eProtocol Investigator

Quick Reference Guide for DePaul University IBC Users

Document Version

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1 Introduction

eProtocol is the Key Solutions software tool used to manage the life of a protocol. eProtocol helps eliminate errors and improves collaboration, communication, and efficiency.

This quick reference guide is intended to be used in conjunction with the eProtocol application for those with the role of Investigator for IBC protocols. This guide introduces the basics of how to navigate through eProtocol and how to create a protocol by effectively using the different protocol response types and protocol checks.

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2 Getting Started

Beginning January 2, 2020, all new protocols must be submitted through the online eProtocol portal. For the IBC, all older protocols were entered in the system by ORS, and new protocol numbers were generated in the system. This allows for all amendments, annual renewals, adverse events, and final reports to be submitted online through the eProtocol portal for all active IBC protocols. Basic information about the system, how to log in, and the link to the online system can be found at here. **The best browsers to use for accessing eProtocol are Mozilla Firefox, Safari, and Chrome.** The direct link to the system is: https://researchcompliance.depaul.edu/. When you go to this link, you will see the main home page for eProtocol.
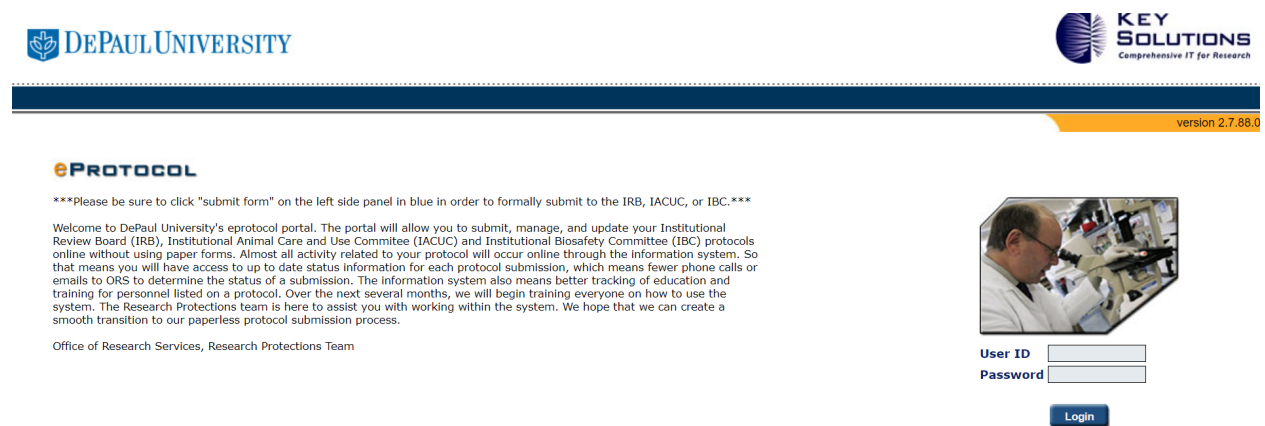
Figure 1: Homepage

You log into the system using your usual DePaul user ID and password. Your DePaul user ID is usually the beginning of your email address; it can also be found as the last item in the Outlook email search screen. When you log into the system for the first time, you will see a pop-up window that tells you that you need to accept pop-ups for the system to work. Select **Allow Pop-ups**. When you do this, the system will log you out and you will need to log back in again. Since the pop-up setting is computer specific, you will need to go through this step for every computer you use with the system.

When you log in to eProtocol, the Investigator Homepage is displayed unless you were assigned another role in the system as your default role (e.g., IBC reviewer) prior to your first log-in attempt. The Homepage consists of shortcuts that allow you to navigate to specific locations or functions. You will know which role you are currently working in because the role will be displayed in the upper right-hand corner of the screen.

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Figure 2: Roles

If you work with more than one board (IRB, IBC, or IACUC), you will need to be sure that you are working in the correct board by ensuring the IBC tab is selected and darker than the other board tabs.

> ⚠️ **Caution:** *Do not use the browser's forward and backward arrows to navigate. Because eProtocol is a secure application, using the forward and backward arrows results in a security violation, an unrecoverable error, and you are logged out of eProtocol.*

> ℹ️ **Note:** *If you have trouble logging in, contact your DePaul University's Office of Research Services, Research Protections section staff at ORP@depaul.edu*

2.1 Investigator Homepage

The Investigator Homepage is divided into two sections: the header and the body. Each section has its own shortcuts.

2.1.1 Header Shortcuts

At the top of the homepage is the header. On the left-side of the header is the Investigator submenu. To navigate to the Investigator submenu, hover over **eProtocol (triggering a drop-down menu)** and then the word **Investigator**. A list of possible actions for an Investigator will become viewable.

1. **View approved protocols**: This page allows the Investigator to view all protocols currently approved by the IRB under their leadership.
2. **Clone a protocol**: This page creates a duplicate of an existing protocol that can be edited and re-submitted as a new study.
3. **Create a protocol**: This page allows you to create a new, blank research protocol application for submission to the IRB/IBC/IACUC.

4. **Delete a protocol**: This allows you to remove a protocol from the eProtocol system. *Do not remove any protocols that are active or currently under review with the IRB without consulting with ORP.*

5. **Navigate to the Homepage**

6. **Search for a protocol**: This allows you to find a particular protocol within the eProtocol system. Please note that you will only have access to protocols for which you are listed as an Investigator.
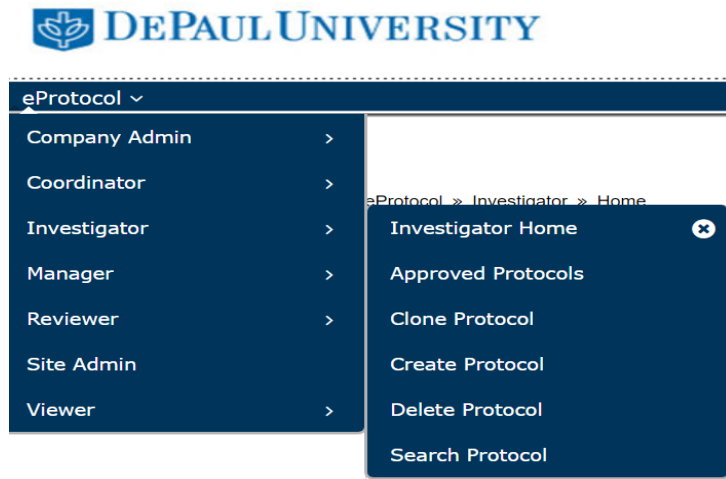
Figure 3: Homepage Header Shortcuts

On the right side of the header, you can perform the following functions (refer to **Figure 3**'s reference numbers):

7. View the eProtocol version number
8. Sign out of eProtocol
9. Navigate to a pop-up that will have help information for you with the homepage. This text may take time to develop, so specific help may not be available initially.

> **Note:** *A Help button is located on every page in eProtocol. Click a Help button at any time for tips about the current page. However, help text will take time for ORS to develop as we see what users need assistance with, so help text may not be immediately available. For immediate assistance, please contact the Research Protections office at orp@depaul.edu.*

2.1.2 Homepage Body Shortcuts

The homepage body is located below the header. In the homepage body, you can view and perform the following functions (refer to **Figure 2**'s reference numbers):

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1. Know your location in eProtocol by viewing the breadcrumbs, a navigation tool that reveals your current location in eProtocol. The breadcrumbs are commonly found at the top-left of a page. You may navigate to a previous page by clicking the link within the breadcrumbs.
2. Read instructional text provided to you by DePaul University
3. Create a protocol
4. Clone a protocol
5. Delete a protocol
6. Switch between committees by clicking on a committee name, if applicable
7. View or edit a protocol by selecting the link under the Protocol ID column
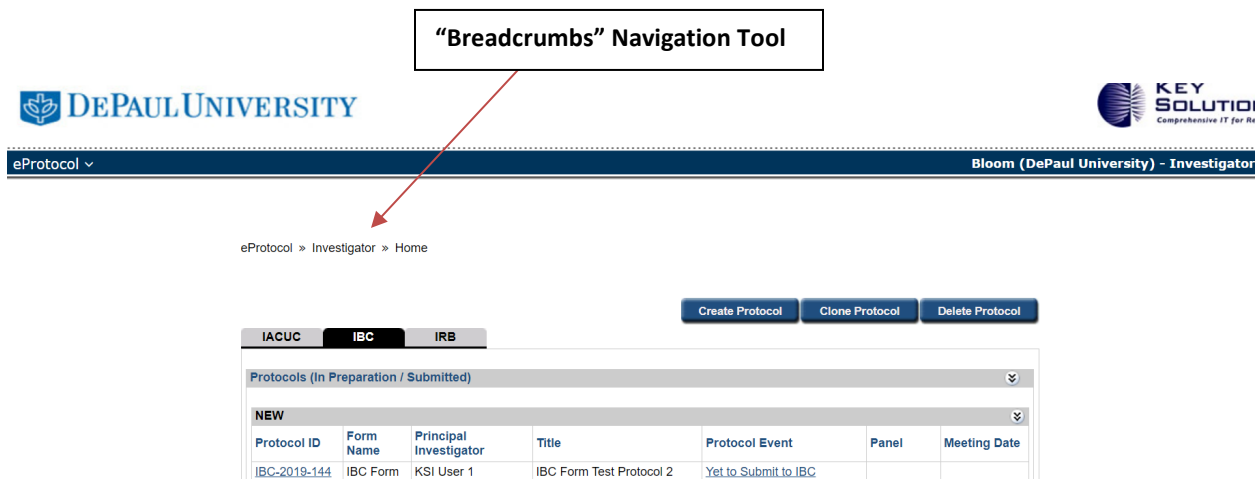
Figure 4: Dashboard

On the protocol submission list, you will see both submitted and unsubmitted protocols, amendments, and renewals. As you scroll down, you will see approved protocols and non-active protocols. This dashboard gives you a full look at all protocols and pending protocol actions for you as an Investigator. If you are a Co-Investigator for a protocol, that protocol will show up on your home page as well.
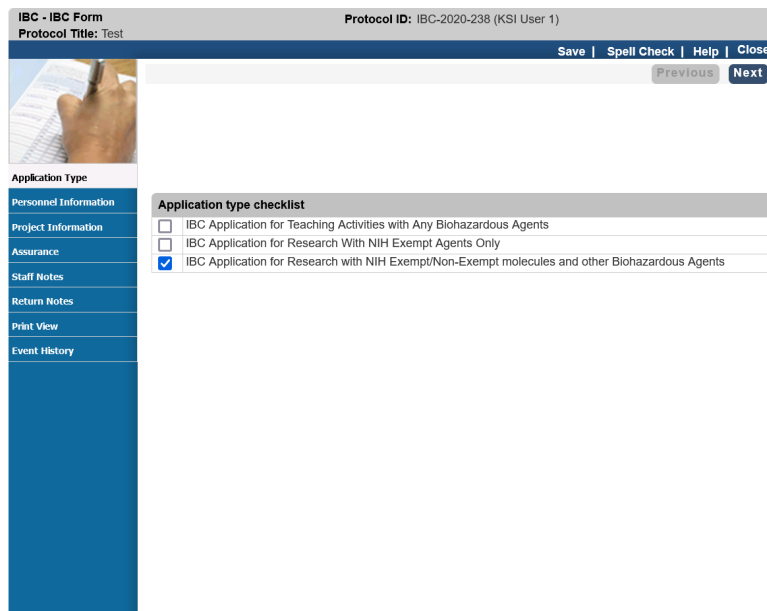
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2.2 The Look of a Protocol

When a protocol is opened, you will notice that you have a header, left-side navigation pane, and the protocol content pane (**Figure 5**). The header will include the IBC Form and protocol title on the left, the protocol number and PI name in the middle, and on the following shortcuts on the right:

- Save your protocol
- Perform a **Spell Check** on the current page
- View the **Help** pop-up
- Close your protocol
- Navigate to the Previous page
- Navigate to the Next page

The left-side navigation pane allows you to perform the following functions:

- Navigate to a specific page in the protocol (Note: When you click on Protocol Information, additional page tabs will appear that relate to each page in the form.)
- Initiate a **Check for Completeness** (usually done when the form is completed)
- Submit the protocol (**Submit Form**)
- Print all or part of the protocol (**Print View**)
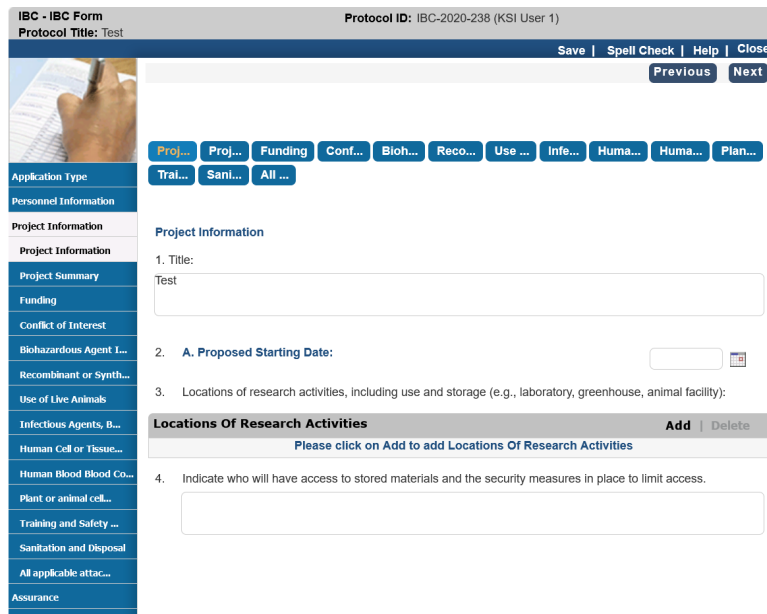- View the **Event History** for the protocol

Figure 5: Header, Left-side Navigation Pane, and Protocol Content Pane

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The protocol content pane contains a variety of questions that you need to complete regarding your study.

When you open the **Protocol Information** section, additional categories appear at the top and bottom of the page (**Figure 6**). The left-side navigation expands to display them, too. You may use any of those shortcuts to quickly navigate to the desired page.

Hover over a category to view its complete title. You may also refer to the left-side navigation pane.

Figure 6: Shortcuts in the Header and Footer

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3 Creating a Protocol

To create a protocol, navigate to the **Investigator Submenu** and select **Create Protocol**. You may also select **Create Protocol** on the dashboard. A new window appears.

When creating a protocol, some of your selections determine which questions become enabled in subsequent sections. You may navigate to previous pages of the protocol at any time if you need to update responses. Examples specific to the IBC are shown in the following sections.

To begin, enter the protocol title, select **IBC Form**, and select the Principal Investigator (PI, **Figure 7**). Complete the PI information. Some information will be completed automatically from DePaul's directory, but you will need to manually complete the remaining information.

Figure 7: Create New Protocol First Page

Your CITI training should automatically link to your eProtocol profile. If you do not see the CITI training in the system, double check that your human subjects training is current and that your CITI institutional profile has been updated to include your DePaul user ID. This piece of information is used to link the data in CITI to eProtocol. If you do not know how to verify the information in CITI and update it, contact ORS at ORP@depaul.edu.

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Once the PI information is complete, you would select 'Create'.
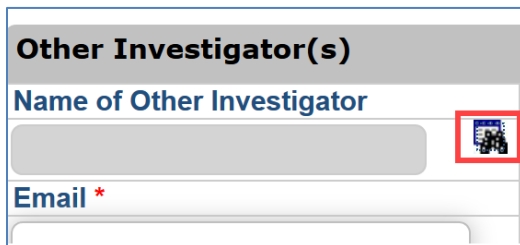
4 Protocol Response Types

To complete a protocol, you need to know the different response options you have and how to use them. The options presented in eProtocol include:

1. Binocular Icons – for selecting an eProtocol user from the existing set of active users
2. Radio Buttons – for selecting one of a small set of options
3. Text Fields – for providing an unstructured response
4. Dropdowns – for selecting one option from a predefined list
5. Yes, No, N/A Buttons – for providing a clear, succinct response to a question
6. Calendar Icons – for selecting a date
7. Add Buttons – for adding items to a structured list
8. Checkboxes – for selecting one or more responses from a predetermined set
9. Attachments – for adding a preexisting file to the protocol

4.1 Binocular Icon

The **binocular icon** (![icon]) is used to search for a user (Figure 8). When you select the icon, the **Find User** pop-up appears (**Figure 9**). You will use this function to add Key Research Personnel to research protocols and Faculty/Staff Instructors and Teaching Assistants (TAs) to teaching protocols.

Figure 8: Binocular Icon

You may choose to search for a user by entering the User ID, the First Name, or the Last Name (**Figure 13**). Then, click **Find**.

Find User	Find
User ID:	
First Name:	
Last Name:	

Figure 1: Find User pop-up

Select the user by clicking the corresponding **radio button**. Then, click **OK**.

If the person you want is not listed, contact ORS at ORP@depaul.edu. This function can only be used for DePaul affiliated individuals or persons who have been given a Friend of DePaul account specifically to use the eProtocol system. If you have someone that needs to be listed on a protocol who is not DePaul affiliated, you need to request the Friend of DePaul account by requesting a form from ORS and sending that form to ORS.

Find User				Find
User ID:				
First Name:				
Last Name:	doe			
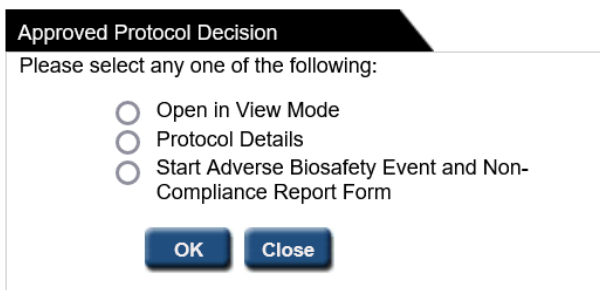
Select User				OK
User ID	**User Name**	**Title**	**Department**	**Email**
⦿ jdoe	Doe, John			
◯ Jane D	Doe, Jane		Biology Department	

Figure 10: Find User Result

4.2 Radio Button

A **radio button** is a circular icon (◯) that you can select. Once you select a radio button, a bold circle appears on the inside (⦿). You may only select one item in a group of radio buttons under the same table (**Figure 11**).
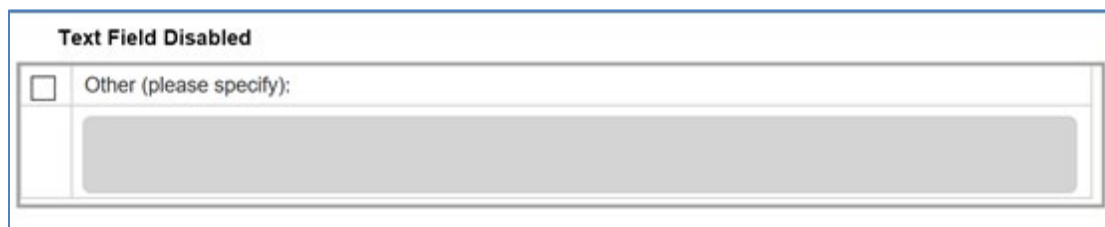
Figure 11: Radio Button

4.3 Text Fields

A **text field** is a box where you can enter text when the text field is enabled (contains a white background). When a text field is disabled (greyed-out), no information is needed. Click into the text field to add information.

Some text fields have character limitations. You receive an error message if you exceed the character limit.

Your responses may determine if a text field is enabled or not. For example, if your response requires additional information, a text field enables and becomes mandatory for the section (**Figure 12 & Figure 13**). It is possible for you to enable text fields that are on subsequent pages in the protocol. (Refer to **Section 3** for more details.) You are required to complete all enabled text fields before continuing with the protocol. In other cases, you may move forward, but be prevented from submitting the protocol when the **Check for Completeness** is run either by you or by the system prior to submission.
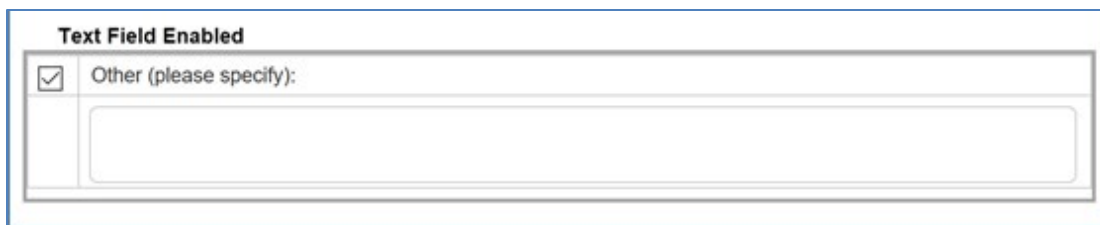
Figure 12: Text Field Disabled

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Text Field Enabled

☑ Other (please specify):

Figure 13: Text Field Enabled

4.4 Dropdowns

Dropdowns allow you to select one value from a list. Click the downward facing arrow (▼) to open the dropdown. Then, click on a list item to select the value.
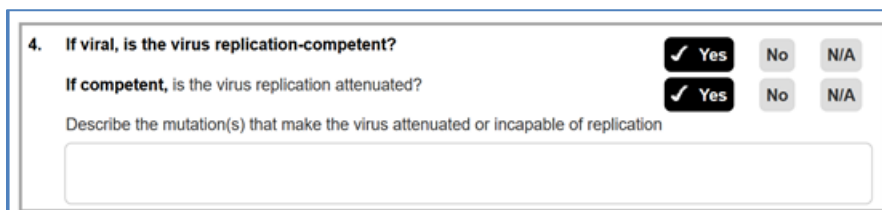
4.5 Yes, No, N/A Buttons

These buttons allow you to answer **Yes** or **No** questions. Depending on the question, the **N/A** button may not always be available.

Select the appropriate button. A selected button has a dark background and displays a checkmark on the left. Your response may enable an additional Yes (Yes), No (No), or N/A (N/A) buttons and/or a text field like in **Figure 14** and **Figure 15**.

4. **If viral, is the virus replication-competent?**   Yes   No   N/A

    If competent, is the virus replication attenuated?   Yes   No   N/A

    Describe the mutation(s) that make the virus attenuated or incapable of replication

Figure 14: Unselected Buttons

4. **If viral, is the virus replication-competent?**   ✓ Yes   No   N/A

    If competent, is the virus replication attenuated?   ✓ Yes   No   N/A

    Describe the mutation(s) that make the virus attenuated or incapable of replication

Figure 15: Yes buttons selected and subordinate text field enabled

A response may also enable the **Add** button.
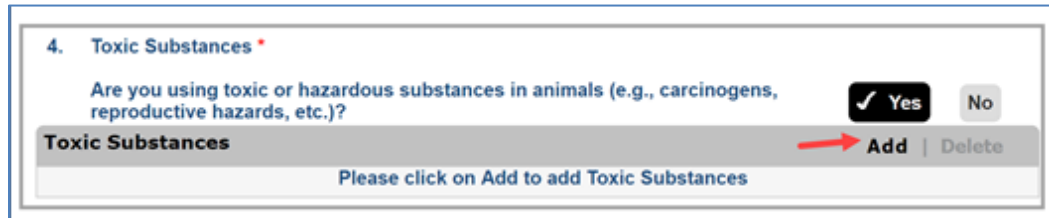
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Figure 16: Without a response, there is no "Add"
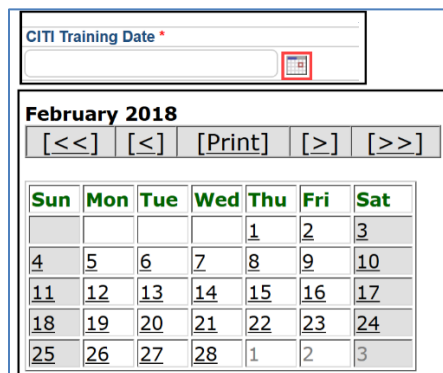
Figure 17: With a Yes response, the Add function is enabled

4.6 Calendar Icon

Use the **calendar icon** (⊞) to input a date. When you click on the icon, a calendar pop-up appears. Select a date on the calendar (Figure 18). Use the singular arrows (**[<] [>]**) to change the month and the double arrows (**[<<] [>>]**) to change the year.

Figure 18: Calendar Icon and the pop-up

4.7 Add Button

Use the **Add** button to add additional information to a subject. When you click **Add**, a pop-up appears (Figure 19). Complete the section and click **Save** (commonly found on the upper-right) when you are finished.

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Figure 19: Add pop-up

4.8 Checkboxes

A **checkbox** is a square icon (☐) that you can select, and a checkmark appears on the inside (☑). Some questions allow you to select multiple checkboxes, as necessary (**Figure 20**).

Figure 20: Checkboxes

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4.9 Attachment

An **attachment** is a document uploaded to your protocol to clarify or explain a process or topic in your study or to supplement the protocol application. Before uploading an attachment, please name it appropriately and use a version date in the name. This naming convention will help you and the IBC track what version of a document is the currently approved version.

To upload an attachment, perform the following tasks:
1. Click **Add** (**Figure 21**).
2. Click **Browse** (**Figure 22**).
3. Select and **Open** the file (**Figure 23**).
4. Click **Save** (**Figure 24**).

Figure 2: Add
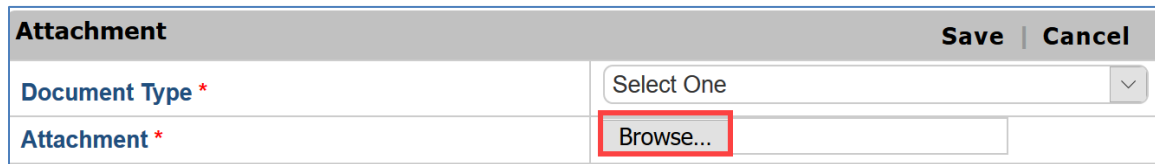
Figure 22: Browse
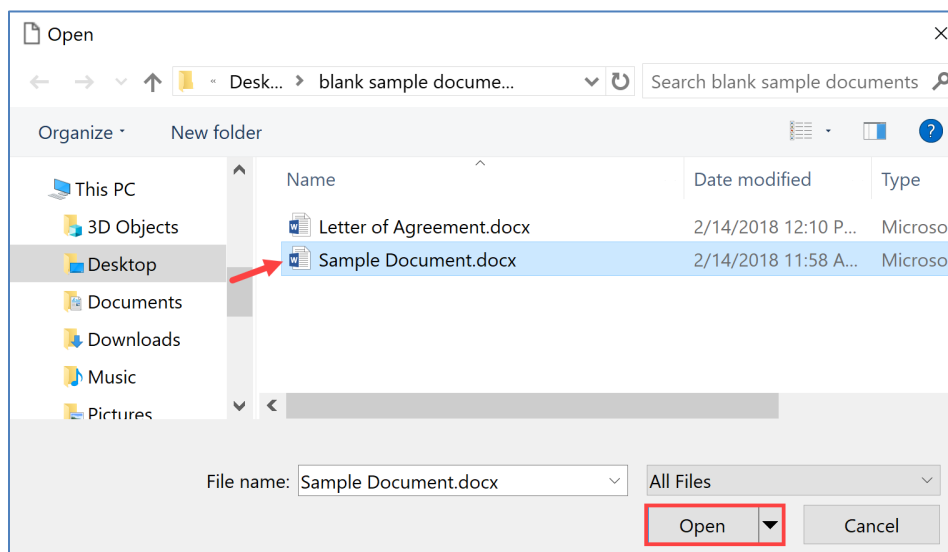
Figure 3: Select a file and click open

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Attachment	Save Cancel
Document Type *	Select One ⌄
Attachment *	Browse... Sample Document.docx
Document Name	Sample Document

Figure 24: Save

ℹ️ Note: *You may need to provide additional information prior to saving. For example, in **Figure 29**, you need to select the Document Type from the dropdown list prior to saving.*

5.0 Completing IBC Protocol Forms

5.1 Application Type Checklist

Once you have completed the PI information and created the protocol, the **Application Type Checklist** will be the first page you see. The selection(s) you make on the Application Type Checklist (**Figure 25**) page determines which form or form pathway will appear. The IBC has three types of forms:

1. IBC Application for Teaching Activities with Any Biohazardous Agents
2. IBC Application for Research with NIH Exempt Agents Only
3. IBC Application for Research with NIH Exempt/Non-Exempt molecules and other Biohazardous Agents

These forms are not interchangeable. If you begin completing one form and decide to switch to another form, some information could be lost. However, you can download the information as a PDF document prior to changing forms and cut and paste the existing text into the new form. If you are not sure which type of form to complete, PDF forms and associated instructions on the IBC website can aid in making that decision. The online forms were built using these fillable PDF paper forms.

As you complete each page of the form, any documents or additional information that may assist in the review of the protocol, such as teaching lab exercises or conflict of interest information, can be added on the **Attachment** tab.

Figure 25: Application Type Checklist

5.2 Personnel Information

The first section you will need to complete is the **Personnel Information** page. You will have completed the PI information to create the protocol.

For a teaching protocol, you will need to complete the Faculty/Staff Instructors and Teaching Assistant sections. For the NIH exempt form or the longer NIH research form, you need to complete the **Key Research Personnel** section of the form. You would add any DePaul personnel to these protocol sections using the search function and manually completing any information that does not auto-populate.
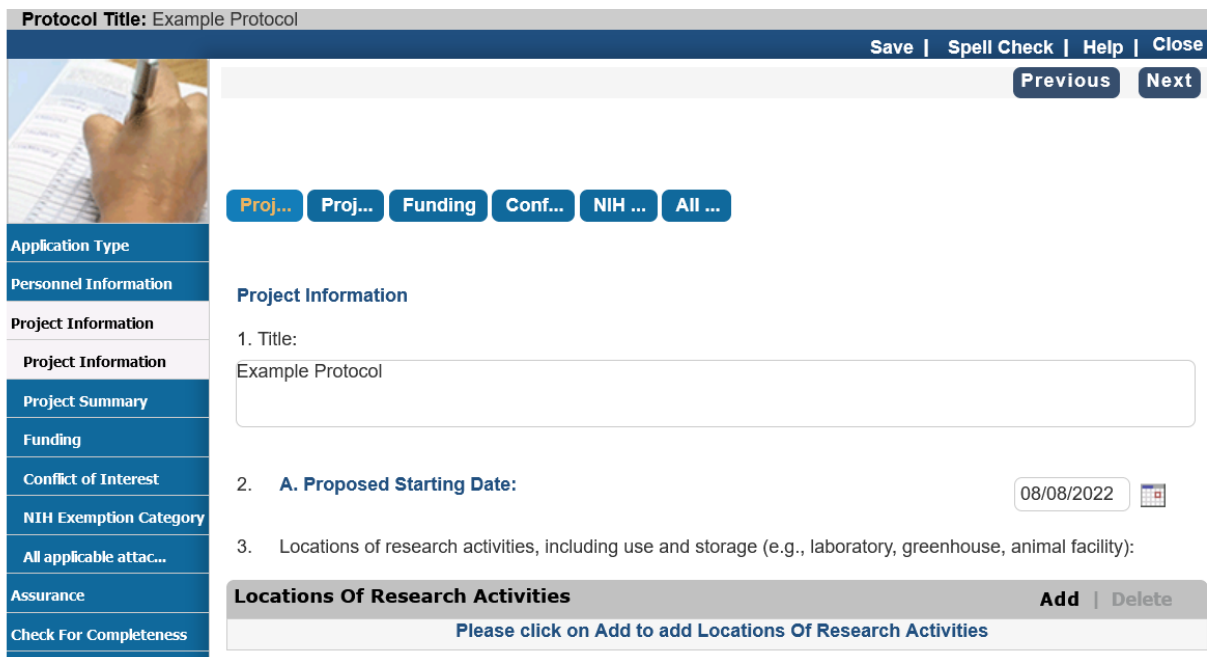
Again, CITI trainings should auto-populate for DePaul personnel. If CITI trainings do not appear, you will need to double check that their human subjects training is current and their CITI institutional profile has been updated to include their DePaul user ID. This piece of information is used to link the data in CITI to eProtocol. If they do not know how to verify the information in CITI and update it, contact ORS at ORP@depaul.edu.

When all the personnel sections are completed, select **Next** to move to the next page.

If you are the PI and would like someone else on your team to complete the remainder of the protocol application, at a minimum, you need to create the protocol, enter your information, and add that person as **Key Research Personnel** or **Faculty/Staff Instructor**. They then can then complete the remainder of the application from their own account.

5.3 The NIH Exempt Only Protocol Form

After completing the **PI** and **Key Research Personnel** information sections and clicking **Next,** you will be taken to the **Project Information** tab. The study title will autofill for you and you will be asked to complete the proposed starting date and fill in the table for locations of research activities. The table has an **Add** function and you can add as many locations as you need to for the research activities (**Figure 26**).

Figure 26: Project Information

Figure 27: Location of Research Activities Pop-up

In the **Add** pop-up, you will be asked to provide the building and room number for study activities, and type of activity taking place in that location. After adding the information, select **Save**. Then once all locations are entered into the table, select **Next** (**Figure 27**).

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The next tab is the **Project Summary** page. On this page, you will be asked questions about the project such as justifying the exempt status, providing the aims and goals of the research, describing the procedures and methods, describing the safe handling and clean up procedures, questions about the specific type of work that will be performed, and describing the disposal process for the material. Once this information is complete, select **Next** (**Figure 28**).

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Protocol Title: Example Protocol

Save | Spell Check | Help | Close

Previous | Next

Proj... | Proj... | Funding | Conf... | NIH ... | All ...

Application Type

Personnel Information

Project Information

Project Information

Project Summary

Funding

Conflict of Interest

NIH Exemption Category

All applicable attac...

Assurance

Check For Completeness

Submit Form

Print View

Event History

Project Summary *

All recombinant or synthetic nucleic acid molecules used in this protocol must be exempt from the **NIH Guidelines**. Under DePaul IBC Policy these activities still require that investigators conducting research with these molecules complete this form and receive confirmation of exempt status from the IBC before work is conducted at DePaul University. It is important to remember that even though research with these molecules may be NIH exempt, other federal and state standards of biosafety may still apply to such research activities (for example, the Centers for Disease Control and Prevention (CDC)/NIH publication Biosafety in Microbiological and Biomedical Laboratories [**BMBL**]). Therefore, it is DePaul IBC policy to require a confirmation process to ensure that the activity is NIH exempt and that other standards for biosafety are met and included in the researcher's protocol plan.

1. Explain why your study is exempt from the **NIH Guidelines**.

2. Briefly describe the project aims and goals in language understandable to an educated lay person.

3. Briefly describe the research experimental design and methodology in sufficient detail for the IBC to be able to make an assessment of risks to those who may be exposed to the agents and any risks to the environment.

4. Describe any safe handling procedures that will be in place, including the type of personal protective equipment (PPE) that will be utilized while working with the agent(s).

5. Describe the source of the recombinant or synthetic nucleic acid molecules, including a description of the type of organism, species, strain, or cultivated cell line from which it was derived.

6. Describe the nature of the inserted recombinant or synthetic nucleic acid molecule, including any regulatory or coding regions, the entire genome, or synthetic antisense sequences, etc.

7. Describe the recipient organism(s) for the recombinant or synthetic nucleic acid molecule. Specify the type of organism, species, strain, cultivated cell line, origin, etc.

8. List any vectors that will be used, such as expression vectors, and briefly specify their purpose.

9. Will there be a deliberate attempt to express a foreign gene?   Yes   No

10. Describe your procedures for cleaning up after any spills or de-contamination of the working surfaces or equipment, if necessary.

11. Describe your procedures for disposal of the agent(s). Include the building and room number where waste will be disposed of.

All applicable documents can be attached in the 'Attachments' tab (in Protocol Information > Attachments)

Proj... | Proj... | Funding | Conf... | NIH ... | All ...

Previous | Next
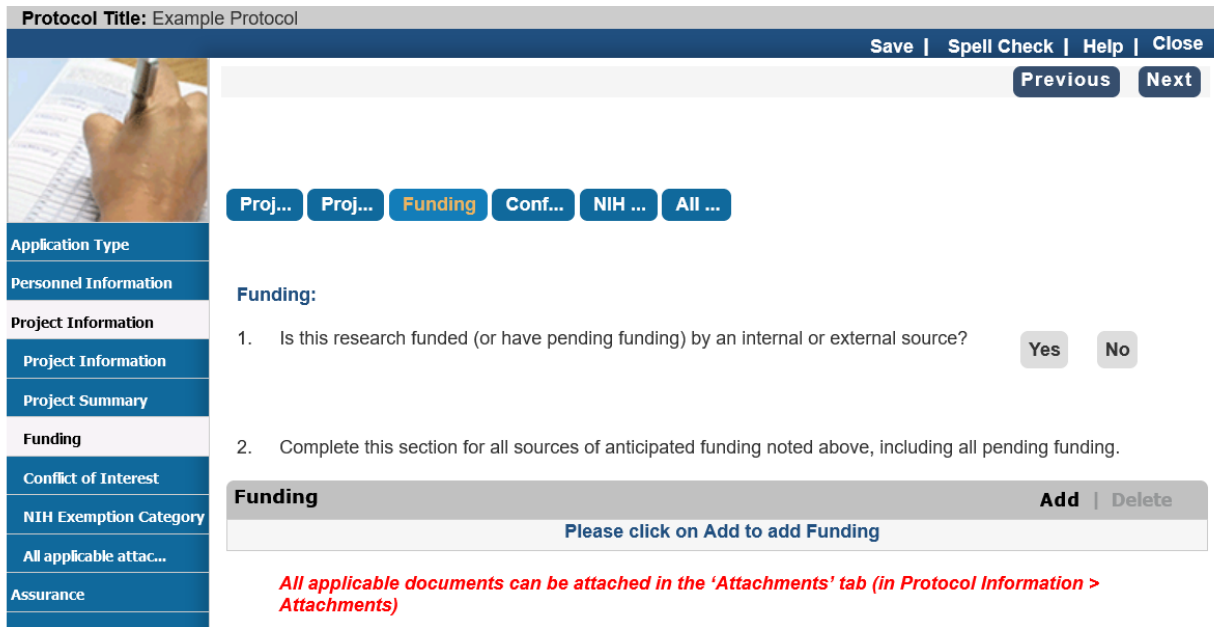
Save | Spell Check | Help | Close

Figure 28: Project Summary Page

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The next tab is the **Funding** page. You will be asked to indicate if the project is funded. If you select yes, new questions will appear asking about the type of funding (**Figure 29**). Complete an entry in the table for each type of funding. When you click add in the table a new window pops up asking for Name of Funding Source, Name of PI for Funding, Grant/Project/Contract Title, and Funding Agency Grant/Contract # (Refer to Figure 19). When you complete the information for the funding source, select, 'Save'. Once all funding sources have been added to the table, on the Funding page, Select 'Next'.

Figure 29: Funding Page

The next tab is the **Conflict of Interest** page. On this page complete the questions and select **Next** (**Figure 30**).

Protocol Title: Example Protocol

Figure 30: Conflict of Interest Page

The next tab is the **NIH Exempt Category** page. On this page, you will be asked to select all the NIH exempt categories that apply to your research. When that task is completed, select **Next** (Figure 31).

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Protocol Title: Example Protocol

Save | Spell Check | Help | Close

Previous | Next

Proj... | Proj... | Funding | Conf... | NIH ... | All ...

Application Type

Personnel Information

Project Information

    Project Information

    Project Summary

    Funding

    Conflict of Interest

    NIH Exemption Category

    All applicable attac...

Assurance

Check For Completeness

Submit Form

Print View

Event History

NIH Exemption Category

All agents and activities conducted for this project must be exempt (i.e., must fit into one or more of the following categories) in order for the project to be reviewed and approved as NIH exempt.

NOTE: The exemption categories listed below do not apply to activities involving recombinant molecules from Risk Groups 3 and 4 Pathogens.

1.   Check which category(ies) apply to your research activity:

☐ **Section III-F-1.** Those synthetic nucleic acids that: (1) can neither replicate nor generate nucleic acids that can replicate in any living cell (e.g., oligonucleotides or other synthetic nucleic acids that do not contain an origin of replication or contain elements known to interact with either DNA or RNA polymerase), and (2) are not designed to integrate into DNA, and (3) do not produce a toxin that is lethal for vertebrates at an LD50 of less than 100 nanograms per kilogram body weight. If a synthetic nucleic acid is deliberately transferred into one or more human research participants and meets the criteria of Section III-C, it is not exempt under this Section.

☐ **Section III-F-2.** Those that are not in organisms, cells, or viruses and that have not been modified or manipulated (e.g., encapsulated into synthetic or natural vehicles) to render them capable of penetrating cellular membranes.

☐ **Section III-F-3.** Those that consist solely of the exact recombinant or synthetic nucleic acid sequence from a single source that exists contemporaneously in nature.

☐ **Section III-F-4.** Those that consist entirely of nucleic acids from a prokaryotic host, including its indigenous plasmids or viruses when propagated only in that host (or a closely related strain of the same species), or when transferred to another host by well-established physiological means.

☐ **Section III-F-5.** Those that consist entirely of nucleic acids from a eukaryotic host including its chloroplasts, mitochondria, or plasmids (but excluding viruses) when propagated only in that host (or a closely related strain of the same species).

☐ **Section III-F-6.** Those that consist entirely of DNA segments from different species that exchange DNA by known physiological processes, though one or more of the segments may be a synthetic equivalent. A list of such exchangers will be prepared and periodically revised by the NIH Director with advice of the RAC after appropriate notice and opportunity for public comment (see **Section IV-C-1-b-(1)-(c)**, Major Actions). See **Appendices A-I** through A-VI, Exemptions under Section III-F-6--Sublists of Natural Exchangers, for a list of natural exchangers that are exempt from the NIH Guidelines.

☐ **Section III-F-7.** Those genomic DNA molecules that have acquired a transposable element, provided the transposable element does not contain any recombinant and/or synthetic DNA.

☐ **Section III-F-8.** Those that do not present a significant risk to health or the environment (see **Section IV-C-1-b- (1)-(c)**, Major Actions), as determined by the NIH Director, with the advice of the RAC, and following appropriate notice and opportunity for public comment. See **Appendix C**, Exemptions under Section III-F-8 for other classes of experiments which are exempt from the NIH Guidelines.

Proj... | Proj... | Funding | Conf... | NIH ... | All ...

Previous | Next

Save | Spell Check | Help | Close

Figure 31: NIH Exemption Category Page

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The next tab is the **Attachment** page. On this page you will attach any documents that support your application. There is a list of examples of the types of documents to attach. To add documents, select **Add** in the table and then in the pop-up window select the document type from the drop-down list and attach the document. Select **Save**.

Be sure to use naming conventions for study documents that include the version number and date. If revisions are required, update that version number and date. Updating version numbers and dates helps to track the current and approved versions of a document. You can add as many documents as necessary using the **Add** function. When all attachments have been added to the table, select **Next**. When uploading a revised document, delete the old document prior to adding the new document. The system will save the old document in the **Event History**. This maintains a complete study record while featuring currently approved documents in the body of the application.

The next tab is the **Assurance** page. On this page you will read the assurance statement and click the box to indicate you agree with all statements. Doing so will work like an electronic signature. Select **Next**.

The system will automatically check for completeness and indicate whether any sections of the form are incomplete. If sections are incomplete, you can go back into the form and complete them. Once you are done, you can check for completeness again by clicking on the **Check for Completeness** tab on the left navigation bar.

YOU MUST CLICK ON SUBMIT FORM ON THE LEFT NAVIATION TABS FOR THE FORM TO BE OFFICIALLY SUBMITTED. Once you hit **Submit Form**, a pop-up window will ask if you want to submit the form and you should select **Yes**. When this process is completed, your protocol will appear on your home page under the Protocols (**In Preparation/Submitted**) column and under the **NEW** category.

5.4 IBC Teaching Form

After completing the **PI/Lead Instructor, Faculty/Staff Instructors**, and **Teaching Assistant** information sections, and clicking **Next**, you will be taken to the **Project Information** page. The title will autofill for you. You will be asked to indicate which quarters the course will be taught (**Figure 32**).

Figure 32: Project Information Page

Then you will add the locations of the teaching activities to the table using the **Add** function. When you click Add, a pop-up window will be available for you to provide the necessary information, such as type of location, building, room number, type of activity in that room, and who will have access to the room. When each entry is complete, select **Save**. You can add as many locations as you need to with the **Add** function.

The final question on this page asks about security measures in place to limit access to the material. When the page is complete, select **Next**.

The next tab is the **Project Summary** page. On this page you will describe your course activities in enough detail necessary so that the IBC can understand what activities occur with biohazardous materials. When this page is complete, select **Next**.

The next tab is the **Biohazardous Agent Information** page. On this page, you will add each agent/biohazardous material to the table using the **Add** function (**Figure 33**). Then you are asked to provide detail about any recombinant materials, infectious materials, human blood/tissue, and any environmental samples that might be involved in the teaching activity.   When the page is complete, select **Next**.

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Biohazardous Agent Information   Save | Cancel

Biohazardous agent (full name & abbreviation) *	
Source of agent i.e., vendor (where it was obtained) *	
Is the agent currently in your possession?	Select One ˅
NIH Category	- N/A III-A-1 III-A-1-a III-B-1
If Not Applicable, choose NA	
Risk Group *	Select One ˅
Biosafety Level *	Select One ˅
List any potential Risks or Side effects related to the agent	
Attach reference documents (in the attachment tab) or provide website links in the text box to the right that support the categorization of the agent into the designated Biosafety Containment Level	

Figure 33: Biohazardous Agent Information Table

The next tab is the **Training and Safety Measures** page. On this page you will be asked to provide the details of any special training the TA and students will receive related to handling biohazardous materials. In addition, you will be asked about the type of PPE that will be used and who is responsible for providing the PPE. When this page is complete, select **Next**.

The next tab is the **Sanitation and Disposal** page. On this page you will be asked for the details about how surfaces and materials will be cleaned and sanitized and about your procedures for cleaning up small and large spills. When this page is completed, select **Next**.

The next page is the **All Applicable Attachments** page. On this page you can attach the documents for your syllabus, lab exercises, or any other documents that will support the teaching protocol. Attachments are added to the table using the **Add** function. When you select the **Add** button, a window will appear to indicate the type of document attach (**Figure 34**).

Be sure to use naming conventions for study documents that include the version number and date. If revisions are required, update that version number and date. Updating version numbers and dates helps to track the current and approved versions of a document. When updating study materials, delete the old document and add the new document. The system will save the old document in the **Event History**. This maintains a complete study record while featuring currently approved documents in the body of the application. When all documents have been attached, select **Next**.

Figure 34: All Applicable Attachments Page

The next tab is the **Assurance** page. On this page you will read the assurance statements and if you agree, check the box at the end. Checking the box functions like an electronic signature. Once you have agreed to the assurance statement, select **Next** (**Figure 35**).

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Figure 35: Assurance Page

The system will then automatically check for completeness and will tell you if any sections of the form are not complete. If sections are not completed, you can go back into the form and complete them. Once you are done, you can check for completeness again by clicking on the **Check for Completeness** tab on the left navigation bar.

YOU MUST CLICK ON SUBMIT FORM ON THE LEFT NAVIATION TABS FOR THE FORM TO BE OFFICIALLY SUBMITTED. Once you hit **Submit Form**, a pop-up window will ask if you want to submit the form. Select

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Yes. When this process is completed, your protocol will then be on your home page under the Protocols (**In Preparation/Submitted**) column and under the **NEW** category.

5.5 IBC Application for Research with NIH Exempt/Non-Exempt Molecules and Other Biohazardous Agents

After completing the **PI** and **Key Research Personnel** information sections, and clicking **Next**, you will be taken to the **Project Information** page. The title will autofill for you and you will be asked to complete the proposed starting date and fill in the table for locations of research activities. The table has an **Add** function and you can add as many locations as you need to for the research activities.

In the pop-up, hit **Add** to enter a building, room number, and type of activity in that room location. After adding the information, select **Save**. The final question on this page asks about security measures in place to limit access to the material. When the page is complete, select **Next**.

The next tab is the **Project Summary** page. On this page there is a check list for the project activities, aims, and goals, as well as a text box for a detailed summary of your project. Once the page is complete, select **Next**.

The next tab is the **Funding** page. Indicate whether the project is funded. Selecting **Yes** will trigger new questions asking about the type of funding. Complete an entry in the table for each type of funding. When you click **Add**, a new window appears asking for the funding source, project PI/grantee, grant/project/contract title, and the associated grant/project/contract number. When you complete the information for the funding source, select, **Save**. Once all funding sources have been added to the table on the **Funding** page, Select **Next** (**Figure 29**).

The next tab is the **Conflict of Interest** page. Complete the questions and select **Next**.

The next tab is the **Biohazardous Agent Information** page. Add each agent/biohazardous material to the table using the **Add** function. Once all agents have been added to the table, you should complete the questions about vaccinations, select agents or toxins, and shipping, receiving and transport of agents. When the page is complete, select **Next** (**Figure 30**).

The next tab is the **Recombinant or Synthetic Nucleic Acid Molecule** page. You will be asked several questions about the recombinant or synthetic nucleic acid molecules, transgenic animals and transgenic plants involved in the stud protocol. If you protocol does not utilize some of the agents, select **No** and skip that section. If you select **Yes**, associated questions will appear. When the page is complete, select **Next**.

The next tab is the **Use of Live Animals** page. Answer the associated questions. When the page is complete, select **Next**.

The next tab is the **Infectious Agents, Biological Toxins, Select Agents or Toxins, Other Biohazardous Agents** page. You will answer several questions about these types of agents used in the study protocol. When the page is complete, select **Next**.

The next tab is the **Human Cell or Tissue Culture** page. If your protocol involves work with this type of material, you will answer several questions about the use of these materials. Cell lines or strains/ will be added in a table using the **Add** function. Each cell type should be one entry. When the page is complete, select **Next**.

The next tab is the **Human Blood, Blood Components, Human Body Fluids, Tissue and/or Excreta** page. If you are using these types of materials in your work, you will answer several questions about their use. You will be prompted to provide a bloodborne pathogen control plan in the **Attachment** tab. When the page is complete, select **Next**.

The next tab is the **Plant or Animal Cell Lines** page. You will be asked for information about the use of these materials. When the page is complete, select **Next**.

The next tab is the **Training and Safety Measures** page. On this page you will detail the training information for personnel, the PPE utilized, and any other safety precautions such as biosafety cabinets. When the page is complete, select **Next**.

The next tab is **Sanitation and Disposal** page. On this page you will detail the handling of contaminated materials, their disposal, and clean up. When the page is complete, select **Next**.

The next tab is the **All Applicable Attachments** page. Attach the documents that will support the protocol, such as blood borne pathogen control plans. Attachments are added to the table using the **Add** function. When you select the **Add** button, a window will appear. Indicate the type of document from the drop-down list and attach the document.

Be sure to use naming conventions for study documents that include the version number and date. If revisions are required, update that version number and date. Updating version numbers and dates helps to track the current and approved versions of a document. When updating study materials, delete the old document and add the new document. The system will save the old document in the **Event History**. This maintains a complete study record while featuring currently approved documents in the body of the application. When all documents have been attached, select **Next** (**Figure 34**).

The next tab is the **Assurance** page. On this page you will read the assurance statements and if you agree, check the box at the end. Checking the box functions like an electronic signature. Once you have agreed to the assurance statement, select **Next** (**Figure 35**).

The system will then automatically check for completeness and tell you if any sections of the form are incomplete. If sections are incomplete, go back into the form and complete them. Once you are done, you can check for completeness again by clicking on the **Check for Completeness** tab on the left navigation bar.

YOU MUST CLICK ON SUBMIT FORM ON THE LEFT NAVIATION TABS FOR THE FORM TO BE OFFICIALLY SUBMITTED. Once you hit **Submit Form**, a pop-up window will ask if you want to submit the form and you should select **Yes**.   When this process is completed, your protocol will then be on your home page under the Protocols (**In Preparation/Submitted**) column and under the **NEW** category.

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5 Protocol Checks

When you are creating a protocol, eProtocol checks for complete sections in two ways:

1. Page Level Check
2. Check for Completeness

5.1 Page Level Check

The Page Level Check (PLC) scans the current page for mandatory questions which are incomplete. If you attempt to proceed to a subsequent (and sometimes a previous) page and without completing the mandatory fields (*), a PLC notification appears at the top of the page (**Figure 36**).

Complete the mandatory fields to proceed.

> * Please select Type of CITI Training for Principal Investigator.

Figure 36: Page Level Check Notification

5.2 Check for Completeness

The Check for Completeness (CFC) scans the entire protocol and notifies you if there are any areas that are incomplete. You cannot submit a protocol until the CFC confirms that all mandatory sections are complete. If you attempt to submit a protocol that contains incomplete sections, the CFC pop-up appears and displays links to the incomplete sections (**Figure 37**).

Click a link to navigate to the desired section and complete it.

IBC Form	
S.No.	**Resolution**
1	Please check the checkbox for 'Assurance' in Assurance section.

Figure 37: Check for Completeness Message

When you complete the initial sections of a protocol, the CFC button appears in the left-side navigation pane. You may use CFC as often as you want. If you use CFC and there are no incomplete sections remaining, the CFC pop-up appears stating that the application is complete (**Figure 38**).

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IBC Form
IBC Application Form is complete

Figure 38: Check for Completeness Complete Notification

6 Responding to Comments

This section describes how to use eProtocol to respond to the IBC reviewer comments.

6.1 View Reviewer's Comments

When a Reviewer sends comments to you, the protocol appears in the **Protocols (In Preparation/Submitted)** table under **NEW** and you will see that Comments have been received versus the protocol being noted as submitted. You will also receive an email from the system alerting you that comments are now noted in the system.

Click the **Protocol Event** status to view the comments (**Figure 39**).
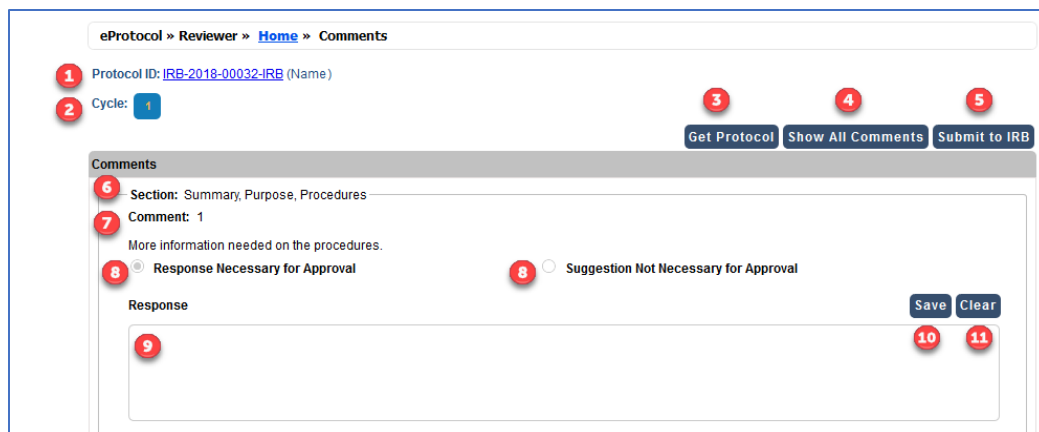
Figure 39: Protocol Event Status to View Comments

The **Comments** page appears. **Table 1** displays the information that is found on the **Comments** page (refer to **Figure 40**).

> ⚠️ *Caution: Read the Reviewer's comments carefully. It may be necessary to make changes to the protocol and respond to the comments for your protocol to be eligible for approval.*

Figure 40: Comment Page

Table 1: Comment Page

Ref #	Name	Description
1.	Protocol ID	This displays the protocol's unique ID. You may open the protocol in View or Edit mode by clicking the Protocol ID.
2.	Cycle Number	This displays what number the current comment/response cycle is on. The first time it is reviewed it is Cycle 1. If a second round is needed, it is Cycle 2.
3.	Get Protocol	This button allows you to quickly open the protocol in Edit or View mode. If the Reviewer requests a change in the protocol, you should open the protocol in Edit mode so you can make the necessary updates to the actual protocol application.
4.	Show All Comments	This button will open up a new page that displays all of the comments between you and the Reviewer throughout every cycle.
5.	Submit to IBC	This button submits your revised protocol and responses directly to the IBC. Once you submit your protocol and responses to the IBC, you cannot edit the protocol or responses. The different committee names that may appear on this button are IRB,IACUC (, and IBC, depending upon which board is reviewing the protocol.
6.	Protocol Section	This lets you know which section of your protocol the Reviewer is commenting on. This is important because after you respond to the comment, you need to go to that section of the application and make the change there.
7.	Comment Number	This displays which comment you are reading. The comment number increases if there are multiple comments.
8.	Comment Type	There are two comment types that a Reviewer may choose from: 1. **Response Necessary for Approval:** A change in the protocol is usually needed with this type of comment. You need to respond to this type of comment (and make changes to your protocol, if necessary) in order for your protocol to be considered for approval. 2. **Suggestion Not Necessary for Approval:** The Reviewer is making a suggestion. You do not have to make any changes or respond to be considered for approval.

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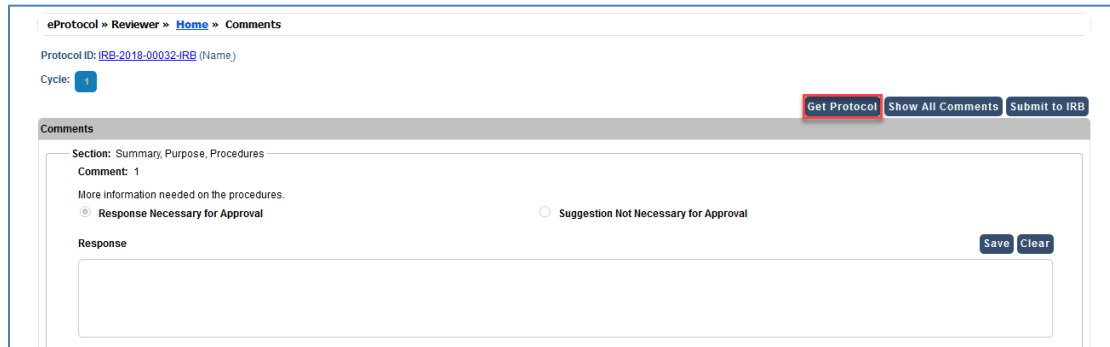
9.	Response Text Field	This text field is where you will respond to Reviewers specifically about the comment before going into the protocol to also update it.
10.	Save	This button saves the responses that you wrote in the text field. When you save a response, you may exit the Comments page and continue later. Clicking **Save** will save your responses. You do not need to click save on each response individually.
11.	Clear	This button clears the responses that you entered in the corresponding text field.

6.2 Make Changes to the Protocol, Respond to Comments, and Resubmit the Protocol

After you have submitted your protocol, you may only make changes when it is returned to you. Therefore, it is very important that you do not submit a protocol until it is complete. When you get a protocol with reviewer comments marked as **Response Necessary for Approval**, you must respond to the comment, and potentially make changes to the protocol application prior to resubmitting the protocol.

To make changes to a protocol, respond to a comment, and resubmit a protocol, perform the following tasks:

1. View the protocol's comments so you know what changes need to be made. (See **Section 6.1: View Reviewer's Comments.**)
2. Click **Get Protocol** on the **Comments** page (**Figure 41**).

Figure 41: Get Protocol

3. Open the protocol in **Edit** mode (**Figure 36**). If you open the protocol in **View** mode, you will not be able to make changes.

Figure 42: Edit a Protocol

4. Make the necessary changes in your protocol. Click **Save** (**Figure 43**). Your updates are not saved if you exit without saving them. When you are finished, close the protocol.

Figure 43: Save Protocol Before Exiting

5. Select the text field and enter your responses. Click **Save** (**Figure 43**).
   a. Once you save, you may exit the Comments page and continue later. Clicking **Save** will save your responses. You do not need to click save after each response, but it is a good idea.
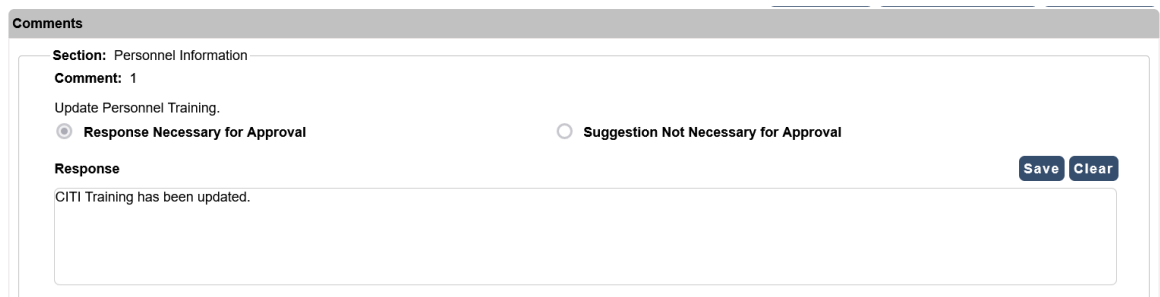
Figure 44: Add Responses and Save

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6. When you have finished making edits to the protocol and responded to all of the appropriate comments and have updated any attachments on the Attachment tab, click **Submit to IBC** (**Figure 45**).

Figure 45: Submit Protocol to IBC

7. A resubmission confirmation pop-up appears. Once you resubmit your revised protocol and responses, you cannot edit them. Click **OK** to confirm (**Figure 46**).

Figure 46**:** Resubmission Confirmation

8. Once you resubmit your protocol, the **Protocol Event** changes to **Responses Sent (Cycle 1)** and the **Status/Comments** changes to **IN-PROGRESS** (**Figure 47**).

Figure 47**:** Responses Sent

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6.2.1 Approval Letters

When the protocol is approved, you will receive an email from the IBC alerting you that your protocol has been approved. You can access the study's approval letter within the eProtocol system **in Event History** (**Figure 48**). The approved attachments will be noted in that window as well.

IBC - IBC Form	Protocol ID: IBC-2019-127 (KSI User 1)		
Protocol Title: Test KSI			

Event History

2020

Date	Status	View Attachments	Letters
09/28/2020	CONTINUING REVIEW 1 FORM CREATED		

2019

Date	Status	View Attachments	Letters
11/11/2019	NEW FORM APPROVED	View Attachments	Approval Letter
11/11/2019	NEW FORM REVIEWER(S) ASSIGNED		
11/11/2019	NEW FORM PANEL ASSIGNED		
11/11/2019	NEW FORM SUBMITTED	View Attachments	
11/11/2019	NEW FORM PROTOCOL CLONED (IBC-2019-115)		

Email History

No Email History Available.

Figure 48: Event History Tab

Each step of the protocol review process and later submissions of Annual Renewal reports, amendments, or Adverse Biosafety Events and Non-Compliance Reports will be clearly noted in the **Event History**.

6.3 Submitting Amendments, Annual Renewal Reports, Adverse Biosafety Event and Non-Compliance Report, and Final Reports

On the **Investigator Home** page, scroll down to the **Approved Protocols** list. Click on the **Protocol ID** link (in the protocol ID column) for the protocol for which you want to create the submission. When you click on the protocol, a pop-up window will appear with options for submission types.

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Select which type of submission you would like to create from the drop-down list and select **OK**. This will take you to the correct submission form. You are able to change personnel and other aspects of the protocol with both an annual renewal report and an amendment.

There can only be one submission in process per protocol at any given time. For this reason, we suggest thinking about your amendments carefully and combining them as much as possible. The only type of submission not directly linked to the primary protocol application is the Adverse Biosafety Event and Non-Compliance Report form. You may submit an Adverse Biosafety Event and Non-Compliance Report form at the same time as other types of submissions, and you may submit multiple reportable events simultaneously.

Once you complete the amendment or annual renewal form, you will be prompted to go into each tab of the protocol and update the information as needed to reflect any amendments introduced at the time of the annual renewal (e.g., personnel changes). Once all changes have been made and saved, including deleting or adding new attachments, submit the protocol to the IBC. If there are no changes at the time of annual renewal, you will not need to update anything. The review process and the process for responding to any IBC comments is similar to an initial review.

7 Glossary

A

Administrative Contact

An individual associated with an IBC study assisting in the development of a protocol. Administrative Contact is also known as Admin Contact or Study Coordinator. See Top Four, below.

Adverse Biosafety Event

Any serious adverse events, any non-compliance with the NIH Guidelines, BMBL, or DePaul policy, or any significant research-related accident or illness leading to, or potentially leading to, harm or that is dangerous to humans, animals, and/or the environment.

Amendment

A revision or update to an approved protocol. Like new protocols, amendments must be submitted and approved by the IBC.

B

Breadcrumbs

A navigation tool that reveals your current location in eProtocol. The breadcrumbs are commonly found at the top-left of a page. You may navigate to a previous page by clicking the link within the breadcrumbs.

C

Check for Completeness

Check for Completeness (CFC) is a button located in the protocol's left navigation pane that searches a protocol for sections that must have additional information prior to submission and provides a list of links to them for easy access. A Check for Completeness is automatically initiated when you submit a protocol.

Clear

A function in eProtocol that clears the associated text field.

Clone a Protocol

A function that creates a copy of the selected protocol or procedure. Cloning a protocol copies most, but not all, of the protocol; use Check for Completeness to identify them.

Close Protocol

A request from a PI to formally terminate a protocol. You need to submit a Final Report Form.

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Co-Investigator (Co-I)

> A Co- Investigator (Co-I) has similar responsibilities of a PI. The Co-I is obligated (along with the PI) to ensure the project complies with applicable laws and regulations, and the institution's policies. **Comments Received (Cycle 1)**
>
> This is a type of Protocol Event status (shown on the homepage) when a protocol has been returned to you and contains comments from the reviewers. If more comment/response cycles occur, the cycle number increase in the status accordingly, e.g., Comments Received (Cycle 2), Comments Received (Cycle 3), etc.

Comment/Response Cycle

> A term to describe the communication between a PI and a Reviewer. The cycle begins when a reviewer sends a comment to the PI and ends when a PI replies to that comment.

Committee

> A compliance group that receives and reviews protocols. Depending on your institution, there may be multiple committees, e.g., an IRB, IACUC, or IBC.

Conflict of Interest

> A Conflict of Interest (COI) is a situation in which the PI, a PI's relatives, or personnel working in a study are involved in interests that may compromise the study. Refer to the Potential Conflict of Interest section of a protocol for more detail.

Co-Investigator (Co-I)

> A Co- Investigator (Co-I) has similar responsibilities of a PI. The Co-I is obligated (along with the PI) to ensure the project complies with applicable laws and regulations, and the institution's policies.

Cycle Number

> A status in the Comments section that displays the number of comment/response cycles that the protocol has gone through.

D

Designated Review

> A type of review where a protocol is selected to be reviewed by a subset of committee members. A protocol may be changed to a Full Committee Review if any one reviewer suggests it. It may also be known as Designated Member Review (DMR).

E

Emergency Contact

> An individual associated with an IBC study with the responsibility to be available to respond to emergency situations related to the animals that are part of the study.

Event History

> Displays a list of all events related to a protocol, including associated emails sent by the system. This button is located in the protocol's left navigation pane.

Expiration Date

> On the homepage, an approved protocol column that contains the date when a protocol will expire.

F

Final Report Form

> A type of form used to close the protocol and provide final updates to the IBC/ORS.

Full Committee Review (FCR)

> A review type that a protocol must go through if it is a new protocol that is not limited to NIH exempt activities.

H

Help

> A button that opens a window containing helpful information about the page you are currently on.

I

Information Resources

> A section on the homepage containing useful links or documents. This is populated by the compliance committee. You can make requests for additions by contacting them.

In-Progress

> The status of a protocol that is currently under review.

Institutional Animal Care and Use Committee

> The Institutional Animal Care and Use Committee (IACUC) is a federally mandated research oversight committee charged with ensuring the proper care and humane treatment of live vertebrate animals used for research, research training, teaching, experimentation, biological testing, exhibition, and related activities at DePaul University. The objective of the IACUC is to oversee the use of animals in pursuit of advancing scientific knowledge and providing quality instruction, while requiring consideration of scientifically valid alternatives and refinements. The IACUC reviews all proposals for the use of live vertebrate animals, inspects the animal facilities, provides education, and ensures that animal research, research training, teaching, experimentation, biological testing, exhibition, and related activities are in compliance with legal statutes, ethical guidelines, and DePaul Policies.

Institutional Biosafety Committee

> The Institutional Biosafety Committee (IBC) is a federally-mandated research oversight
> committee charged with ensuring the safe acquisition, use, and disposal of all bio hazardous
> agents (including recombinant and synthetic nucleic acid molecules, infectious materials, and
> select agents) at DePaul University. It is the responsibility of the IBC to establish appropriate
> health and safety policies in accordance with federal regulations and guidelines that govern
> biological safety and to evaluate research and teaching activities at DePaul for biological safety

Institutional Review Board

The Institutional Review Board (IRB) is a university-wide committee formally appointed by DePaul's
President to review all research activities involving human subjects conducted by DePaul faculty, staff,
or students.   The IRB fulfills DePaul's contract with the federal Office of Human Research Protections
(OHRP) to ensure that all human subjects research (whether federally funded or not) conducted by
DePaul faculty, staff, and students comply with the federal regulations (45 CFR 46) and adhere to the
statement of principles contained in the Ethical Principles and Guidelines for the Protection of Human
Subjects of Research (The Belmont Report). IRB approval affirms the methodological and ethical quality
of the research, and it is the primary responsibility of the IRB to review research activities that involve
human subjects or their data to ensure that:

- The risks to the participant are outweighed by the possible benefits to the participant and/or
  the importance of the knowledge to be gained or its benefit to society.
- The rights and welfare of each participant will be adequately protected.
- Informed consent is obtained by adequate and appropriate means, when applicable.
- Long-term research protocols are reviewed at least annually, when applicable.
- The participant is fully aware of his/her rights, risks, benefits, and the nature of the procedures.

Investigator Submenu

> A navigational aid found by hovering over **eProtocol** on the menu bar on the homepage and
> then hovering over **Investigator** in the menu. The submenu is displayed to the right and allows
> you to jump to one of the pages listed in the submenu.

L

Lab Supervisor

> An individual for an IBC study that is responsible for supervising lab personnel.

Last Approval Date

> On the homepage, an Approved Protocol column that displays the date when the protocol was
> last approved, e.g., the date when an amendment was approved.

M

Meeting Date

> On the homepage a protocol status column that contains the date that the protocol is scheduled to be discussed in the panel meeting or reported to the IBC (DMR and AR submissions).

N

Next

> A navigation button inside the protocol for that saves the current page and takes you to the "next" page of the protocol.

Non-Active Protocol

> A protocol that is no longer active to a PI. I.e., Not Human Subjects Research, Withdrawn, or Closed protocols.

Not Approved

> The protocol was not approved and is now inactive.

P

Page Level Check

> Page Level Check (PLC) scans the current page for mandatory questions which are incomplete.

Panel

> A panel reviews and discusses protocols. A panel consists of a Panel Manager and a set of reviewers. These individuals may be scientists, non-scientists, or individuals who are not affiliated with the institution.

Panel Manager

> A Panel Manager (PM) is an individual who is responsible for coordinating the overall review processes on behalf of the compliance committee.

Personal Protective Equipment

> Personal Protective Equipment (PPE) are items that are worn to protect oneself from injury or illness due to exposure to substances, e.g., mask or gloves.

Portable Document Format

> A Portable Document Format (PDF) is the Adobe file type accepted by eProtocol.

Previous

> The navigation button on a protocol page that takes you to the previous page of the currently open protocol.

Principal Investigator

> A Principal Investigator is the primary individual responsible for the creating and submitting of a protocol. Furthermore, the PI is responsible for ensuring that the activities associated with the

research study comply with applicable laws, regulations, and institutional policies and procedures.

Print View

A button in the left-side navigation pane that allows you to print all or sections of a protocol. This is an option to save a PDF version to a file.

Protocol ID

A unique ID used for identification purposes that is assigned to a protocol when it is created. The Protocol ID stays with the protocol throughout its life.

Protocols (In Preparation/Submitted)

The table on the PI homepage that contains protocols that are yet to be approved.

R

Response Necessary for Approval

When a reviewer makes a comment and marks it as **Response necessary for** approval, you must provide a response in the **response field** to resubmit your protocol for review and to be considered for approval.

Responses Sent (Cycle 1)

A Protocol Event status when you have submitted your responses to the reviewers along with any changes to the protocol. If more comment/response cycles occur, the cycle number will increase in the status accordingly.

Resubmit the Protocol

A Protocol Event status when a protocol is returned to you and changes must be made to the protocol for it to become "reviewable."

Resubmitted to IBC

A Protocol Event status when you resubmitted the returned protocol after making the necessary changes, e.g., Resubmitted to IRB

Returned

The protocol status when the committee office has requested changes to the protocol that must be completed before the protocol can be forwarded to reviewers.

S

Save

A button that allows you to manually save all the data you have entered on that page.

Section Name

Protocols are organized into named sections for ease of navigation. They appear in the left-side

navigation pane. Comments by reviewers are also organized and presented based on Section Names. The first section in a new protocol is Personnel Information. The subsequent section names vary by committee.

Show All Comments

A button in the comments page that displays all of the comments between you and the reviewer organized by cycle.

Spellcheck

A button inside a protocol that initiates a scan to check for spelling errors on the current page.

Submitted to (committee name)

A Protocol Event status when a protocol has been submitted to a committee, e.g., Submitted to IRB.

Suggestion Not Necessary for Approval

A comment type when a Reviewer gave a suggestion for the protocol.

W

Withdrawn

A protocol status when you decide that you do not want to proceed with your study.

Y

Yet to Submit to IBC

A Protocol Event status when a protocol has been created but has not yet been submitted to a committee.

8 Frequently Asked Questions (FAQs)

1. **Which browsers can I use for eProtocol?**
   Mozilla Firefox, Google Chrome and Safari.

2. **Why do I need to disable the browser's pop-up blocker?**
   eProtocol contains various pop-ups that you need to be able to view. For instance, a protocol is a pop-up.

3. **How do I create a protocol?**
   Click Create Protocol on the dashboard or select Create Protocol on the Investigator submenu.

4. **What do the asterisks (*) mean in a protocol?**
   Asterisks represent a mandatory field.

5. **Who needs to be added to the Personnel Information page?**
   All personnel who are involved with the study must be added.

6. **Does my protocol need to have *all* personnel types listed in the Personnel Information page?**
   No. Usually the PI is the only required person. There are fields identified with an asterisk that only need to be completed when you add that specific type of personnel.

7. **Can I change the protocol Application Type after I already started on an application?**
   Yes. However, the content you provided for the initial Application Type may be cleared and is not recoverable once you change the application type.

8. **How do I submit a protocol?**
   Select **submit form** in the protocol's navigation pane.

9. **How do I search for a protocol?**
   Select **Search Protocol** from the Investigator submenu; enter your search parameters; and click **Search**.

10. **How do I withdraw a protocol?**
    Contact the Office of Research Services, Research Protections staff directly. A protocol can only be withdrawn if it has been submitted to the compliance office and the committee has not made a decision.

11. **Can you edit a protocol after submission?**
    You may only edit a protocol if the protocol is sent it back to you or it has been approved. Any changes after approval need to be submitted as an amendment.

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12. How do I view a Reviewer's comments?
From the homepage click the Protocol Event link >> Show All Comments (use this button if there are multiple comment/response cycles).

13. How do I view my protocol's approval letter?
On the homepage, click on the **Protocol ID link** and open the protocol in **View Mode.** In the left-side navigation pane, select **Event History**, and click on the **Approval Letter** link (located in the Letters column).

14. How do I view all of my approved protocols?
On the dashboard, scroll down until you see the Approved Protocols table or select **Approved Protocols** on the Investigator Submenu.

15. What is preventing me from deleting my protocol?
You cannot delete a protocol that has already been submitted.

16. What is preventing me from submitting an amendment?
If a continuing review or another amendment is in progress, you must wait for it to be completed (approved or withdrawn) before submitting an amendment.

17. Can I withdraw an amendment?
Yes. Contact your committee directly.

18. What is preventing me from submitting an annual renewal?
If an amendment is in progress, you must wait for it to be complete. If you do not have an amendment in progress, then your protocol is not yet eligible for an annual renewal. You will receive an email when your protocol is eligible.

19. Can I withdraw an annual renewal?
Yes. Contact the Office of Research Services directly.