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.

Some screenshots in this guide were taken from an IRB protocol, while others were taken from IACUC. Though the functions are similar, your institution's layout may differ from what is shown here.

For a more in-depth eProtocol guide, please view Key Solutions' eProtocol Principal Investigator User Guide.
Key Solutions makes improvements to its software on a regular basis. 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 logging in to eProtocol, the Investigator Homepage will be displayed. The Homepage contains shortcuts that allow quick navigate to specific locations or functions.

Caution: *The first time you log into eProtocol, a dialog box will appear regarding pop-up menus. Enable pop-ups from the Key Solutions site, and then log out and back in to the application.*

Caution: *Do not use the browser's forward and back arrows to navigate. eProtocol is a secure application, and using the browser arrows may break the authentication, requiring the user to log out and back in to the application.*

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

2.1 Investigator Dashboard

The Investigator Dashboard is divided into the header and body sections, each with their own menus and functions.

Dashboard Header

The dashboard header contains the module menus and account menu. To access the Investigator functions, click on the eProtocol pull-down, and then select Investigator (see **Figure 1**). This submenu allows you to do the following:

1. Navigate back to the Investigator Dashboard
2. View a list of approved protocols
3. Clone a protocol
4. Create a protocol
5. Delete a protocol
6. Search for a protocol, including new submissions, amendments, renewals, and reports
7. Access the account menu (right side)

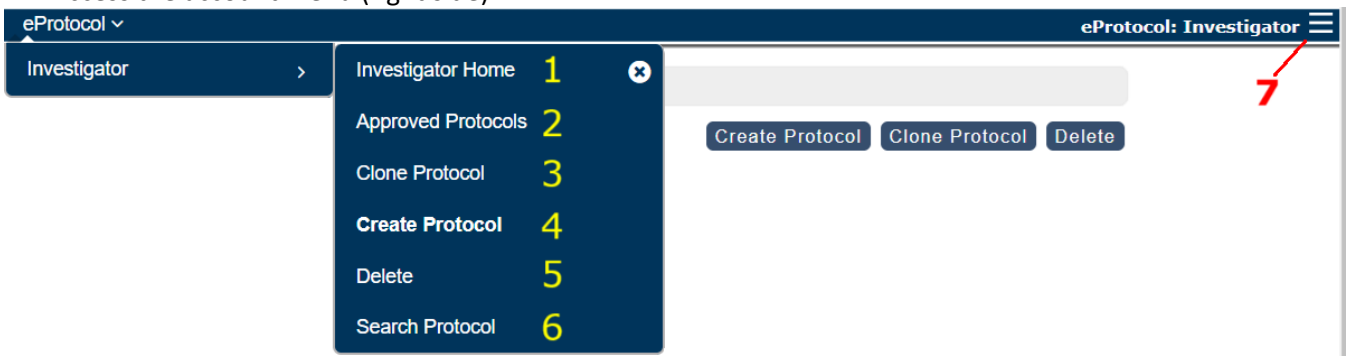

Figure 1: Investigator Dashboard Header

The account menu functions (see **Figure 2**) allow you to do the following:

8. Access the Help menu
9. Change your password
10. Identify the current version of the software
11. Sign out

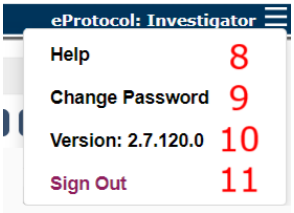

Figure 2: Account Menu

Note: *Click on the Help button at any time for tips about the current page.*

Dashboard Body

The dashboard body allows you to perform the following functions (see **Figure 3**):

1. Find your current location in eProtocol using the Breadcrumbs
2. Determine meanings of colors in the protocol table
3. Switch between committees (if applicable) by clicking on a committee name
4. Select a protocol to View or Edit (click on the link under the Protocol ID column)
5. Create a protocol
6. Clone a protocol
7. Delete a protocol

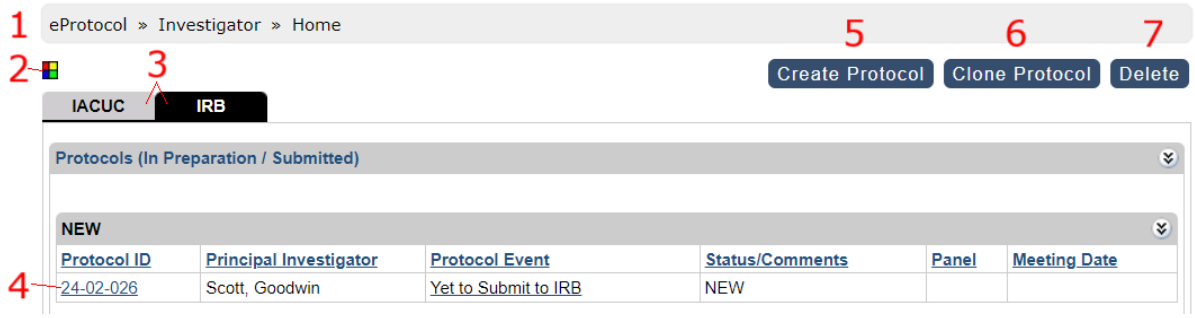

Figure 3: Investigator Dashboard

Note: *If the Create, Clone, or Delete Protocol buttons are not visible, the functions can still be accessed from the Investigator pull-down menu.*

2.2 Navigating the Protocol Form

Select a Protocol ID link from the "New" section of the Investor dashboard, and a dialog will ask whether to Edit or View the protocol (see **Figure 4**).

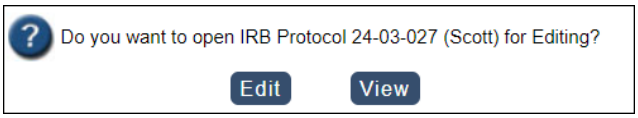

Figure 4: Protocol Open Methods

Select Edit, and the Protocol Form will appear in a separate window. The protocol form consists of a header, left-side navigation pane, and protocol content pane (see **Figure 5**). The header functions (outlined in red) include the following:

- Save the protocol
- Perform a Spell Check on the current page
- View the Help menu
- Close the protocol
- Navigate to the Previous page
- Navigate to the Next page

The left-side navigation pane (outlined in yellow) allows you to do the following:

- 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)
- See the submissions, modifications, and approvals of the protocol (Event History)

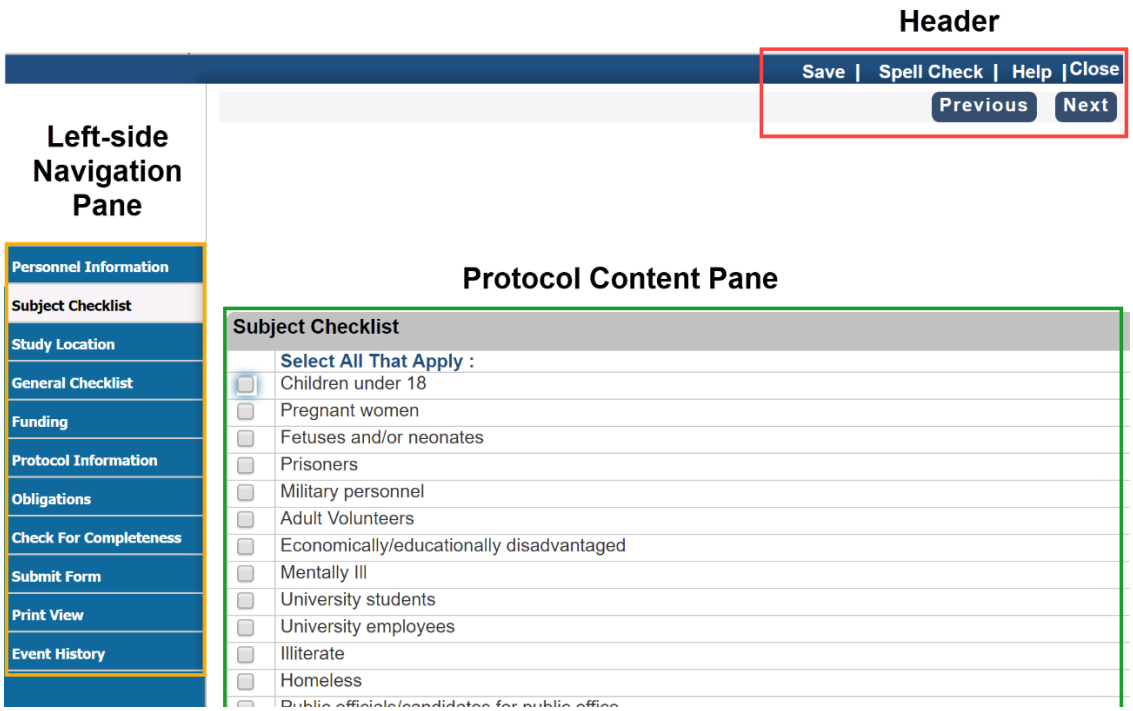

Figure 5: Header, Left-side Navigation Pane, and Protocol Content Pane

The protocol content pane (outlined in green) contains a variety of questions that must be considered for your study.

2.3 Left-Side Sub-Sections

The left-side navigation pane is designed to walk the user through the many details that must be considered when submitting a study for approval. Some sections relate to a single topic, while other sections (such as Protocol Information) will expand to show multiple sub-sections (see **Figure 6**). The sub-sections can be accessed via the left-side navigation pane, or by using the shortcuts at the top of the page (outlined in red).

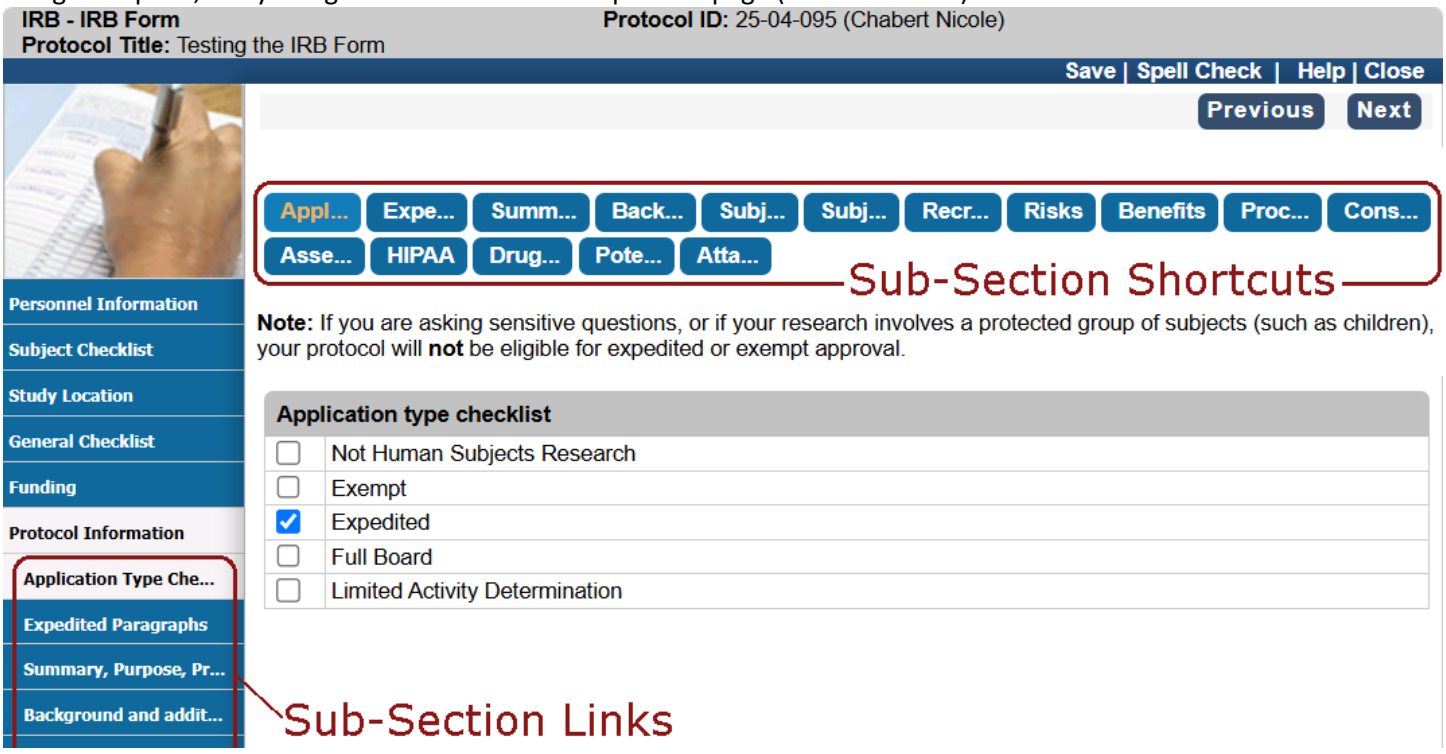

Figure 6: Sub-Section Navigation

To see the full name of the sub-section, hover the mouse over the category button (see **Figure 7**).

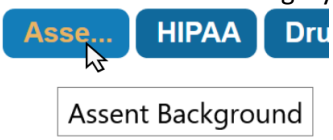

Figure 7: Hover Over an Icon to View its Name

3 Creating a Protocol

To create a protocol, Select Create Protocol from either the Investigator Homepage shortcut or the Investigator Submenu (see **Figure 8**). A new page will appear asking for the Study Title and form type (IRB, IACUC, etc.).

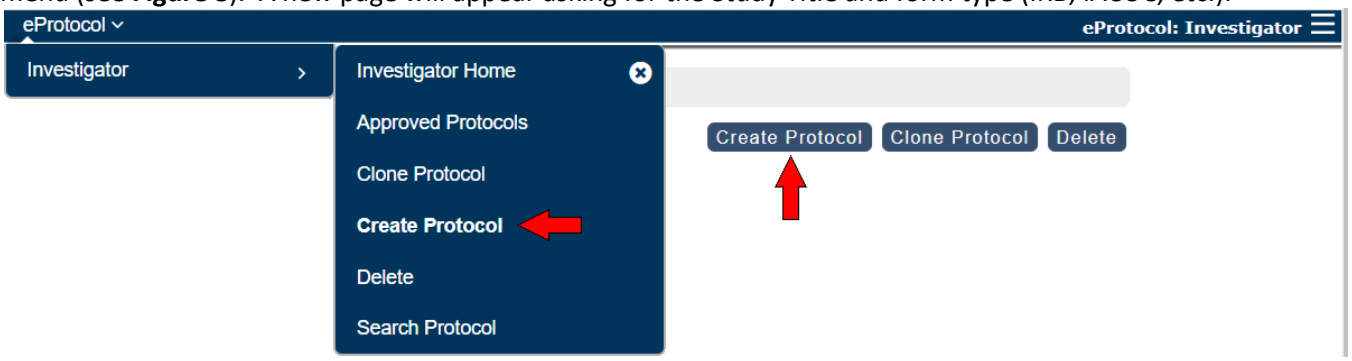

Figure 8: Create a Protocol

When creating a protocol, some selections determine which questions are enabled in subsequent sections. If a mistake has been made, you can navigate to previous pages at any time. Examples from IRB, IACUC, IBC, and RSC are shown in the following sections.

3.1 IRB Protocols

In the IRB Protocol Form, the Subject Checklist allows the Investigator to identify the groups of people that will become the focus of the research (see **Figure 9**). The General Checklist allows the Investigator to select the types of data that will be collected during the study (see **Figure 10**). The Application Type Checklist relates to the level of oversight that the protocol will require (see **Figure 11**). Selections in each of these three checklists determine which questions are 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 9: 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 10: General Checklist

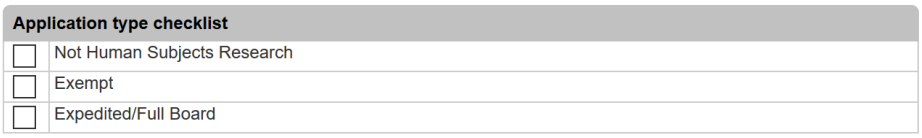

Figure 11: Application Type Checklist

3.2 IACUC Protocol

Adding a Category E procedure on the Procedures page (see **Figure 12**) will enable a question in the Alternative Search section. For some institutions, other pain category procedures may also enable this question.

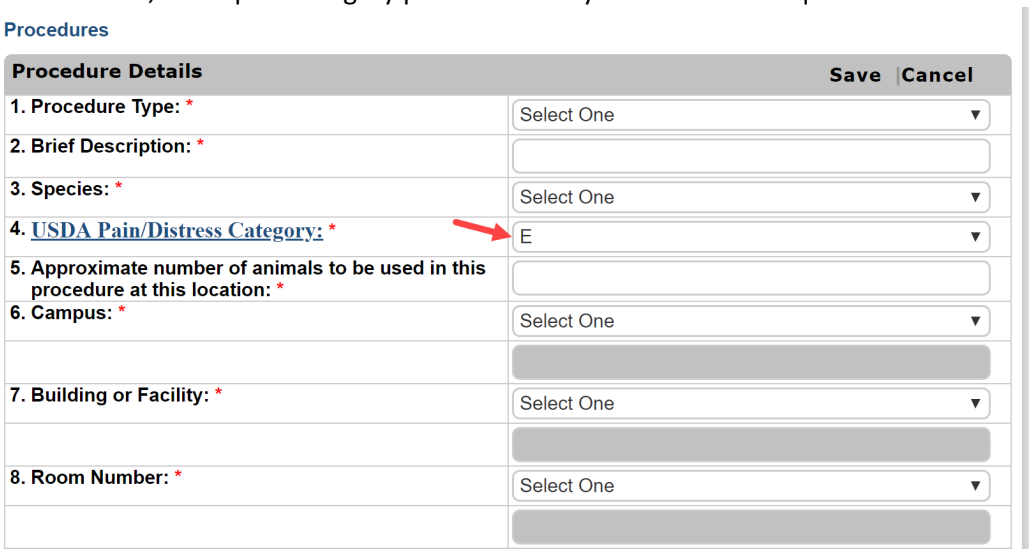

Figure 12: Category E in Procedures

3.3 IBC Protocol

Selection on the Project Registration page (see **Figure 13**) determine which questions are enabled in subsequent sections.

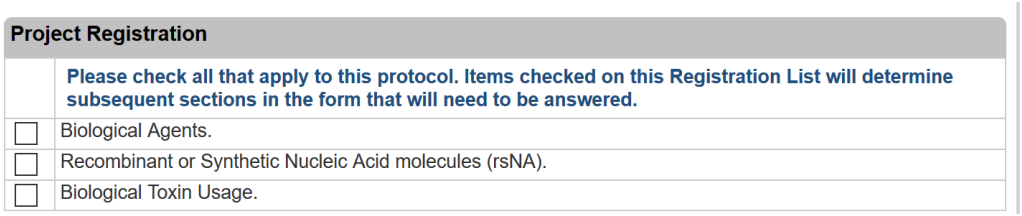

Figure 13: Project Registration

3.4 RSC Protocol

Selections on the Purpose page (see **Figure 14**) determine which questions are enabled in subsequent sections.

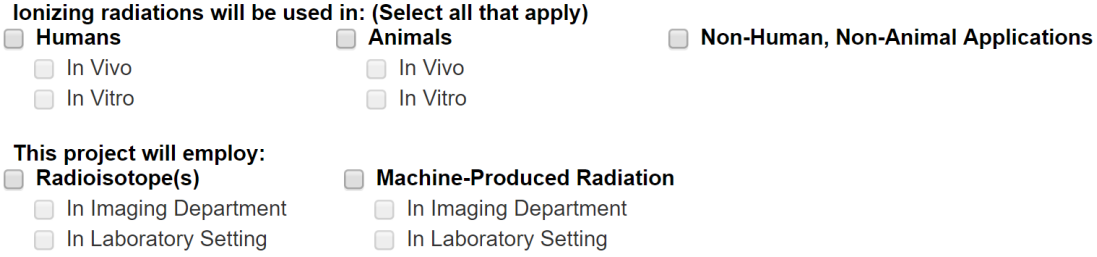

Figure 14: Purpose

4 Protocol Form Navigation

Multiple tools are used to complete a protocol, including the Binocular Icon, Calendar Icon, Radio Buttons, etc. The following sections describe the use of each technology within the protocol form.

Caution: *Any item whose title is followed by a red asterisk (*) is a mandatory field. If no response is given, eProtocol will display a warning message, either immediately on the page, or later during the Check for Completeness.*

4.1 Binocular Icon

The binocular icon ( ) is used to search for a user. When you select the icon, the Find User pop-up menu appears (see **Figure 15**). Enter a User ID, First Name, or Last Name, and then click Find.

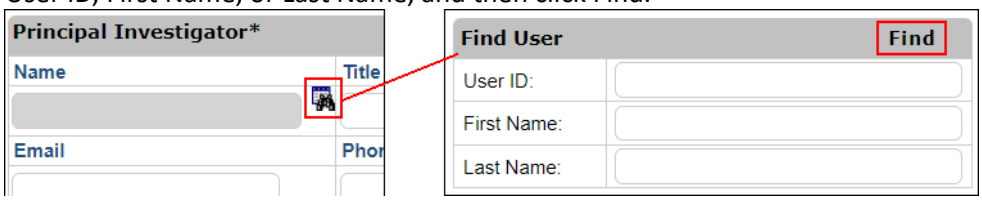

Figure 15: Binocular Icon and Find User Pop-up

Select the user by clicking the corresponding radio button, and then click OK (see **Figure 16**).

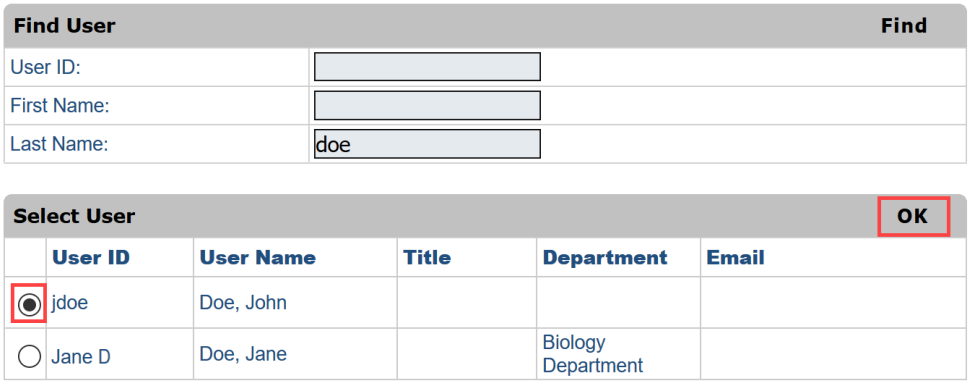

Figure 16: Find User Result

If the expected user is not listed, contact your Company Admin or Committee Staff.

4.2 Calendar Icon

Use the calendar icon ( ) to enter a date (see **Figure 17**) Your institution may configure holidays & blackout dates.

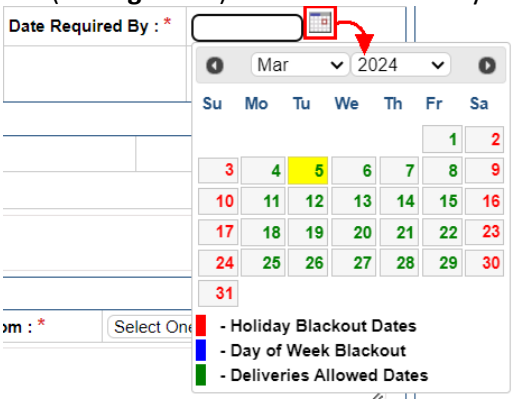

Figure 17: Calendar Icon and Pop-up Date Picker

4.3 Radio Buttons and Checkboxes

A radio button is a selectable circular icon (○). Only one radio button in the group can be selected. A checkbox is a selectable square icon (☐). Some questions allow multiple checkboxes to be selected (see **Figure 18**).

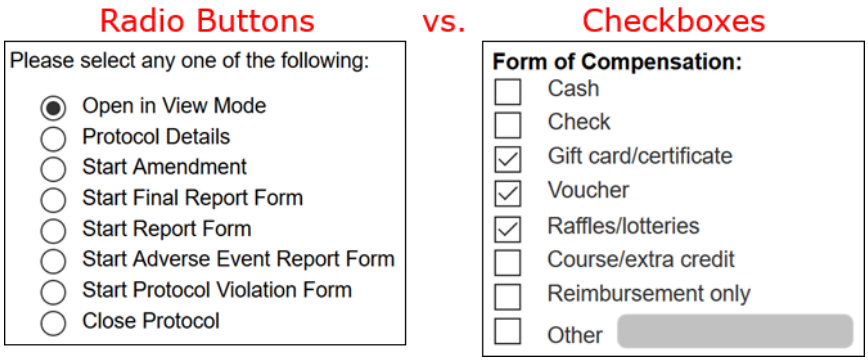

Figure 18: Radio Buttons and Checkboxes

4.4 Text Field

Text fields with a white background are active. If the description is followed by a red asterisk (*), the text field is mandatory and requires a response. If there is no asterisk, the field is optional.

Some selections require additional information, and will activate a text field (see **Figure 19**). In this case, the text field's background changes from grey to white, and a response becomes mandatory. In addition, some text fields have character limitations, and will display an error message if the limit is exceeded.

Figure 19: Text Field Enabled

4.5 Dropdown

With dropdown menus, one value can be selected from a predefined list (see **Figure 20**). In many cases, the list will be preconfigured to reflect the needs of the institution.

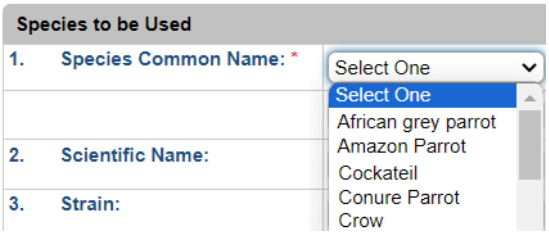

Figure 20: Dropdowns

4.6 Multi-Select Combo Box

In a multi-select combo box, multiple values can be selected from a predefined list (see **Figure 21** & **Figure 22**). To select several values within a continuous range, select the first value, and then hold the Shift key while selecting the last value. To select multiple separate values, hold the Control key while selecting the values.

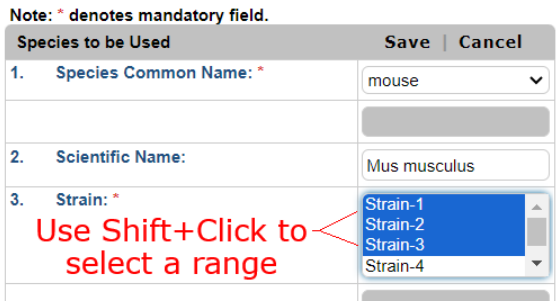

Figure 21: Shift+Click for Selecting a Range

Figure 22: Ctrl+Click for Selecting Individual Items

4.7 Add Button

The Add button appears at the top of information tables. Selecting an Add button will open a pop-up menu for additional information. Enter the required info and click Save (top-right corner). In some cases, the Add button is only enabled by answering Yes to a previous question (see **Figure 23**).

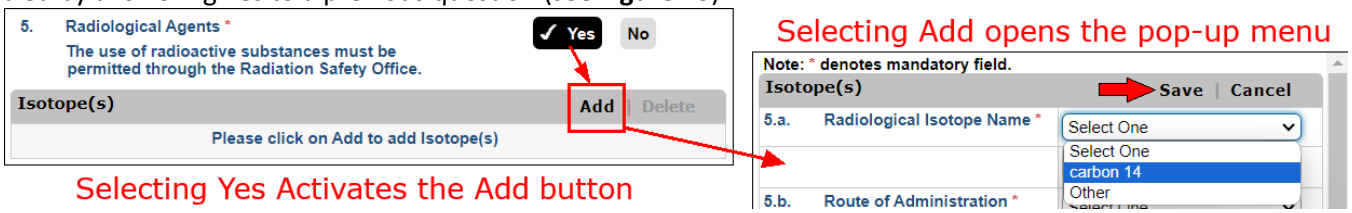

Figure 23: Add Button and Pop-up Menu

4.8 Delete Button

The Delete button also appears at the top of information tables. If an item in a table is no longer required, select the item's checkbox and click Delete (see **Figure 24**).

Figure 24: Delete Unnecessary Items from Tables

4.9 Yes, No, N/A Buttons

Concrete questions are typically followed by Yes and No buttons, and in some cases N/A buttons. A selected button has a dark background and a checkmark. In some cases, the response will enable a text field, or an additional Yes, No, N/A question (see **Figure 25**).

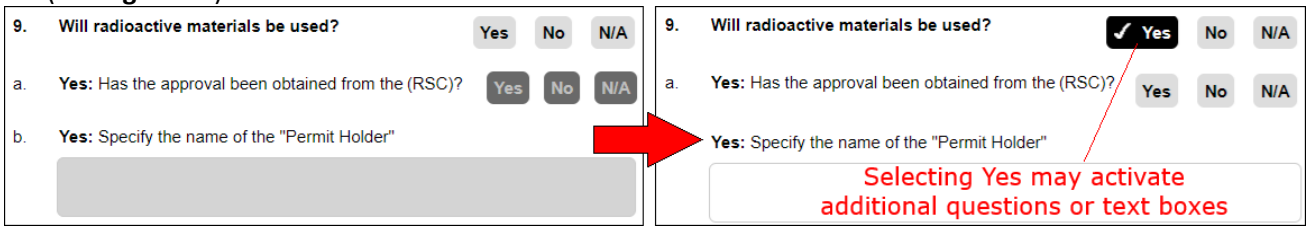

Figure 25: Yes Button May Activate Additional Fields

A selection may also enable the Add button (see **Figure 26**).

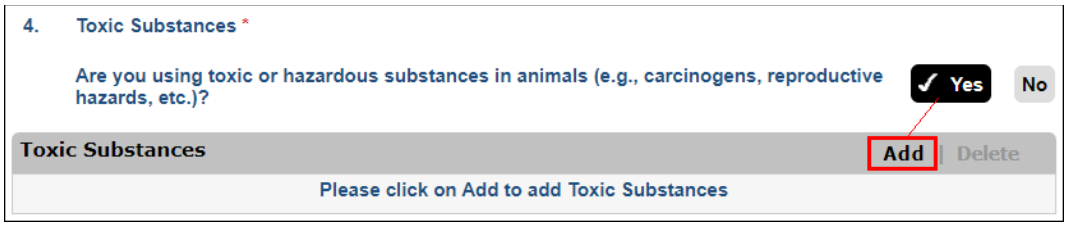

Figure 26: Yes Button May Activate Add Function

4.10 Attachments

Attachments allow additional information to be included in a study. To upload a document, select Add in the Attachments table on the Attachments page (see **Figure 27**), and a pop-up menu will appear. Select the document type, add the document using Browse, and hit Save to close the pop-up.

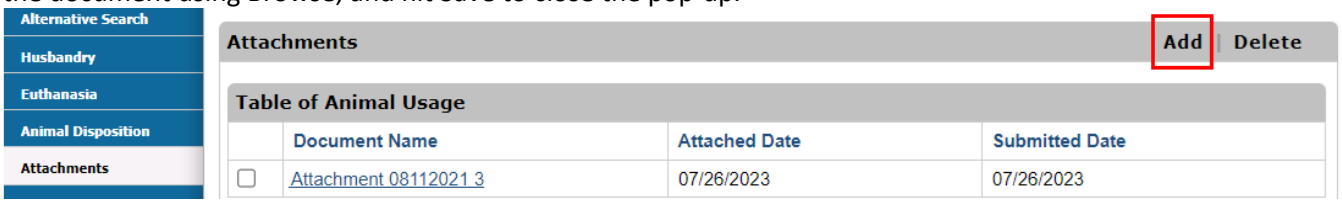

Figure 27: Add Attachments

5 Protocol Checks

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

- Page Level Check
- Check for Completeness

5.1 Page Level Check

The Page Level Check (PLC) scans the current page for any mandatory information (*) that is missing. The scan occurs when navigating to a different page. eProtocol will list the required information at the top of the page (see **Figure 28**), and the mandatory fields must be completed in order to proceed.

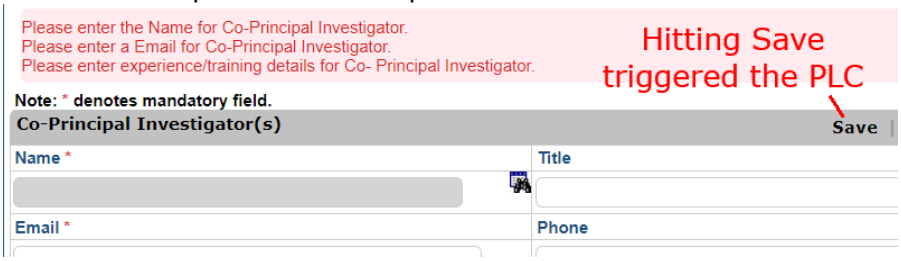

Figure 28: Page Level Check Notification

5.2 Check for Completeness

A protocol cannot be submitted until all mandatory sections are complete. The Check for Completeness (CFC) scans the entire protocol for missing mandatory information. If information is missing, the Check for Completeness will open a pop-up menu with links to the incomplete sections (see **Figure 29**).

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.

Figure 29: Check for Completeness Pop-up Menu with Links

The CFC function will appear in the left-side navigation pane once the initial project information is entered. The user can run the CFC manually at any time. The CFC will also be launched automatically when the user submits the protocol for approval. When all mandatory information is entered, the CFC pop-up menu will state that the application is complete (see **Figure 30**).

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

Figure 30: Check for Completeness – Protocol is Complete

At this point, eProtocol will direct the user to Submit the protocol for approval. Once submitted, no further changes can be made to the protocol until the Reviewers have returned comments to the Investigator.

6 Responding to Comments

Once submitted, all protocols must be reviewed, and reviewers are able to leave comments for the Investigator. This section describes how to respond to Reviewer comments in eProtocol.

6.1 View Reviewer's Comments

When a protocol receives comments from a Reviewer, the protocol will appear on the Investigator Homepage in the "NEW" table. The Protocol Event will show "Comments Received (Cycle N)". Select this link to view the comments (see **Figure 31**).

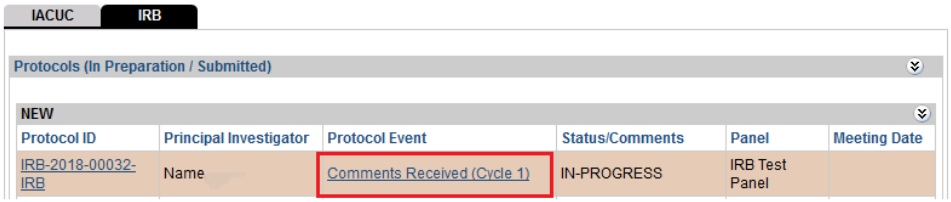

Figure 31: Protocol Event to View Comments

The Comments page will appear with the following information (see **Figure 32** and **Table 1**):

Figure 32: Reviewer Comments Page

Table 1: Reviewer Comments Page

#	Name	Description
1	Protocol ID	Select the Protocol ID to open the protocol in View or Edit mode.
2	Cycle Number	Shows the current comment/response cycle.
3	Get Protocol	Opens the protocol in View or Edit mode.
4	Show All Comments	Opens a new page showing the protocol's comment history.
5	Submit to IACUC/ Submit to IRB	Submits the revised protocol and responses to the committee. Once submitted, the protocol and comments can no longer be edited.
6	Section	Lists the protocol section associated with the Reviewer's comment.
7	Comment Number	Lists the unique comment ID and comment text.
8	Comment Type	Response Necessary for Approval: The Reviewer requires changes to the protocol. Update the protocol and respond to the comment before resubmitting for approval Suggestion Not Necessary for Approval: The Reviewer is making a suggestion, but neither a change nor a response is required.
9	Response Field	Write a response to the comment.
10	Save	Saves the responses in the text field. Saves all responses; each response does not need to be saved individually.
11	Clear	Clears the response field only for the selected comment.

Caution: *Pay close attention to the Comment Type. Any comment set to "Response Necessary for Approval" must be addressed before the protocol can be returned to the Committee.*

6.2 Make Changes, Respond, and Resubmit the Protocol

To make changes to a protocol, respond to comments, and resubmit for approval, do the following:

1. View the protocol's comments (see section 6.1).
2. Open the protocol in Edit mode.
3. Make the necessary changes in the protocol.
4. Save the protocol (see **Figure 33**). Changes will be lost if the protocol is closed without saving first.

Figure 33: Save Protocol Before Exiting

5. When finished, Close the protocol.
6. Enter response(s) in the Comments Page. Save the responses (see **Figure 32**).

Note: *Responses and protocol updates do not have to be completed in a single session. Hit Save to safely exit, and then return to the protocol or Comments Page when ready.*

7. When all protocol updates are complete, and all comments marked "Response Necessary for Approval" have received responses, hit the "Submit to Committee" button (see **Figure 34**).

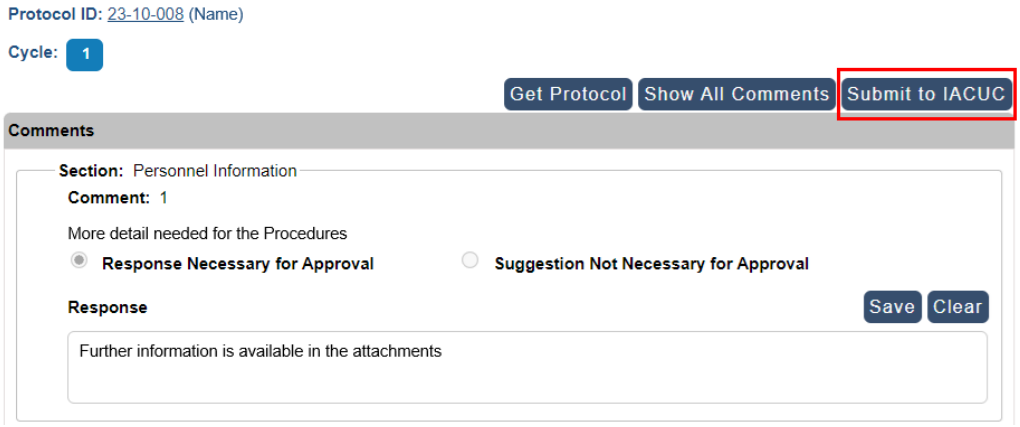

Figure 34: Submit Protocol to IRB or IACUC

A resubmission confirmation pop-up will appear. Once resubmitted, the revised protocol and responses cannot be edited. Click OK to confirm (see **Figure 35**).

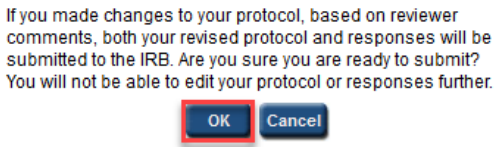

Figure 35: Resubmission Confirmation

Once resubmitted, the Protocol Event will show "Responses Sent (Cycle x)" (see **Figure 36**).

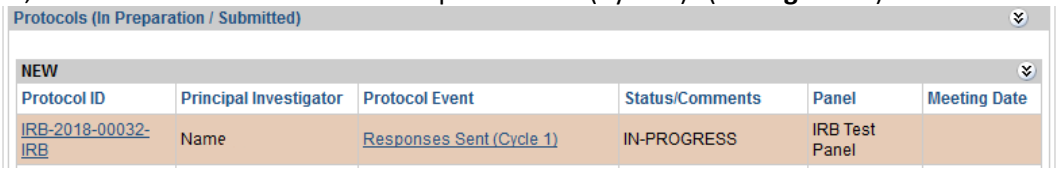

Figure 36: Responses Sent

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 study participants (17 years or younger) about the research project. If the study contains a broad range of minors, more than one assent form may be necessary. (For example, it may be appropriate to use different assent forms for teenagers and small children.)
- **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 any missing mandatory 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 will copy most, but not all of the protocol; use Check for Completeness to identify missing mandatory information.
- **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 used to replace identifying information (such as a name or SSN) that would enable the investigator to readily ascertain the identity of the individual to whom the private information or specimens pertain. The coded data consists of a code (number, letter, symbol, or combination thereof), and a key to decipher the code. The code allows participants to remain anonymous while still retaining a link between the participant and their specimens.
- **Co-Investigator:** see Co-Principal Investigator
- **Comments Received (Cycle 1):** A Protocol Event status (visible on the homepage), shown when a protocol has been returned to the Investigator with comments from the Reviewers. If more comment/response cycles occur, the cycle number increases in the status (for example, Comments Received (Cycle 2)).
- **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), or 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 details 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 included 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:** The date when the protocol will expire, listed on the homepage under Approved Protocols.

F

- **Final Report Form:** A type of form used to close the protocol and provide final updates to the Compliance Office. Some institutions do not use this function, and instead rely on the Close Protocol option.
- **Full Board, Full Board Review, or 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. To update this section with additional links, contact your institution's compliance committee.
- **In-Progress:** The status of a protocol that is currently under review.
- **Institutional Animal Care and Use Committee (IACUC):** 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 (IBC):** 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 (IRB):** 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:** The menu of functions available to Investigators in eProtocol (See Section 2).

L

- **Lab Supervisor:** An individual for an IBC study that is responsible for supervising lab personnel.
- **Last Approval Date:** The date when the protocol was last approved (for example, the most recent amendment approval), listed on the homepage under Approved Protocols.

M

- **Meeting Date:** The date when the protocol is scheduled to be discussed.

N

- **Next:** A navigation button that saves the current page within the protocol and takes you to the "next" page.
- **Non-Active Protocol:** A protocol that is no longer active to an Investigator, such as 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 involve the collection of new data directly from human subjects.
- **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 Principal Investigator and/or radioactive materials.
- **Other Investigator:** see Co-Principal Investigator. See Top Four, below.
- **Other Personnel:** Individuals who assist the Principal Investigator 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 a file type accepted and produced by eProtocol.
- **Pre-Approval Process:** For some institutions, a protocol may go through an additional pre-review process before it can be submitted to a committee for formal review. May also be known as a Pre-Review process.
- **Pre-Approver:** For institutions with a Pre-Approval Process, a Pre-Approver reviews the protocol prior to the formal review.
- **Previous:** A navigation button that saves the current page within the protocol before returning you to the previous page.
- **Principal Investigator:** A Principal Investigator (PI) 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. There 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 Investigator homepage that lists protocols that are yet to be approved.

R

- **Radiation Safety Committee (RSC):** 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 where radioactive material is used, stored, and disposed.
- **Report Form:** A submission from a PI updating the committee on the progress of the study. May also be known as a General Report Form. Note: This form should not be used revise either the protocol or any consent forms.
- **Response Necessary for Approval:** When a reviewer makes a comment and marks it as Response Necessary for Approval, the Investigator must respond in the response field in order to resubmit the protocol for review and approval.
- **Responses Sent (Cycle 1):** A Protocol Event status that appears when the Investigator has submitted responses to the Reviewers along with any changes to the protocol. If more comment/response cycles occur, the cycle number in the status will increase accordingly.
- **Resubmit the Protocol:** A Protocol Event status that appears when a protocol is returned to the Investigator and changes must be made to the protocol for it to become "reviewable."
- **Resubmitted to (committee name):** A Protocol Event status that appears when the Investigator resubmits the returned protocol after making the necessary changes (for example, Resubmitted to IRB).
- **Returned:** The protocol status that appears 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 the user to manually save all the data 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 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 that appears when a protocol has been submitted to a committee (for example, Submitted to IRB).
- **Suggestion Not Necessary for Approval:** When a reviewer makes a comment as a suggestion only, and does not require either a change to the protocol or a response to the comment for resubmission.

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 that appears when a protocol has been created but has not yet been submitted to a committee (for example, Yet to Submit to IRB).

8 Frequently Asked Questions (FAQs)

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

2. Why do I need to disable the browser's pop-up blocker?
    a. eProtocol makes extensive use of pop-up menus that must be used to enter all protocol information

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

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

5. Who needs to be added to the Personnel Information page?
    a. 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?
    a. 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?
    a. 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?
    a. Select submit form in the protocol's navigation pane.

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

10. How do I withdraw a protocol?
    a. 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?
    a. You may only edit a protocol if the protocol is sent it back to you. If modifications are needed after submission, contact your Committee Office staff for assistance.

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

13. How do I view my protocol's approval letter?
    a. 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?
    a. 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?
    a. Your protocol is inactive because it does not require approval. You may proceed with your study.

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

17. What is preventing me from submitting an amendment?
    a. 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?
    a. Yes. Contact your committee directly.

19. What is preventing me from submitting a continuing review?
    a. 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?
    a. Yes. Contact your committee directly.