



eProtocol



Investigator Role Manual



Table of Contents

Table of Contents

1	Overview	4
	1.1 Things to Remember	4
2	Creating a New Protocol Entry Screen.....	5
	2.1 Administrative & Standard Protocol Application	5
3	Protocol Entry Process Navigation 7	
	3.1 Top & Bottom Navigation Buttons 7	
	3.2 Spell Check, Help, Save, Auto-Save, Close, Previous & Next.....	8
	3.3 Error Message Location	9
4	Left Side Navigation Bar.....	10
	4.1 Overview.....	10
5	Protocol Entry Process	12
	5.1 Requirements to Begin.....	12
	5.2 Interacting with Data Fields.....	12
	Required Fields Designation.....	13
	Single and Multi-line Text Box.....	13
	Text Box with Rich Editor.....	13
	Drop-down Data Fields.....	13
	Field Dependence and Input Display Linkage	13
	Add/Delete/Clone Functionality of Data Grids	15
	5.3 Personnel Information	16
	Find User Search Functionality	16
	Auto-Population of Stored User Data.....	17
	5.4 Module Specific Work Flow Sections.....	18
	5.5 Protocol Information	22
	Top Tab Layout and Functionality.....	22
	Working Through Tabs and Inputting Information	22
	How to Add an Attachment.....	23
	5.6 Certifications & Disclosures.....	24
	5.7 Check for Completeness	25
	5.8 Submit Form & Department Certification Process	25
	Submit Form Process	25
	Department Certification Process.....	25
	5.9 Print View	26
	5.10 Event History.....	27
	5.11 Approval Letter	27
6	Approved Protocols.....	28
	6.1 Start an Amendment.....	28
	6.2 Start Continuing Review	29
7	Edit / Clone / Delete Protocol.....	30
	7.1 Who can edit a Protocol	30
8	Comments/Responses.....	32
	8.1 Responding to Comments	32
	Comments Cycle Explanation	33
9	Search Protocol	34
10	Summary	35



1 OVERVIEW

The Investigator Role Manual examines the functions, job duties and requirements of an eProtocol user logged in as an Principal Investigator (PI). The following pages show screen shots as well as examples of the Investigator dashboard and walks the user through the process of creating a protocol.

1.1 Things to Remember

Before getting started on the Investigator Role Manual, please review the following the following information from in the General Functionality and Dashboard Manual.

1. Choose a supported browser

Using an unsupported browser will cause the software to not work properly; limiting the users full functionality. The browsers compatible with eProtocol are: Firefox 12 and above, and Safari 7.

2. Make sure the Pop-Up Blocker is turned OFF

The steps in the Investigator Role Manual cannot be completed if the pop-up blocker is still active. See the General Functionality & Dashboard Manual for more information and instructions

3. Avoid using the Back button

Using the Back button will log the user out.

4. Resizing the screens

There are numerous pop-up windows used in the software. Don't forget you can resize the screens to better suit your view.

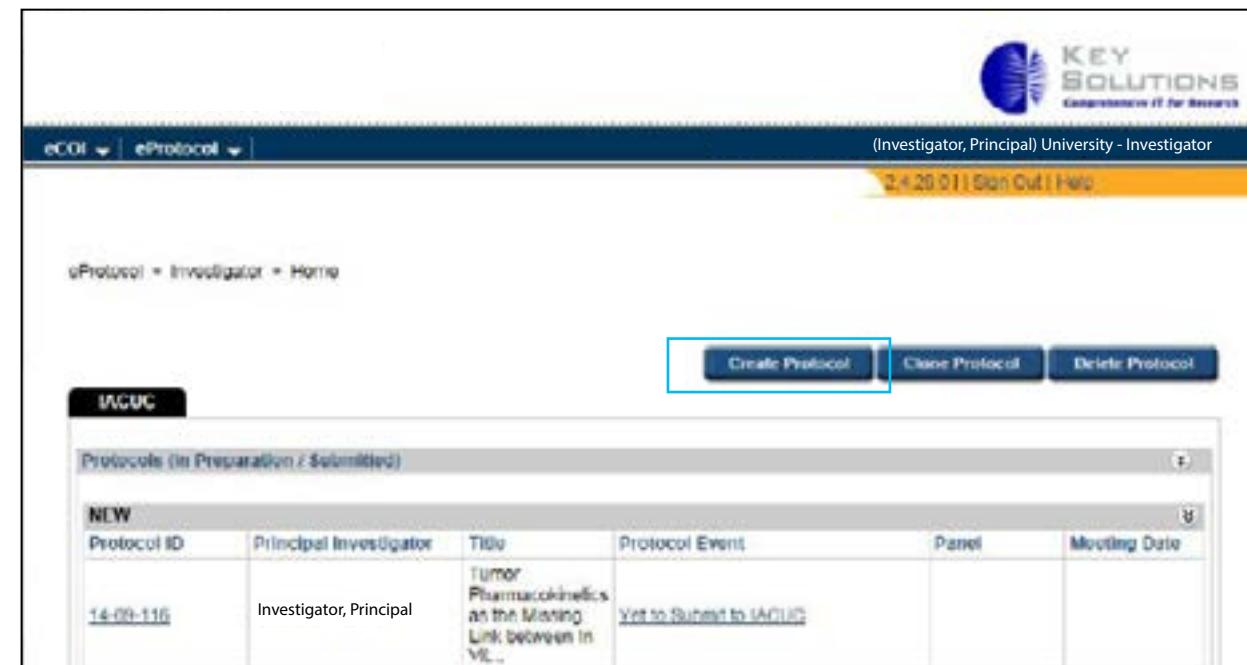
NOTE: For the purpose of this manual, IACUC is used as an example. Based on your research discipline, some options may vary.

2 CREATING A NEW PROTOCOL: ENTRY SCREEN

2.1 Administrative & Standard Protocol Application

In order to create a new protocol, follow the steps below. It is important to note the initial setup for both the administrative and standard protocol application is the same. You may follow the same general steps when creating the protocol, however some data fields may differ depending on the form type.

1. Click on the blue Create Protocol action button on your home screen [Figure 2.1] or select the tab from the top menu bar drop-down. You will then be directed to another page as seen in Figure 2.2.



The screenshot shows a web-based application for protocol management. At the top, there's a navigation bar with links for 'eCOI', 'eProtocol', 'Logout', and 'Help'. Below the navigation is a status bar with the text '(Investigator, Principal) University - Investigator' and a timestamp '24-01-2011 Sat Oct 11:45:20'. The main content area has a title 'IACUC' and a sub-section 'Protocols (In Preparation / Submitted)'. A table lists one protocol entry:

Protocol ID	Principal Investigator	Title	Protocol Event	Panel	Meeting Date
14-09-116	Investigator, Principal	TUMOR Pharmacokinetics at the Meningo- Link between In VIL...	Yet to Submit to IACUC		

At the bottom right of the table, there are buttons for 'Create Protocol', 'Close Protocol', and 'Delete Protocol'.

Figure 2.1



The screenshot shows the 'Create Protocol' interface. At the top, there's a breadcrumb navigation: 'eProtocol > Investigator > Home > Create Protocol'. Below this is a 'Study Title' input field. Underneath it is a dropdown menu labeled 'IACUC' with two options: 'Administrative Application' and 'IACUC'.

Figure 2.2

2. Give your study a title.

3. Select a form type from the two options available. Upon your selection, more content will appear on your screen [Figure 2.3].

4. Search and add the Principal Investigator to the protocol. A PI must be named at the time of the creation of the form. For more information on the search and add functionality, please see page 16.

5. After completing the necessary data forms, click the Create action button.

The screenshot shows the 'Principal Investigator' data entry form. It includes fields for Name (with 'Investigator, Principal' selected), Degree, University Title, WSIU Access ID, Department (with 'seec:line' selected), Division, Office Address, Office Phone, E-mail Address, Laboratory Phone, and Emergency Phone.

Figure 2.3

3 PROTOCOL ENTRY PROCESS NAVIGATION

3.1 Top & Bottom Navigation Buttons

There are several ways to navigate through your newly created protocol. The top and bottom of the page contain the same menu bar for easier navigation throughout the protocol setup. The buttons, shown in Figure 3.1 and 3.2, are: Save, Spell Check, Help, Close, Previous and Next. The next three pages will explore the functionality of the navigation buttons.

The screenshot shows the 'Principal Investigator' form with the top navigation bar highlighted. The bar contains buttons for 'SAVE | SPELL CHECK | HELP | CLOSE' and 'Previous' and 'Next' buttons. The main form area displays fields for Name, Degree, University Title, WSIU Access ID, Department, Division, Office Address, Office Phone, E-mail Address, Laboratory Phone, and Emergency Phone.

Figure 3.1

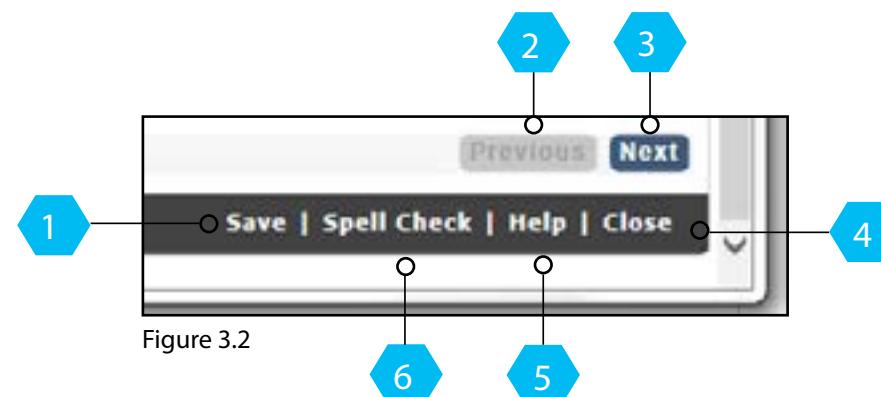
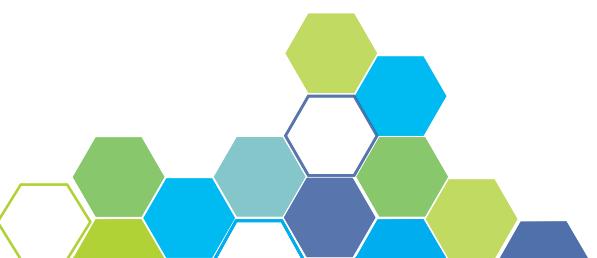


Figure 3.2



3.2 Spell Check, Help, Save, Auto-Save, Close, Previous & Next

- 1 Clicking the Save button will save any information entered when creating the protocol. The information will continue to be saved regardless of being logged in or out. Navigating from one page to the next will Auto-Save any work documented before moving to the next page.

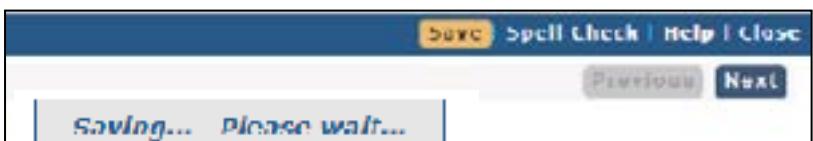


Figure 3.3

- 2 The Previous button allows the user to go to the previous page while saving any data before re-navigating [Figure 3.4]. The Previous and Next buttons have the same functionality as clicking up and down the left navigation menu and Auto-Save any data before navigating to another page.



Figure 3.4



Figure 3.5

- 3 The Next button has the same functionality as the Previous button only it moves to the next consecutive page rather than the one prior. [Figure 3.5].

NOTE: The functionality of the Previous and Next buttons are dependent on all mandatory fields being completed. If there are any required fields left empty, you may not be able to proceed to the next page.

- 4 In order to close the protocol, you may click the Close button at the top or bottom navigation bar. Clicking the Close button results in a pop-up window prompting the user if they wish to proceed before closing the protocol.

- 5 The Help button generates a pop-up window that displays relevant help information specific to the page the user is on.
- 6 The Spell Check button in the top navigation bar checks for any words that have been misspelled [Figure 3.6].



Figure 3.6

NOTE: When the spell check window initially opens, it hides behind open windows. It also gets hidden after clicking any of the action buttons within the spell check pop-up. Resizing the windows and setting them side by side when editing may be the best alternative to avoid this issue.

Spell check does not work with Rich Text Editor Fields.

3.3 Error Message Location

An error message will appear on any dashboard or pop-up window when information was not entered correctly or a step was missed. The red text alerts the user of an error and notes the reason for the error.

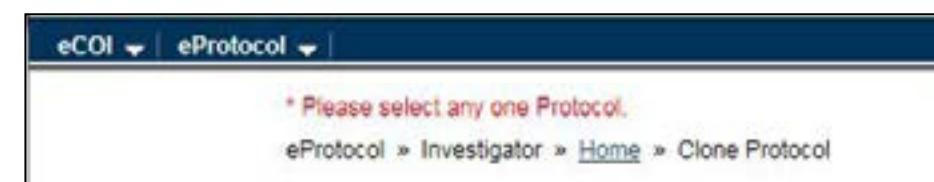


Figure 3.7

4 LEFT NAVIGATION BAR

4.1 Overview

On the left side of the protocol window is a blue menu bar. This menu is one of several ways to navigate through the protocol forms. Clicking on a menu tab will direct the user to the specified page. Every page contains important forms and information required to complete and submit the protocol. Figure 4.1 below demonstrates what the left menu bar looks like and gives a brief definition to the tabs on page 11. Next to the definitions is a page number where the user can view a more in-depth explanation of each tab and its functionality.

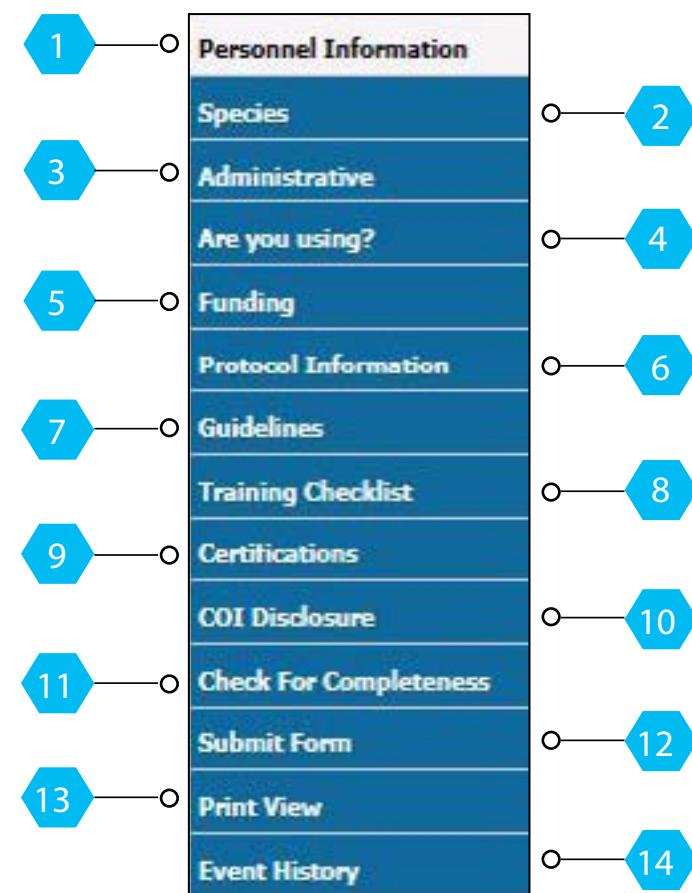
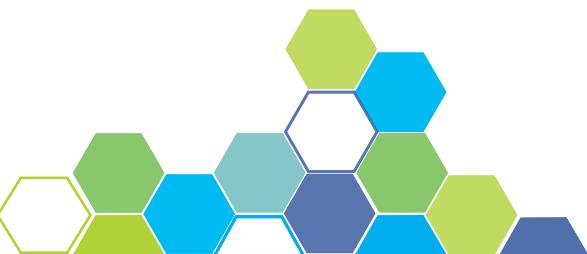


Figure 4.1

- 1 Personnel Information - Use this section to add all members of the research team based on their individual roles [page 15].
- 2 Species - This is a module specific tab. For instance, the Species tab is shown for IACUC protocols. This form is used to document any species being used in the protocol [page 18].
- 3 Administrative - The Administrative tab shows a list of general questions pertaining to the purpose and methods used in the protocol [page 19].
- 4 Are you using? - This form is used to document any occupational health and hazardous agents being used in the protocol [page 19].
- 5 Funding - This page allows for any funding for the protocol to be entered [page 20].
- 6 Protocol Information - This navigation tab contains a sub-menu of different forms and are specific to each module. For the purpose of this manual, IACUC pages are illustrated by the following sub-menu tabs: Purpose and Value, Justification of Animal Use, Husbandry and Breeding, List of Procedures, Non-Surgical Procedures, Surgery Relationships, Schedule of Procedures, Euthanasia and Attachments [page 22].
- 7 Guidelines - A list of both mandatory and non-mandatory guidelines are displayed [page 21].
- 8 Training Checklist - Provides a checklist form [page 21].
- 9 Certifications - The Certifications page is to ensure that you and the fellow research members comply and will abide by the rules and guidelines pertaining to the protocol and research being performed [page 24].
- 10 COI Disclosure - The Conflict of Interest (COI) Disclosure is to make note of any financial conflicts of interest within the research team [page 24].
- 11 Check For Completeness - Use this feature to check for any unanswered questions before submitting the protocol [page 25].
- 12 Submit Form - When the protocol is finalized and all mandatory signatures have been received, the PI must click Submit Form in the left navigation menu [page 25].
- 13 Print View - PDF versions of all sections of the protocol with or without comments can be generated with this tab [page 27].
- 14 Event History - A catalog of dates in the life of the protocol and a list of all e-mail correspondence from the system are listed here. Through this tab you can access the approved supplemental documents, approval letter and past PDF versions of the protocol to be printed or saved [page 28].



5 PROTOCOL ENTRY PROCESS

Protocol Entry Process

5.1 Requirements to Begin

In order to begin the protocol entry process, the user must know the general information regarding the protocol. A Principal Investigator and Department Chair are mandatory in creating any protocol and must be known before the initial set up. Any required data pertaining to specific modules must be known. For example, the user creating the protocol must know the species being used for an IACUC module.

5.2 Interacting with Data Fields

The following pages will explore the functionality and user interaction with the data fields.

Figure 5.1

1 Required Fields Designation

Any entry field with a red asterisk, denotes it is a mandatory field. If mandatory fields have not been filled, an error message will appear at the top of the dashboard.

2 Single and Multi-Line Text Box

Single and multi-line text boxes are found throughout eProtocol. You can tell the difference between the two as a single line box [Figure 5.1] typically has an 'X' in the box indicating the box only allows for a single line of text. Clicking on the 'X' will delete any information entered in the single line text box. Multi-line text boxes are usually much larger and allow for multiple lines of text.

3 Text Box with Rich Text Editor

The Rich Text Editor box only appears in some content area fields and allows the user to change the look and feel of their text. Certain features of the rich text editor may be useful in areas that the user wants to highlight or call out for importance.

4 Drop-down Data Fields

Drop-down data fields allows the user to filter through specific data.

5 Field Dependence and Input Display Linkage

Upon entering information in mandatory data fields, the user may notice other data fields have become active or inactive. Certain data fields are dependent upon the inputted information. The example in Figure 5.1 shows an inactive text box that is dependent on other information to be entered in order to become active.

This same functionality also holds true when using the Yes/No buttons within a form. Certain data fields can become active or inactive depending on which of the Yes/No buttons have been selected. An example of this can be seen in Figure 5.2 and 5.3.

NOTE: Any gray text boxes indicates the box is not active.

Is this wildlife field research?

Yes No

Wildlife Field Research

- List all State, Federal and International permits required for your research.
Note: Permits must be obtained before research is initiated (attach copies to this application).
- Describe precautions taken to ensure the health and safety of personnel working in the field and handling wild animals (e.g. rabies immunization, Lyme disease, Hanta virus)
- List the study site location(s). Include country, state, county.

Figure 5.2

7. Is this wildlife field research?

Yes No

[Previous](#) [Next](#)

[Save](#) | [Spell Check](#) | [Help](#) | [Close](#)

Figure 5.3

Species to be used

[Add](#) | [Delete](#) | [Clone](#)

Please click on Add to add Species to be used

Figure 5.4

6

6 Add/Delete/Clone Functionality of Data Grids

The Add/Delete/Clone Functionality allows for the Investigator to change information within the protocol. An example of this can be seen under the species tab on page 18.

Add - Clicking this button will generate a pop-up with a number of data fields to be completed. Complete the required data fields and press the Save button at the upper right of the pop-up to complete the addition. An example of the pop-up created when adding a species can be found in Figure 5.1 on page 12.

Delete - Check the box next to the species you wish to eliminate from the protocol followed by clicking the Delete button. A pop-up window confirming your decision will appear for your final approval [Figure 5.5].

Species to be used					Add	Delete	Clone
Species	Strain	Animal Sex	USDA Category	Source of these animals	Number		
<input checked="" type="checkbox"/> Zebrafish	Other	Female	B	Purchased	50		
<input type="checkbox"/> Mouse	DRA/1	Either	C	Bred/Rom in-house	25		

Please review
Brief example
Category B
Category C
Category D
Category E

eProtocol - University - Confirmation - Internet Explorer

Do you want to delete the selected Species?

[Yes](#) [No](#)

Figure 5.5

Clone - Check the box next to the species you wish to clone followed by clicking on the Clone button. A window identical to the one that appears for the Add button [Figure 5.1] will appear, allowing you to alter any information necessary. Click on the Save button to complete this process. Cloning allows for adding the same species, but with different information.

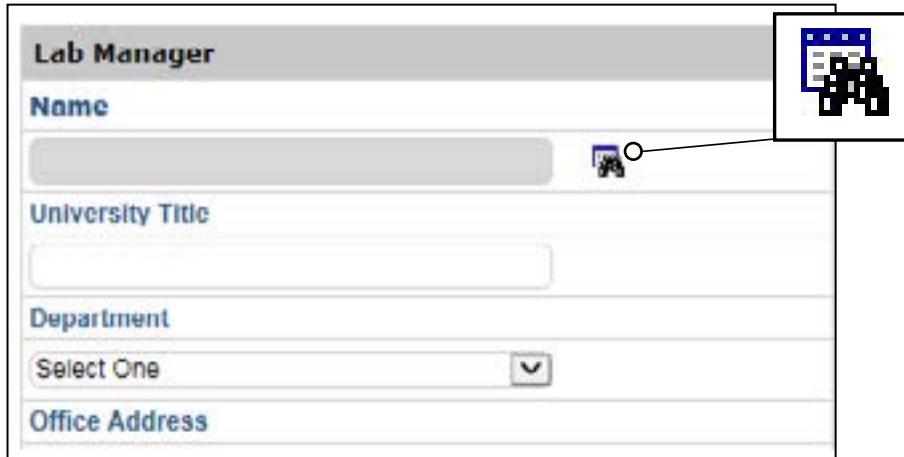
5.3 Personnel Information

The Personnel tab is the area of the protocol where the members involved are entered. Every member's job title, function, role and contact information should be entered in this section of the protocol upon initial creation.

Find User Search Functionality

Some fields have a binocular icon next to them [Figure 5.6] which signifies the search and add functionality. Clicking on the icon generates a pop-up window like the one in Figure 5.7.

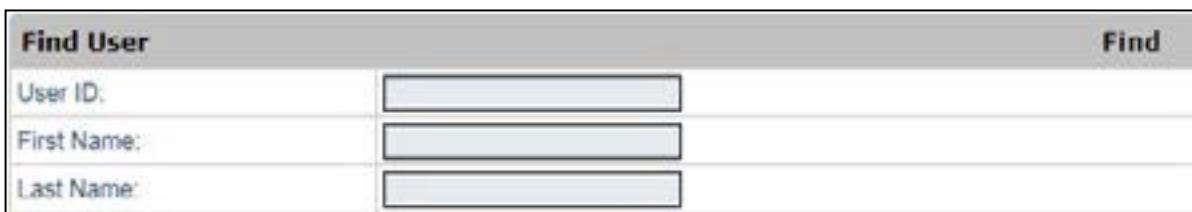




The screenshot shows a 'Lab Manager' form with the following fields:

- Name: A text input field with a small user icon.
- University Title: A text input field.
- Department: A dropdown menu labeled 'Select One'.
- Office Address: A text input field.

Figure 5.6



The screenshot shows a 'Find User' form with the following fields:

- User ID: A text input field.
- First Name: A text input field.
- Last Name: A text input field.

A 'Find' button is located at the top right of the form.

Figure 5.7

1. Find a user by filling out any one of the entry fields or a combination of the first and last name, followed by clicking the Find button.

NOTE: The Find User functionality will not work if all three search fields are entered as they do not work together.

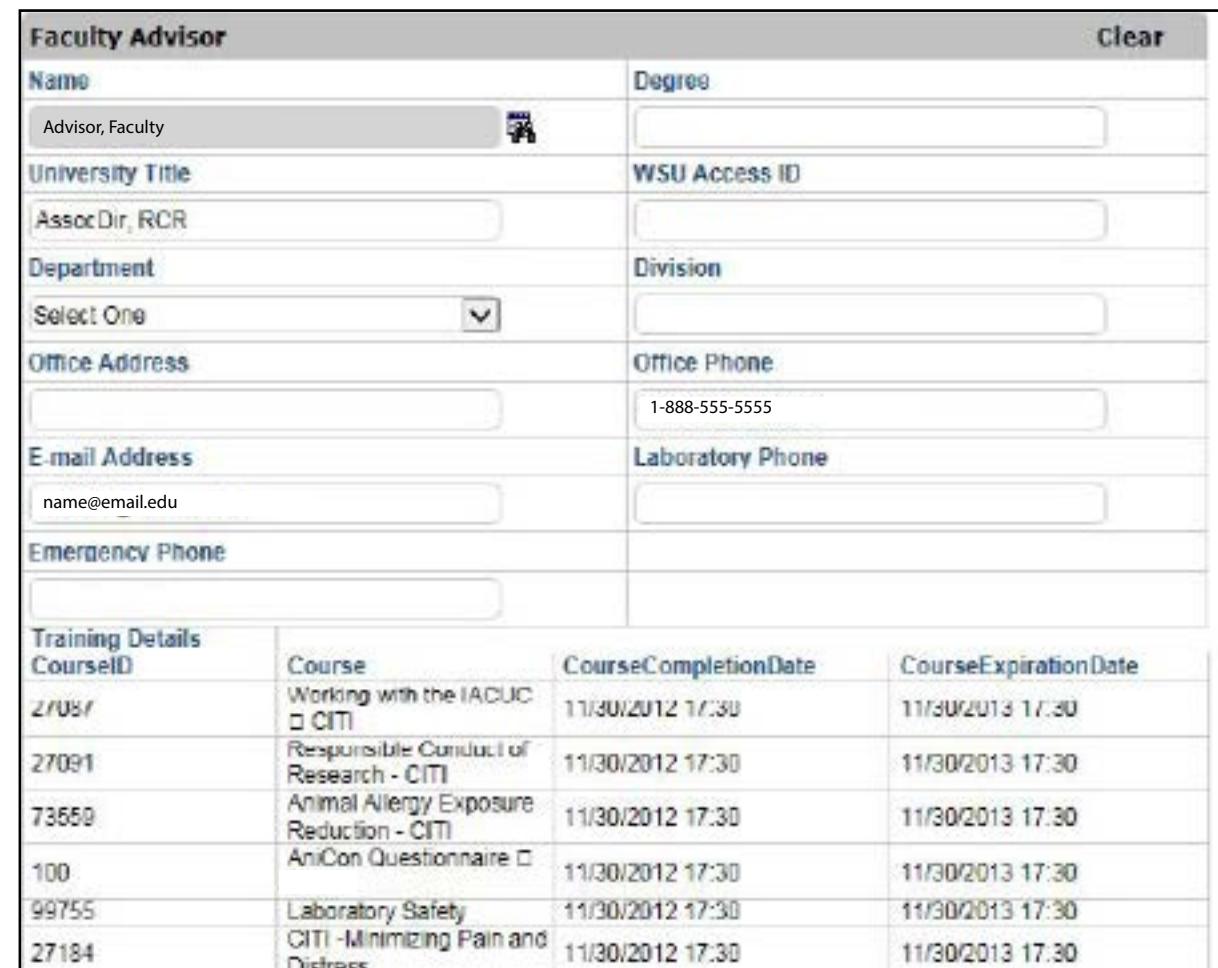
2. After clicking Find, another pop-up window is displayed with a list of users matching the information entered in the Find User function.

3. Select the user you wish to add by checking the circle next to their name.

4. Click on the OK button and resume to the original page.

Auto-Population of Stored User Data

After you have selected a member using the search and add function, any previously saved information regarding the user will auto-populate in the data fields. After adding the designated Faculty Advisor, fields such as Office Phone, E-mail Address, and Training Details will automatically be filled out from saved user data [Figure 5.8].



The screenshot shows a 'Faculty Advisor' form with the following fields:

Name	Degree		
Advisor, Faculty			
University Title	WSU Access ID		
AssocDir, RCR			
Department	Division		
Select One			
Office Address	Office Phone		
	1-888-555-5555		
E-mail Address	Laboratory Phone		
name@email.edu			
Emergency Phone			
Training Details			
CourseID	Course	CourseCompletionDate	CourseExpirationDate
27087	Working with the IACUC □ CITI	11/30/2012 17:30	11/30/2013 17:30
27091	Responsible Conduct of Research - CITI	11/30/2012 17:30	11/30/2013 17:30
73659	Animal Allergy Exposure Reduction - CITI	11/30/2012 17:30	11/30/2013 17:30
100	AniCon Questionnaire C	11/30/2012 17:30	11/30/2013 17:30
99755	Laboratory Safety	11/30/2012 17:30	11/30/2013 17:30
27184	CITI -Minimizing Pain and Distress	11/30/2012 17:30	11/30/2013 17:30

Figure 5.8

5.4 Module Specific Work Flow Sections

The following pages further investigate several of the tabs on the left menu bar. The tabs that will be explained in section 5.4 are: Species, Administrative, Are you using, Funding, Guidelines, and Training Checklist.

Species

The Species tab is a module specific tab for IACUC and is required if any animals are being used in the protocol. If the protocol created is for IACUC, entering a species is mandatory.

1. To add a species, click on the Add button highlighted in Figure 5.9 below. Clicking this button will create a pop-up window of the Add Species form. An example of this form can be found in Figure 5.1 on page 12.
2. Fill out all of the mandatory data fields.
3. After entering all of the necessary information, click the Save button and return to the species page where the species has now been added [Figure 5.10].

Figure 5.9

Species to be used					
Species	Strain	Animal Sex	USDA Category	Source of these animals	Number
<input type="checkbox"/> Zebrafish	Other	Either	B	Purchased	50

Figure 5.10

Administrative

The Administrative tab is a list of general questions that pertain to the overall purpose of the protocol. This page requires the use of Yes/No buttons with connected data fields as well as multi-line text boxes.

Figure 5.11

Are You Using?

This form is used to document hazardous agents to be used in the protocol such as, but not limited to, recombinant DNA, toxins, infectious agents, chemicals, and radioactive materials. If hazardous biological agents or toxins are being used, an application to the Institutional Biosafety Committee (IBC) is required. This page has active links as well as Yes/No buttons with connected data fields [Figure 5.12, page 20].

Figure 5.12

Guidelines

The Guidelines page is a list of all Mandatory and Non-Mandatory guidelines for the protocol that must be reviewed and affirmed by the PI. Each guideline is an active link that generates a new window when clicked on [Figure 5.14].

Figure 5.14

Funding

The Funding page allows for the Investigator to enter how the protocol will be funded. Adding a Funding Source can be done by clicking the Add but as seen in Figure 5.13. A pop-up window will appear with required data fields. Clicking Save will complete this process and allow for more funding sources to be added if necessary.

Figure 5.13

Training Checklist

As attributes within the protocol change, the check box becomes available. This function is necessary for assigning a person to training. Clicking on the blue PDF action button [Figure 5.15] will generate a PDF view of the required and completed training. The training is broken down into two parts and are as follows:

Part 1: Required training is based on the protocol submission (e.g biological hazards, surgical procedures).

A - Training that is required before a PI can submit the protocol to the Department Chair.

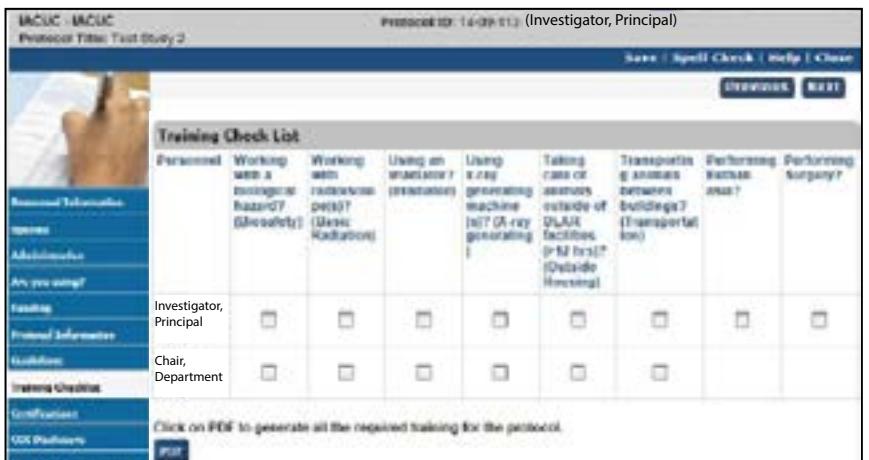
B - Training that is required before the protocol can be approved.

Part 2: Required training for each individual.

A - Individual training that needs to be completed before a PI can submit the protocol to the Department chair.

B - Individual Training that must be completed before the protocol can be approved.

(Investigator, Principal)



	Performed	Working with a radioactive hazard? (Sheets/Radiation)	Working with radioactive pets? (Mice/Radiation)	Using an unstructured presentation	Using X-ray generating machine?	Taking care of animals outside of UALAC facilities (P.M hrs)? (Update Personnel)	Transporting animals between buildings? (Transportation)	Performing Versus? (Anesthesia)	Performing Surgery?
Investigator, Principal	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Chair, Department	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>			

Click on PDF to generate all the required training for the protocol.

Figure 5.15

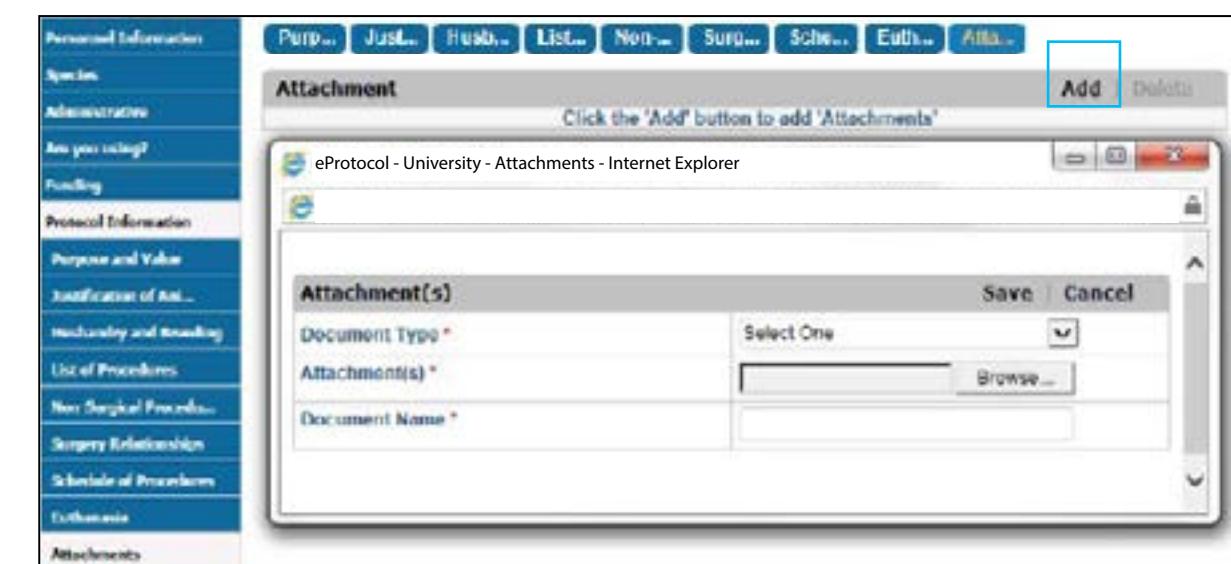
Working Through Tabs and Inputting Information

The row of tabs allows for easier navigation from one page to the other. Clicking on a tab opens up a specific page. The majority of the pages under the Protocol Information tab are forms for the protocol. Click each tab to fill out the necessary information on each form.

How to Add an Attachment

In order to add an attachment, go to the Attachments tab on the top tab bar or the side menu bar and follow the steps below.

1. Click the Add button highlighted in the image below. A pop-up window will appear [Figure 5.18] with mandatory data fields.
2. Use the drop-down tab to select the Document Type and select the Browse button to navigate through documents on your computer.
3. Select the document you wish to attach and press OK, which will result in bringing you back to the attachment pop-up window.
3. Click Save as your process is now complete.



Document Type	Attachment(s)	Document Name
Select One		

Figure 5.18

NOTE: All files are uploaded here.

5.5 Protocol Information

The Protocol Information tab is different than the rest because it is the only tab with a sub-menu of tabs. The list of the secondary tabs will appear upon clicking the Protocol Information menu tab. The new list of tabs are as follows: Justification of Animals, Husbandry and Breeding, List of Procedures, Non-Surgical Procedures, Surgery Relationships, Schedule of Procedures, Euthanasia and Attachments. Depending on what module you are working in will determine which tabs appear. For this manual, IACUC tabs will be used as an example.

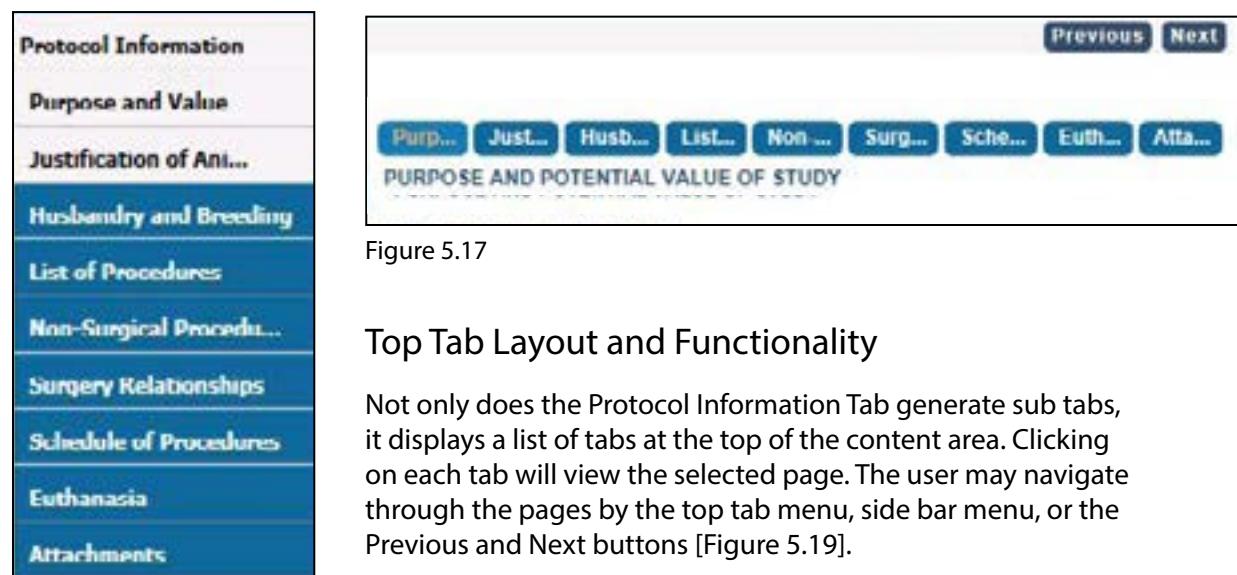
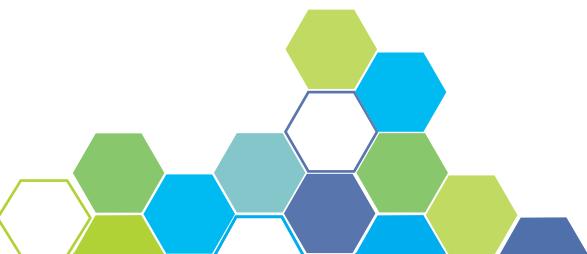


Figure 5.16

Top Tab Layout and Functionality

Not only does the Protocol Information Tab generate sub tabs, it displays a list of tabs at the top of the content area. Clicking on each tab will view the selected page. The user may navigate through the pages by the top tab menu, side bar menu, or the Previous and Next buttons [Figure 5.19].



5.6 Certifications & Disclosures

It is mandatory that the Principal Investigator of the protocol sign and complete the required certifications and disclosures in order for a protocol to be approved. A check mark is listed next to the names of all members on the research team. Check the box next to your name to signify you have read and understand the document.

The Certification is to ensure you and fellow research members comply and will abide by the rules and guidelines pertaining to the protocol and research being performed.

The Conflict of Interest(COI) Disclosure is to disclose any financial conflicts of interest within the research team.

NOTE: Each person must individually open the protocol and sign their own certification and disclosure form.



Certification
As principal investigator I certify the following:

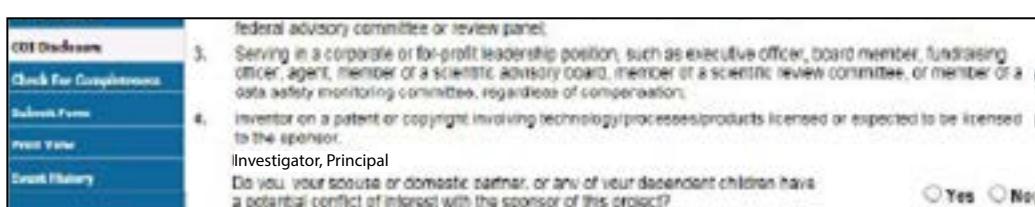
1. My staff and I will comply with all standards for animal care and investigation established in the [Guide for the Care and Use of Laboratory Animals](#) (the Guide, NRC 2011) and the [Federal Animal Welfare Act](#), and will follow all policies established by the University to ensure that these standards are met.
2. I assume responsibility for the work described here.
3. All individuals working with the animals on this protocol are qualified by virtue of training or experience to perform proper handling, experimental, and restraint techniques required for the species to be used.
4. I recognize my responsibility to identify occupational health hazards related to this protocol including identifying hazards, providing the necessary training for those involved, and supplying the appropriate protective clothing and equipment to minimize the risks.
5. This research does not represent unnecessary duplication of previous experiments.
6. I realize that failure to adhere to policies related to animal care and use may result in suspension or revocation of permission to perform animal research in Wayne State University facilities.

For additional requirements and expectations please review and affirm the [Principal Investigator Responsibilities Guideline](#).

Investigator, Principal

I have read this protocol, understand my role in the project, and will comply with all standards for animal care and investigation established in the [Guide for the Care and Use of Laboratory Animals](#) (the Guide, NRC 2011) and the [Federal Animal Welfare Act](#), and will follow all policies established by the University to assure that these standards are met.

Figure 5.19



federal advisory committee or review panel

3. Serving in a corporate or for-profit leadership position, such as executive officer, board member, fundraising officer, agent, member of a scientific advisory board, member of a scientific review committee, or member of a data safety monitoring committee, regardless of compensation;

4. Inventor on a patent or copyright involving technology/processes/products licensed or expected to be licensed to the sponsor.

Investigator, Principal

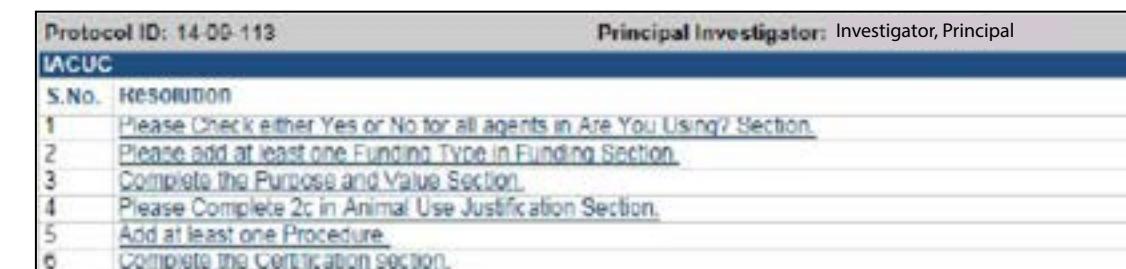
Do you, your spouse or domestic partner, or any of your dependent children have a potential conflict of interest with the sponsor of this project?

Yes No

Figure 5.20

5.7 Check for Completeness

As you near the end of filling out the protocol form, click the Check for Completeness tab in the left menu bar to check that all mandatory fields have been completed. Clicking this menu button will result in a pop-up window that shows the user the areas that have not yet been completed. Click on the active blue links within the pop-up to navigate to the pages still awaiting mandatory fields to be entered.



Protocol ID: 14-00-113		Principal Investigator: Investigator, Principal
IACUC		
S.No.	RESOLUTION	
1	Please Check either Yes or No for all agents in Are You Using? Section.	
2	Please add at least one Funding Type in Funding Section.	
3	Complete the Purpose and Value Section.	
4	Please Complete 2c in Animal Use Justification Section.	
5	Add at least one Procedure.	
6	Complete the Certification Section.	

Figure 5.21

5.8 Submit Form & Department Certification Process

Submit Form Process

Before the protocol can be submitted to the Department Chair for approval, it must have electronic signatures for the Certifications and COI Disclosures. After you have signed the proper forms and filled out the necessary data fields, you may click the Submit Form tab in the left menu bar.

NOTE: Submitting the form for Department Certification does not submit to IACUC. Once the Department Certification is completed, an additional step is required to submit to IACUC.

Department Certification Process

The Department Chair must check for the agreement of certification in order for the protocol to be approved. To approve the protocol, follow the steps below.

1. In the Dept Certifications section of the grid, click on “Receipt of Dept Certification” under the Protocol Event column. A pop-up window will appear like the one seen in Figure 5.22.
2. Click on the protocol ID number in the top left corner of the pop-up window to open the protocol in another window.
3. Once in the protocol, go to the Certification page and check the circle next to your name to confirm you endorse the certifications made by the PI [Figure 5.19, pg 24].
4. After confirming the certifications, go to the COI Disclosure page within the protocol. Check the Yes or No button next to your name to indicate any financial conflict of interest you may have with the protocol [Figure 5.20, pg 24].

NOTE: The first of the two checkboxes shown below in Figure 5.22 will remain disabled until steps 3 and 4 have been completed.

Figure 5.22

5. Save and close your changes in the protocol and return to the Dept Certification pop-up window [Figure 5.22].
6. Click the Refresh button to update the window - enabling the first checkbox.
7. Choose to send off your certification by checking the appropriate box.
8. Click the Submit button to send your completed certification to the PI.

5.9 Print View

PDF versions of any or all sections of the form can be generated using the Print View. Upon clicking the Print View tab in the left menu bar, a pop-up window will appear like in Figure 5.23. You may then check which sections you would like to view and print, followed by the page orientation and whether or not you would like any comments within the protocol to be viewed. Click the OK action button to see the Print View PDF.



Figure 5.23



6 APPROVED PROTOCOLS

5.10 Event History

The Event History section of the protocol [Figure 5.24] enables the user to view all transactions and submissions regarding the protocol. Any of the blue links under the "Status" column generate a pop-up window like that of the Print View window [Figure 5.23], allowing the user to see a list view of the form. Approval Letters can be found in the "Letters" column.

Event History					
		Date	Status	View Attachments	Letters
Specie		09/22/2014	CONTINUING REVIEW 1 FORM CREATED		
Administrative		09/23/2014	NEW FORM APPROVED		Approval Letter
Are you using?					
Pooling		09/22/2014	NEW FORM REVIEWER(S) ASSIGNED		
Protocol Information		09/23/2014	NEW FORM PANEL ADDED/CHANGED		
Guidelines		09/22/2014	NEW FORM SUBMITTED		
Training Records		09/22/2014	NEW FORM PREREVIEWED		
Amendments		09/22/2014	NEW FORM DEPT CERTIFICATION		
IACUC Workflows		09/22/2014	NEW FORM PROTOCOL CLONED (14-09-109)		
Email History		Email Date	Email Type	Attachments	
Email		09/22/2014	IACUC Protocol Approved - 14-09-109 Investigator, Principal		

Figure 5.24

5.11 Approval Letter

Approval letters notify the user that their request has been approved. For example, upon creating a protocol, the PI must submit it for review. Once the protocol has been approved, the PI will be notified with an Approval Letter, which can be found in the Event History tab. Clicking on the Approval Letter link will prompt a pop-up asking if you want to 'Open' or 'Save' the letter [Figure 5.25].

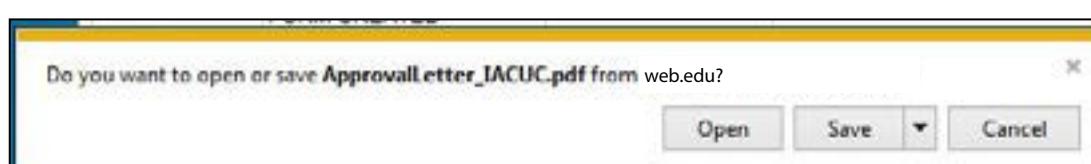


Figure 5.25

Whether you are proposing a change to an existing study, requesting a renewal, reporting safety information, or officially closing an Expedited/Full Board study, you are looking to create another form or change an approved protocol. In order to do so, read pages 29 and 30 as they will guide you in the process of changing a protocol.

6.1 Start an Amendment

In order to start an Amendment, go to the PI home dashboard and click on a Protocol ID of an 'Approved protocol'. Clicking on the ID number will generate a pop-up window providing the option to Start Amendment [Figure 6.1]. Upon pressing OK, the user is taken to the protocol [Figure 6.2]. Fill out the required data fields on the Amendment form and submit the amendment for review when finished.

NOTE: If an amendment is in progress, that option will not be available.

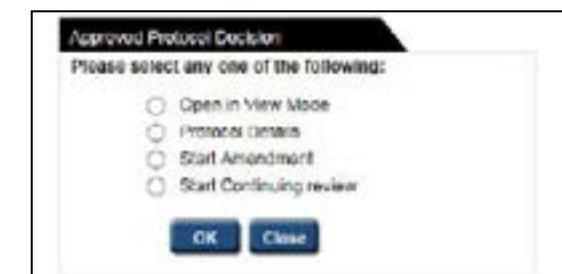


Figure 6.1

Amendment

- Is this an amendment to add personnel? Yes No
- Review General Amendment Requirements for guidance. All changes must be incorporated into this protocol application.
- Describe why this amendment is necessary and how it integrates with the original protocol and approved amendments.

Figure 6.2

7 EDIT/CLONE/DELETE

6.2 Start Continuing Review

Continuing Review is necessary when a protocol is nearing the end of its allotted time period. If the research is still ongoing, the PI must fill out a Continuing Review form to renew the protocol. The continuing review process is similar to starting an amendment. Click on a Protocol ID to generate a pop-up window with the option to Start Continuing review [Figure 6.1]. The Annual Review Form will open in a separate window where the PI may fill out the required data fields.

NOTE: In the case that you do not see the Continuing Review option, it is because continuing review will not become available until the protocol is within a certain number of days of needing a review. A protocol is good for three years but must go up for a continuing review each year.

The screenshot shows the 'Annual Review Form' for protocol 14-03-110. The main title bar says 'IACUC - IACUC' and 'Protocol ID: 14-03-110 (Investigator, Principal)'. The page header includes 'Save | Spell Check | Help | Close' and navigation buttons 'Previous' and 'Next'. On the left, a sidebar lists 'CONTINUING REVIEW', 'Personal Information', 'Species', 'General Questions', 'Am I processing?', 'Coding', 'Protocol Information', 'Guidelines', 'Training Checklist', 'Documentation', 'Non-invasive', 'Check for completeness', and 'Submit Form'. The main content area has three sections: 1. 'Animals within the last year' with a 'Project Summary' table showing data for 'Mouse' and 'Albino Nude' strains across 'Year 1' and 'Year 2'. 2. 'Protocol Status' with options to keep the protocol active or close it. 3. 'PROGRESS REPORT' with a note about including a brief description of the protocol's progress if it has been initiated.

Figure 6.3

7.1 Who can edit a Protocol

The PI has the ability to edit or view protocols within the Protocols (In Preparation/Submitted) grid on the home dashboard, highlighted in the image below. Clicking on any of the Protocol ID numbers results in a pop-up, as seen below, prompting the user to either 'Edit' or 'View' the selected protocol.

The only other members that are allowed to edit a protocol within the Investigator role are the CO-PI and Lab Manager.

The screenshot shows the 'Protocols (In Preparation / Submitted)' grid under the 'IACUC' tab. The grid has columns for 'Protocol ID', 'Principal Investigator', 'Title', 'Protocol Event', 'Panel', and 'Meeting Date'. It lists several protocols, including '14-09-113', '14-09-111', '14-09-070', '14-09-085', '14-09-108', '14-09-100', and '14-09-110'. Below the grid, a confirmation dialog box is open with the message 'Do you want to open IACUC Protocol 14-08-078 (Investigator, Principal) for Editing?'. The dialog has 'Edit' and 'View' buttons. The bottom of the screen shows a taskbar with icons for 'eProtocol - University - Confirmation - Internet Explorer' and 'eProtocol - University - Confirmation - Internet Explorer'.

Figure 7.1



Edit/Clone/Delete

eProtocol > Investigator > Home > Clone Protocol

IACUC						
Protocol ID	Principal Investigator	Title	Protocol Event	Form Type	Panel	Meeting Date
<input checked="" type="checkbox"/> 14-09-085	Investigator, Principal	Example Study	NEW	NEW		

Figure 7.2

- 2 The Clone Protocol action button is used to duplicate a protocol. Clicking on the action button will direct the user to another page as seen in Figure 7.2. Check the circle next to the Protocol ID number you wish to clone followed by clicking the Clone Protocol button. A duplicate protocol will appear with a newly assigned Protocol ID number [Figure 7.3].

Protocol 14-09-121 is created by cloning the protocol 14-09-110

eProtocol > Investigator > Home

IACUC						
Protocols (In Preparation / Submitted)						
NEW						
Protocol ID	Principal Investigator	Title	Protocol Event	Panel	Meeting Date	
14-09-121	Investigator, Principal	new protocol for additional test	Debt Certification Required			
<u>14-09-085</u>	Investigator, Principal	Example Study	Debt Certification Required			
14-09-079	Investigator, Principal	Test Study	Debt Certification Required			

Figure 7.3

- 3 Clicking on the Delete Protocol button takes the user to a page where a list of 'In Preparation' protocols are displayed as shown in Figure 7.4. Check the box to the left of the Protocol ID number you want to delete. Complete this action by clicking on the Delete Protocol action button.

eProtocol > Investigator > Home > Delete Protocol

IACUC						
<input type="checkbox"/> Protocol ID	Principal Investigator	Title	Protocol Event	Form Type	Panel	Meeting Date
<input checked="" type="checkbox"/> 14-09-120	Investigator, Principal	new protocol additional test for	NEW	NEW		
<input type="checkbox"/> 14-09-110	Investigator, Principal	new protocol additional test for	NEW	CONTINUING REVIEW	IACUC	
<input type="checkbox"/> 14-09-085	Investigator, Principal	Example Study	NEW	NEW		

Figure 7.4

8 COMMENTS/RESPONSES

eProtocol > Investigator > Home

IACUC						
Protocols (In Preparation / Submitted)						
NEW						
Protocol ID	Principal Investigator	Title	Protocol Event	Panel	Meeting Date	
14-10-122	Investigator, Principal	Tumor Pharmacokinetics as the Missing Link between In Vitro...	SUBMITTED TO IACUC	IACUC		
14-10-136	Investigator, Principal	Tumor Pharmacokinetics as the Missing Link between In Vitro...	Comments Received (Cycle 1)	IACUC		
14-10-159	Investigator, Principal	Test	Debt Optimization Received			
14-10-149	Investigator, Principal	ANOTHER Tumor Pharmacokinetics as the Missing Link between In Vitro...	Yet to Submit to IACUC			
14-10-121	Investigator, Principal	Meeting on October 9th	Responses Sent (Cycle 2) (TABLED)	Test Panel		

Figure 8.1

8.1 Responding to Comments

Reviewers have to ability to comment on Protocols which are then sent to the Investigator. Some of the comments sent require a response from the Investigator. If that is the case, the Investigator will see a link in the Protocol Event column titled "Comments Received (Cycle1)" [Figure 8.1].

In order to respond to the comment(s) follow the steps below.

1. Click on the link to be directed to the Comments page [Figure 8.2] where you can view the comments sent and if your response is required.

NOTE: The checked circle next to Response Necessary for Approval [Figure 8.2] lets the Investigator know a response is needed.

2. Write your response in the text box and save your work.

3. Click on the Submit to IACUC action button to send off your response. The protocol event on your dashboard will now read "Responses Sent (Cycle 2)".

9 SEARCH PROTOCOL



eProtocol > Investigator > Home > Comments

Protocol ID: 14-10-132 (Investigator, Principal)

Cycle: 1

[Get Protocol](#) [Show All Comments](#) [Submit to IACUC](#)

Comments

Section: Purpose and Value
Comment: 1
please expand on the purpose and value
 Response Necessary for Approval Suggestion Not Necessary for Approval

Response

[Save](#) [Clear](#)

Figure 8.2

Comments Cycle Explanation

Comments Received (Cycle 1) means at least one Reviewer assigned for review sent comments on the protocol. The RCA is responsible for taking the comments and sending them to the Principal Investigator which is also referred to as Comments Sent (Cycle 1).

Responses Received (Cycle 1) is when the Investigator has responded to the comments written by the Reviewer(s) and/or Panel Manager. The Investigator must then send his/her responses to the comments to the RCA(s) which is called Responses Sent (Cycle 1).

Completing those four steps is considered a Cycle. Should the four steps be repeated, the comments will then be in their second cycle and so on.

Overview

No matter your role, all members have the ability to search a protocol. A user can access the Search Protocol page by first selecting the eProtocol menu on the top menu bar. Hover your mouse over your role and click on the menu tab titled Search Protocol.

You will be directed to a search page like the one shown in Figure 9.1. On this screen, you may search for all protocols that you have access rights to. Protocols can be searched by Study Title, Principal Investigator, and Protocol ID. Searches can be saved for future use. Saved searches maintain the search criteria for faster subsequent searches.

eProtocol > Investigator > Home > Search Protocol

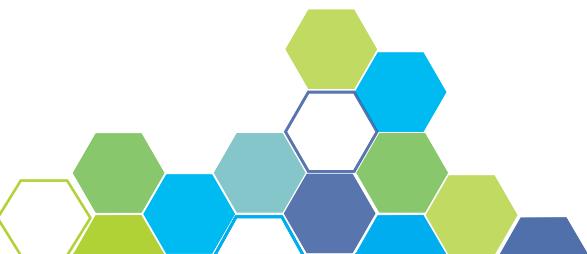
IACUC:

Protocol ID	Study Title
Principal Investigator	Investigator
Form Type	Please Select... Panel
Department	Please Select... Meeting Date

Form Name	Please Select...
Sponsor	Please Select... SPO #
Animal Type	Please Select...

[Search](#) [Clear](#) [Save](#) [Cancel](#)

Figure 9.1



10 SUMMARY

You have successfully completed the Investigator Role Manual. We hope you have a better understanding of the overall functionality of the Investigator portion of eProtocol. To review the overall functionality of eProtocol, please see the General Functionality and Dashboard Manual.

For more information on the functionality of other operating roles in eProtocol, please see The Committee Manager and RCA Role Manual or the Reviewer Role Manual.

