DEPAUL UNIVERSITY | OFFICE OF RESEARCH SERVICES

eProtocol Investigator

Quick Reference Guide for DePaul University Users

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KEY SOLUTIONS
Comprehensive IT for Research

Table of Contents

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. 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.

The screenshots you see in this guide were taken from an IRB protocol.

Key Solutions makes improvements to its software on a regular basis. This guide was developed in reference to the eProtocol software version 2.7.42.15.

2 Getting Started

Beginning June 1, 2020 all new IRB protocols must be submitted through the online eProtocol portal. Older studies will not be entered into the system and will remain on paper until it is determined on a case by case basis whether it makes sense to have them re-submitted using the online system. Basic information about the system, how to log into the system, and the link to the online system can be found at https://offices.depaul.edu/research-services/research-protections/irb/Pages/IRB-Protocol-Portal.aspx. **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 DePaul's eProtocol portal. (See **Figure 1**)

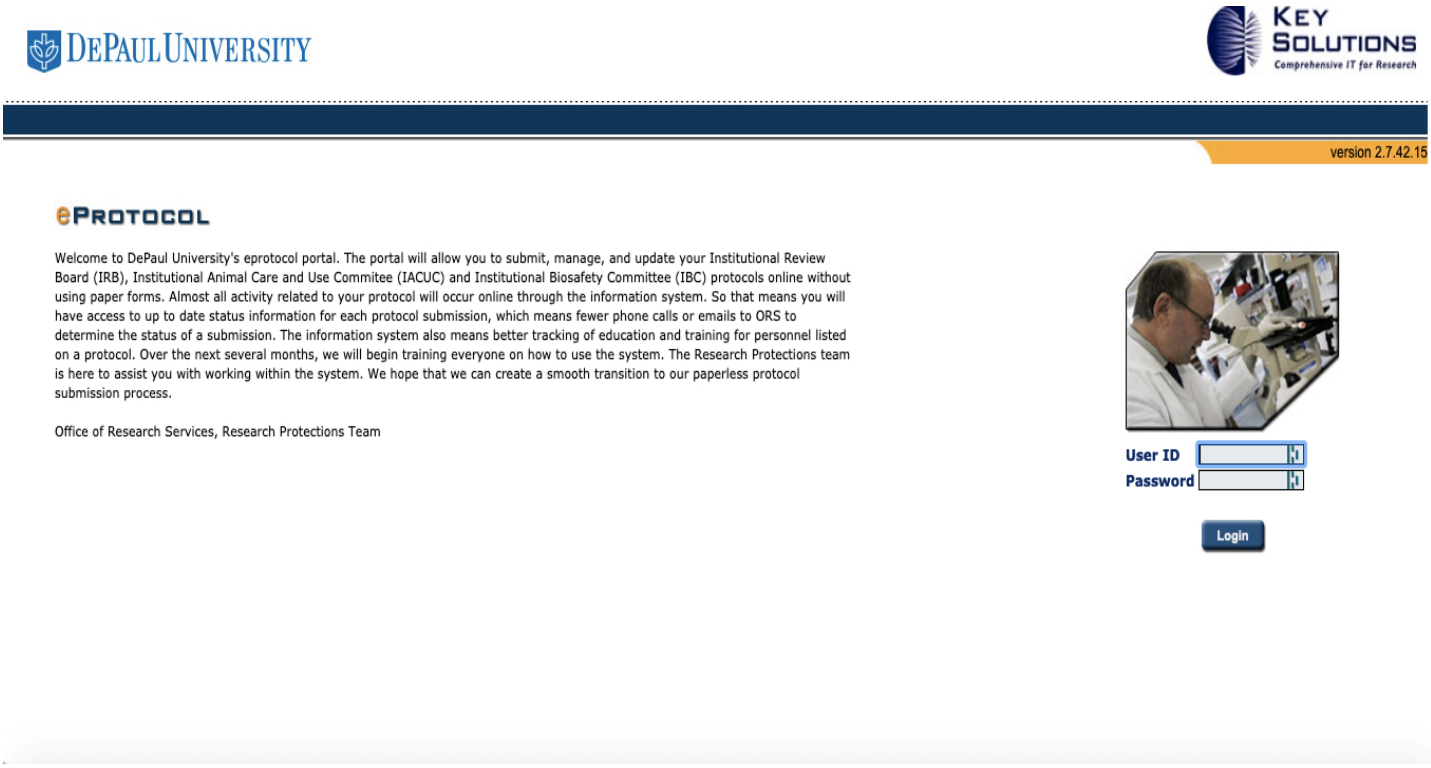


Figure 1: Main Home Page

You log into the system using your DePaul user ID and the same password used to log into Campus Connect. Your DePaul user ID is usually the beginning of your email address or it can 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 in order for the system to work. Select allow popups. 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. You should only need to do this once per computer.

When you log in to eProtocol, the Investigator Homepage is displayed (See **Figure 2**), unless you were assigned another role in the system as your default role (e.g., IRB 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.

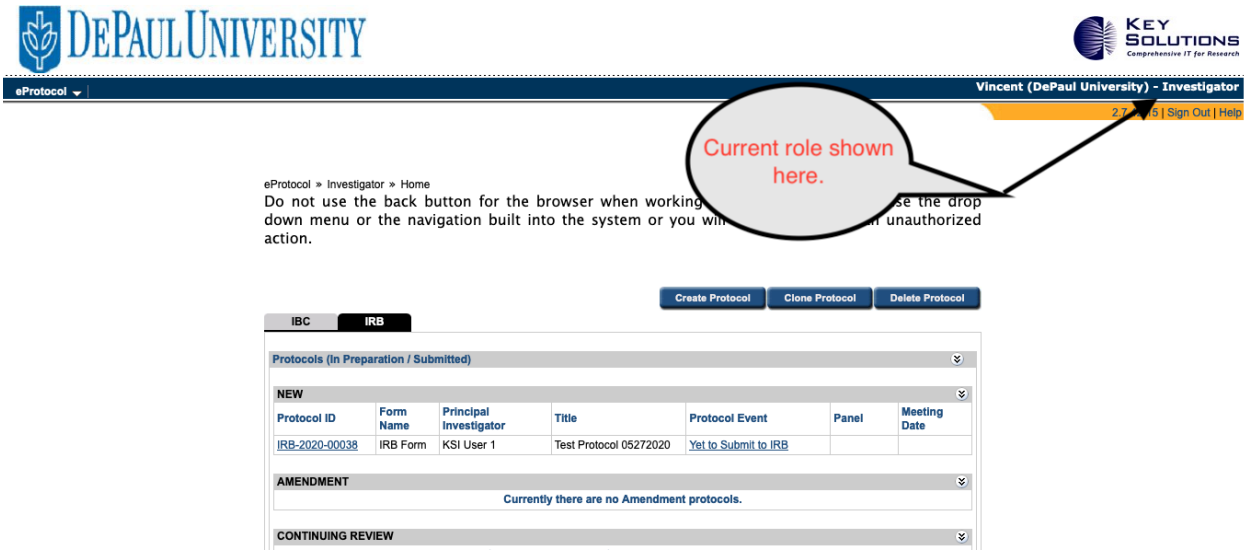


Figure 2: Current Role Designation

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 IRB tab (See **Figure 3**) is selected and darker than the other board tabs.

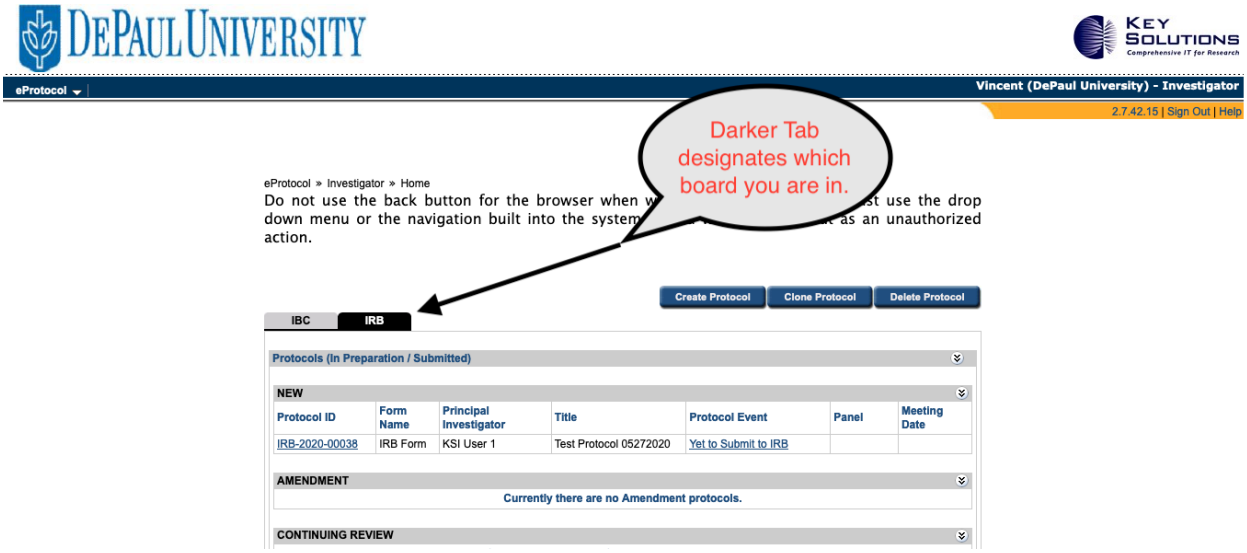


Figure 3: Board Designation

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.*

Note: *If you have trouble logging in, contact 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 (See **Figure 4**). To navigate to the Investigator submenu, hover over **eProtocol (and a drop down list becomes viewable)** and then the word **Investigator**. A list of possible actions for an Investigator will become viewable.

Figure 4: Role Drop Down Menu

From this submenu, you may perform the following functions (See **Figure 5** and reference numbers):

1. View approved protocols
2. Clone a protocol

4. Delete a protocol
5. Information Resources
6. Navigate to the Homepage
7. Non active protocols list
8. Search for a protocol

Figure 5: Homepage Header Shortcuts

On the right side of the header, you can perform the following functions (refer to **Figure 5**'s reference numbers above):

9. View the eProtocol version number
10. Change Password
11. Sign out of eProtocol
12. 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. Currently help text is only available on the informed consent page related to waivers and alterations of consent and waivers of documentation of consent.*

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 (See **Figure 6**'s reference numbers below):

1. Know your location in eProtocol by viewing the breadcrumb, 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

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

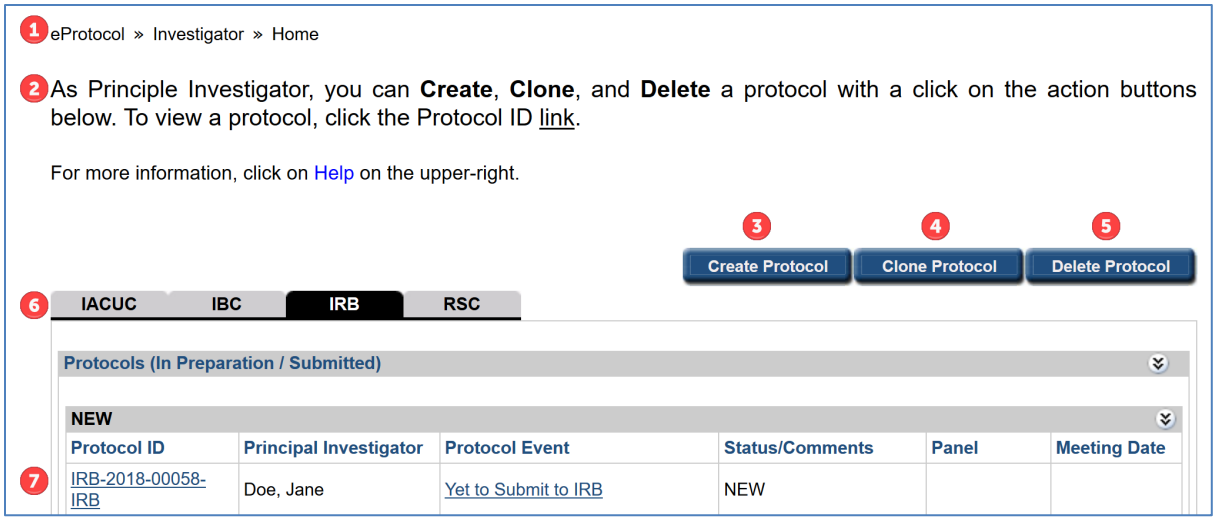


Figure 6: Dashboard

On the protocol submission list you will see submitted and not yet approved submissions and protocols and then as you scroll down, you will see approved protocols and non-active protocols. This dashboard gives you a full look at all the 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.

2.2 The Look of a Protocol

When a protocol is opened, you notice that you have a header, left-side navigation pane, and the protocol content pane (See **Figure 7)**. The header will include the IRB-IRB Form and protocol number on

the left, the protocol number and the PI name in the middle, and on the right (outlined in red) (See **Figure 7**) includes shortcuts that allow you to perform the following:

- 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 (outlined in yellow)(See **Figure 7**) 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

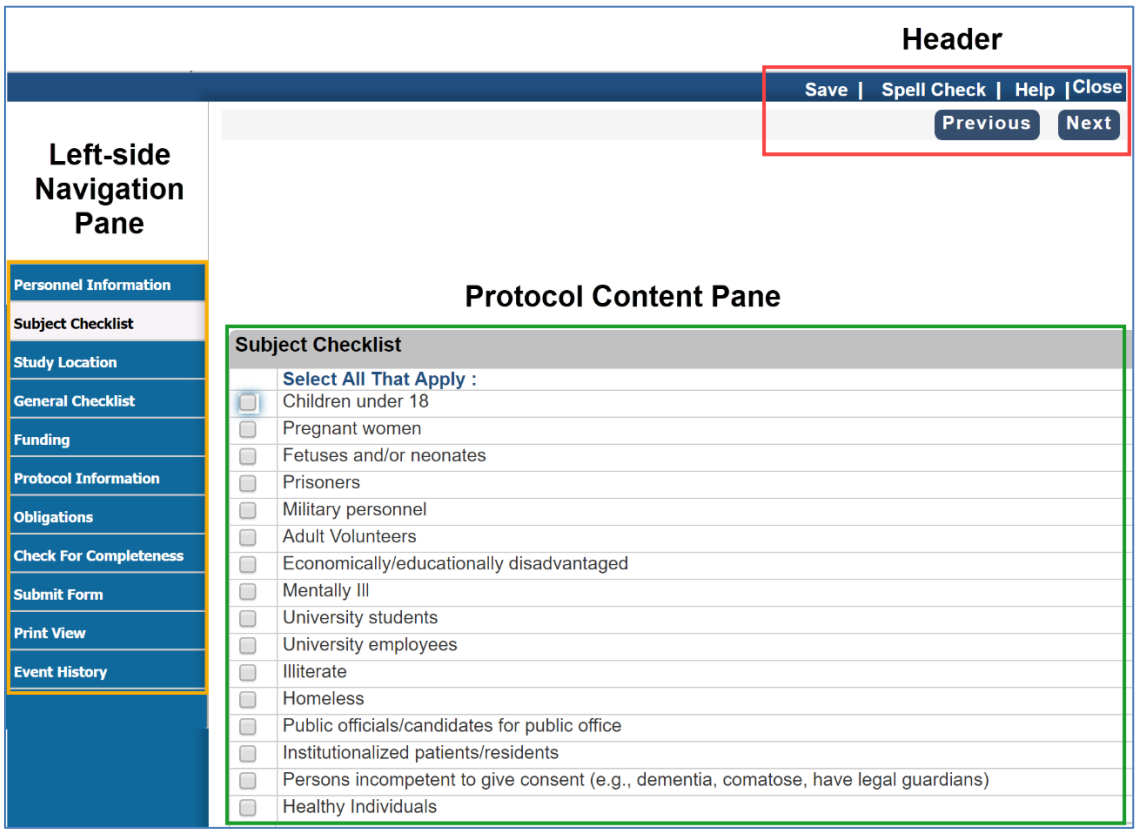


Figure 7: Header, Left-side Navigation Pane, and Protocol Content Pane

The protocol content pane (outlined in green) (See **Figure 7** above) 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 The left-side navigation (outlined in yellow) (See **Figure 8**) expands to display them, too. You may use any of those shortcuts to quickly navigate to the desired page.

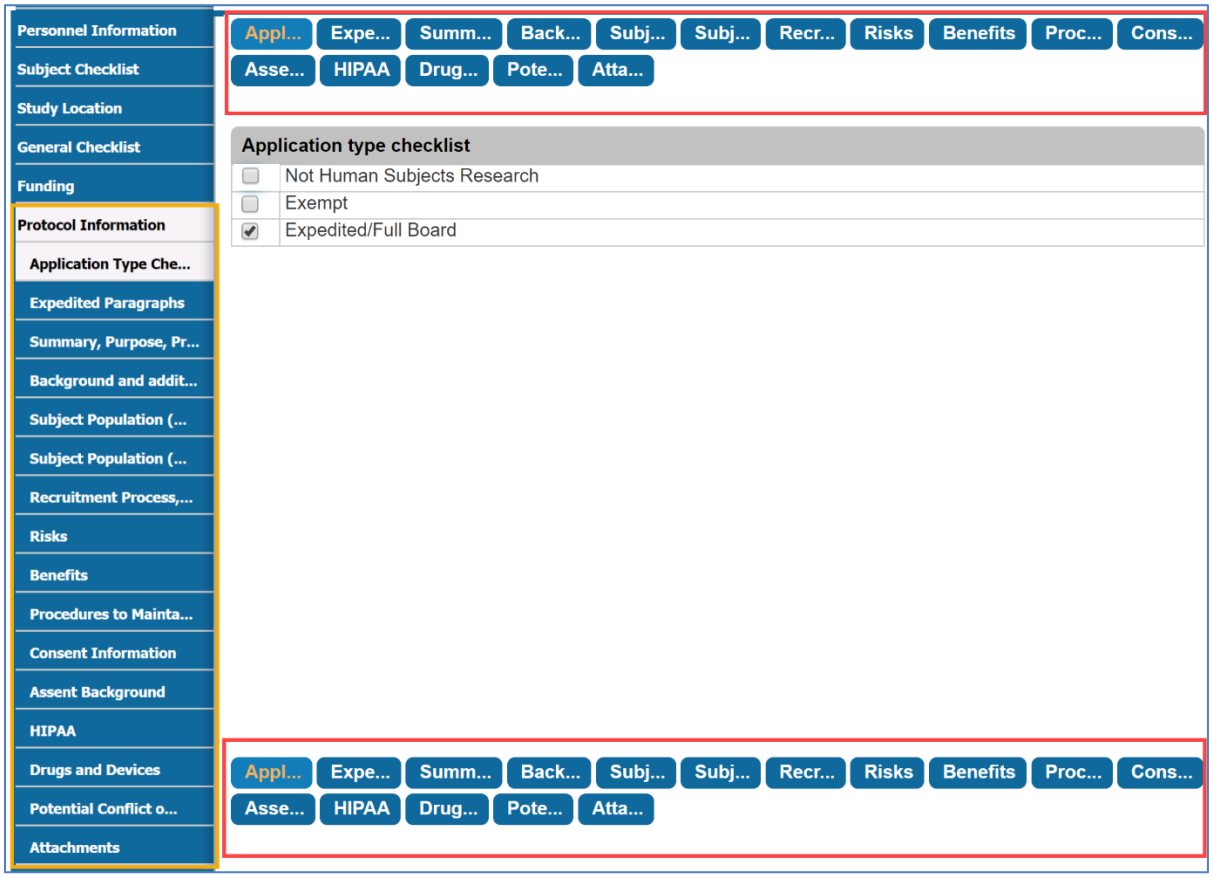


Figure 8: Shortcuts in the Header and Footer

Hover over a category to view the whole name (See **Figure 9**). You may also refer to the left-side navigation pane.

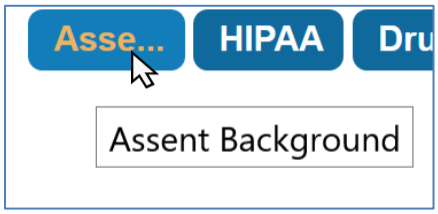


Figure 9: Hover over an icon to view name

3 Creating a Protocol

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

When you are 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 feel you made a mistake in your responses. Examples specific to the IRB are shown in the following sections. The first thing you will be asked to do is to type in the protocol title select the IRB form, and select the Principal Investigator (PI). (See **Figure 10**) You will need to first complete the Principal Investigator (PI) information. Some information will automatically fill in for your information from DePaul's directory, but you will need to manually complete the remaining information.

Figure 10: Creating a protocol

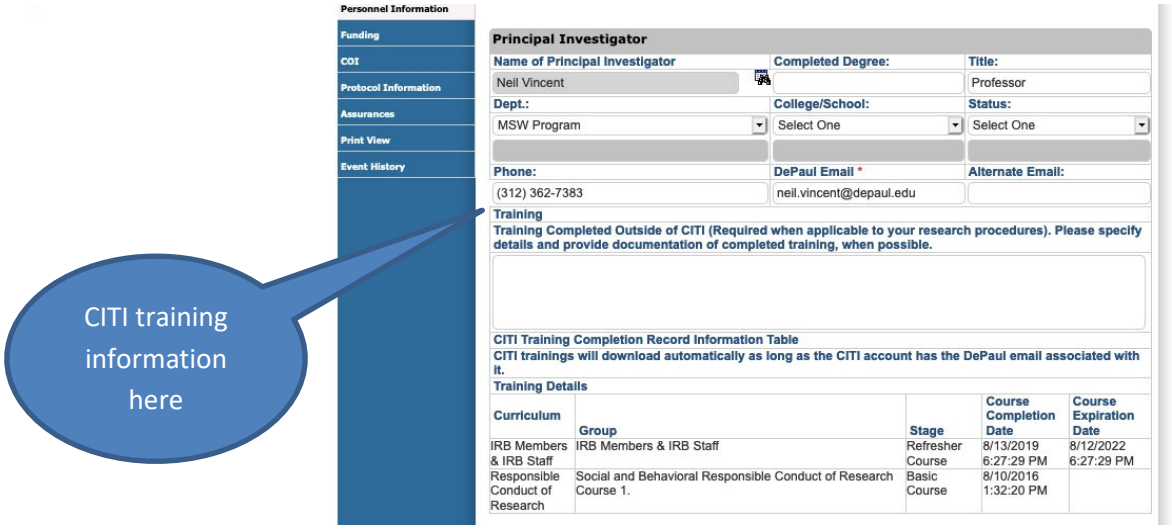


Figure 11: CITI training information

Your CITI training should automatically download into the system (See **Figure 11** above). If you do not see the CITI training downloaded into the system, you will need to double check that your human subject 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.

Once the PI information is complete, you would select 'Create'.

3.1 Protocol Field Form Response Types

In order 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

3.2 Binocular Icon

The **binocular icon** ( ) is used to search for a DePaul user (Figure 12). When you select the icon, the **Find User** pop-up appears (See **Figure 12**). You will use this function to add Faculty Sponsors, Co-investigators and Key Research Personnel

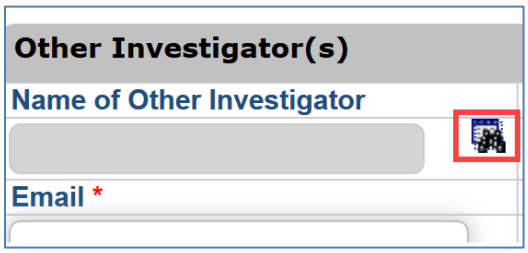


Figure 12: Binocular Icon

You may choose to search for a user by entering the User ID, the First Name, or the Last Name (See **Figures 13 and 14**). Then, click **Find**.

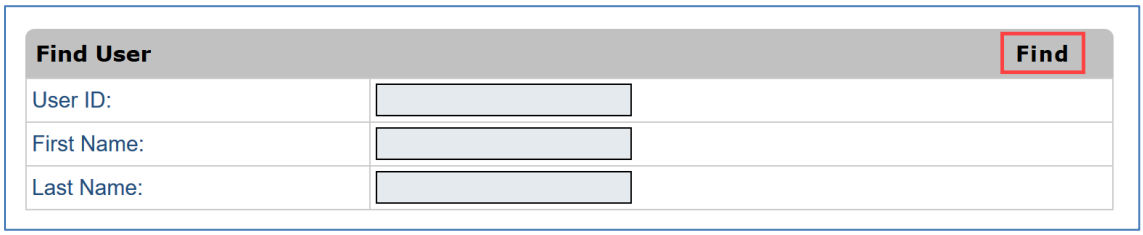


Figure 13: Find User pop-up

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 access to the system, you need to request the Friend of DePaul account using the form on the IRB forms and Templates page or on the eProtocol portal page. **Persons who are not DePaul affiliated and who do not need access to the system should be added manually using the 'Other Personnel' field.**

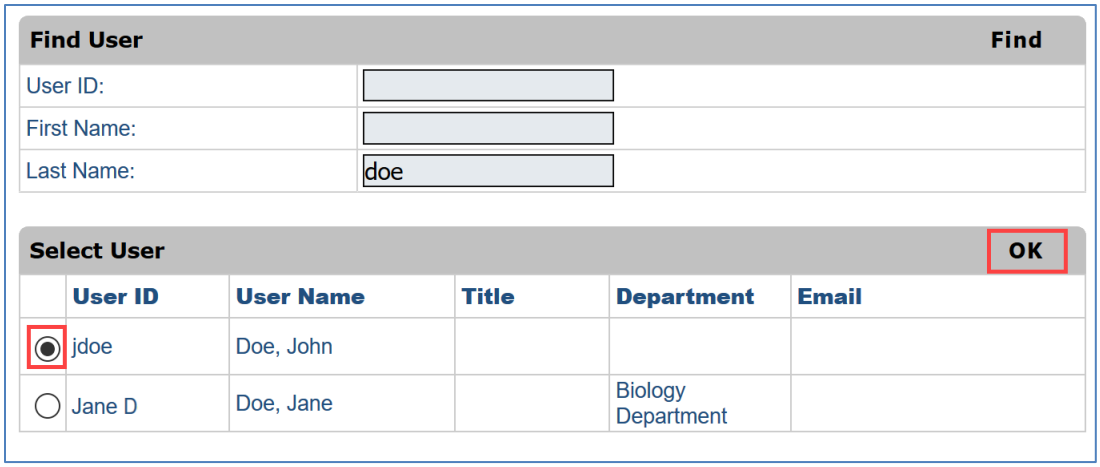


Figure 14: Find User Result Keep screenshot

3.3 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 (See **Figure 15**).

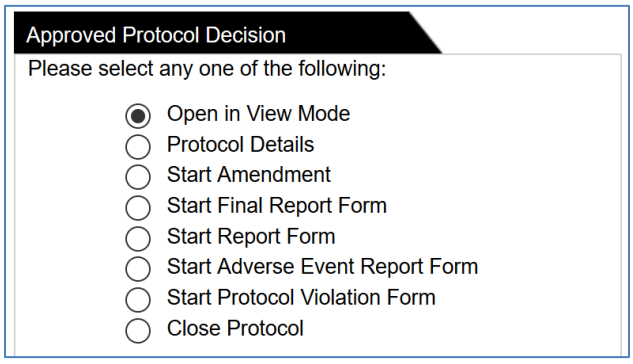


Figure 15: Radio Button

3.4 Text Field

A **text field** is a box where you can enter text, as long as 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 (See **Figures 16 a, b**).

It is possible for you to enable text fields that are on subsequent pages in the protocol. (Refer to Section 3 for more details.) When completing certain parts of a protocol, you are required to complete the newly-enabled text field before you may continue 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 16a: Text Field Disabled

Figure 16b: Text Field Enabled

3.5 Dropdown

Dropdowns allow you to select one value from a list. Click the downward facing arrow (▼) to open the dropdown (See **Figure 17**). Then, click on one to select a value.

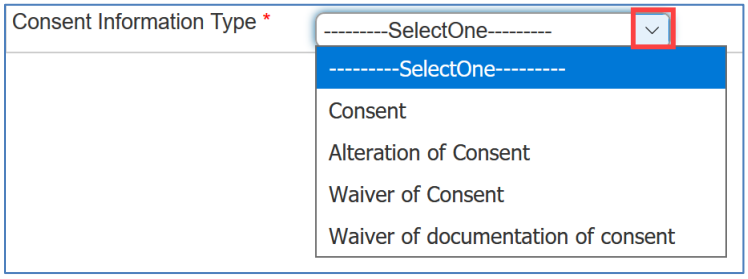


Figure 27: Dropdown

3.6 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 (See **Figures 18a, b, c, d**).

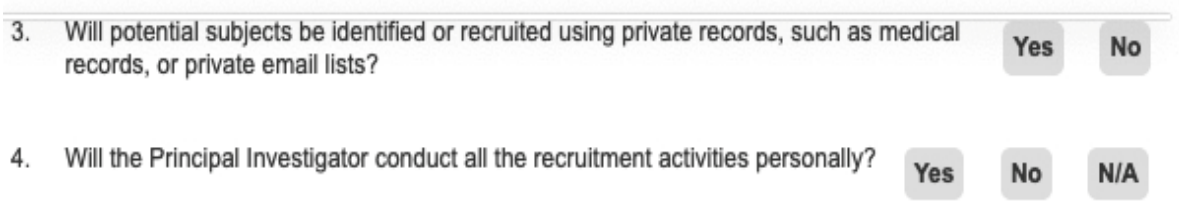


Figure 38a: Unselected Buttons, subordinate field disabled

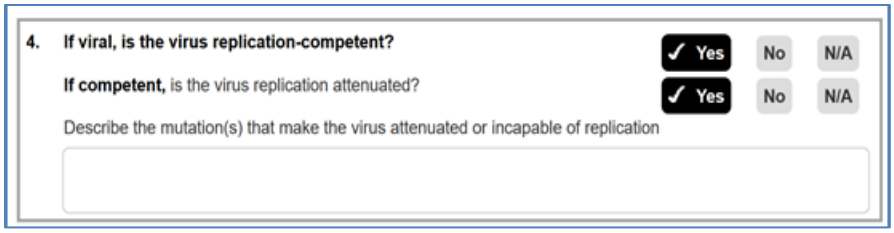


Figure 18b: Yes buttons selected and subordinate text field enabled

A response may also enable the **Add** button.

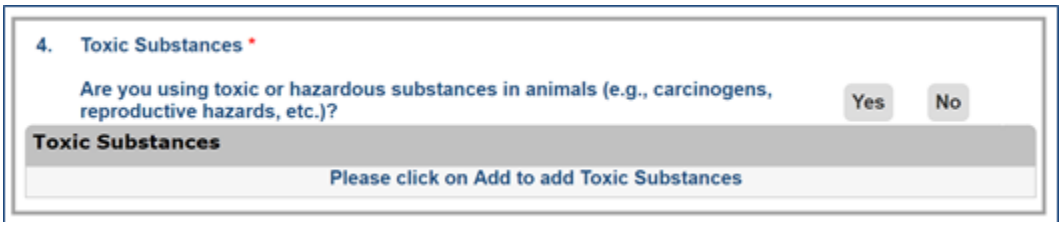


Figure 18c: Without a response, there is no "Add"

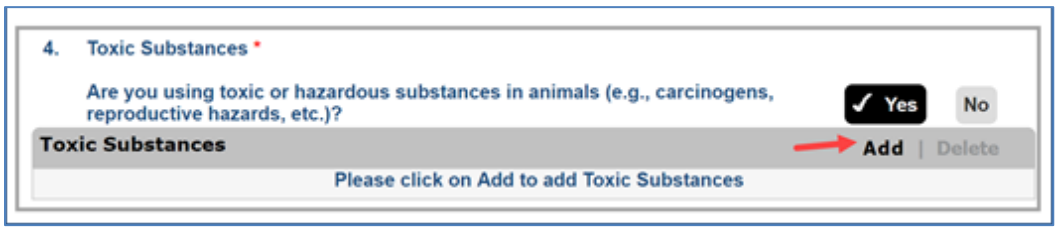


Figure 18d: With a Yes response, the Add function is enabled same as above

3.7 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 (See **Figure 19**). Use the singular arrows **([<] [>]**) to change the month and the double arrows **([<<] [>>]**) to change the year.

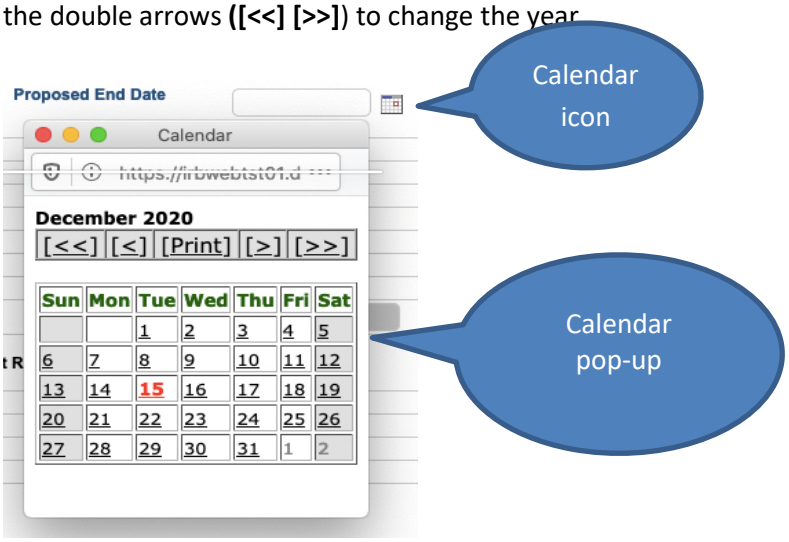


Figure 19: Calendar Icon and the pop-up

3.8 Add Button

Use the **Add** button to add additional information to a subject. When you click **Add**, a pop-up appears (See **Figure 20**). Complete the section and click **Save** (commonly found on the upper-right) when you are finished.

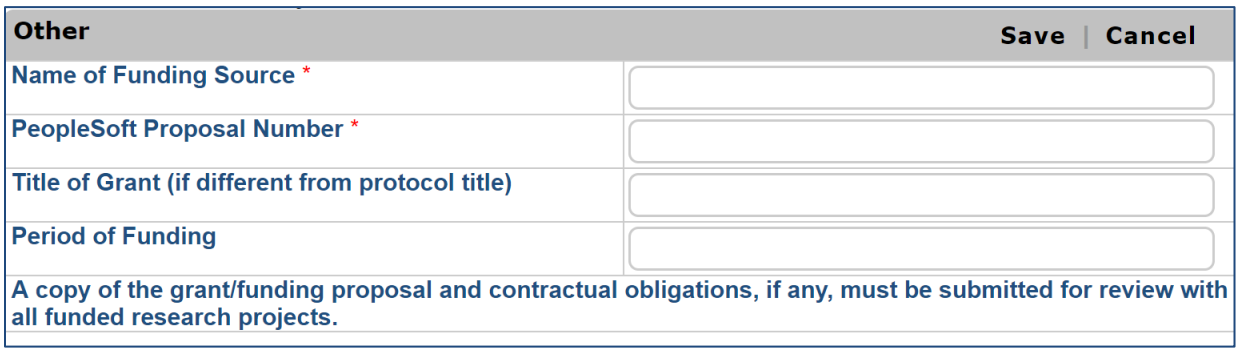


Figure 20: Add pop-up

3.9 Checkbox

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 (See **Figure 21**).

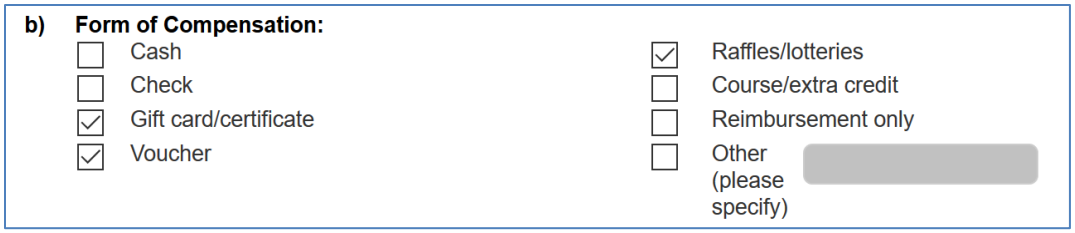


Figure 21: Checkboxes

3.10 Attachment

An **attachment** is a document that you need to upload to your protocol in order 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 IRB track what version of a document is the currently approved version and what that document actually is.

To upload an attachment, perform the following tasks:

1. Click **Add** (See **Figure 22**).
2. Click **Browse** (See **Figure 23**).
3. Select and **Open** the file (See **Figure 24**).
4. Click **Save** (See **Figure 25**).

Figure 22: Add

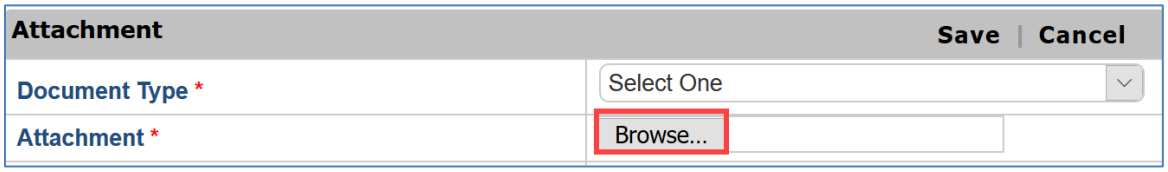


Figure 23: Browse

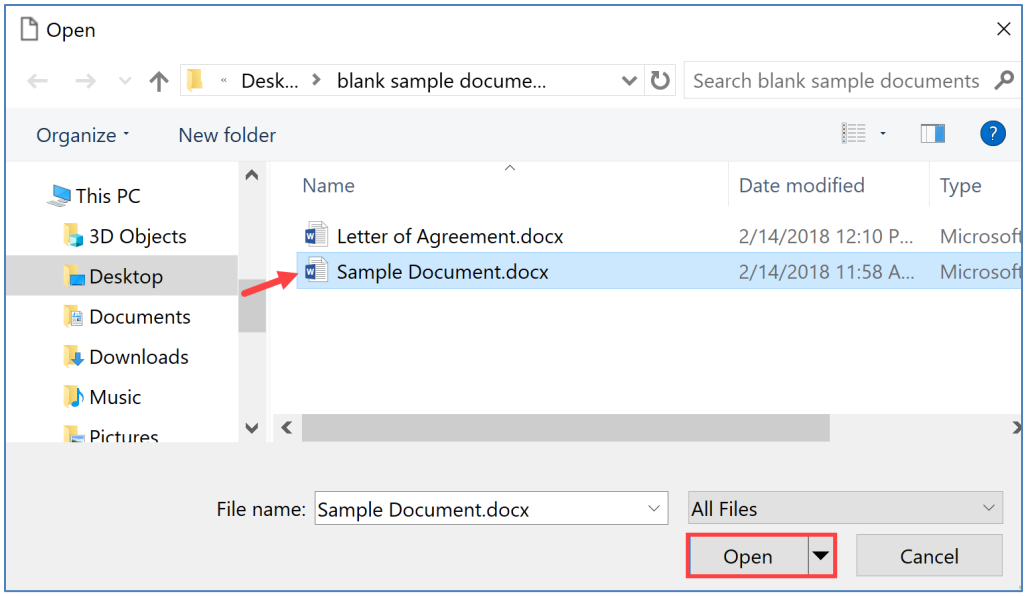


Figure 24: Select a file and click open

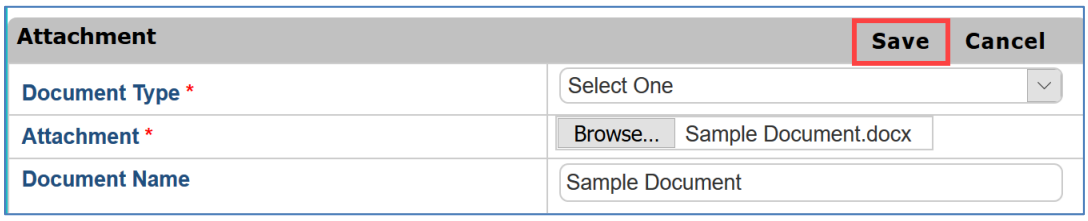


Figure 25: Save

Note: *You may need to provide additional information prior to saving. For example, in* ***Figure 25****, you need to select the Document Type from the dropdown list prior to saving.*

4 Completing IRB Protocol Forms

4.1 Personnel Information

The first section you will need to complete is the Personnel Information page. You will have completed the Principal Investigator (PI) information in order to create the protocol.

If you are an undergraduate student or graduate student as selected in the Status drop down list, you must have a Faculty Sponsor when you are the Principal Investigator. You will complete the Faculty Sponsor section in a similar fashion to the PI section. If you cannot find your Faculty Sponsor through the search function contact ORS at ORP@depaul.edu for assistance.

Next, you would add any DePaul co-investigators to the protocol using the search function and manually completing any information that does not download automatically. If you have other Key Research Personnel, you will add them in a similar fashion.

Again, the CITI training should automatically download into the system for your Faculty Sponsor, Co-Investigators, and Key Research Personnel. If you do not see the CITI training downloaded into the system, you will need to double check with the individual whether their human subject training is current and that 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.

The final personnel field is called 'Other Personnel'. This section is for adding personnel who are not affiliated with DePaul, who do not require access to the system, and who do not have a DePaul user ID. The process will work similar, except that when you see the pop up after clicking 'Add', you will see a link to click on that allows you to add someone manually (See **Figures: 26 a, b**). For these persons, you will need to attach the external training documents in the Attachment tab, since ORS will not be able to access their training information directly.

Figure 26a: Adding other research personnel

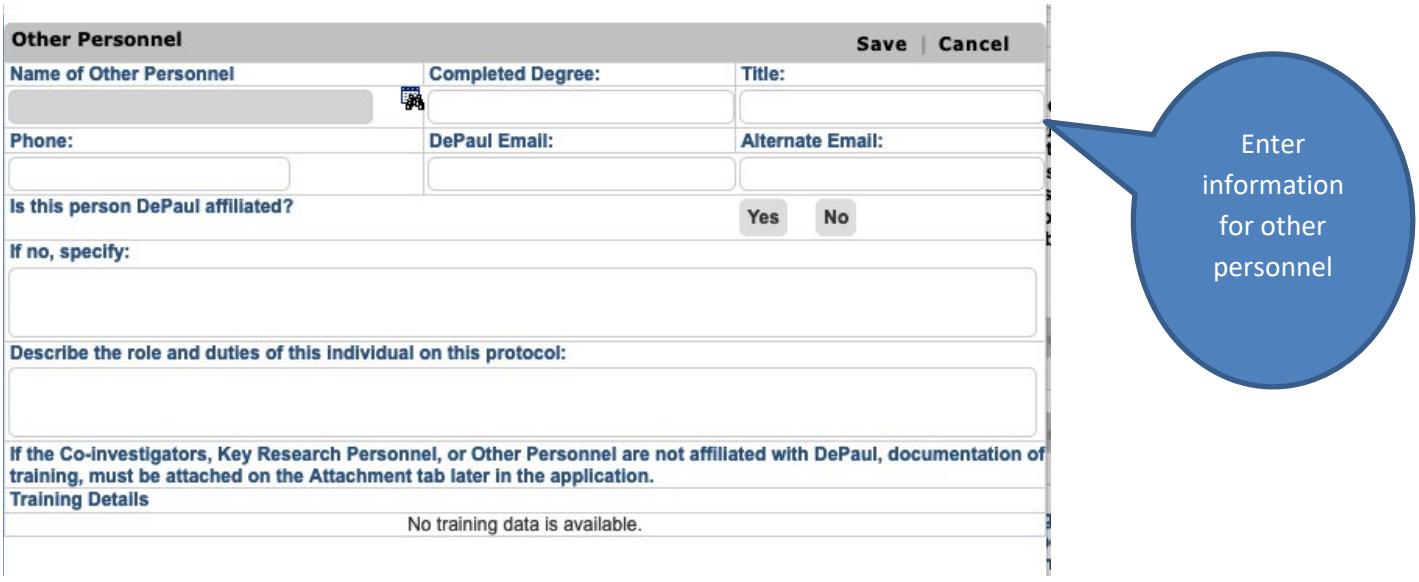


Figure 26b: Adding information for other personnel

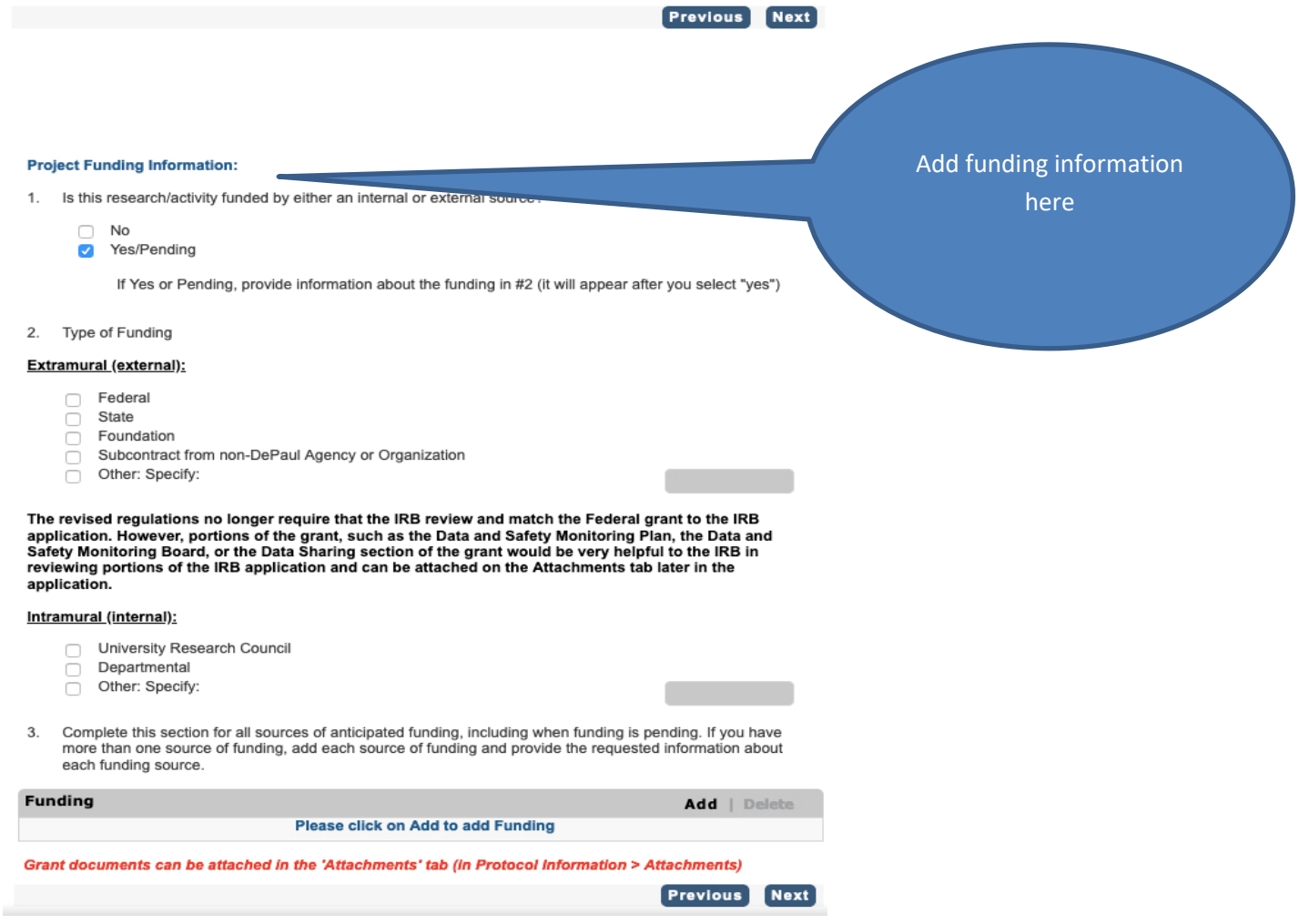
When all the personnel sections are completed, select 'Next' to move to the next page.

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 a Co-Investigator or Key Research Personnel. They then can sign in as themselves and complete the remainder of the application.

4.2 Project Funding Information Tab

In this tab, you will indicate whether or not you have funding. (See **Figure 27**) If you select yes that you have funding, you will indicate whether the funding is internal or external, and you will need to complete the table to add each individual source of funding. You can add as many funding sources as apply to your protocol. When this tab is complete, select 'Next'.

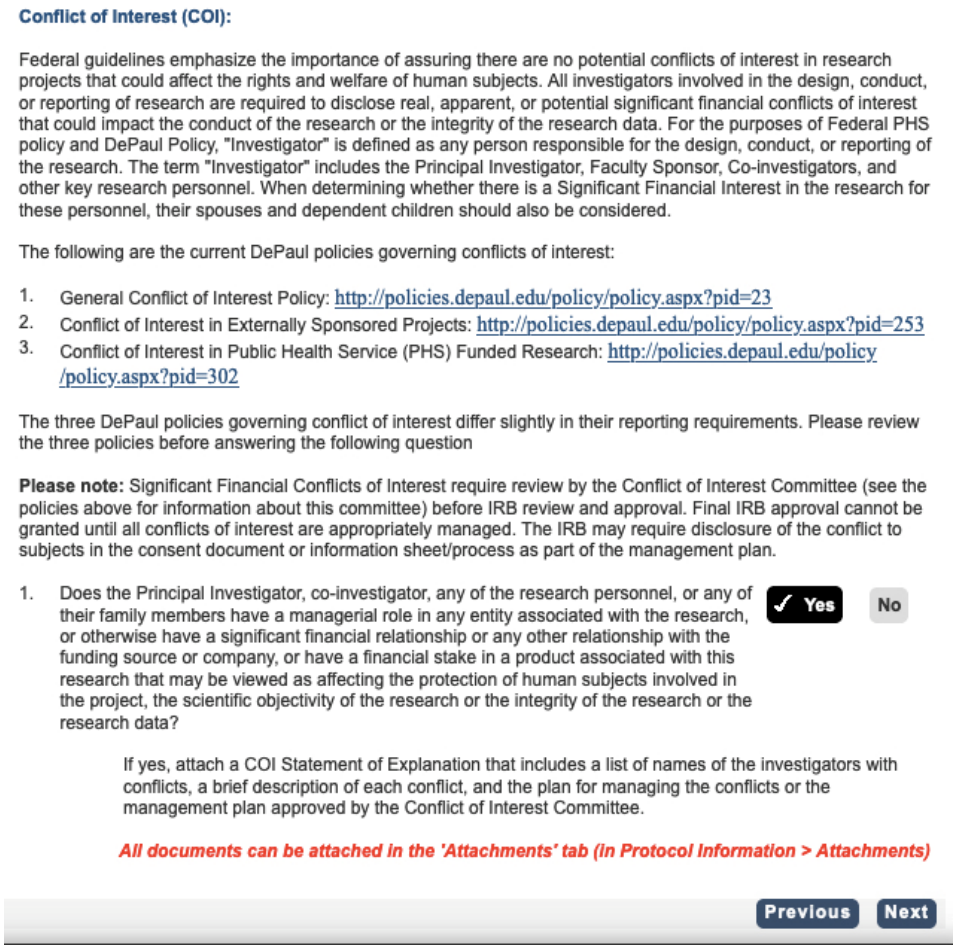
Figure 27: Adding funding information



4.3 Conflict of Interest Tab

In this tab you will indicate whether you, the PI, or any of the listed personnel have a financial conflict of interest (See **Figure 28**) as defined by DePaul Policies. If you select 'yes', you would attach any conflict management information on the Attachment tab of the form. When this tab is completed, select 'yes'.

Figure 28: Reporting conflict of interest of research personnel



4.4 Protocol Information- Application Type Checklist

The IRB eProtocol system was designed with different pathways or forms. The tabs already completed are common to all IRB protocols. The application Type Checklist tab helps to select the remaining tabs that need to be completed by having pathways for Not Research/Not Human subject/Not engaged, Exempt, Development Only, Expedited, Full, or Request an IRB Reliance Agreement where DePaul is the lead site (Must choose exempt, expedited, or full when choosing this choice), or Request for an IRB Reliance Agreement where DePaul relies on another IRB (Must choose level of review the protocol was

approved at the lead site and attach supporting documentation of approval as noted on the Attachment page). You should think very carefully about which pathway to select to move forward because the various forms have different tabs and switching between forms after you have begun the process can result in losing some information. So for example, the exempt form has many fewer tabs than the expedited form and some tabs are unique to exempt protocols. So if you begin completing the exempt form and then decide the work should be submitted for expedited review, you will lose the information unique to exempt forms when you select expedited. Additionally, sections like exempt categories and expedited categories are completely different, and switching forms would require that you complete the correct information on the tabs that apply to that form. To help you determine the correct pathway and form, the instructions for the paper forms that correspond to the online eProtocol forms can still be accessed on the IRB section of the ORS website. In addition, the IRB website Getting Started and Level of Review pages offer guidance regarding when activities require IRB review (or might be not research or not involve human subjects) and approval and what level of review is required.

Once you have decided which form/pathway to select, click the appropriate box and then select 'Next'.

4.5 Not Research/Not Human Subject Research/Not Engaged

If you select this form/pathway, the first tab (See **Figure 29**) you will see is the Research/Human Subject/Not Engaged checklist.

Figure 29: Designating protocol not research/Not human subjects/Not engaged

Application type checklist	
☑	**Not Research/Not Human Subjects/ Not Engaged** - Classroom based activities that for which the project data will be used solely for a class grade or paper and not used in any other manner, would not meet the generalizable criteria for the definition of research and therefore would meet the criteria for not research.
☐	**Exempt**
☐	**Expedited** Note: Research involving prisoners as research subjects must be reviewed by the convened IRB
☐	**Development Only** - Check this box if you have a grant that includes human subjects at some point. but the human subject portion of the grant activities is still under development
☐	**Full**
☐	**Request for Reliance Agreement (IRB Authorization Agreement- IAA) where DePaul is the lead site.**
☐	**Request for Reliance Agreement (IRB Authorization Agreement-IAA) where DePaul relies on another IRB -** Note: Only complete the Funding, COI, Application Checklist (level of review for lead site), Project Information, Performance Site, and the Research Objectives tabs and skip past all other tabs. Then, attach the IRB approval letter, approved consent document, and IRB application from the lead IRB site, which explains the research in detail.

In the research checklist, if the response to all the questions is 'yes', then you are conducting research and would move on to the next section about human subjects. If you answer no, to one or

more of the research questions, you will still be asked to complete the next two sections (with no being the response to each item) in order for the form to be considered complete by the completeness check process built into the system.

In the human subject research checklist, (See **Figures 30a, 30b, 30c**) you will indicate yes or no to the questions. Some activities may be research, but not involve human subjects. In order for the protocol to be not research/not human subjects research/not engaged, you must answer 'No' to all the questions in this section.

In the not engaged section, select 'no' to the question if the reason the activity does not need review is you and DePaul ae not engaged in the conduct of the research activity. If you are conducting the activity, the correct response would be 'yes'.

When the tab is completed, select 'Next'.

Figure 30a: Completing not research checklist

Not Research/Not Human Subject Research/Not Engaged

A. RESEARCH

As defined by Department of Health and Human Services' (DHHS) regulations: "*a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge*."

- **If all checked YES, the activities meet the DHHS definition**
- **If ANY checked NO, the activity does not meet this definition.**

For purposes of this part, the following activities are deemed not to be research:

(1) Scholarly and journalistic activities (e.g., oral history, journalism, biography, literary criticism, legal research, and historical scholarship), including the collection and use of information, that focus directly on the specific individuals about whom the information is collected.

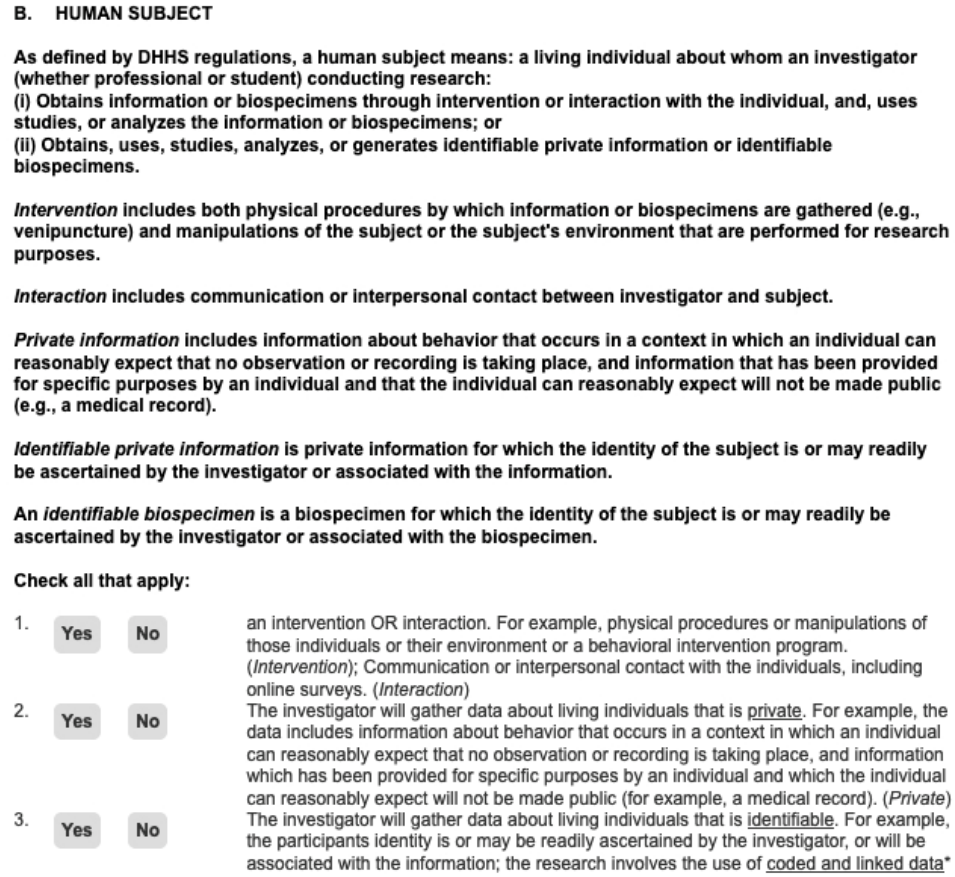
(2) Public health surveillance activities, including the collection and testing of information or biospecimens, conducted, supported, requested, ordered, required, or authorized by a public health authority. Such activities are limited to those necessary to allow a public health authority to identify, monitor, assess, or investigate potential public health signals, onsets of disease outbreaks, or conditions of public health importance (including trends, signals, risk factors, patterns in diseases, or increases in injuries from using consumer products). Such activities include those associated with providing timely situational awareness and priority setting during the course of an event or crisis that threatens public health (including natural or man-made disasters).

(3) Collection and analysis of information, biospecimens, or records by or for a criminal justice agency for activities authorized by law or court order solely for criminal justice or criminal investigative purposes.

(4) Authorized operational activities (as determined by each agency) in support of intelligence, homeland security, defense, or other national security missions.

1.	Yes	No	Is the activity an investigation? (*Investigation*: a searching inquiry for ascertaining facts; detailed or careful examination)
2.	Yes	No	Is the investigation systematic? (*Systematic*: having or involving a system, method, or plan)?
3.	Yes	No	Is the systematic investigation designed to develop or contribute to knowledge? (*Designed*: done with purpose and intent. *Develop*: to elaborate or expand in detail. *Contribute*: to be an important factor in; help to cause. *Knowledge*: truths, facts, information.)
4.	Yes	No	Is the knowledge generalizable? (*Generalizable*: made applicable to others outside of the current subjects, i.e., through publication or other means)

Figure 30b: Completing not research checklist



B. HUMAN SUBJECT

As defined by DHHS regulations, a human subject means: a living individual about whom an investigator (whether professional or student) conducting research:
(i) Obtains information or biospecimens through intervention or interaction with the individual, and, uses studies, or analyzes the information or biospecimens; or
(ii) Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.

***Intervention* includes both physical procedures by which information or biospecimens are gathered (e.g., venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes.**

***Interaction* includes communication or interpersonal contact between investigator and subject.**

***Private information* includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information that has been provided for specific purposes by an individual and that the individual can reasonably expect will not be made public (e.g., a medical record).**

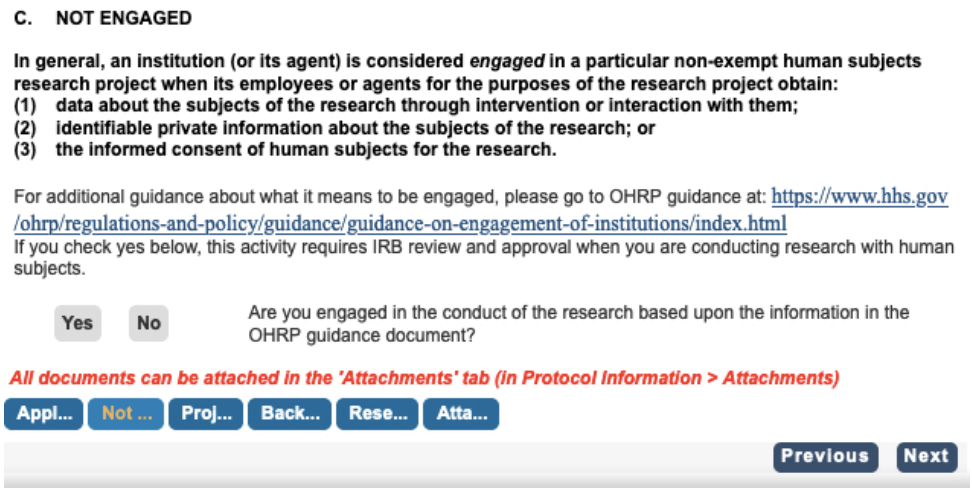
***Identifiable private information* is private information for which the identity of the subject is or may readily be ascertained by the investigator or associated with the information.**

An *identifiable biospecimen* is a biospecimen for which the identity of the subject is or may readily be ascertained by the investigator or associated with the biospecimen.

Check all that apply:

1. Yes No — an intervention OR interaction. For example, physical procedures or manipulations of those individuals or their environment or a behavioral intervention program. (*Intervention*); Communication or interpersonal contact with the individuals, including online surveys. (*Interaction*)
2. Yes No — The investigator will gather data about living individuals that is private. For example, the data includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical record). (*Private*)
3. Yes No — The investigator will gather data about living individuals that is identifiable. For example, the participants identity is or may be readily ascertained by the investigator, or will be associated with the information; the research involves the use of coded and linked data*

Figure 30c: Completing the not research checklist



C. NOT ENGAGED

In general, an institution (or its agent) is considered *engaged* in a particular non-exempt human subjects research project when its employees or agents for the purposes of the research project obtain:
(1) data about the subjects of the research through intervention or interaction with them;
(2) identifiable private information about the subjects of the research; or
(3) the informed consent of human subjects for the research.

For additional guidance about what it means to be engaged, please go to OHRP guidance at: https://www.hhs.gov/ohrp/regulations-and-policy/guidance/guidance-on-engagement-of-institutions/index.html
If you check yes below, this activity requires IRB review and approval when you are conducting research with human subjects.

Yes No — Are you engaged in the conduct of the research based upon the information in the OHRP guidance document?

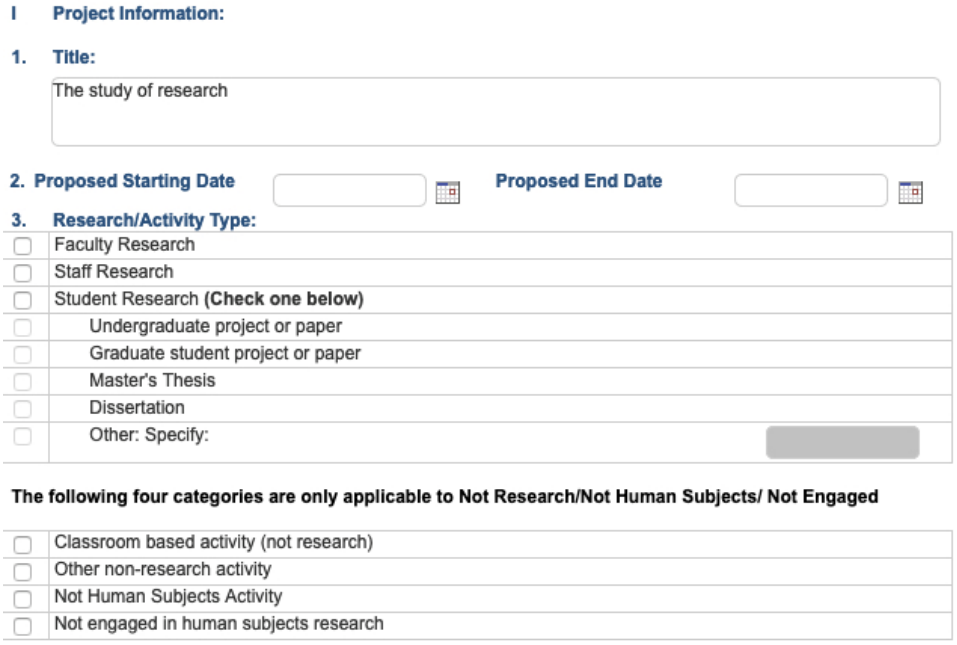
All documents can be attached in the 'Attachments' tab (in Protocol Information > Attachments)

Appl... Not ... Proj... Back... Rese... Atta...

Previous Next

The next tab that must be completed is the Project Information Tab (See **Figure 31**). In this tab, you will indicate the proposed stop and start date and select the appropriate box in the table at the end of the page. Your selection will choose the reason the activity is not research/Not Human Subject Research/Not Engaged. When this page is completed, select 'Next'.

Figure 31: Project information for not research protocol



I **Project Information:**

1. **Title:**

The study of research

2. **Proposed Starting Date** **Proposed End Date**

3. **Research/Activity Type:**

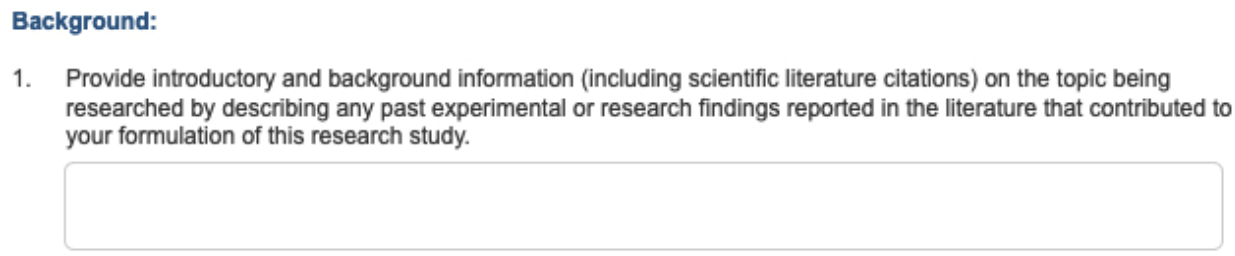
- ☐ Faculty Research
- ☐ Staff Research
- ☐ Student Research **(Check one below)**
  - ☐ Undergraduate project or paper
  - ☐ Graduate student project or paper
  - ☐ Master's Thesis
  - ☐ Dissertation
  - ☐ Other: Specify:

The following four categories are only applicable to Not Research/Not Human Subjects/ Not Engaged

- ☐ Classroom based activity (not research)
- ☐ Other non-research activity
- ☐ Not Human Subjects Activity
- ☐ Not engaged in human subjects research

The next tab is the Background tab (See **Figure 32**). Here you would enter some information that provides the IRB with the necessary information to understand the background or foundation of your research. You can provide literature citations in this section. When this section is complete, select 'next'.

Figure 32: Background information for not research protocols

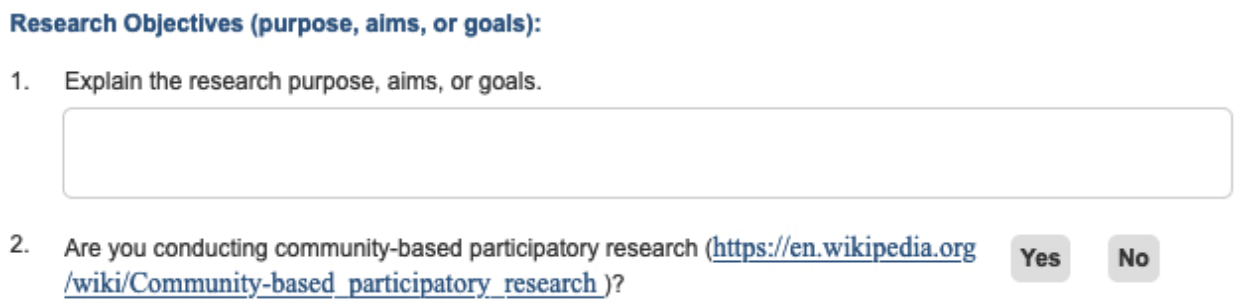


Background:

1. Provide introductory and background information (including scientific literature citations) on the topic being researched by describing any past experimental or research findings reported in the literature that contributed to your formulation of this research study.

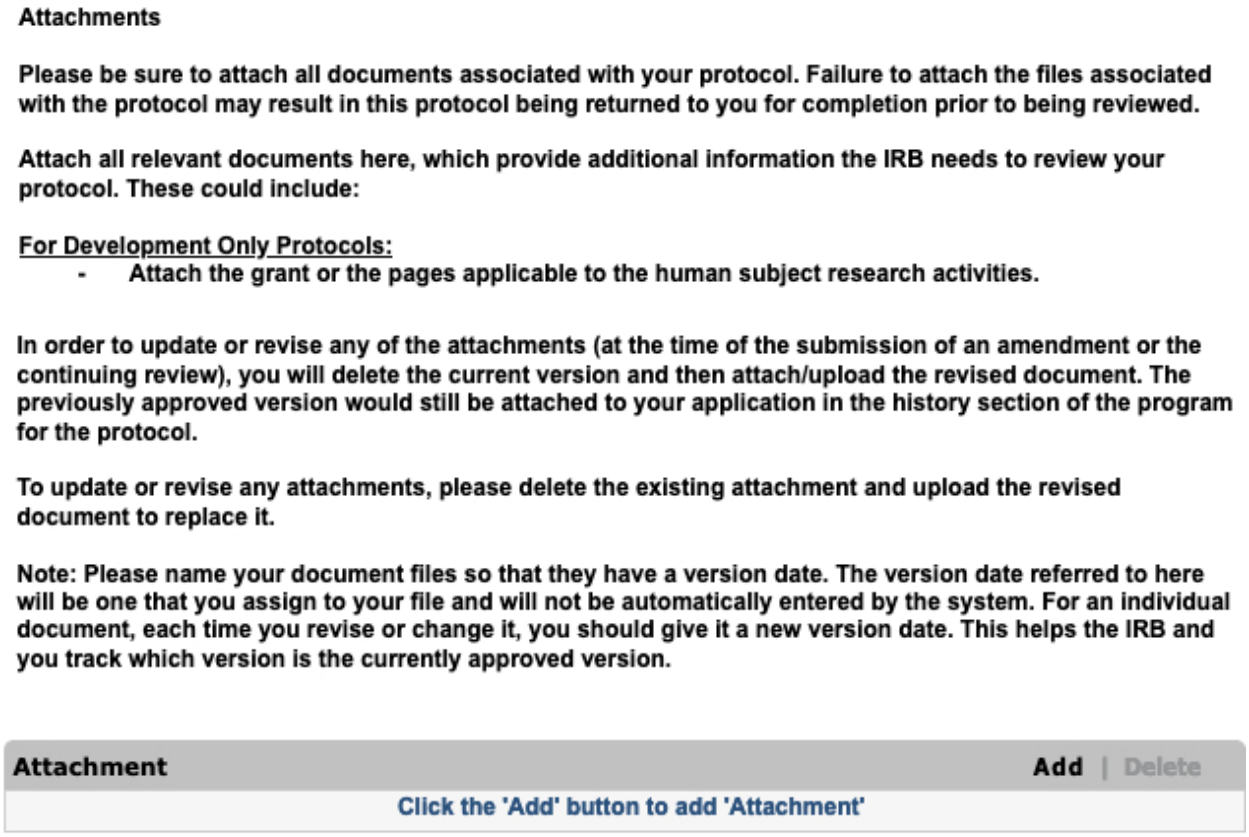
The next tab is the Research Objectives (purpose, aims, or goals) tab (See **Figure 33**). On this tab, you will provide the objectives. In addition, there is a question related to whether this project is community-based participatory research protocol. When this tab is complete select 'Next'.

Figure 33: Inputting research objectives for a not research protocol



The next page is the Attachments page (See **Figure 34**). On this page, there are general instructions for the type of attachments that may be needed for various types of submissions. For Not Research/Not Human Subject/Not Engaged activities, you might have no attachments or you might have a letter or grant to attach. You may attach any type of document that you feel might help the IRB understand your activity and make the requested determination. Once this page is completed, select 'Next'.

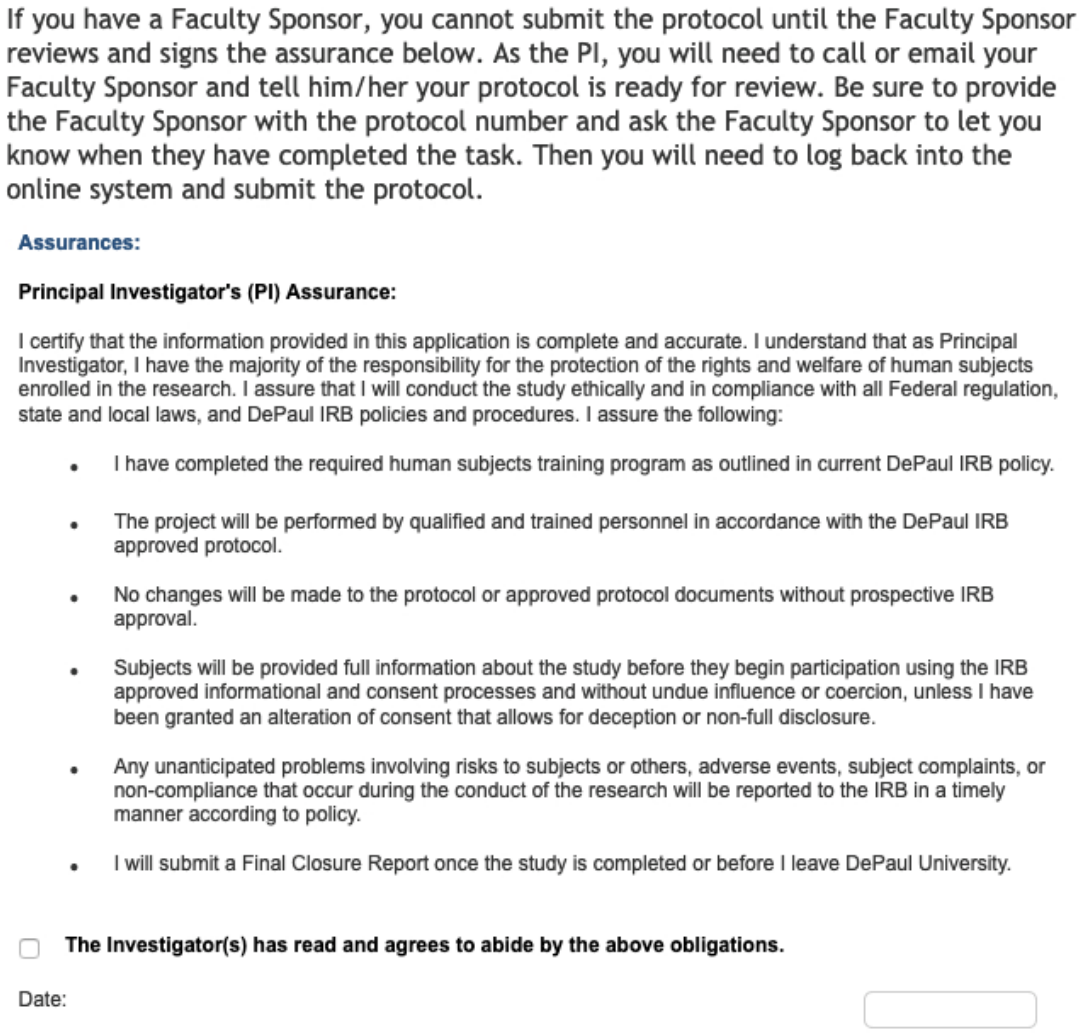
Figure 34: Attach documents for not research protocol



The next tab is the Assurance tab (See **Figure 35**). On this page, if you are the PI, you select the check box that you agree with the assurance statements. If you are a student PI, select the box and save the protocol. You will then, need to email your Faculty Sponsor who will need to log in as themselves and

check the box for agreement with the assurance statements and then email you that they have completed that task. You will then be able to log back into the system and click 'Next'.

Figure 35: Complete assurance page for not research protocols



If you have a Faculty Sponsor, you cannot submit the protocol until the Faculty Sponsor reviews and signs the assurance below. As the PI, you will need to call or email your Faculty Sponsor and tell him/her your protocol is ready for review. Be sure to provide the Faculty Sponsor with the protocol number and ask the Faculty Sponsor to let you know when they have completed the task. Then you will need to log back into the online system and submit the protocol.

Assurances:

Principal Investigator's (PI) Assurance:

I certify that the information provided in this application is complete and accurate. I understand that as Principal Investigator, I have the majority of the responsibility for the protection of the rights and welfare of human subjects enrolled in the research. I assure that I will conduct the study ethically and in compliance with all Federal regulation, state and local laws, and DePaul IRB policies and procedures. I assure the following:

- I have completed the required human subjects training program as outlined in current DePaul IRB policy.
- The project will be performed by qualified and trained personnel in accordance with the DePaul IRB approved protocol.
- No changes will be made to the protocol or approved protocol documents without prospective IRB approval.
- Subjects will be provided full information about the study before they begin participation using the IRB approved informational and consent processes and without undue influence or coercion, unless I have been granted an alteration of consent that allows for deception or non-full disclosure.
- Any unanticipated problems involving risks to subjects or others, adverse events, subject complaints, or non-compliance that occur during the conduct of the research will be reported to the IRB in a timely manner according to policy.
- I will submit a Final Closure Report once the study is completed or before I leave DePaul University.

☐ **The Investigator(s) has read and agrees to abide by the above obligations.**

Date:

By clicking agree here and moving to the next page, you are providing your electronic signature which indicates that all information provided is accurate and complete. When you click next, the system will check the form for completeness. If you missed some required areas, the system will tell you. If the system says the form is complete you then close the pop-up window and then click on the submit form tab on the left navigation bar.

Faculty Sponsor's Assurance for Student, staff position functioning as a training position or fellow, such as a research fellow:

By my signature as faculty sponsor on this research application, I certify that the student, staff member in a training position, or fellow is knowledgeable about the regulations and policies governing research with human subjects and has sufficient training to conduct this particular study in accordance with the approved protocol. In my role as faculty sponsor, I assure the following:

- I acknowledge that I have the ultimate responsibility for the legal and ethical performance of the project and ensuring that all duties of the Principal Investigator are fulfilled.
- I have completed the required human subjects training program as outlined in current DePaul IRB policy.
- I have read the research application and supporting materials and approved them for submission to the IRB.
- As the faculty mentor for this student on this project, I agree to meet with the student, staff member in training, or fellow investigator on a regular basis to monitor and assist them with conducting the research.
- I agree to be available, personally, to supervise and assist the investigator in the event problems arise during the conduct of the study.
- I ensure that the investigator will promptly report any unanticipated problems involving risks to subjects or others, adverse events, subject complaints, or non-compliance that occur during the conduct of the research in a timely manner and in accordance with IRB policy and procedures.
- **I will ensure that a Final Study Closure Report will be submitted to the IRB when the research is completed or before the investigator leaves the university. If the student or staff member does not submit the final report, I am responsible for doing so on their behalf.**
- If I am unavailable for an extended period of time, such as when on sabbatical or leave, I will arrange for an alternate faculty sponsor to assume my responsibilities during my absence and the DePaul IRB will be informed of the change via an amendment.

*The faculty sponsor must be a member of the DePaul faculty (full time, part time, or adjunct). The faculty sponsor is considered the party ultimately responsible for the legal and ethical performance of the project and ensuring that all duties of the Principal Investigator are fulfilled.

☐ **The Faculty(s) has read and agrees to abide by the above obligations.**

Date:

Then, the system will conduct a completeness check automatically (See **Figure 36**). If there is any portion of the form that is required, but which you have not completed, a pop up window will show you what portions of the form still need to be completed before you can submit the protocol.

Figure 36: Completeness check pop up window

Protocol ID: IRB2020-255	**Principal Investigator:** Neil Vincent
IRB Form	
S.No.	**Resolution**
1	Background - Complete Background Section. Specify N/A as appropriate.
2	Research Objectives - Complete Research Objectives Section. Specify N/A as appropriate.
3	Assurances - Please select the checkbox certifying that PI abides by the obligations.

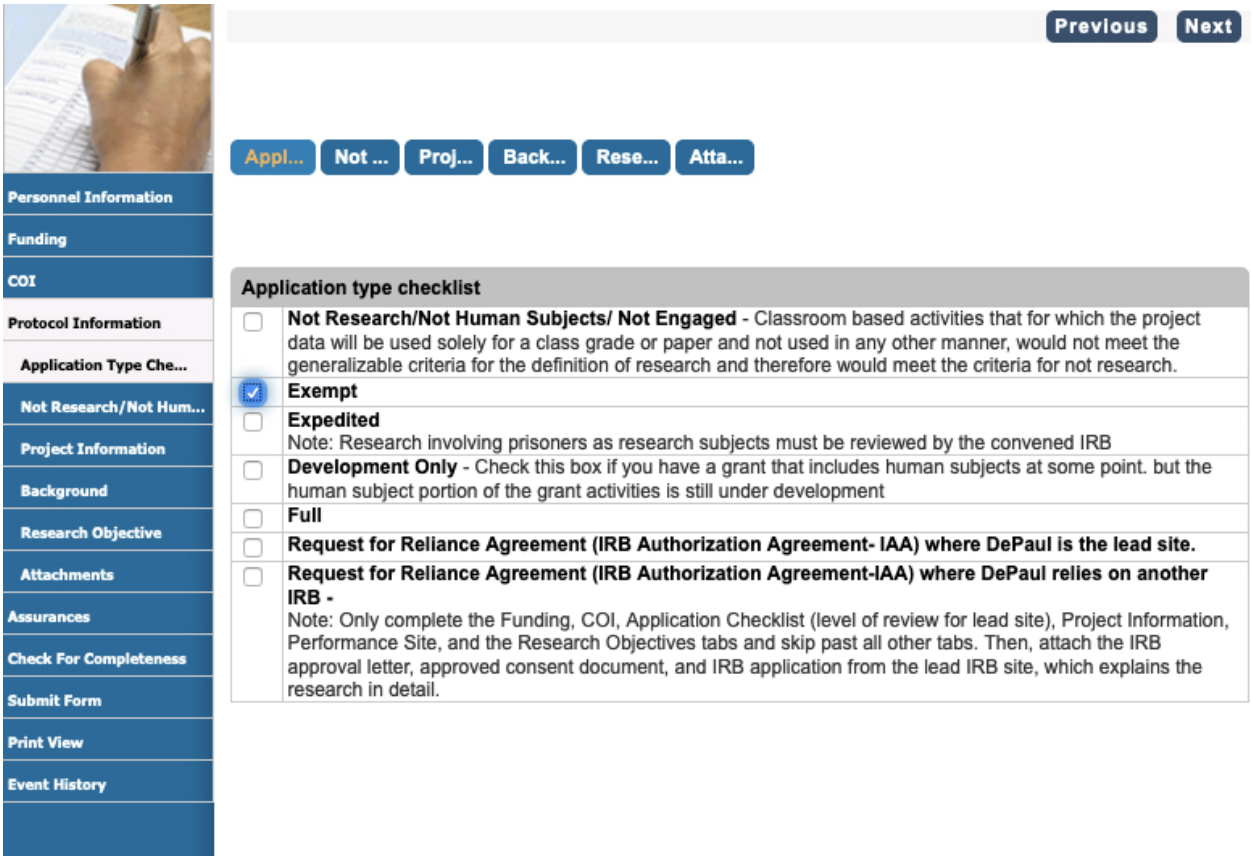
Once the form is complete, you would select Submit Form from the left navigation bar. A pop up will ask you if you really want to submit the protocol. Select yes, if you are ready to do so. Please note that

once you submit the protocol, you cannot go back and edit it further. When you close out of the protocol, you should see that the status of the protocol is noted as submitted on the investigator home page. You would then wait for any comments or feedback from the IRB/ORS.

4.6 Exempt Protocol Submission

After creating the protocol as noted above in section 3, complete the personnel, funding and COI pages as noted above. The next set of information is under the Protocol Information tab on the left navigation bar, which is broken down into the subtabs or pages of the exempt online form. On the Application Type Checklist Page, you will select Exempt (See **Figure 37**) and then select 'Next'.

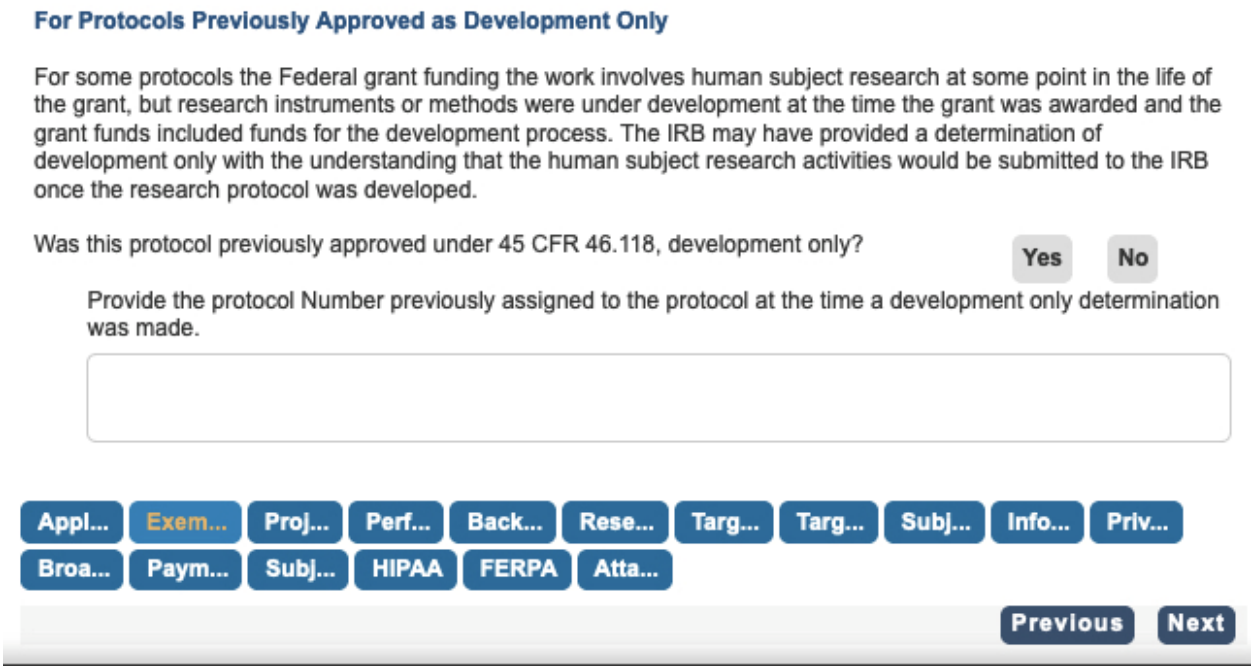
Figure 37: Selecting exempt category



You will then see the Exempt categories page. You would check which exempt categories apply to your research. Your research may meet the criteria for more than one exempt category, although the majority of the work conducted at DePaul is exempt category 1, 2 or 3. If you need assistance determining the categories, refer to the information on the ORS website for levels of review and the link to the Office for Human Research Protections (OHRP) decision charts. At the bottom of the page, there

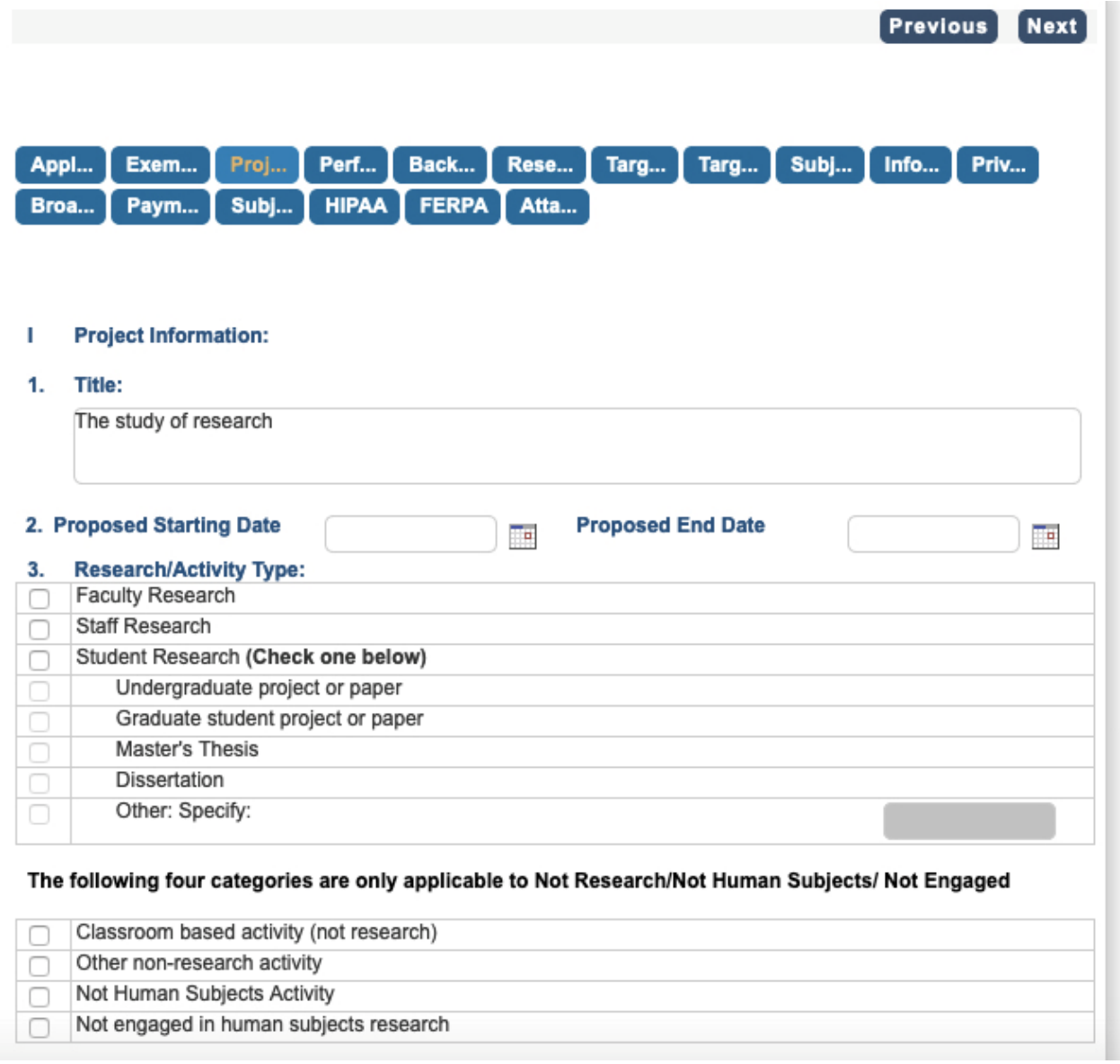
is a question about whether this study was previously approved under development only. For most people the correct response to this question is no. A few rare protocols with Federal funding may have been approved previously under development only and before the human subject activities were developed or ready for review. After you have selected all applicable exempt categories and responded to the question about development only, select 'Next'. (See **Figure 38**)

Figure 38: Development only protocol designation



The next page is the Project Information (See **Figure 39**) tab/page. On this page, you would enter in the proposed start and stop date and information about the type of project this is. The title will transfer for you from the initial creation page. At the bottom of the page, there are items to select that only apply if the overall protocol is being submitted for not research/not human subjects/not engaged. For an exempt protocol, you would not complete this section. When the information is complete, select 'Next'.

Figure 39: Exempt protocol information page



The next tab/page is the performance site page. There is informational text to explain the difference between an engaged and non-engaged performance site. You should respond to the questions and any IRB approval letters for collaborating sites, letters of support, or letters of collaboration related to these performance sites should be attached on the Attachments page at the end of the form. When the page is completed, select 'Next'.

The next tab/page is the background page. Here you would enter information about the background for the research, including any literature citations, which will aid the IRB in understanding why the research is important and the scientific foundations of the research. When this section is completed, select 'Next'.

The next tab/page is the objectives page. Here you would detail the purpose/aims/objectives of your research. Once that explanation is complete, select 'Next'.

The next tab/page is the Target Study Population Questions page. On this page, you will enter information about the total number of subjects (a definitive number that cannot be exceeded without additional approval) for which you want approval and the gender break down (an estimate which helps the IRB ensure that subject selection is equitable). You then provide information about the age ranges and the inclusion/exclusion criteria. When the information is complete, select 'Next'.

The next tab/page is the Study Population Checklist page. On this page, you will indicate if you are targeting vulnerable populations for recruitment, which might require additional procedures in your protocol and additional considerations by the IRB for concerns such as coercion or undue influence or as required by regulations and guidance for vulnerable populations. If the research does not involve vulnerable populations, do not select anything. Next, you are asked to provide a detailed and complete summary of your research plan. There are bullet points for the information the IRB requires. In general, more information is better than too little. The IRB needs to understand what you are doing, how you are doing it, what type of information is gathered, and how it is gathered from or about the subjects. When the summary is complete, select 'next'.

The next tab/page is Subject Recruitment. On this page, first indicate yes or no to recruitment materials. Almost all studies utilize recruitment materials or some sort. When you select yes, a checklist will pop up with the common forms of recruitment materials. Indicate which ones will be utilized for your study. Then, you are asked to provide a summary of the recruitment process, being sure to indicate how each type of recruitment item noted in item 1 will be used and when it will be used during the recruitment process. For example, if you will send the initial recruitment email followed by follow up emails, indicate how many follow up emails will be sent and how long after the initial email they will be sent. When the recruitment information is complete, select 'Next'.

The next tab/page is the Information Sheet process. You are asked to provide a detailed description of how and when the exempt information sheet text is provided to the subject. For example, is it via email, a combined as a recruitment item/information sheet in an email, on paper, online before a survey, before a study meeting, at the study meeting, will you review the information with them, etc. When this item is completed, select 'Next'.

The next tab/page is the Privacy and Confidentiality page. On this page, you will be asked about how the privacy of the subject is protected during the initial identification/recruitment process and how the confidentiality of the data is protected from others outside of the research. This information is particularly important under the revised regulations as for some exempt research, the IRB must conduct a Limited IRB Review and make the determination that the Privacy and Confidentiality provisions are appropriate to the research protocol. The IRB cannot make this determination unless we obtain enough information about these processes. When the information is complete, select 'Next'.

The next tab/page is about Broad Consent. Broad Consent will only apply to very specific research studies under categories 7 or 8. Most of the time NA will be selected for both items on this page. Select 'Next'.

The next tab/page is Payment, Compensation, and Reimbursement. On this page, if applicable, you will detail the plan for providing incentives to the subjects, including any incentives paid for by the PI from their own money. If there is more than one step in the research for the subject to complete, you must prorate payment (pay them for the steps they completed). You cannot withhold payment until all tasks are completed, which might coerce subjects to stay in the research when they want to withdraw. This would be counter to the voluntary nature of research. When the payment section is completed, select 'Next'.

The next tab/page is the Subject Complaints, Unanticipated Problems Involving Risks to Subjects or Others (UPIRSOs), Non-Compliance, and Adverse Events page. When conducting research, unanticipated issues happen all the time. The IRB just wants to be sure you have a plan to deal with them that is compliant with current policy. When completed, select 'Next'.

The next tab/page is the HIPAA page. If your research involves the collection and use of private health information (PHI), then you would provide information about the procedures you have in place to be compliant with the HIPAA regulations. Then, select 'Next'.

The next tab/page is the FERPA page. If your research involves the collection and use of private and identifiable information from school records, then you should complete this page and describe how you will be compliant with the FERPA regulations. The most important thing to keep in mind is that just because you have access to student records or materials as an instructor (a legitimate educational use), it does not mean you can access and use those records for your research without written approval from the student, because research is not a legitimate educational use. For example, students records, assignments and grades in D2L and rosters are FERPA protected. You cannot use the roster to send recruitment materials to students and you cannot farm the assignments stored in D2L for your research. When completed, select 'Next'.

The final tab/page of the application is the Attachments page (See **Figure 40**). This page is used to attach any supporting documents related to any of the preceding tabs or any documents that in any way supports your application. The instructions provide a list of possible attachments for each type of protocol. On this page, you select 'add' in the table and add each document separately. **Each document should be named as to what it is and provided with a version date on your computer file.** You will select a type of document from the pull down list in the table and then attach your document.

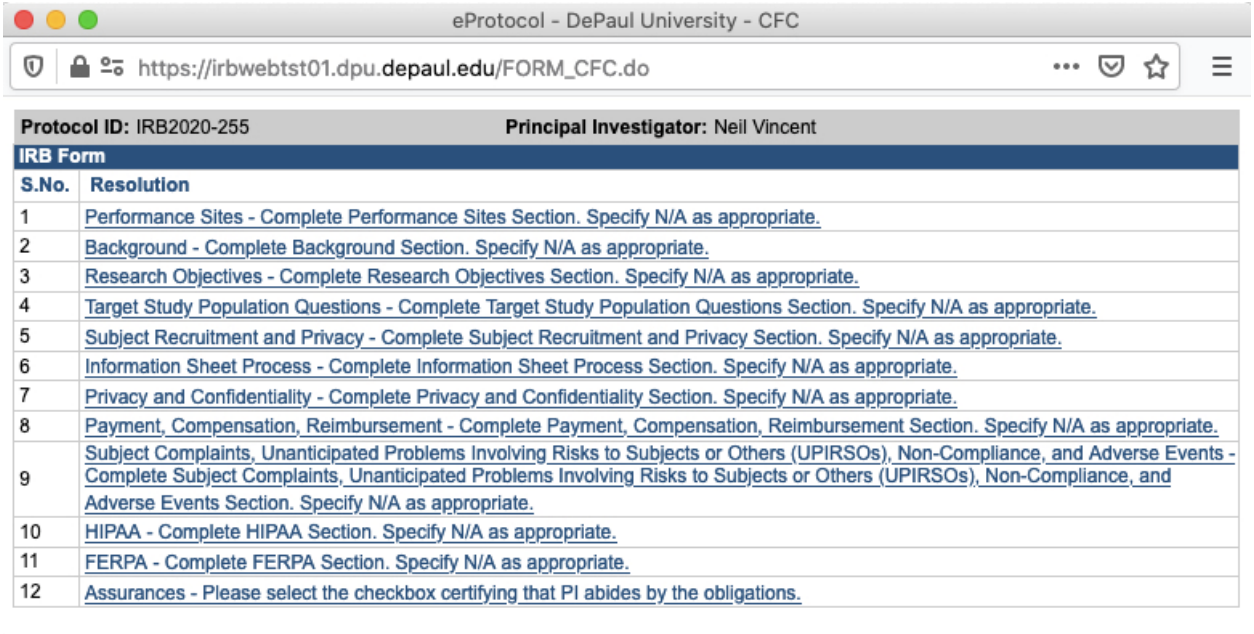
Figure 40: Attachment page

Later, if the IRB asks for revisions or you update documents later via an amendment, you would delete the old document and attach the new document with a new version date in the file name. The system will save the historical documents in the Event History tab, but the protocol itself would contain only the currently approved versions of documents. Once all documents are attached, select 'Next'.

The next tab/page is the Assurance page. On this page, if you are the PI, you select the check box that you agree with the assurance statements. If you are a student PI, select the box and save the protocol. You will then, need to email your Faculty Sponsor who will need to log in as themselves and check the box for agreement with the assurance statements and then email you that they have completed that task. You will then be able to log back into the system and click 'Next'.

Then, the system will conduct a completeness check automatically. If there is any portion of the form that is required, but which you have not completed, a pop up window (See **Figure 41**) will show you what portions of the form still need to be completed before you can submit the protocol.

Figure 41: Completeness check pop up window



Protocol ID: IRB2020-255 **Principal Investigator:** Neil Vincent

IRB Form

S.No.	Resolution
1	Performance Sites - Complete Performance Sites Section. Specify N/A as appropriate.
2	Background - Complete Background Section. Specify N/A as appropriate.
3	Research Objectives - Complete Research Objectives Section. Specify N/A as appropriate.
4	Target Study Population Questions - Complete Target Study Population Questions Section. Specify N/A as appropriate.
5	Subject Recruitment and Privacy - Complete Subject Recruitment and Privacy Section. Specify N/A as appropriate.
6	Information Sheet Process - Complete Information Sheet Process Section. Specify N/A as appropriate.
7	Privacy and Confidentiality - Complete Privacy and Confidentiality Section. Specify N/A as appropriate.
8	Payment, Compensation, Reimbursement - Complete Payment, Compensation, Reimbursement Section. Specify N/A as appropriate.
9	Subject Complaints, Unanticipated Problems Involving Risks to Subjects or Others (UPIRSOs), Non-Compliance, and Adverse Events - Complete Subject Complaints, Unanticipated Problems Involving Risks to Subjects or Others (UPIRSOs), Non-Compliance, and Adverse Events Section. Specify N/A as appropriate.
10	HIPAA - Complete HIPAA Section. Specify N/A as appropriate.
11	FERPA - Complete FERPA Section. Specify N/A as appropriate.
12	Assurances - Please select the checkbox certifying that PI abides by the obligations.

Once the form is complete, you would select Submit Form from the left navigation bar. A pop up will ask you if you really want to submit the protocol. Select yes, if you are ready to do so. When you close out of the protocol, you should see that the status of the protocol is noted as submitted on the investigator home page. You would then wait for any comments or feedback from the IRB/ORS.

4.7 Expedited Application Submission

After creating the protocol as noted above in section 3, complete the personnel, funding and COI pages as noted above. The first section you will need to complete is the Personnel Information page. You will have completed the Principal Investigator (PI) information in order to create the protocol.

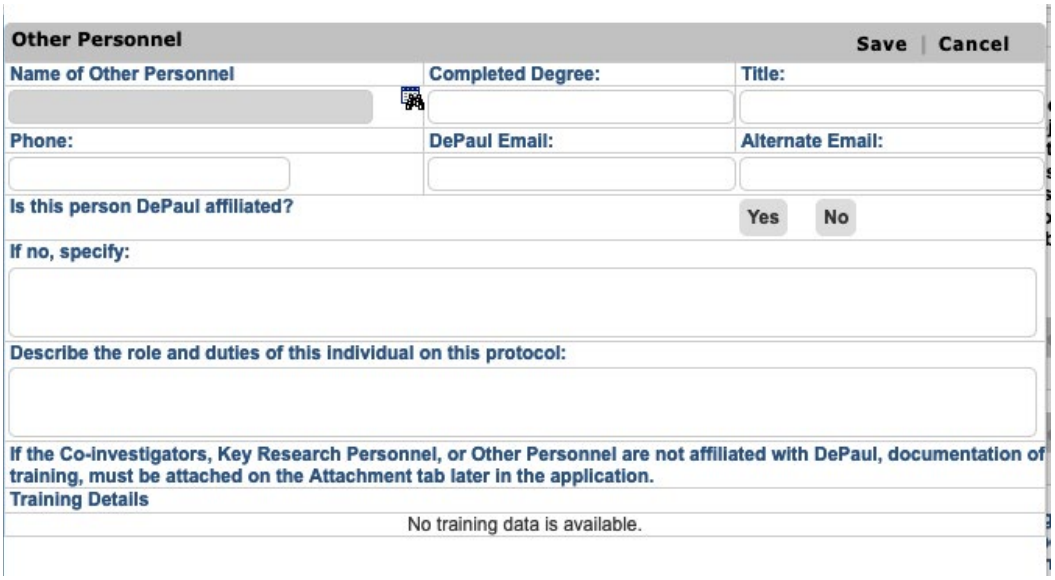
If you are an undergraduate student or graduate student as selected in Status drop down list, you must have a Faculty Sponsor when you are the Principal Investigator. You will complete the Faculty Sponsor section in a similar fashion to the PI section. If you cannot find your Faculty Sponsor through the search function contact ORS at ORP@depaul.edu for assistance.

Next, you would add any DePaul co-investigators to the protocol using the search function and manually completing any information that does not download automatically. If you have other Key Research Personnel, you will add them in a similar fashion.

Again, the CITI training should automatically download into the system for your Faculty Sponsor, Co-Investigators, and Key Research Personnel. If you do not see the CITI training downloaded into the system, you will need to double check with the individual whether their human subject training is current and that 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.

The final personnel field is called 'Other Personnel'. (See **Figure 42**) This section is for adding personnel who are not affiliated with DePaul, who do not require access to the system, and who do not have a DePaul user ID. The process will work similar, except that when you see the pop up after clicking 'Add', you will see a link to click on that allows you to add someone manually. For these persons, you will need to attach the external training documents in the Attachment tab, since ORS will not be able to access their training information directly.

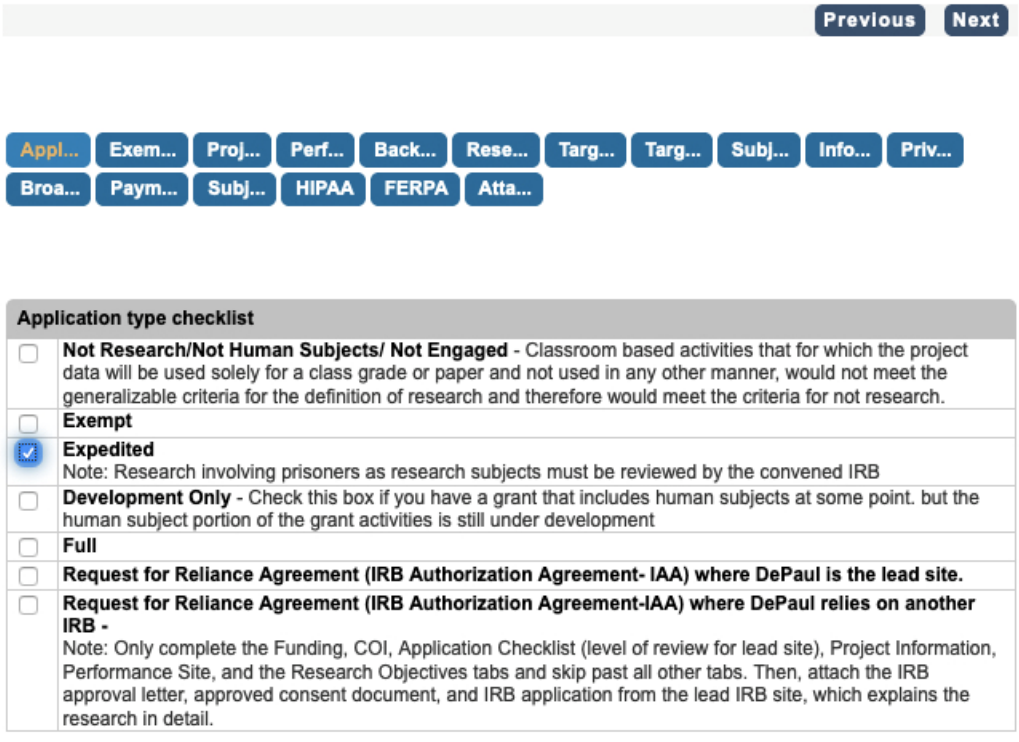
Figure 42: Adding other research personnel



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

The next set of information is under the Protocol Information tab on the left navigation bar, which is broken down into the subtabs or pages of the expedited online form. The first page is the Application Type Checklist. On this page, you will select Expedited. (See **Figure 43**)

Figure 43: Selecting expedited protocol category



If you are requesting an IRB Reliance Agreement, you would select the appropriate box either Request an IRB Reliance Agreement where DePaul is the lead site (Must choose exempt, expedited, or full when choosing this choice), or Request for an IRB Reliance Agreement where DePaul relies on another IRB (Must choose the level of review the study was approved at the lead site and attach supporting documentation). Then select, 'Next'.

The next tab/page is the expedited categories page. On this page, you would provide the rationale for why the research meets the criteria for minimal risk and then select the expedited categories that apply to your research. Keep in mind that more than one category may apply to your research. At the bottom of the page, there is a question about whether this study was previously approved under development only. (See **Figure 38 above**) For most protocols the correct response to this question is no. A few rare protocols with Federal funding may have been approved previously under development only and before the human subject activities were developed or ready for review. After you have selected all applicable expedited categories and responded to the question about development only, select 'Next'.

The next page is the Project Information tab/page. On this page, you would enter the proposed start and stop date and information about the type of project this is. The title will transfer for you from the initial creation page. At the bottom of the page, there are items to select that only apply if the overall protocol is being submitted for not research/not human subjects/not engaged. For an expedited protocol, you would not complete this section (See **Figure 39 above**). When the information is complete, select 'Next'.

The next tab/page is the Performance Site page. There is informational text to explain the difference between an engaged and non-engaged performance site. You should respond to the questions and any IRB approval letters for collaborating sites, letters of support, or letters of collaboration related to these performance sites should be attached on the Attachments page at the end of the form. When the page is completed, select 'Next'.

The next tab/page is the background page. Here you would enter information about the background for the research, including any literature citations, which will aid the IRB in understanding why the research is important and the scientific foundations of the research. When this section is completed, select 'Next'.

The next tab/page is the Objectives page. Here you would detail the purpose/aims/objectives of your research. In addition, there is a question about community-based participatory research. Once the questions are completed, select 'Next'.

The next tab/page is the Target Study Population Questions page. On this page, you will enter information about the total number of subjects (a definitive number that cannot be exceeded without additional approval) for which you want approval and the gender break down (an estimate which helps the IRB ensure that subject selection is equitable). You then provide information about the age ranges,

the inclusion/exclusion criteria, and the subject selection process. When the information is complete, select 'Next'.

The next tab/page is the Study Population Checklist page. On this page, you will indicate if you are targeting vulnerable populations for recruitment, which might require additional procedures in your protocol and additional considerations by the IRB for concerns such as coercion or undue influence or as required by regulations and guidance for vulnerable populations. If the research does not involve vulnerable populations, do not select anything. For some of the types of vulnerable populations (e.g., prisoners, children), additional questions will pop up for you to answer. Keep in mind that research targeting prisoners as subjects cannot be reviewed under expedited review. Once you complete this page, select 'Next'.

The next tab/page is the Subject Recruitment and Privacy Page. The concept of privacy is related to how you initially identify and contact the research subject during the recruitment process, so it is directly linked to your recruitment process as described on this page. You will be asked whether you are using recruitment materials. Most research protocols utilize some type of recruitment material. When you check yes, a check list of common types of recruitment materials will pop up. Complete the checklist. Then, you are asked to provide a summary of the recruitment process, being sure to indicate how each type of recruitment document/type noted in item 1 will be used and when it will be used during the recruitment process. For example, if you will send the initial recruitment email followed by follow up emails, indicate how many follow up emails will be sent and how long after the initial email they will be sent. Then, you are asked about the use of private records and who will be conducting the recruitment process. When the recruitment information is complete, select 'Next'

The next tab/page is the Informed Consent Process. The informed consent process includes the parent/legal guardian permission and assent processes. On this page, you are asked for a summary of how these processes will work in the context of your research plan. Some bullet points outline the type of information the IRB needs to know to understand your plans and to assure the consent process is adequate and follows the regulatory requirements. You are asked whether you are requesting a waiver or alteration of consent or a waiver of documentation of consent. If these items are chosen, additional questions will pop up for you to answer. There is some help text provided in the help menu to assist you with explaining waivers and alterations. Yu can also see this text on the older paper forms still available on the web site for reference sake. Then, you will be asked about whether some or all of the subjects may speak English as a second language or be non-English speaking. Additional questions will pop up if you respond yes to these questions. Then, you will be asked about whether some or all of the subjects will be decisionally impaired. If you select yes, additional questions will pop up. All the questions help the IRB make sure the consent process is understandable to the subject or their legally authorized representative and the process follows all the regulatory requirements. Once all the questions have been completed, select 'Next'.

The next tab/page is the Research Summary/Plan of Work. On this page, you are asked to provide a detailed summary of the research plan, in a step-wise manner. There are bullet points listing the type of

information the IRB generally likes to receive. In general, more information is better than too little. When the summary is completed, select 'Next'.

The next tab/page is Resources. Provide a description of any special resources utilized during the research. Sometimes utilizing a resource, like space or equipment, requires some type of approval and you should note you have the approval in place. When the information is completed, select 'Next'.

The next tab/page is Potential Risks. On this page, you are asked to complete the risk checklist and then describe the potential risks and the protections you have put in place to minimize each risk noted. Keep in mind that if the research involves different groups of subjects who may be asked to complete differing tasks, the risks to the individual groups of subjects may differ. Therefore, the risks should be discussed for each target population group. Each risk noted, should have a plan in place to minimize the risk. Any risks mentioned here in the application should be noted in the consent document. Once the questions are completed, select 'Next'.

The next tab/page is Potential Benefits. On this page you will be asked to indicate if there are any direct benefits (to the individual subject- rare for social behavioral and educational research) or indirect benefits (usually the type of benefit for social behavioral or educational research and related to the knowledge gained for a field of study for future people and not the current subjects). There needs to be a benefit to the research in order for the IRB to approve the research. Then, you will be asked to rationalize how the risks to the research are reasonable as related to the stated benefits. Generally speaking, the risks of the research need to be outweighed by the benefits. Once the questions are completed, select 'Next'.

The next tab/page is Available Alternatives. This page asks about alternative treatments, interventions, procedures, educational programs, or therapies that might be available to subjects who choose not to participate in the research, and is for protocols that involve some kind of treatment or intervention. If this does not apply to your research, select NA. Keep in mind that if there are alternative treatments, educational programs, or therapy available outside of the research as part of standard of care, then the consent document must include an alternative section and explain the options clearly to the subject. Usually this means stating, "You can have this treatment (therapy, educational program) outside of the research by…." Once the question is completed, select 'Next'.

The next tab/page is the Confidentiality page. This page asks several questions about how the data is kept confidential after it is collected. Protecting the data properly relates to the potential risks of the research, but also is a separate IRB approval criterion under the regulations. The consent document confidentiality section should agree with this section of the application as to what protections are in place or what the limitations to confidentiality are so that the subject is truly informed. Once the questions are completed, select 'Next'.

The next tab/page is the Payment, Compensation and Reimbursement page. On this page, if applicable, you will detail the plan for providing incentives to the subjects, including any incentives paid for by the

PI from their own money. Keep in mind that if the subjects are asked to complete more than one task, the payment must be prorated. You cannot withhold payment until they complete all the study tasks, as that would be considered coercive and might prevent someone from withdrawing from the research when they want to do so. This would be counter to the voluntary nature of the research. Once this section is completed, select 'Next'.

The next tab/page is Costs to Subjects page. On this page, you are asked to describe any costs that the subject might incur because they participated in the research. Costs might be travel expenses, babysitting expenses, or program expenses. Any costs to the subjects must be clearly noted in the consent document and you would need to be clear as to whether the subject is responsible for the cost and whether you will be covering any of the costs. Once the questions are completed, select 'Next'.

The next tab/page is Data and Safety Monitoring page. On this page, you are asked to provide information about your data and safety monitoring plan, which is required for some Federally funded research. Then, if you have a Data and Safety Monitoring Board –DSMB (required for some clinical trials), you are asked to provide information about how the board will function. Most research at DePaul will not have a DSMB. Finally, you are asked if you will obtain a Certificate of Confidentiality (COC). The IRB needs to know this because if this is the case, very specific language needs to be in the consent document as required by NIH or the funding agency issuing the certificate. For a COC, IRB approval must be granted before the application for the certificate is submitted and then approved by the funding agency or issuing agency. Once the questions are completed, select 'Next'.

The next tab/page is the Subject Complaints, Unanticipated Problems Involving Risks to Subjects or Others (UPIRSOs), Non-Compliance, and Adverse Events page. When conducting research, unanticipated issues happen all the time The IRB just wants to be sure you have a plan to deal with them that is compliant with current policy. When completed, select 'Next'.

The next tab/page is the HIPAA page. If your research involves the collection and use of private health information (PHI), then you would provide information about the procedures you have in place to be compliant with the HIPAA regulations. Then, select 'Next'.

The next tab/page is the FERPA page. If your research involves the collection and use of private and identifiable information from school records, then you should complete this page and describe how you will be compliant with the FERPA regulations. The most important thing to keep in mind is that just because you have access to student records or materials as an instructor (a legitimate educational use), it does not mean you can access and use those records for your research without written approval from the student, because research is not a legitimate educational use. For example, students records, assignments and grades in D2L and rosters are FERPA protected. You cannot use the roster to send recruitment materials to students and you cannot farm the assignments stored in D2L for your research. When completed, select 'Next'.

The final tab/page of the application is the Attachments page. This page is used to attach any supporting documents related to any of the preceding tabs or any documents that in any way support your application, such as consent documents, recruitment materials, data collections tools, interview scripts, focus group scripts, etc. The instructions provide a list of possible attachments for each type of protocol. On this page. You select 'add' in the table and add each document separately. **Each document should be named as to what it is and provided with a version date on your computer file**. You will select a type of document from the pull down list in the table and then attach your document (See **Figure 40 above**). Later, if the IRB asks for revisions or you update documents later via an amendment, you would delete the old document and attach the new document with a new version date in the file name. The system will save the historical documents in the event history tab, but the protocol itself would contain only the currently approved versions of documents. Once all documents are attached, select 'Next'.

The next tab/page is the Assurance page. On this page, if you are the PI, you select the check box that you agree with the assurance statements. If you are a student PI, select the box and save the protocol. You will then, need to email your Faculty Sponsor who will need to log in as themselves and check the box for agreement with the assurance statements and then email you that they have completed that task. You will then be able to log back into the system and click 'Next'.

Then, the system will conduct a completeness check automatically. If there is any portion of the form that is required, but which you have not completed, a pop up window (See **Figure 41 above**) will show you what portions of the form still need to be completed before you can submit the protocol.

Once the form is complete, you would select Submit Form from the left navigation bar. A pop up will ask you if you really want to submit the protocol. Keep in mind that once you submit a protocol, you cannot go back and add materials or edit it. Select yes, if you are ready to do so. When you close out of the protocol, you should see that the status of the protocol is noted as submitted on the investigator home page. You would then wait for any comments or feedback from the IRB/ORS.

4.8 Full Protocol Submission

Full protocols are very similar to expedited protocols, except you do not complete the page for expedited categories or rationalize how the study meets the criteria for minimal risks. The boxes for the categories will be greyed out. Therefore, you skip this page by selecting 'Next' and then complete the application as described for the expedited protocol.

4.9 Development Only

Development only protocols are for federally funded work on a grant that includes human subjects at some point in the life of the grant, but the human subject portion of the grant activities is still under development. In this case, we need some general information about the protocol and the funding agency. The process would be similar to submitting other protocol types described above, but with a much abbreviated number of tabs. The IRB needs enough information to say the human subject portion is not ready yet, but that human subject research activities will occur as part of the grant plan at some point. These types of approvals are provided with the understanding that once you are ready to conduct the human subject research activities, you will submit the appropriate protocol for IRB review.

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 without completing the mandatory fields (*), a PLC notification appears at the top of the page (See **Figure 44**).

Complete the mandatory fields in order to proceed.

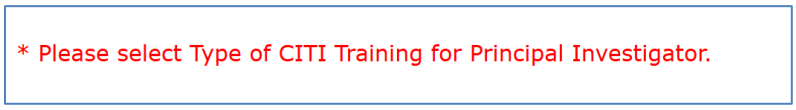


Figure 44: Page Level Check Notification

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 (See **Figure 45**).

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

IRB Form	
S.No.	Resolution
1	Summary - Complete the Section 1(a).
2	Purpose - Complete the Section 2(a) and 2(b).
3	Procedures - Complete Sections 3(a) through 3(f). Specify N/A as appropriate.
4	Background and additional procedures - Complete Section 4(a) through 4(f). Specify N/A as appropriate.
5	Subject Population - Complete Sections 5(a) through 5(f).Specify N/A as appropriate.
6	Subject Population - Complete Sections 5(g) through 5(j).Specify N/A as appropriate.
7	Recruitment Process - Complete Sections 6(a) through 6(c).Specify N/A as appropriate.
8	Subject Compensation and Costs - Select will subjects receive compensation for participation in Sections 7

Figure 45: Check for Completeness Messages

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 (See **Figure 46**).

Protocol ID: IRB-2018-00046-IRB	**Principal Investigator:**
IRB Form	
IRB Application Form is complete	

Figure 46: Check for Completeness Complete Notification

6 Responding to Comments

This section describes how to use eProtocol to respond to IRB 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 (See **Figure 47**).

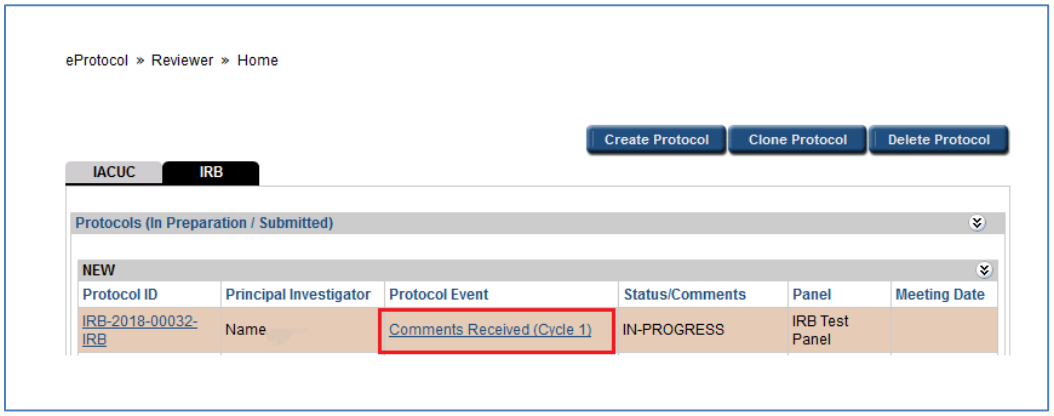


Figure 47: Protocol Event Status to view comments

The Comments page appears. Table 1 displays the information that is found on the Comments page. Refer to **Figure 48**'s reference numbers.

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

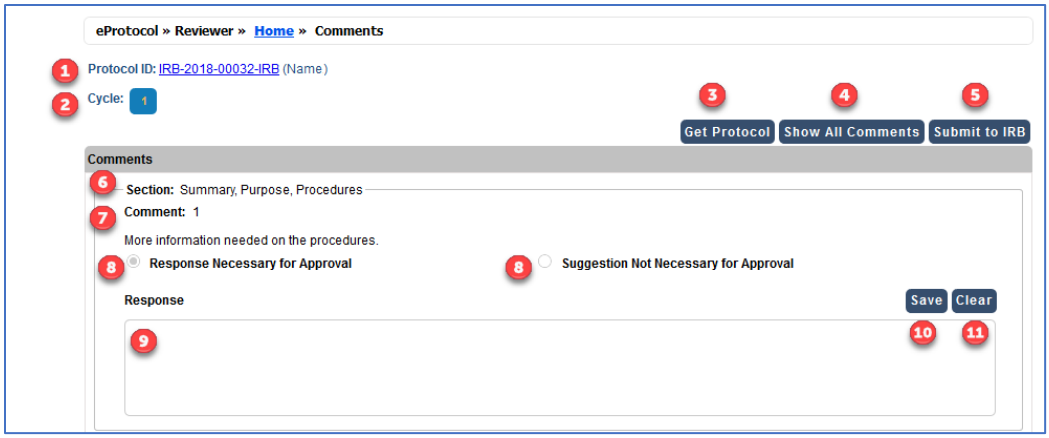


Figure 48: Comment page

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 IRB	This button submits your revised protocol and responses directly to the IRB committee. Once you submit your protocol and responses to the IRB committee, you cannot edit the protocol or responses. The different committee names that may appear on this button are IRB and 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.
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 all of 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 to the protocol when it is sent back to you. Therefore, it is very important that you do not submit a protocol until it is complete and you are ready to do so. When you get a protocol with the reviewer comment marked as **Response Necessary for Approval**, you must respond to the comment, and almost always make changes to the protocol application, where the topic is discussed, prior to resubmitting the protocol.

Note: *These processes are the same in all protocols. The screenshots in the following steps were taken in an IRB 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 (See **Figure 49**).

Figure 49: Get Protocol

3. Open the protocol in **Edit** mode (See **Figure 50**). If you open the protocol in **View** mode, you will not be able to make changes.

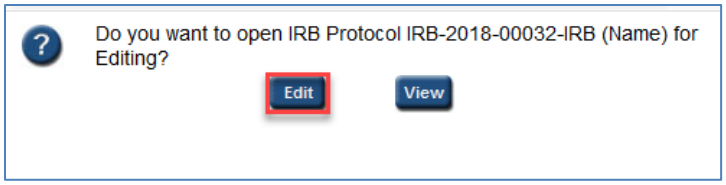


Figure 50: Edit a Protocol

4. Make the necessary changes in your protocol. Click **Save** (See **Figure 51**). **Your updates are not saved if you exit without saving them.** When you are finished, close the protocol.

Figure 51: Save Protocol Before Exiting

5. Select the text field and enter your responses. Click **Save** (See **Figure 52**).
    a. Once you save, you may exit the Comments page and continue later. Clicking **Save** will save all of your responses. You do not need to click save after each response, but it is a good idea.

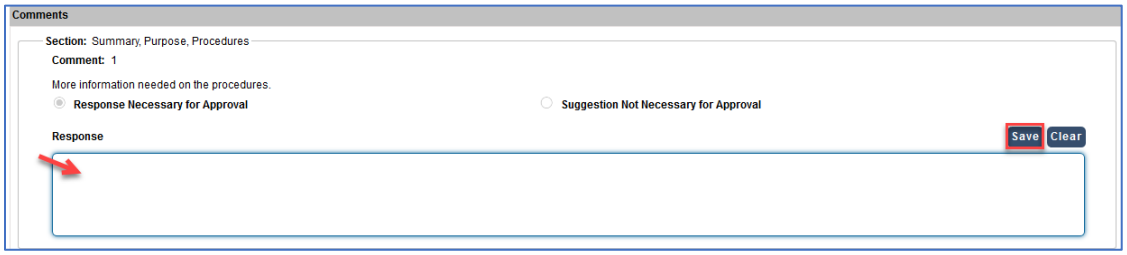


Figure 52: Add Responses and Save

6. When you have finished making edits to the protocol and have responded to all of the appropriate comments and have updated any attachments on the Attachment tab that need to be revised based upon the reviewer's comments, click **Submit to IRB** (See **Figure 53**).

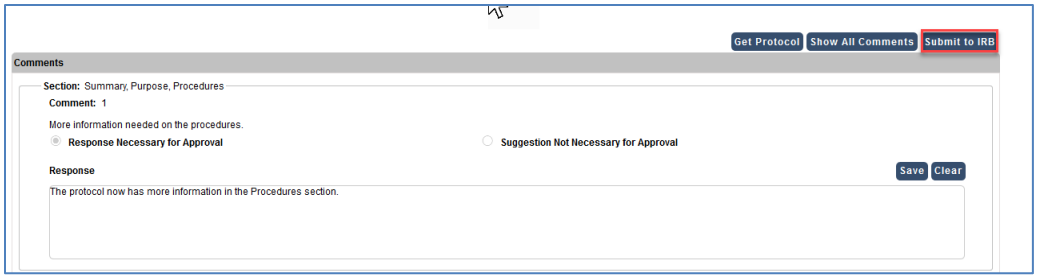


Figure 53: Submit Protocol to IRB

7. A resubmission confirmation pop-up appears. Once you resubmit your revised protocol and responses, you cannot edit them. Click **OK** to confirm (See **Figure 54**).

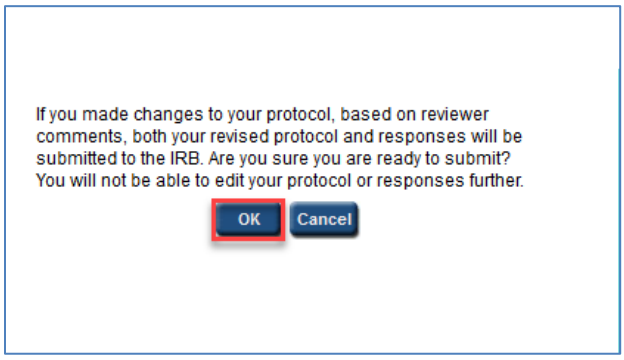


Figure 54: 4 Resubmission Confirmation

8. Once you resubmit your protocol, the Protocol Event changes to **Responses Sent (Cycle 1)** and the Status/Comments changes to **IN-PROGRESS** (See **Figure 55**).

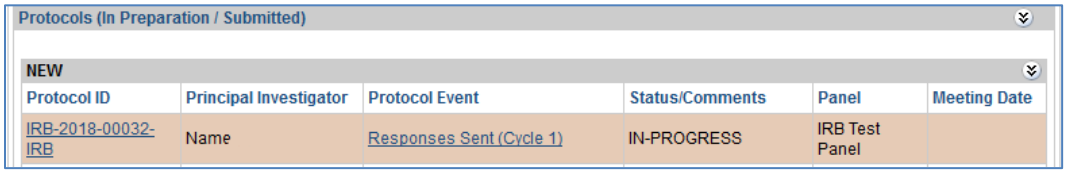


Figure 55: Responses Sent

9. Approval letters

When the protocol is approved, you will receive an email from the IRB that tells you to go into the system Event History to access the approval letter. The approved attachments will be noted in that window as well.

Each step of the protocol review process and later submissions of continuing review reports, amendments, or reportable events will be clearly noted in the Event History.

7 Submitting Amendments, Continuing Review Reports, Reportable Events and Final Reports

On the main Investigator page, scroll down to the approved protocol list. Click on the protocol number 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 open with the possible selections.

Select which type of submission you would like to create from the pull down list and then select OK. This will take you to the correct submission form. Since you are allowed to change personnel and other aspects of the protocol with a continuing review report and an amendment, and there can only be one version of the protocol itself in the process of being changed at a given time, you will only be able to submit on type of submission at a time. For this reason, we suggest thinking about your amendments carefully and combining as many changes as possible into one amendment. The only type of submission not directly linked to a form version is the Reportable Event Form. You may submit a Reportable Event Form at the same time as other types of submissions and you may submit multiple reportable events at the same time.

Once you complete the specific amendment or continuing review form information, you will be prompted to go into each tab of the protocol and update/change the information, as needed, to reflect the amendment changes or any changes introduced at the time of the continuing review (e.g., personnel changes). Once all changes have been made and saved, including deleting or adding new attachments (if applicable), you would submit the protocol submission. The review process and the process for responding to any IRB comments would be similar to an initial review.

8 Glossary

Administrative Contact

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

Adverse Event

Any untoward or unfavorable medical occurrence in a human subject, including any abnormal sign (for example, abnormal physical exam or laboratory finding), symptom, or disease, temporally associated with the subject's participation in the research, whether or not considered related to the subject's participation in the research.

- Adverse events may be physical or psychological harms. They occur most often in the context of biomedical research, but can occur in the context of social/behavioral/educational research.

Amendment

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

Assent Document

A form or script containing information to be conveyed to minor (17 years or younger) study participants about the study. If the study contains a broad range of minors, more than one assent form may be necessary, e.g., an assent form for a 17-year-old would not be appropriate for a 7-year-old.)

Assent Waiver

A request to waive a minor's assent.

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 will need to submit a Final Report Form for a study that is already approved and begun.

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. There are multiple committees, e.g., an IRB, IACUC, and 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.

Consent

An agreement from adult subjects (18 years or older) to participate in a study.

Continuing Review Report

A request from a PI to continue an approved study beyond the current approval period. A Continuing Review report is required under the revised regulations for research that is greater

than minimal risk and requires convened review or may be specifically requested for some expedited/minimal risk studies.

Cycle Number

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

D

E

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.

Exempt

A protocol that qualifies under federal regulations as exempt under the revised regulations, meaning it is human subject research that specifically meets one or more of the exempt criteria. Exempt studies are not exempt from review, but can be reviewed administratively depending upon the institution's written policy. At DePaul, all ORS staff members supporting the IRB are voting IRB members, so all exempt research is reviewed by the IRB.

Expedited Review

An expedited review is performed by a subset of the voting IRB committee members. The protocol must meet certain criteria to be eligible for an expedited review; involve minimal risk to the subjects and meet the criteria for one or more of the expedited categories.

Expiration Date

On the homepage, an approved protocol column that contains the date when a protocol will expire, if it has been given an approval period

F

Final Report Form

A type of form used to close the protocol and provide final updates to the IRB.

Full Board/ Full Board Review

A review type that a protocol may go through if it contains research that involves greater than minimal risk, sensitive topics, or some vulnerable populations (e.g., prisoners), or does not meet the criteria for one or more of the expedited categories, but involves minimal risk. In the latter case, the protocol must be reviewed by the full IRB and determined by the board to involve minimal risk and that it may be reviewed under expedited review at the time of continuing review under category 9 expedited review, if applicable

G

H

Help

A button that opens a window containing helpful information about the page you are currently on. The Help menu may take time to develop at DePaul, so help text may not be available for all pages.

I

Information Resources

A section on the homepage containing useful links or documents. This is populated by the ORS. 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 considerations.

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

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 IRB meeting.

N

Next

A navigation button inside the protocol 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.

Not Human Subjects Research

A study that does not include research, human subjects, or does not engage DePaul or DePaul faculty, staff or students in the activity.

Not Research/Not Human subjects/ Not Engaged

A protocol status when the protocol was found to be a not research, not involve human subjects, or not to engage DePaul or DePaul faculty, staff or students in the activity.

O

Other Personnel

Individuals who assist the PI and/or work with subjects, but who are not affiliated with DePaul and who do not need access to the eProtocol system (usually non-DePaul research team members).

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. The IRB is one panel and the IBC and IACUC are other panels.

Panel Manager

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

Portable Document Format

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

Pre-Review Process

The process where a protocol goes through an extra review, a pre-review, process before it can be submitted to a committee for formal review. This will be performed by a member of the ORS staff as a process that can clean up submission prior to committee review.

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

protocol. Furthermore, the PI is responsible for ensuring that the activities associated with the research study is conducted ethically and in compliance 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 just 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 lifetime.

Reportable Event Prompt Reporting Form

A submission from a PI informing the committee about any type of reportable event that needs to be reported to the IRB, such as:

- Unanticipated adverse events and Unanticipated Problems Involving Risks to Subjects or Others (UPIRSOs)
- New information that unexpectedly alters the risk or benefits to the research subjects
- Subject death
- Significant protocol deviations
- Significant protocol violations
- Serious adverse events
- Noncompliance
- Subject complaints that cannot be handled by the PI
- Any other events that require prompt reporting according to DePaul policy, i.e., breaches in confidentiality

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** in order 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 IRB

A Protocol Event status when you resubmitted the returned protocol after making the necessary changes.

Returned

The protocol status when ORS 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.

Serious Adverse Event

Any adverse event temporally associated with the subject's participation in research that meets any of the following criteria:

1. results in death;
2. is life-threatening (places the subject at immediate risk of death from the event as it occurred);
3. requires inpatient hospitalization or prolongation of existing hospitalization;
4. results in a persistent or significant disability/incapacity;
5. results in a congenital anomaly/birth defect; or
6. any other adverse event that, based upon appropriate medical judgment, may jeopardize the subject's health and may require medical or surgical intervention to prevent one of the other outcomes listed in this definition (examples of such events include allergic bronchospasm requiring intensive treatment in the emergency room or at home, or convulsions that do not result in inpatient hospitalization, or the development of drug dependency or drug abuse).

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 IRB

A Protocol Event status when a protocol has been submitted to a committee.

Suggestion Not Necessary for Approval

A comment type when a Reviewer gave a suggestion for the protocol that is not necessary for approval.

T

W

Withdrawn

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

Y

Yet to Submit to (committee name)

A Protocol Event status when a protocol has been created but has not yet been submitted to a committee, e.g., Yet to Submit to IRB

9 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. The PI can delete a protocol or a protocol submission before it is submitted.

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.

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. **Why is my Not Human Subjects Research protocol no longer active?**
    Your protocol is inactive because it does not require approval and has been determined to be non-reviewable. You may proceed with your study.

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

17. **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.

18. **Can I withdraw an amendment?**
    Yes. Contact ORS directly.

19. **What is preventing me from submitting a continuing review?**
    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 a continuing review. You will receive an email when your protocol is eligible.

20. **Can I withdraw a continuing review?**
    Yes. Contact ORS directly.