check the box and enter your login name and password to sign the form. You can also provide comment back to the IBC on this page.

2. As a Department Head/Chair, Dean or Director
   a. After the PI signs off on the form, a notification email is sent to the assigned Dept. Head/Chair, Dean or Director for their approval.
   b. When you navigate to the Protocol that needs your signature (see p. 18-20 for instructions) you will see the screen below with your name listed where “Brenda Osthus” appears.
   c. Enter your login information to electronically sign the form and use the dropdown box to indicate your decision on the protocol (“approve” or “request revisions”). If you request revisions, be sure to provide detail in the comment box available.
Once the protocol routing has been completed, it is released for viewing by the IBC committee members. It will be assigned to an IBC meeting and reviewed at the meeting. If the committee requests revisions, you will be notified by email and asked to make the required changes before approval. Once changes have been submitted and approved, you will receive a formal approval letter from the Biosafety Officer on behalf of the IBC. A copy of this letter should be kept in your Biosafety Manual along with the final approved version of your protocol which can be downloaded as a PDF from NUgrant.