eProtocol Investigator

Quick Reference Guide

Key Solutions, Inc.
2803 Lakeview Ct.
Fremont, CA 94538
www.keyusa.com

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(Please note that most figures are general, but very closely match our configuration). For general questions, please reach out to IRB@hartford.edu

eProtocol Investigator Quick Reference Guide

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1 Introduction

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

This quick reference guide is intended to be used in conjunction with the eProtocol application for those with the role of Investigator. 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.

Most of the screenshots you see in this guide were taken from an IRB protocol. Depending on your institution and the type of protocol you are creating, your screen may differ from what you see here.

For a more in-depth eProtocol guide, please view Key Solutions' eProtocol Investigator User Guide.

Key Solutions makes improvements to its software on a regular basis. This guide was developed in reference to the eProtocol software version 2.5.64.2.

Key Solutions is interested in making documentation more useful to people that use the eProtocol software and is always interested in feedback—both supportive and constructive. For comments and feedback, please email techpubs@keyusa.com.

2 Getting Started

When you log in to eProtocol, the PI Homepage is displayed. The Homepage consists of shortcuts that allow you to navigate to specific locations or functions.

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

ℹ️ **Note:** *If you have trouble logging in, contact your institution's admin.*

2.1 Investigator Homepage

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

At the top of the homepage is the header. On the left-side of the header is the Investigator submenu. To navigate to the Investigator submenu, hover over **eProtocol** and then **Investigator**. From this submenu, you may perform the following functions (refer to Figure 1's reference numbers):

1. View approved protocols

3. Create a protocol
4. Delete a protocol
5. View information resources
6. Navigate to the Homepage
7. View non-active protocols
8. Search for a protocol

Figure 1 Homepage Header Shortcuts

On the right-side of the header, you can perform the following functions (refer to Figure 1's reference numbers):

9. View the eProtocol version number
10. Change your password
11. Sign out of eProtocol
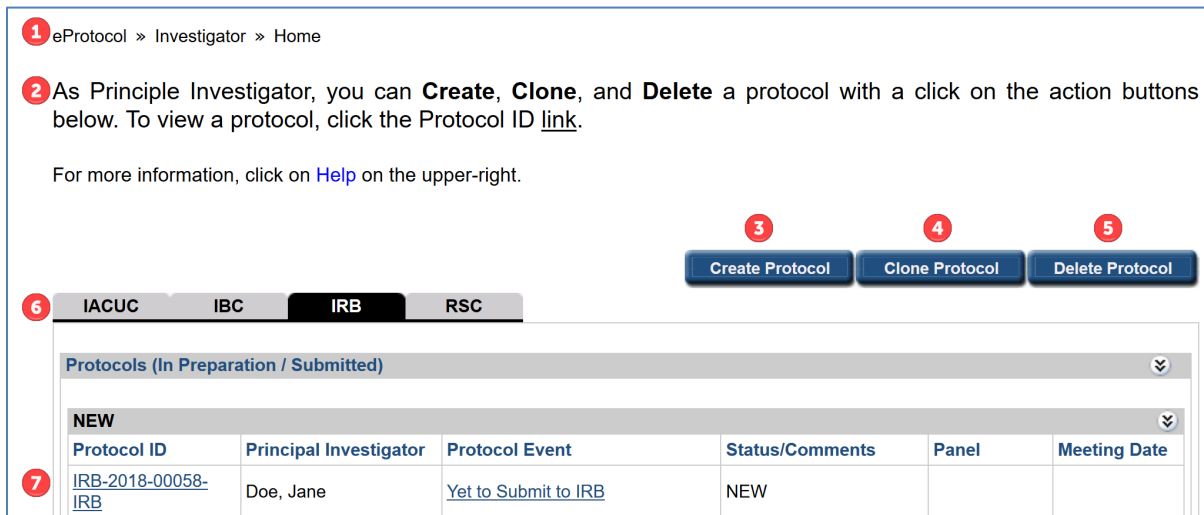12. Navigate to a pop-up that will help you with the homepage

Note: *A Help button is located on every page in eProtocol. Click a Help button at any time for tips about the current page.*

2.1.2 Homepage Body Shortcuts

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

1. Know your location in eProtocol by viewing the breadcrumbs
2. Read instructional text provided to you by your institution
3. Create a protocol
4. Clone a protocol
5. Delete a protocol
6. Switch between committees by clicking on a committee name, if applicable

1 eProtocol » Investigator » Home

2 As Principle Investigator, you can **Create**, **Clone**, and **Delete** a protocol with a click on the action buttons below. To view a protocol, click the Protocol ID link.

For more information, click on Help on the upper-right.

3 Create Protocol **4** Clone Protocol **5** Delete Protocol

6 | IACUC | IBC | IRB | RSC |

Protocols (In Preparation / Submitted)

NEW

Protocol ID	Principal Investigator	Protocol Event	Status/Comments	Panel	Meeting Date
7 IRB-2018-00058-IRB	Doe, Jane	Yet to Submit to IRB	NEW		

Figure 2 Dashboard

Note: *Depending on your institution, you may not have the Create Protocol (3), Clone Protocol (4), and Delete Protocol (5) shortcuts on your dashboard. If they are not, use the Investigator submenu.*

2.2 The Look of a Protocol

When a protocol is opened, you notice that it is comprised of a header, left-side navigation pane, and the protocol content pane (Figure 3). The header (outlined in red) consists of 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) allows you to perform the following functions:

- Navigate to a specific page in the protocol
- Initiate a Check for Completeness
- Submit the protocol (Submit Form)
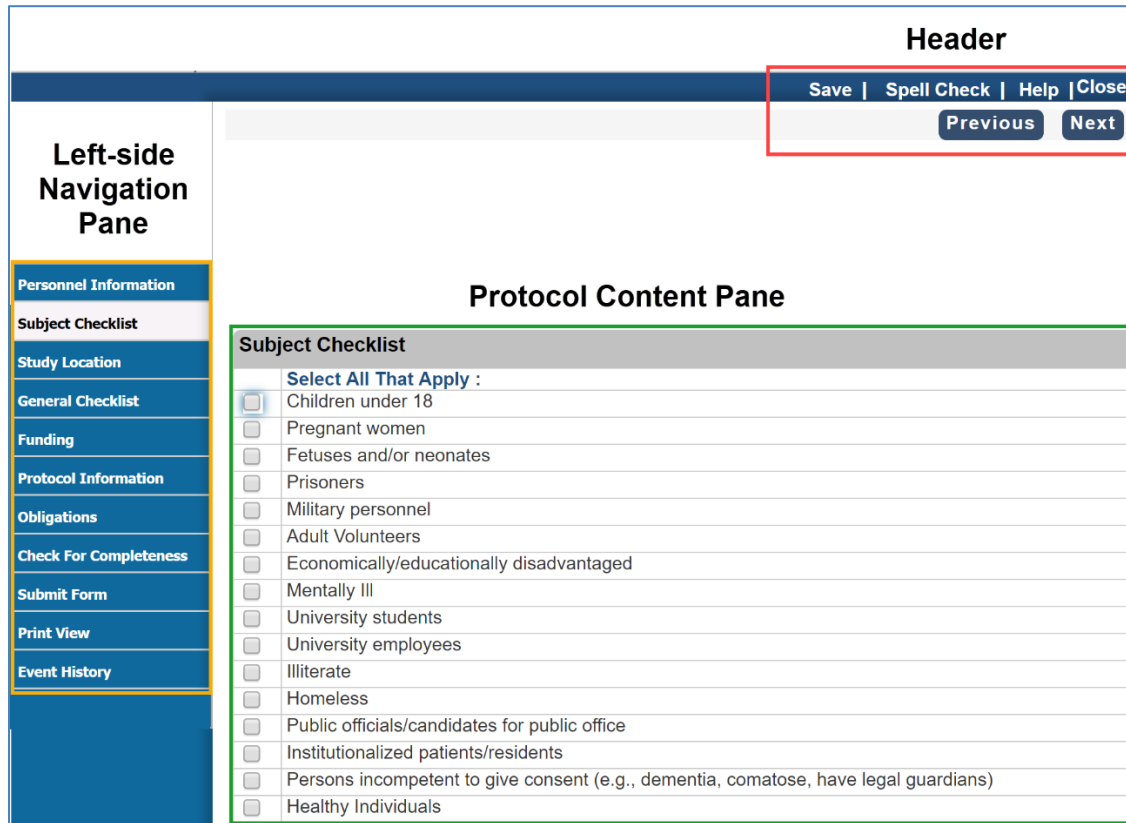- Print all or part of the protocol (Print View)

Figure 3 Header, Left-side Navigation Pane, and Protocol Content Pane

The protocol content pane (outlined in green) 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 (outlined in red in Figure 4). The left-side navigation (outlined in yellow) expands to display them, too. You may use any of those shortcuts to quickly navigate to the desired page.
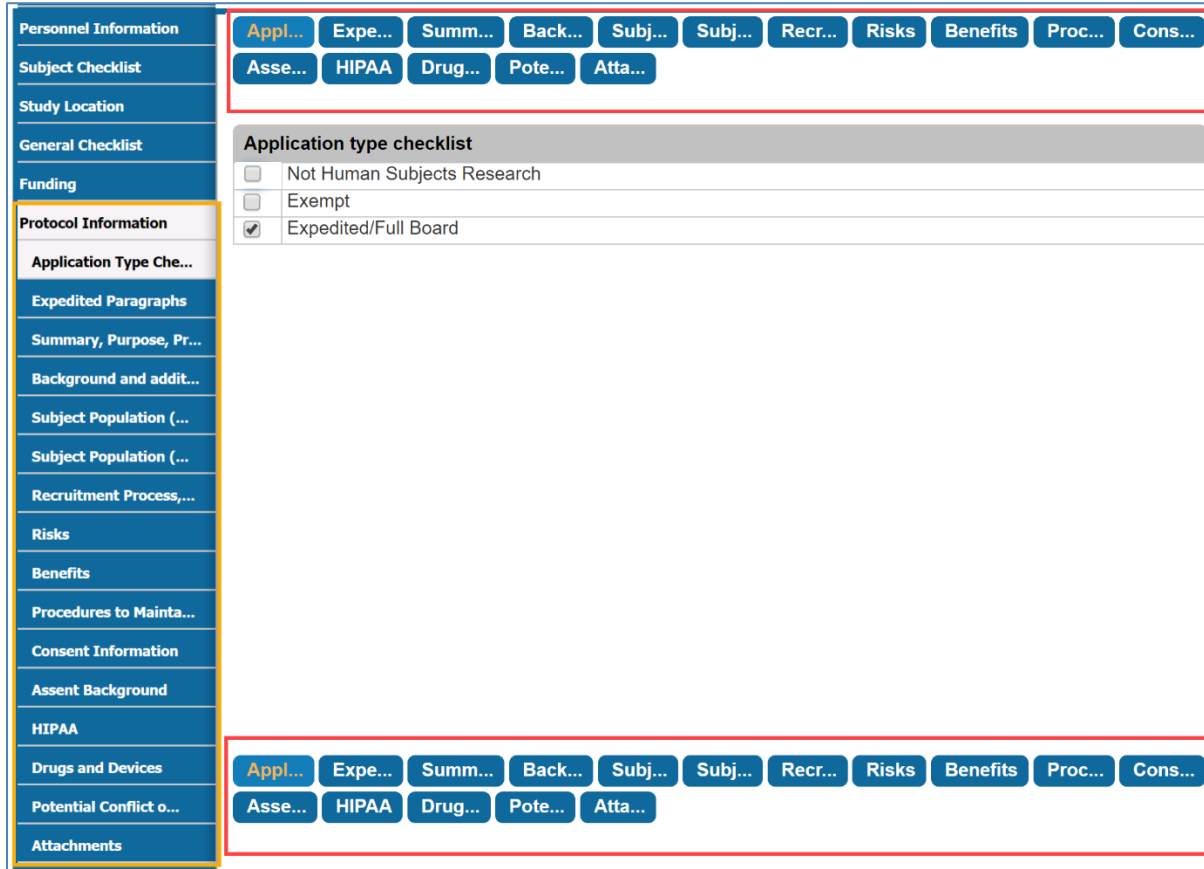

Figure 4 Shortcuts in the Header and Footer

Hover over a category to view the whole name (Figure 5). You may also refer to the left-side navigation pane.
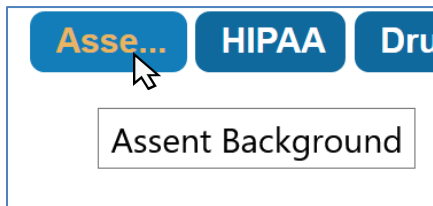

Figure 5 Hover over an icon to view name

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 from IRB, IACUC, IBC, and RSC are shown in the following sections.

3.1 IRB Protocols

The selections you make in the Subject Checklist (Figure 6), the General Checklist (Figure 7), and the Application Type Checklist (Figure 8) determine which questions become enabled in subsequent sections.

Subject Checklist	
Select All That Apply :	
☐	Children under 18
☐	Pregnant women
☐	Fetuses and/or neonates
☐	Prisoners
☐	Military personnel
☐	Adult Volunteers
☐	Economically/educationally disadvantaged
☐	Mentally Ill
☐	University students
☐	University employees
☐	Illiterate
☐	Homeless
☐	Public officials/candidates for public office
☐	Institutionalized patients/residents
☐	Persons incompetent to give consent (e.g., dementia, comatose, have legal guardians)
☐	Healthy Individuals
☐	Other (please specify):

Figure 6 Subject Checklist

General Checklist

Select All That Apply :

- [ ] Request to Rely on Another IRB - Please upload completed Request to Rely and associated documents in attachment section
- [ ] IRB Authorization Agreement (IAA), Memorandum Of Understanding (MOU), etc.(attach in the Attachments section (This only applies to studies where the Client IRB is the Reviewing IRB).
- [ ] Industry-Sponsored Clinical Trial
- [ ] Interview
- [ ] Questionnaire/Survey
- [ ] Thesis or Dissertation Project (Please upload proposal and dissertation/thesis committee approval in Attachments section.)
- [ ] Radioisotopes/radiation-producing machines, even if standard of care (Radiation Safety)
- [ ] Human blood, cells, tissues, or body fluids (Institutional BioSafety)
- [ ] Tissues to be stored for future research projects
- [ ] Tissues to be sent out of this institution as part of a research agreement (Material Transfer Agreement (MTA))
- [ ] Human Embryos
- [ ] Human Embryonic Cells? Provide NIH Code Number(s) or state that no federal funding will be used to support this research.
- [ ] Use of Patient related equipment? If Yes, specify what equipment is being used.
- [ ] Medical equipment used for human patients/subjects also used on animals.
- [ ] Protocol involves studying potentially addicting drugs.
- [ ] Investigational drugs, reagents, or chemicals
- [ ] Commercially available drugs, reagents, or other chemicals administered to subjects (even if they are not being studied)
- [ ] Investigational Device
- [ ] This study involves drugs or devices regulated by FDA
- [ ] Cancer Subjects (e.g., clinical trials, behavior/prevention) or Cancer Tissues (e.g., blood, cells, body fluids).
- [ ] This study is or will be posted on ClinicalTrials.gov

If checked, Specify number:

- [ ] Protected Health Information (PHI) will be viewed, created, accessed, used, or disclosed.
  - [ ] HIPAA Authorization
  - [ ] Waiver or Alteration of Authorization
  - [ ] Activities Preparatory to Research
  - [ ] Limited Data Set and Data Use Agreement
  - [ ] Use and Disclosure of Decedents PHI without Authorization
- [ ] Class Project
- [ ] Other (clarify in text box to the right)

Figure 7 General Checklist

Application type checklist

- [ ] Not Human Subjects Research
- [ ] Exempt
- [ ] Expedited/Full Board

Figure 8 Application Type Checklist

4 Protocol 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

4.1 Binocular Icon

The **binocular icon** (   ) is used to search for a user (Figure 12). When you select the icon, the **Find User** pop-up appears (Figure 13).

Figure 9 Binocular Icon

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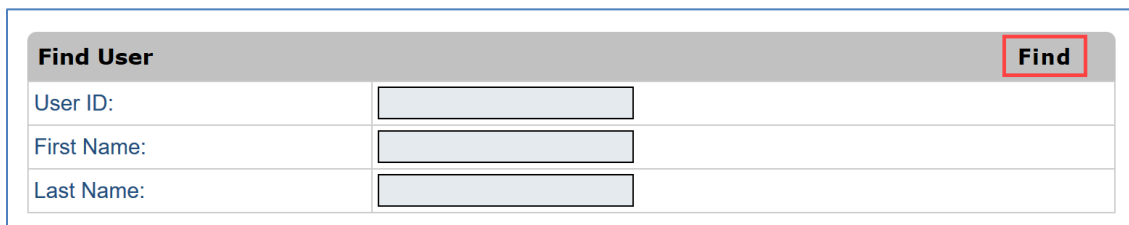

Figure 10 Find User pop-up

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

If the person you want is not listed, contact your compliance office. They can help you.

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

Select User					OK
	User ID	**User Name**	**Title**	**Department**	**Email**
◉	jdoe	Doe, John			
○	Jane D	Doe, Jane		Biology Department	

Figure 11 Find User Result

4.2 Radio Button

A **radio button** is a circular icon (○) that you can select. Once you select a radio button, a bold circle appears on the inside (◉). You may only select one item in a group of radio buttons under the same table (Figure 15).

Approved Protocol Decision
Please select any one of the following:
- ◉ Open in View Mode
- ○ Protocol Details
- ○ Start Amendment
- ○ Start Final Report Form
- ○ Start Report Form
- ○ Start Adverse Event Report Form
- ○ Start Protocol Violation Form
- ○ Close Protocol

Figure 12 Radio Button

4.3 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 (Figure 17). 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 13 Text Field Disabled
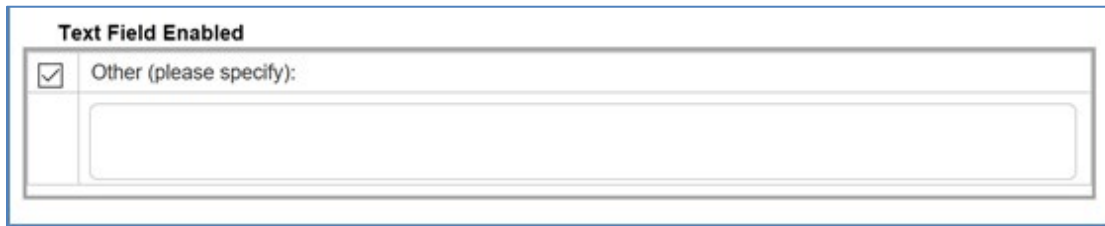

Figure 14 Text Field Enabled

4.4 Dropdown

Dropdowns allow you to select one value from a list. Click the downward facing arrow (▼) to open the dropdown (Figure 18). Then, click on one to select a value.
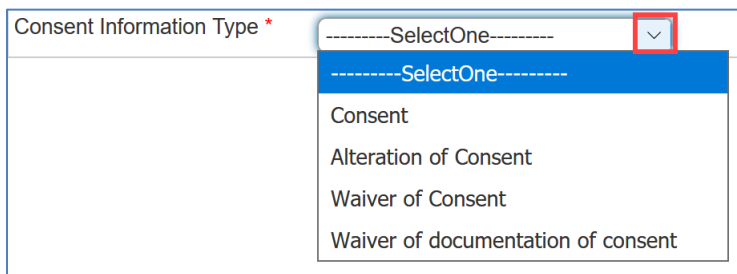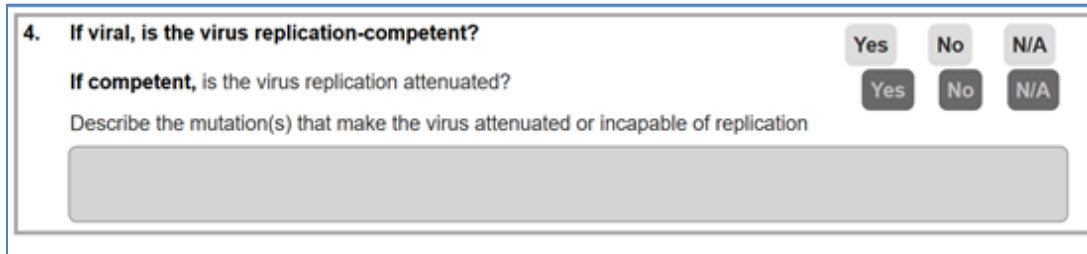
Figure 15 Dropdown

4.5 Yes, No, N/A Buttons

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

Select the appropriate button. A selected button has a dark background and displays a checkmark on the left. Your response may enable an additional Yes (Yes), No (No), or N/A (N/A) buttons and/or a text field like in Figure 20.

Figure 16 Unselected Buttons, subordinate field disabled

Figure 17 Yes buttons selected and subordinate text field enabled

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

Figure 18 Without a response, there is no "Add"
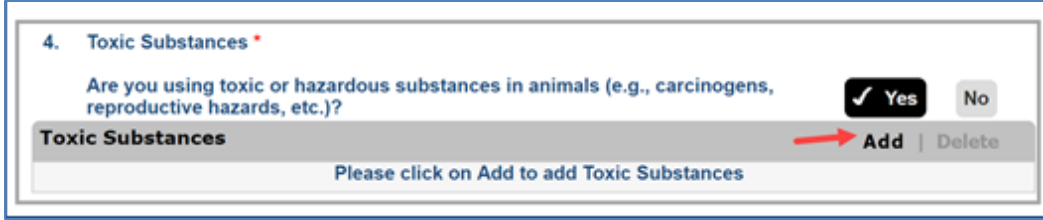
Figure 19 With a Yes response, the Add function is enabled

4.6 Calendar Icon

Use the **calendar icon** (▦) to input a date. When you click on the icon, a calendar pop-up appears. Select a date on the calendar (Figure 23). Use the singular arrows **([<] [>])** to change the month and the double arrows **([<<] [>>])** to change the year.
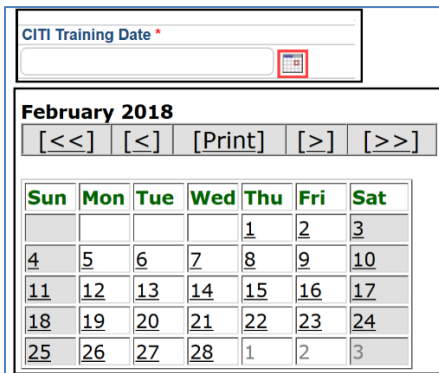
Figure 20 Calendar Icon and the pop-up

4.7 Add Button

Use the **Add** button to add additional information to a subject. When you click **Add**, a pop-up appears (Figure 24). Complete the section and click **Save** (commonly found on the upper-right) when you are finished.

Figure 21 Add pop-up

4.8 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 (Figure 25).

b) Form of Compensation:
- ☐ Cash
- ☐ Check
- ☑ Gift card/certificate
- ☑ Voucher
- ☑ Raffles/lotteries
- ☐ Course/extra credit
- ☐ Reimbursement only
- ☐ Other (please specify)

Figure 22 Checkboxes

4.9 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.

To upload an attachment, perform the following tasks:
1. Click **Add** (Figure 26).
2. Click **Browse** (Figure 27).
3. Select and **Open** the file (Figure 28).
4. Click **Save** (Figure 29).

Attachment	Add	Delete
Click the 'Add' button to add 'Attachment'		

Figure 23 Add

Attachment	Save	Cancel
Document Type *	Select One	
Attachment *	Browse...	

Figure 24 Browse
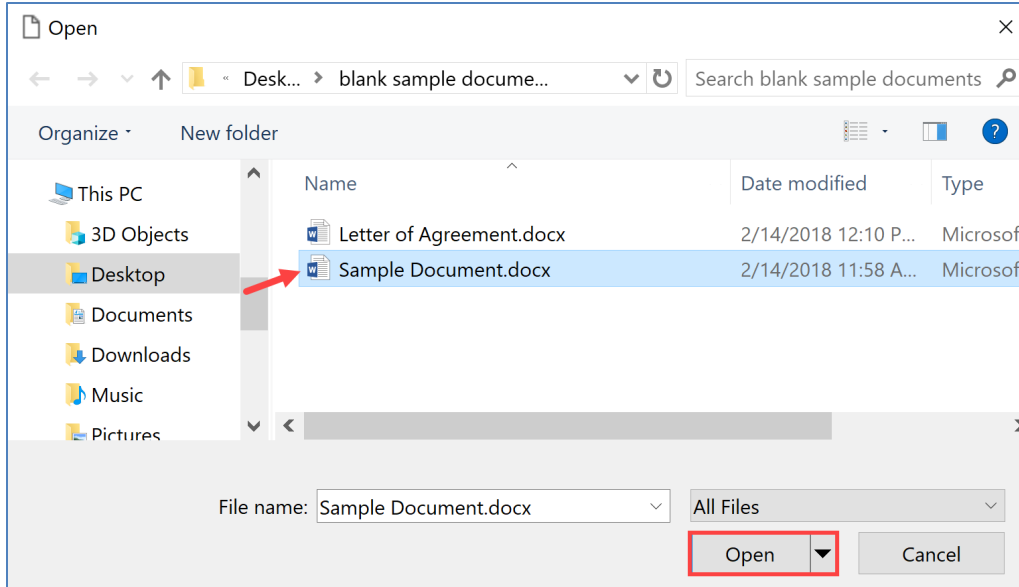
Figure 25 Select a file and click open
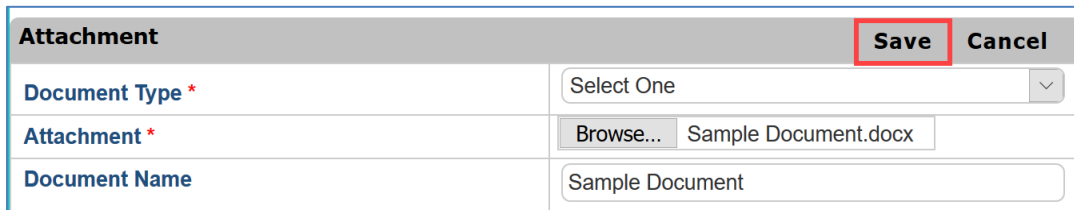
Figure 26 Save

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

5 Protocol Checks

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

1. Page Level Check
2. Check for Completeness

5.1 Page Level Check

The Page Level Check (PLC) scans the current page for mandatory questions which are incomplete. If you attempt to proceed to a subsequent (and sometimes a previous) page and without completing the mandatory fields (*), a PLC notification appears at the top of the page (Figure 30).

Complete the mandatory fields in order to proceed.

* Please select Type of CITI Training for Principal Investigator.

Figure 27 Page Level Check Notification

5.2 Check for Completeness

The Check for Completeness (CFC) scans the entire protocol and notifies you if there are any areas that are incomplete. You cannot submit a protocol until the CFC confirms that all mandatory sections are complete. If you attempt to submit a protocol that contains incomplete sections, the CFC pop-up appears and displays links to the incomplete sections (Figure 31).

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 28 Check for Completeness Messages

When you complete the initial sections of a protocol (the first four pages for IRB, the first two pages for IACUC, the first two pages for IBC, and the first page for RSC), the CFC button appears in the left-side

navigation pane. You may use CFC as often as you want. If you use CFC and there are no incomplete sections remaining, the CFC pop-up appears stating that the application is complete (Figure 32).

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

Figure 29 Check for Completeness Complete Notification

6 Responding to Comments

This section describes how to use eProtocol to respond to 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**.

Click the Protocol Event status to view the comments (Figure 33).

Figure 30 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 34's reference numbers.

> ⚠️ **Caution:** *Read the Reviewer's comments carefully. It may be necessary to make changes to the protocol and respond to the comments in order for your protocol to be eligible for approval.*
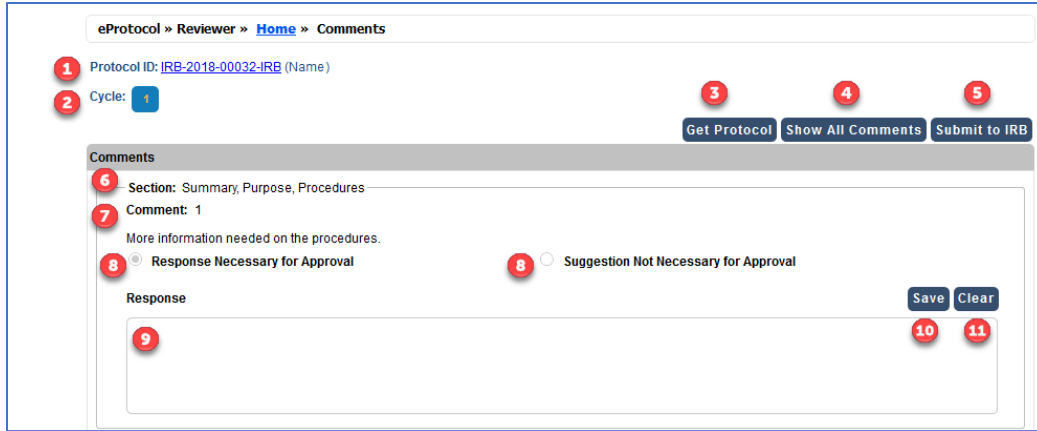
Figure 31 Comment page

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.
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.
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 (committee name)	This button submits your revised protocol and responses directly to the committee. Once you submit your protocol and responses to the committee, you cannot edit the protocol or responses. The different committee names that may appear on this button are IRB and IACUC (e.g., Submit to IRB).
6.	Protocol Section	This lets you know which section of your protocol the Reviewer is commenting on.
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.
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. When you get a protocol with reviewer comment marked as **Response Necessary for Approval**, you must respond to the comment, and potentially make changes to the protocol 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 (Figure 35).
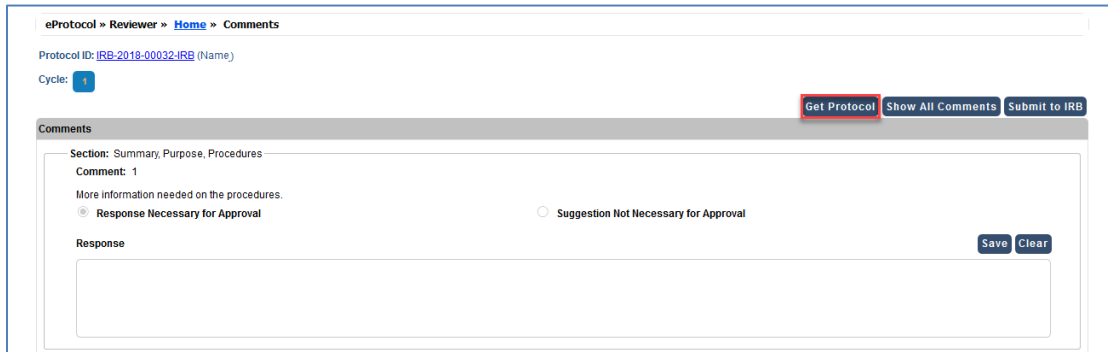
Figure 32 Get Protocol

3. Open the protocol in **Edit** mode (Figure 36). If you open the protocol in **View** mode, you will not be able to make changes.
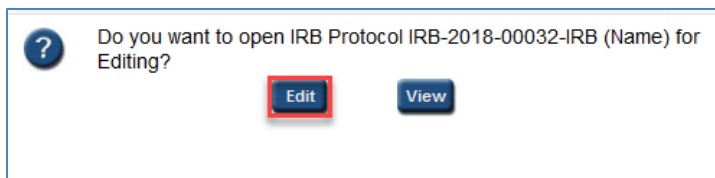
Figure 33 Edit a Protocol

4. Make the necessary changes in your protocol. Click **Save** (Figure 37). Your updates are not saved if you exit without saving them. When you are finished, close the protocol.

Figure 34 Save Protocol Before Exiting

5. Select the text field and enter your responses. Click **Save** (Figure 38).
   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.
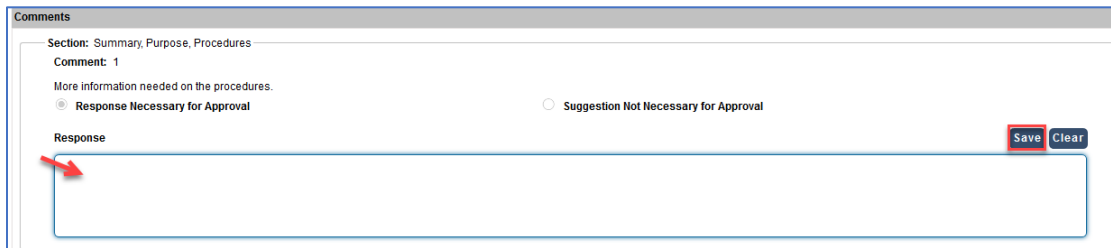
Figure 35 Add Responses and Save

6. When you have finished making edits to the protocol and responded to all of the appropriate comments, click **Submit to IRB** (or Submit to IACUC) (Figure 39).
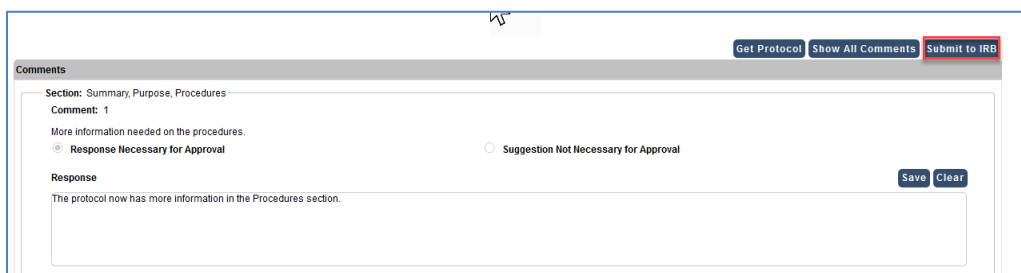
Figure 36 Submit Protocol to IRB

7. A resubmission confirmation pop-up appears. Once you resubmit your revised protocol and responses, you cannot edit them. Click **OK** to confirm (Figure 40).
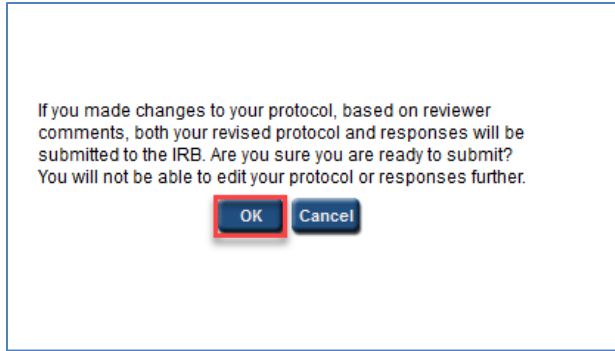
Figure 37 Resubmission Confirmation

8. Once you resubmit your protocol, the Protocol Event changes to **Responses Sent (Cycle 1)** and the Status/Comments changes to **IN-PROGRESS** (Figure 41).

Figure 38 Responses Sent

7 Glossary

A

Administrative Contact

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

Administrative Editor

An individual associated with IACUC study that assists in the development of a protocol. It may also be known as the Study Coordinator. See Top Four, below.

Adverse Event

An Adverse Event (AE) is an event that occurs during the course of a research protocol that either causes physical or psychological harm, or increases the risk of physical or psychological harm, or results in a loss of privacy and/or confidentiality to a research participant or others (such as family members).

Amendment

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

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 no all of the protocol; use Check for Completeness to identify them.

Close Protocol

A request from a PI to formally terminate a protocol. Depending on your institution, you may not have this function; you may need to submit a Final Report Form instead.

Coded Data

Coded data is identifying information (such as a name or social security number) that would enable the investigator to readily ascertain the identity of the individual to whom the private information or specimens pertain has been replaced with a number, letter, symbol, or combination thereof (i.e., the code); and a key to decipher the code exists, enabling linkage of the identifying information to the private information or specimens.

Co-Investigator

see Co-Principal Investigator

Comments Received (Cycle 1)

This is a type of Protocol Event status (shown on the homepage) when a protocol has been returned to you and contains comments from the reviewers. If more comment/response cycles occur, the cycle number increase in the status accordingly, e.g., Comments Received (Cycle 2), Comments Received (Cycle 3), etc.

Comment/Response Cycle

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

Committee

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

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.

Contingent

>The protocol has some issues that must be addressed before the protocol can be approved.

Continuing Review

>A request from a PI to continue an approved study beyond the current approval period.

Co-Principal Investigator (Co-PI)/ Co-Protocol Director (Co-PD) / Co-Investigator (Co-I)

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

Cycle Number

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

D

Designated Editor

>An individual in an IACUC study that may edit the protocol prior to submission. See Top Four, below.

Designated Review

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

E

Emergency Contact

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

Event History

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

Exempt

>A protocol that qualifies under federal regulations as exempt from IRB oversite.

Expedited Review

>An expedited review is performed by a subset of the full IRB committee. The protocol must meet certain criteria to be eligible for an expedited review; have minimal risk and contain only

procedures that are listed in the list of regulated procedures confirmed by the U.S. Food & Drug Administration (FDA) or the U.S. Department of Health and Human Services (HHS).

Expiration Date

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

F

Final Report Form

A type of form used to close the protocol and provide final updates to the Compliance Office. Depending on your institution, you may not have this function. Instead, you will need to use the Close Protocol option.

Full Board/ Full Board Review/ Full Committee Review (FCR)

A review type that a protocol may go through if it contains research that involves Vulnerable or Special Subject Populations, more than minimal risk, or sensitive topics.

G

General Report Form

see Report Form

H

Help

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

I

Information Resources

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

In-Progress

The status of a protocol that is currently under review.

Institutional Animal Care and Use Committee

The Institutional Animal Care and Use Committee (IACUC) oversees procedures, programs, and facilities that focus on animal testing and research. The IACUC ensures that studies comply with federal, state, and local regulations by providing guidance and inspecting animal facilities and laboratories.

Institutional Biosafety Committee

> The Institutional Biosafety Committee (IBC) is responsible for reinforcing guidelines on studies related to potentially hazardous or infectious agents, such as recombinant DNA, RNAi, or pathogens. The IBC ensures that the research will not cause significant health or safety risks to the researchers, public, or environment.

Institutional Review Board

> The Institutional Review Board (IRB) serves to protect the rights and safety of human subjects in a research study. The IRB adheres to the ethical standards listed in the Belmont report, Common Rule, and the FDA.

Internal Permit Holder

> An individual in an RSC study who holds a permit and is authorized to work with radioactive materials.

Investigator Submenu

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

L

Lab Supervisor

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

Last Approval Date

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

M

Meeting Date

> On the homepage a protocol status column that contains the date that the protocol is scheduled to be discussed in the panel meeting.

N

Next

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

Non-Active Protocol

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

Not Approved

The protocol was not approved and is now inactive.

Not Human Subjects Research

A study that does not include research, human subjects, or a clinical investigation.

Not HS Research

A protocol status when the protocol was found to be a not-human subject research.

O

Other Contact

An individual who is linked to an RSC study and may be working with the PI and/or radioactive materials.

Other Investigator

see Co-Principal Investigator. See Top Four, below.

Other Personnel

Individuals who assist the PI and/or work with subjects or substances.

P

Page Level Check

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

Panel

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

Panel Manager

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

Personal Protective Equipment

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

Portable Document Format

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

Pre-Approval 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 is an optional function for institutions. It may also be known as a Pre-Review process.

Pre-Approver

> An individual who reviews a protocol prior to a formal review in a pre-review process. The pre-review process may not be implemented at your institution.

Previous

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

Principal Investigator

> A Principal Investigator is the primary individual responsible for the creating and submitting of a protocol. Furthermore, the PI is responsible for ensuring that the activities associated with the research study comply with applicable laws, regulations, and institutional policies and procedures. See Top Four, below.

Print View

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

Protocol ID

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

Protocol Violation Form

> A submission from a PI informing the committee about a violation that occurred during the study.

Protocols (In Preparation/Submitted)

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

R

Radiation Safety Committee

> The Radiation Safety Committee (RSC) serves to protect individuals from studies that use radioactive materials and radiation-producing equipment that may cause harmful radiation exposure. The RSC ensures the safety of others by monitoring and inspecting all areas that radioactive material is used, stored, and disposed.

Report Form

> A submission from a PI updating the committee on the progress of the study. This is not the correct form to use to revise either the protocol or any consent forms. It may also be known as a General Report Form.

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 (committee name)

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

Returned

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

S

Save

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

Section Name

Protocols are organized into named sections for ease of navigation. They appear in the left-side navigation pane. Comments by reviewers are also organized and presented based on Section Names. The first section in a new protocol is Personnel Information. The subsequent section names vary by committee.

Serious Adverse Event

Serious Adverse Event (SAE) is a serious occurrence from an approved protocol that may result in a death, life-threatening experience, hospitalization or prolonging of an existing hospitalization, congenital anomaly or birth defect, or the necessity to prevent one of the above outcomes by use of medical or surgical intervention.

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.

Study Coordinator

An individual who works alongside a PI during an IRB or IBC study. It may also be known as the Administrative Contact or Administrative Editor. See Top Four, below.

Submitted to (committee name)

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

Suggestion Not Necessary for Approval

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

T

Top Four

A nick name for the top four sets of people in the personnel information section of a protocol. Usually, the top four can create, submit, clone, or delete a protocol and reply to comments on the protocol. The names of the top four are usually: Principal Investigator, Co-Investigators, Administrative Editor, and Designated Editor, but the names and what they can do vary from institution to institution.

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

8 Frequently Asked Questions (FAQs)

1. **Which browsers can I use for eProtocol?**

   Mozilla Firefox, Internet Explorer, 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 is 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 your compliance office directly. A protocol can only be withdrawn if it has been submitted to the compliance office and the committee has not made a decision.

11. **Can you edit a protocol after submission?**

    You may only edit a protocol if the protocol is sent it back to you.

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. **My protocol was approved by a Pre-Approver. Where is my approval letter?**

    Obtaining the approval from a Pre-Approver is the first step of a two-step approval process. When a protocol is approved by a Pre-Approver, it must then be submitted to the committee for a formal review. Once approved by the committee, an approval letter is available.

14. **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).

15. **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.

16. **Why is my Not Human Subjects Research protocol no longer active?**

    Your protocol is inactive because it does not require approval. You may proceed with your study.

17. **What is preventing me from deleting my protocol?**

    You cannot delete a protocol that has already been submitted.

18. **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.

19. **Can I withdraw an amendment?**

    Yes. Contact your committee directly.

20. **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.

21. **Can I withdraw a continuing review?**

    Yes. Contact your committee directly.