eProtocol

IRB Investigator Role Manual

MARCH 2018

Table of Contents

1 OVERVIEW

The IRB 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: Internet Explorer 10 and above, 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. WSU Access ID and Password required

If you do not have, or have forgotten your Access ID and password, see the General Functionality & Dashboard Manual for more information

4. Avoid using the Back button

Using the Back button will log the user out.

5. 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: 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.

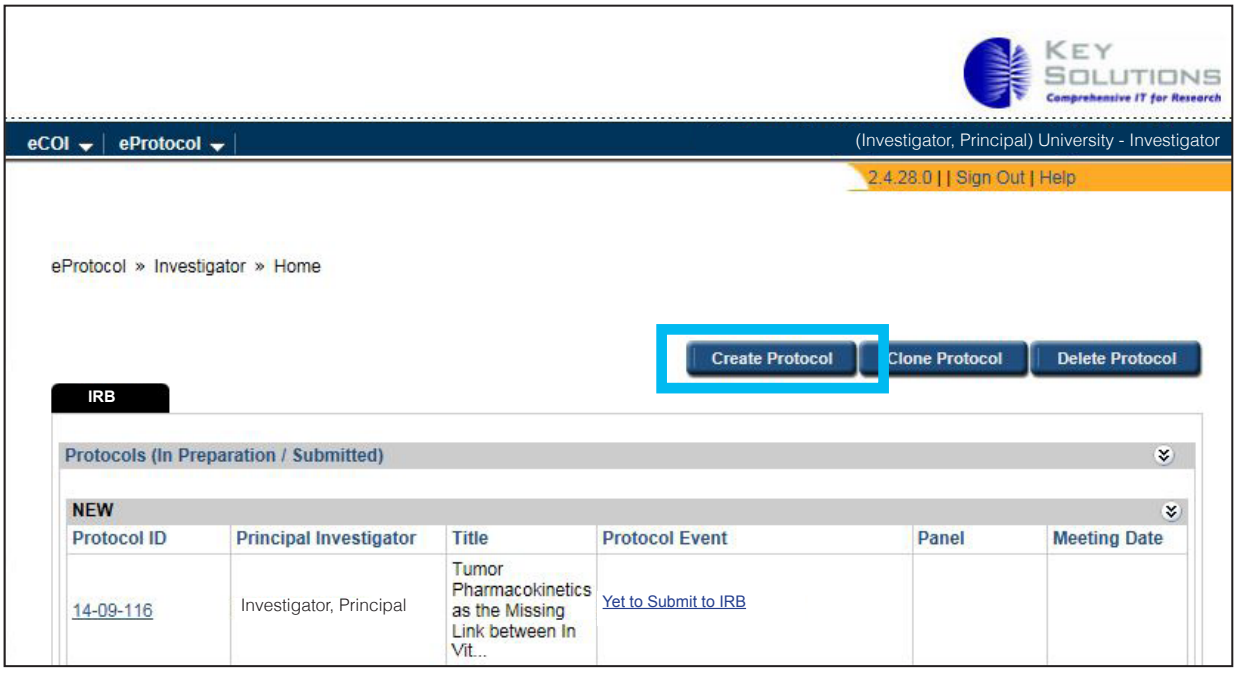


Figure 2.1

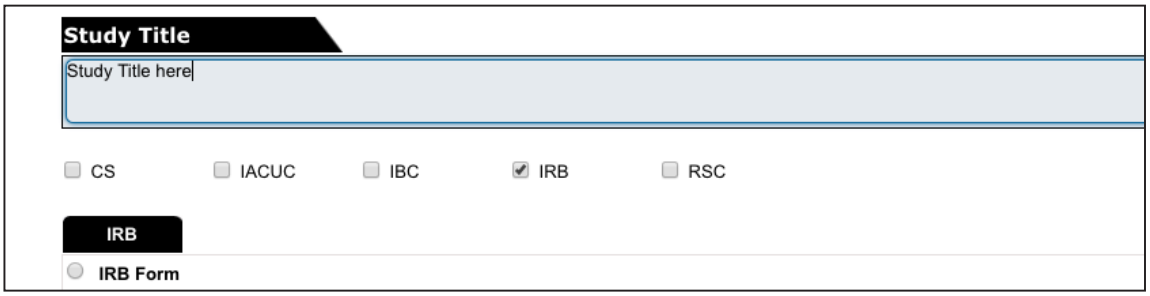


Figure 2.2

2. Enter full study title.

3. Select 'IRB Form'. 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 15.

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

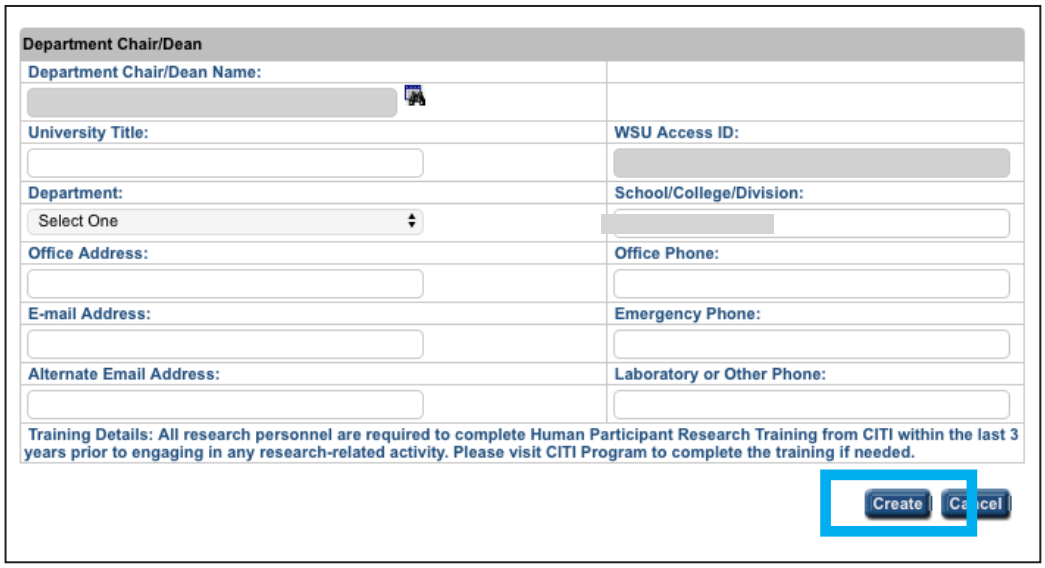


Figure 2.3

3 PROTOCOL ENTRY PROCESS NAVIGATION

3.1 Top & Bottom Navigation Buttons

There are several ways to navigate through a 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.

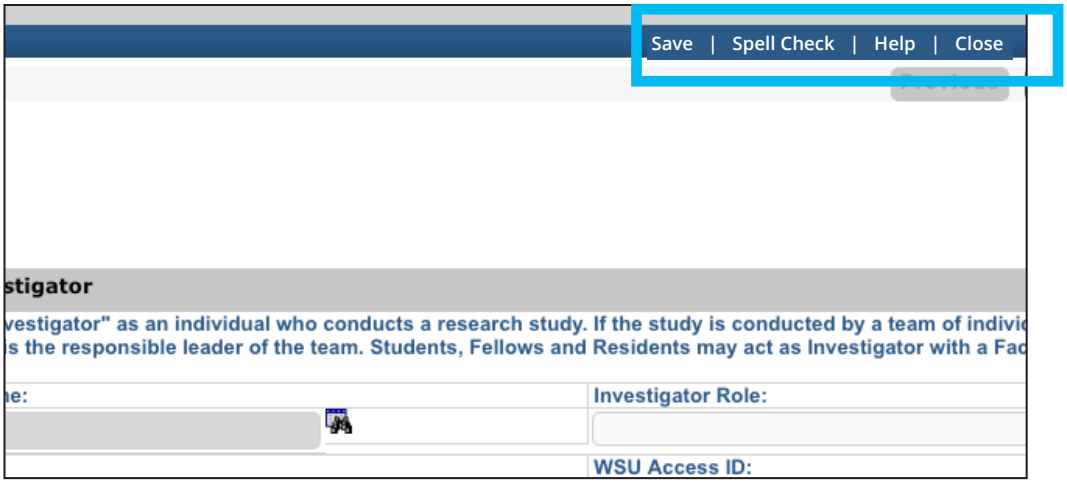


Figure 3.1

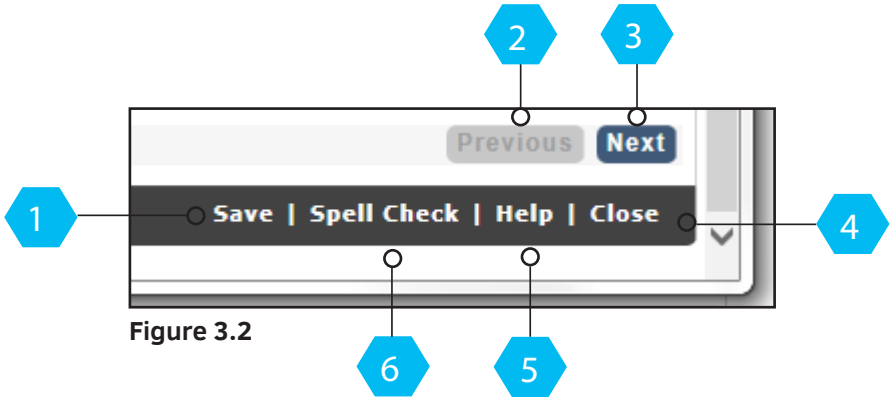


Figure 3.2

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.

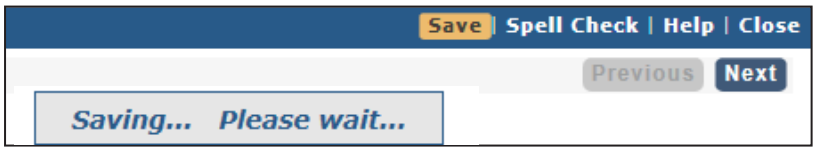


Figure 3.3

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.

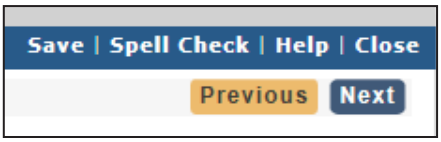


Figure 3.4

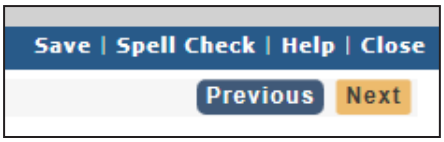


Figure 3.5

3 The **Next** button has similar functionality as the Previous button, but 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 will 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 asking 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].

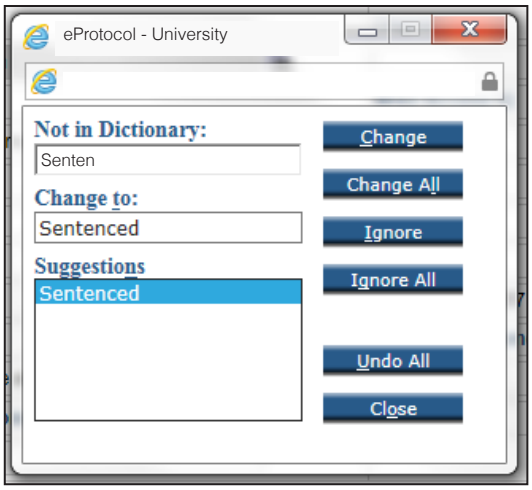


Figure 3.6

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.

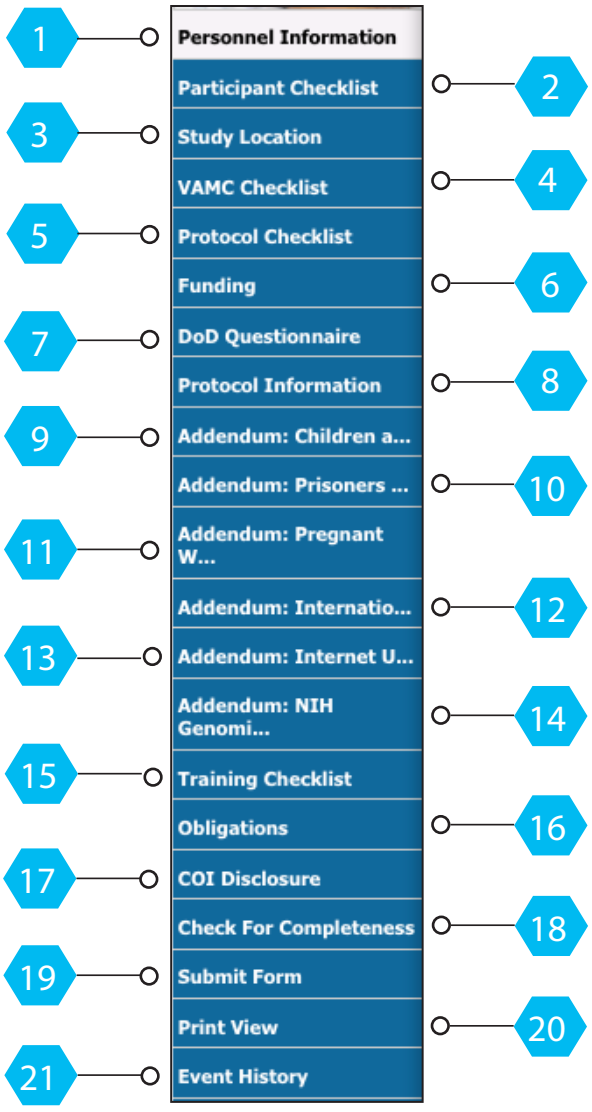


Figure 4.1

1..... **Personnel Information** - This section specifies who the Principal Investigator is on the protocol. [Page 15]

2..... **Participant Checklist** - This section identifies the specific participant population that will be included in the protocol (check all that apply). [Page 18]

3..... **Study Location** -This section will identify where study activities will take place, whether that be a Wayne State facility or an affiliate site. [Page 19]

4..... **VAMC Checklist** - This section will be completed if the study will be conducted at the J.D. Dingell Veteran Affairs Medical Center (VAMC). [Page19]

5..... **Protocol Checklist** - This section will be used to specify any checklists associated with the protocol. [Page 20]

6..... **Funding** - This section allows for indicating the funding source for the protocol. [Page 21]

7..... **DoD Questionnaire** - This section is completed if funded or sponsored by the U.S. Department of Defense. [Page 21]

8..... **Protocol Information** - This section's form's sub-tabs are used to give more detail about the protocol and the protocol participants. [Page 29]

9..... **Addendum: Children as Participants** - This section is completed when children are included as research participants. [Page 22]

10..... **Addendum: Prisoners as Participants** - This section is completed when prisoners are included as research participants. [Page 23]

11..... **Addendum: Pregnant Women, Fetuses and Neonates** - This section is completed when Pregnant Women, Fetuses and Neonates are included as research participants. [Page 24]

12..... **Addendum: International Research** - This section is completed when research activities will be conducted outside of the United States. [Page 25]

13..... **Addendum: Internet Use in Research** - This section is completed when the internet will be used for study recruitment or research activities.. [Page 26]

14..... **Addendum: NIH Genomic Data Sharing** - This section is completed when research activities include collection/sharing of genomic data/material for a NIH supported study. [Page 27]

15..... **Training Checklist** - This section is used to keep track of all mandatory CITI training for all study key personnel listed on the protocol. [Page 28]

16..... **Obligations** - This section is used by the PI and all study key personnel must acknowledge and complete the study obligations section. [Page 31]

17..... **COI Disclosure** - This section is used to make note of any financial conflicts of interest within the research team. [Page 32]

18..... **Check For Completeness** - This section is used to check for any unanswered questions or missing CITI training for study key personnel. [Page 33]

19..... **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 33]

20..... **Print View** -This section of the protocol is used to generate PDF's with or without comments. [Page 35]

21..... **Event History** - This section is used to catalog dates in the life of the protocol and generate a list of all e-mail correspondence from the system. 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 36]

5 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 Faculty Sponsor/Mentor 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 subject matter being used for an IRB module.

5.2 Interacting with Data Fields

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

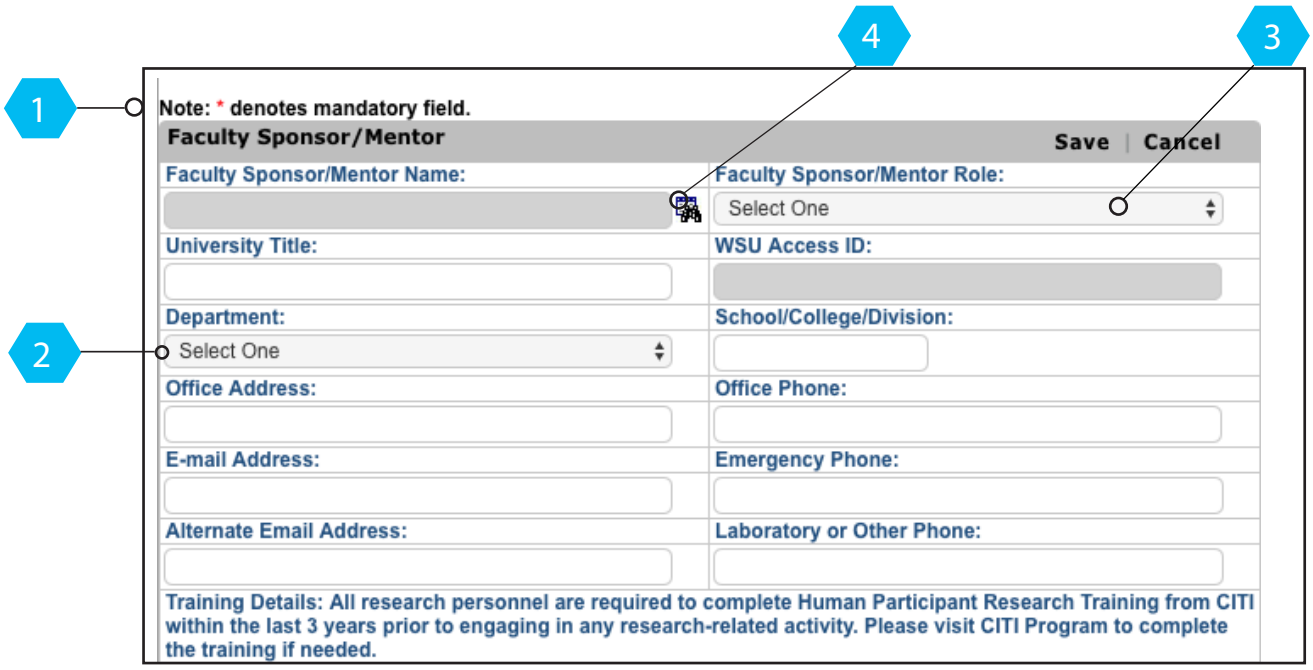
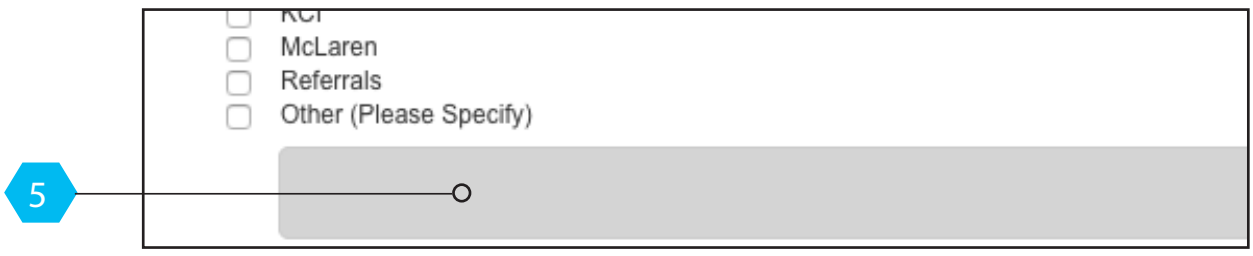


Figure 5.1a

Figure 5.1b



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-Line and Multi-Line Text Box

Single and multi-line text boxes are found throughout eProtocol. Multi-line text boxes are usually much larger and allow for multiple lines of text.

3 Drop-down Data Fields

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

4 Searchable Data Fields

Certain instances an icon will appear, such as a calendar or binoculars, that will allow the user to search for information browse for specific information.

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 5.1b shows a 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.

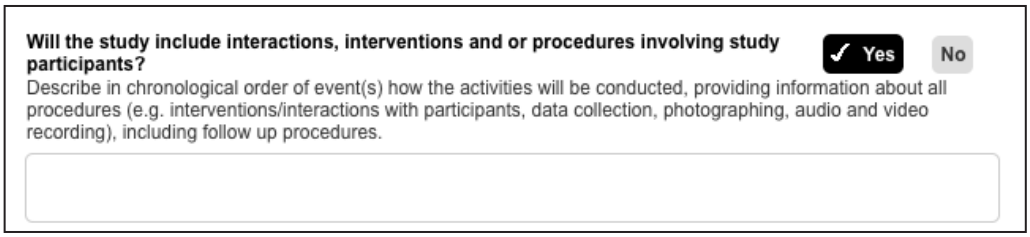


Figure 5.2

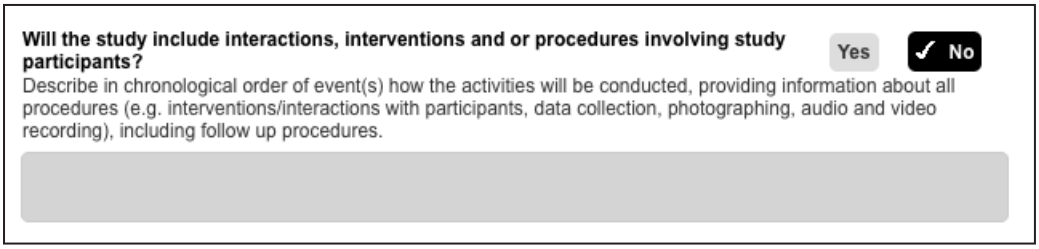


Figure 5.3

Figure 5.4

6 Add/Delete Functionality

The Add/Delete Functionality allows for the Investigator to change information within the protocol. An example of this can be seen under the Personnel Information when adding or removing individuals information to the protocol. [Refer to page 15 for more information on Personnel Information.]

Add - Clicking this button will generate a new window where the additional individuals can be added to the protocol as needed.

Delete - Check the box next to the individual 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].

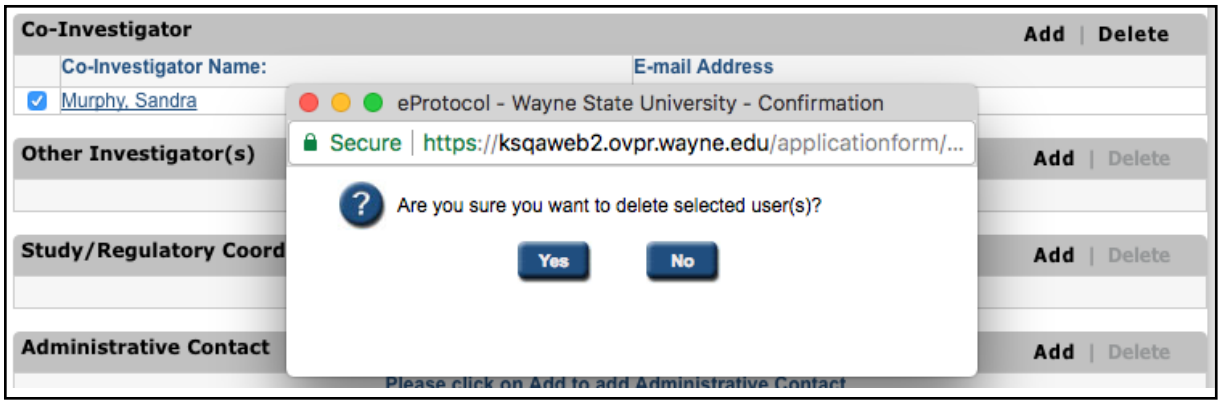


Figure 5.5

5.3 Personnel Information

The Personnel tab is the area of the protocol where all study key personnel are entered. Study key personnel should be entered for each applicable section (i.e. Co-Investigator, Study Regulatory, Other Investigator, Study/Regulatory Coordinator(s) etc.). All study key personnel will need a WSU Access ID & password. All study key personnel will need to log into eProtocol to complete the Obligations and COI Disclosure sections.

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.

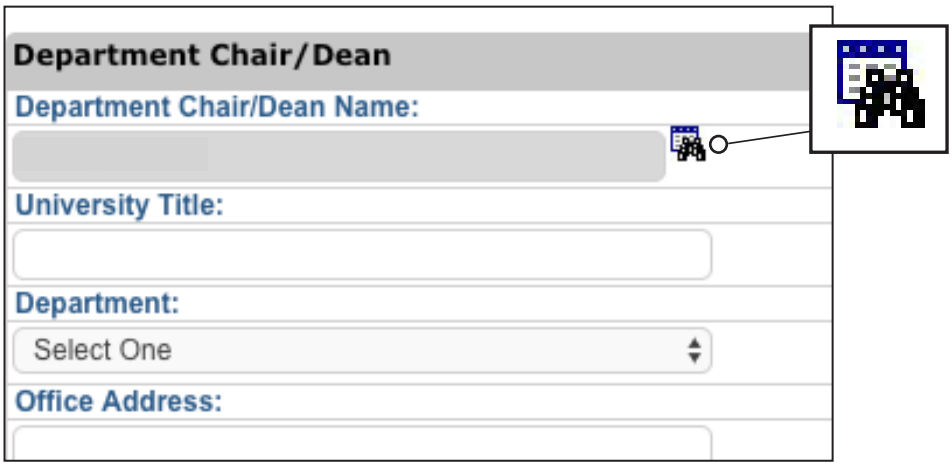


Figure 5.6

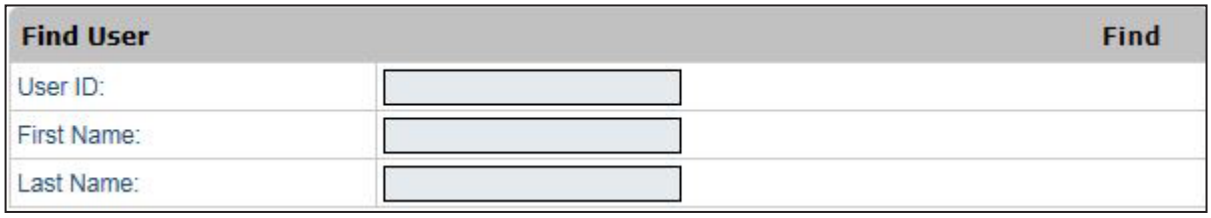


Figure 5.7

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 selecting 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].

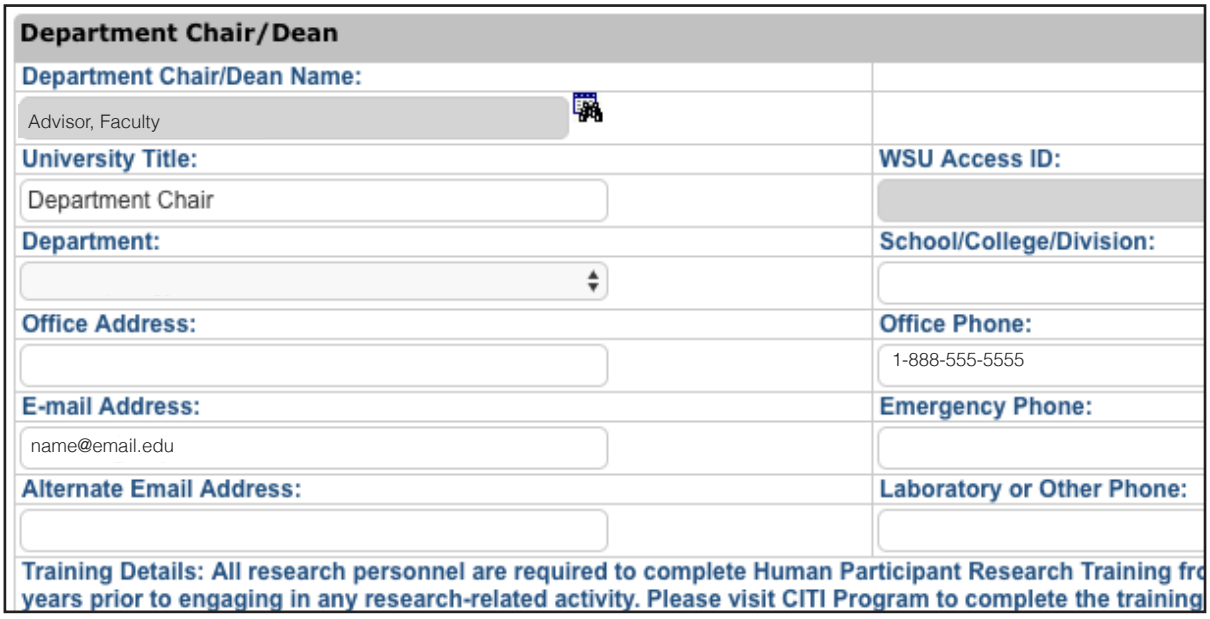


Figure 5.8

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: Participant Checklist; Study Location; VAMC Checklist; Protocol Checklist; Funding; DoD Questionnaire; Addendums: Children as Research Participants; Prisoners as Research Participants; Pregnant Women, Fetuses and Neonates as Research Participants; International Research; Internet Use in Research; and NIH Genomic Data Sharing; and Training Checklist.

Participant Checklist

The Participant Checklist is a module specific tab for the IRB and is required to indicate the study population that will be included as research participants in the study. Check all instances that apply to the proposed research project. If there is a group that will be included in the study that is not listed, check the "Other" box. After checking the "Other" box, a multi-line data field will become active to specify the additional type of participants that will be included in the research project.

To unselect a group, click the box again to remove the check mark.

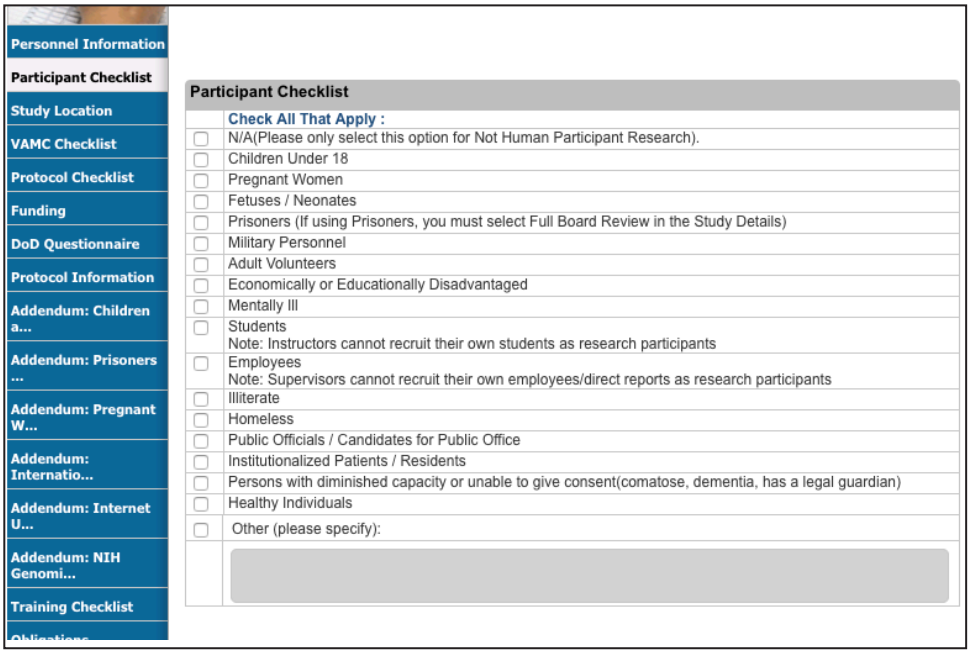


Figure 5.9

Study Location

The Study Location tab is used to specify what location(s) the protocol will take place at. Users may select all options that apply. Several of the options will require more information if selected. If WSU will function as the coordinating center or lead institution, the user will be required to attached the coordinating center application form at the bottom of the section.

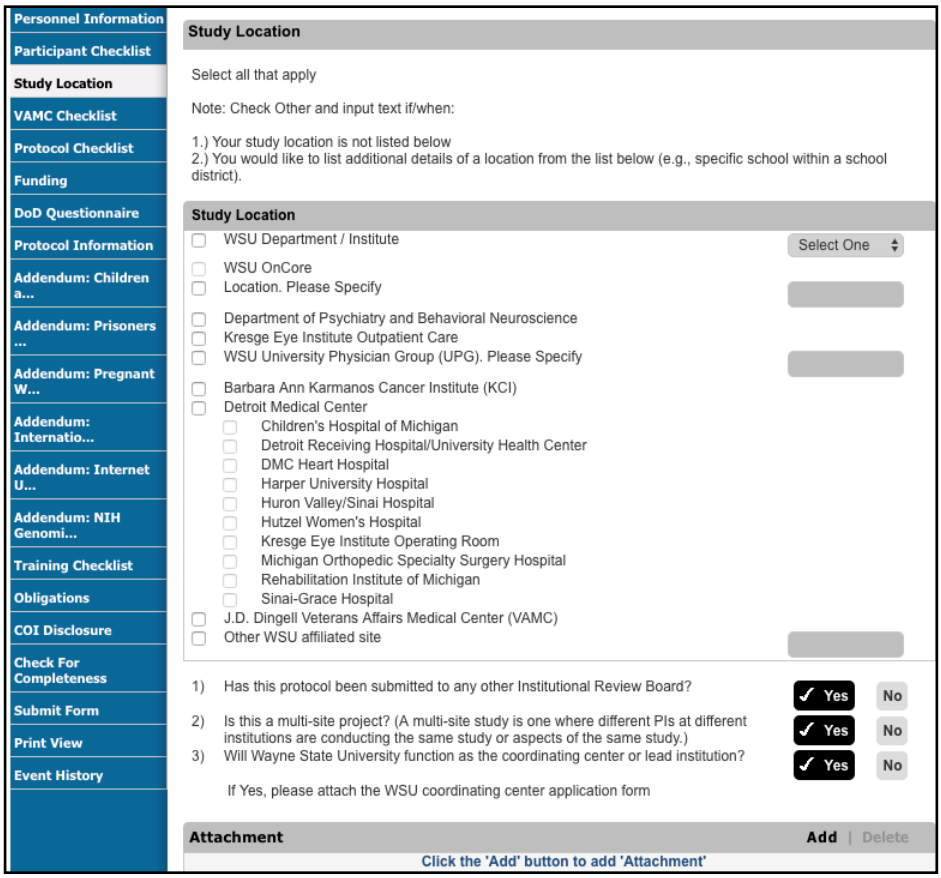


Figure 5.11

VAMC Checklist

This section of the module will only be required if the user selected the J.D. Dingell Veterans Affairs Medical Center on the Study Location Form [FIGURE 5.12]. Fill out the form accordingly and attach any required documents.

NOTE: This section will be inactive if it was not checked on the Study Location and the user may press NEXT to continue to the next tab.

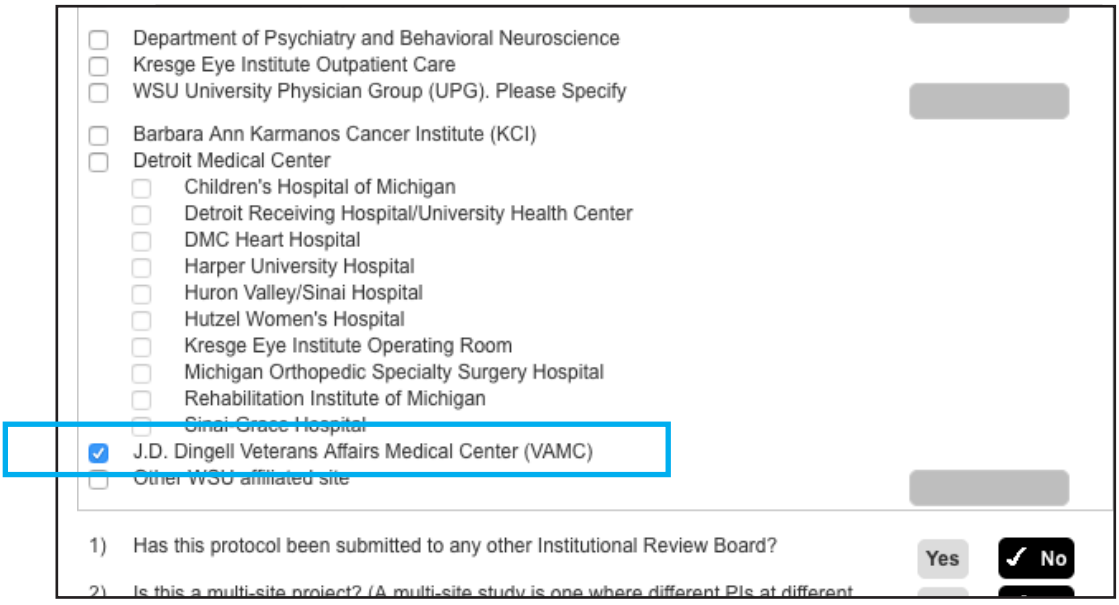


Figure 5.12

Protocol Checklist

Use this section to specify further details of the protocol. Certain sections may require more information in a single-line data field once selected.

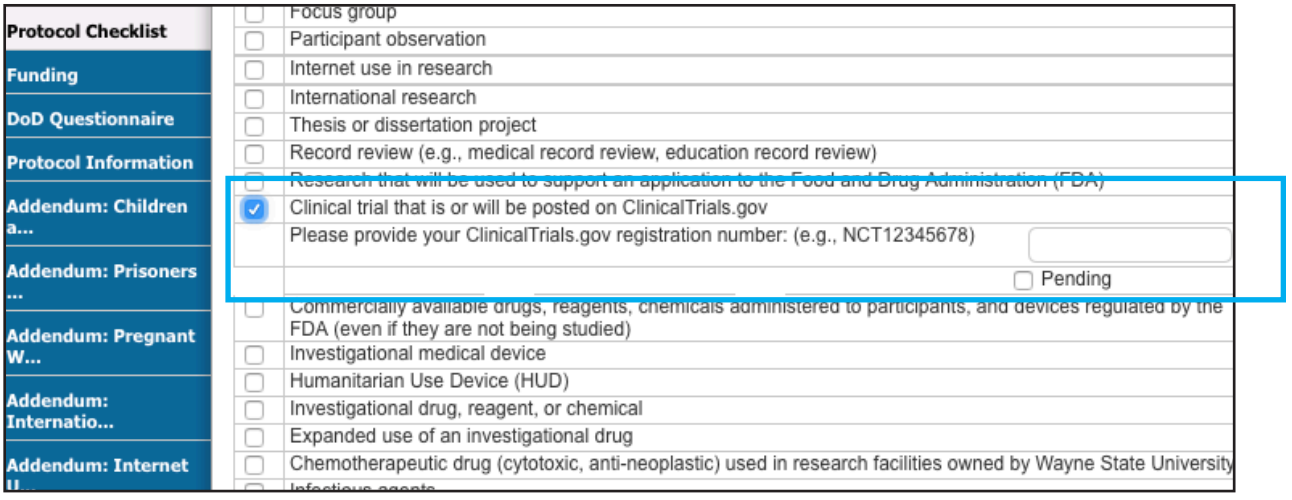


Figure 5.13

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** button as seen in Figure 5.14. 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.

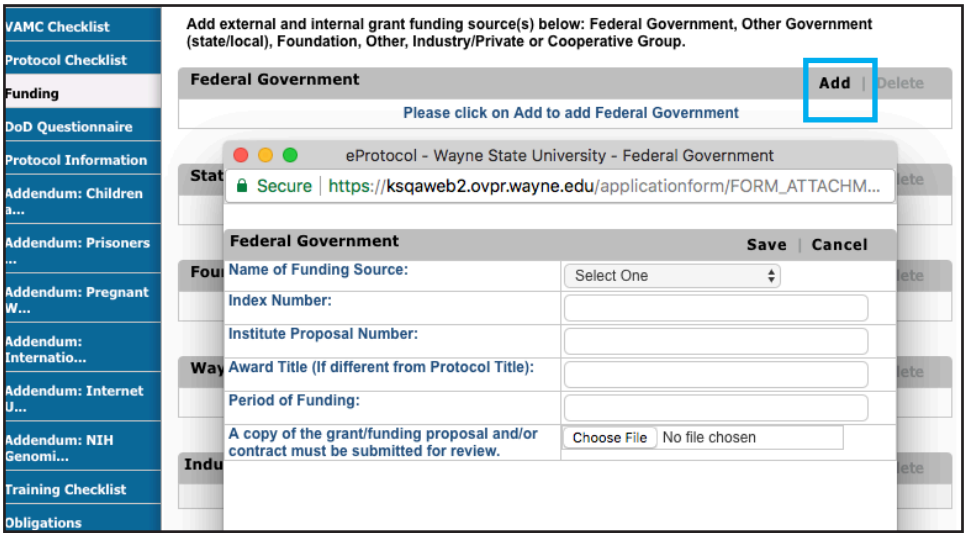


Figure 5.14

DoD Questionnaire

This section of the module will only be required if the user selected the Department of Defense as a funding source [FIGURE 5.15]. If the Department of Defense was added as a funding source, fill out the form accordingly.

NOTE: This section of will be inactive if it was not checked on the Funding section and the user may press NEXT to continue to the next tab.

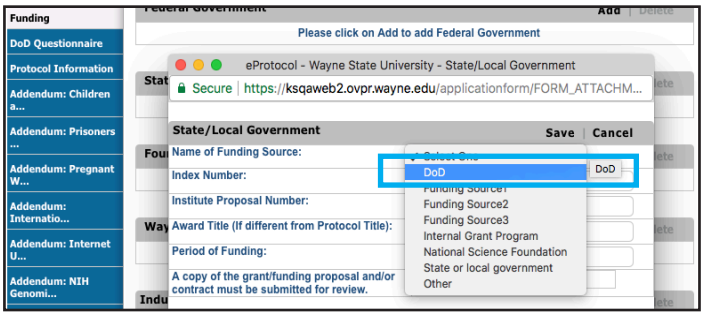


Figure 5.15

Addendums

The following sections are only required if the appropriate categories were selected from the Participant Checklist. If the category was not selected from the Participant Checklist, click **Next** to continue to the next step of the module.

NOTE: These sections will not be activated if the appropriate selection was not checked on the Participant Checklist.

Children as Research Participants [FIGURE 5.16 and 5.17]

This tab requires the risk assessment and any documents when the protocol involves children (study participants under the age of 18). Users will answer the following questions by using a series of check boxes, single-line data fields, and multi-line data fields. If needed, appropriate documents can be uploaded to the Protocol Information tab in the blue menu on the left of the screen.

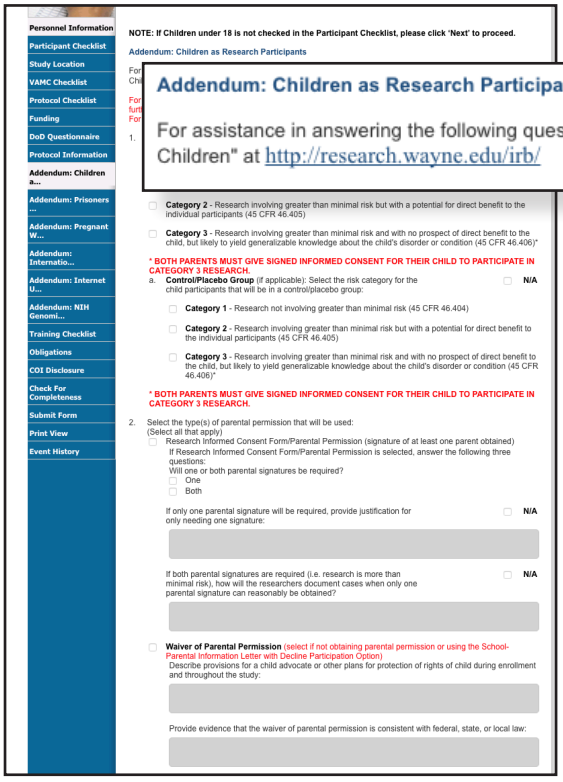


Figure 5.16

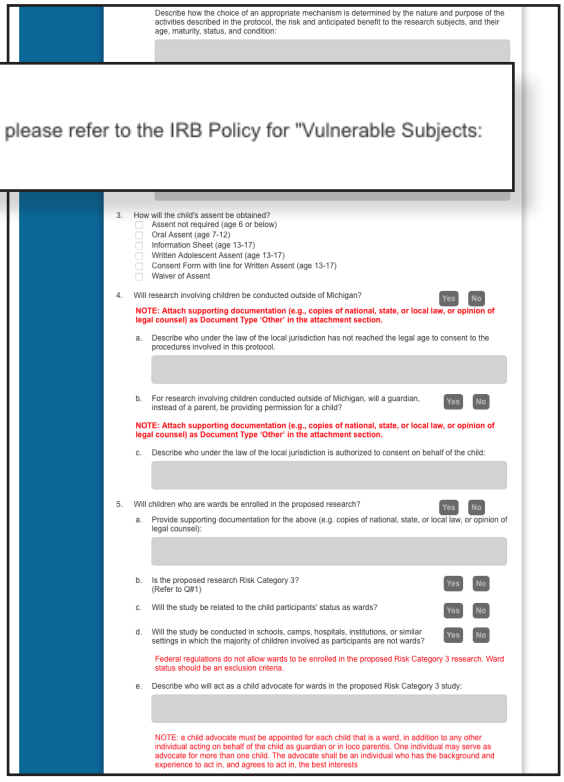
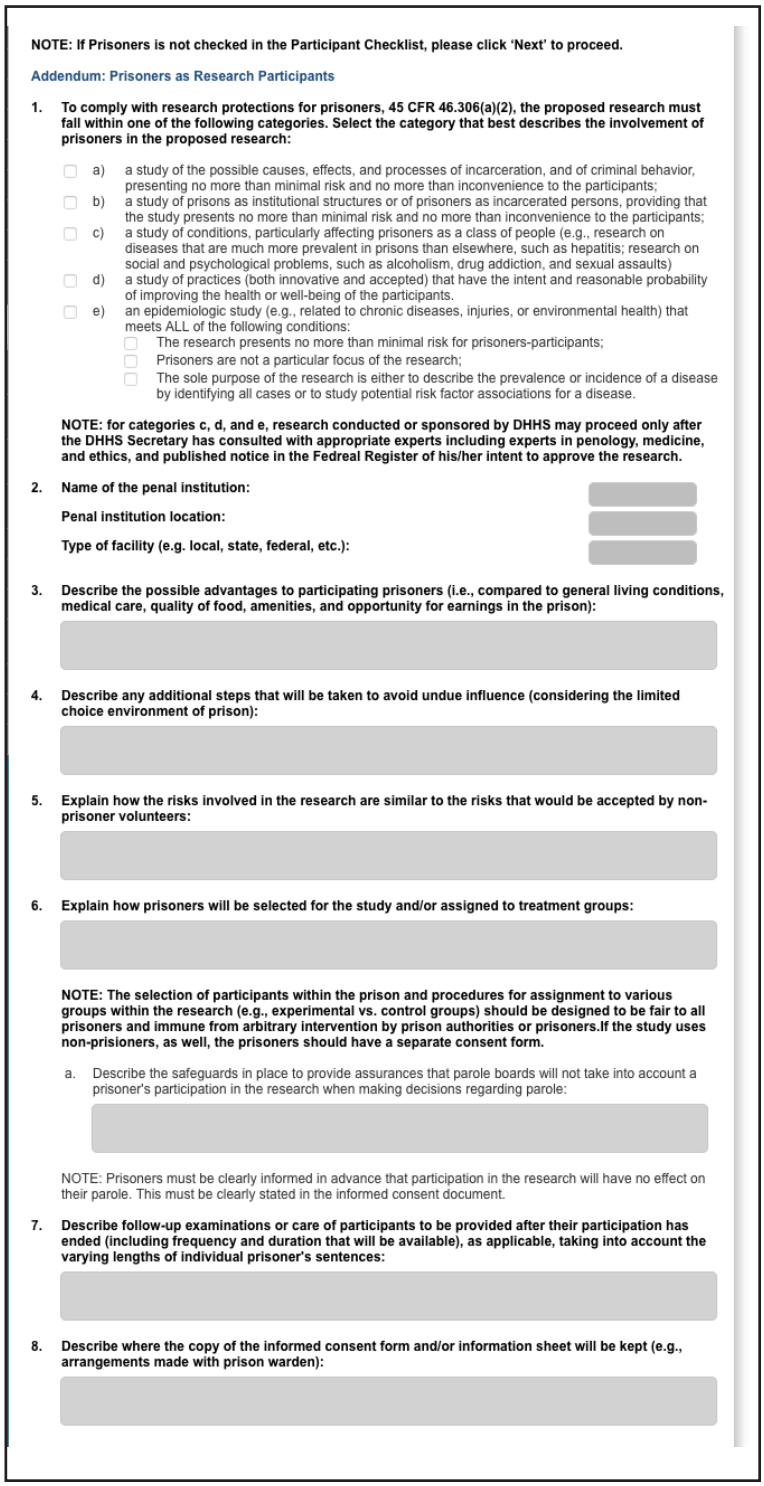


Figure 5.17

Prisoners as Research Participants [FIGURE 5.18]

This tab is to gather additional information when the protocol involves prisoners. Users will answer the following questions by using a series of check boxes, single-line data fields, and multi-line data fields.



NOTE: If Prisoners is not checked in the Participant Checklist, please click 'Next' to proceed.

Addendum: Prisoners as Research Participants

1. **To comply with research protections for prisoners, 45 CFR 46.306(a)(2), the proposed research must fall within one of the following categories. Select the category that best describes the involvement of prisoners in the proposed research:**

   - ☐ a) a study of the possible causes, effects, and processes of incarceration, and of criminal behavior, presenting no more than minimal risk and no more than inconvenience to the participants;
   - ☐ b) a study of prisons as institutional structures or of prisoners as incarcerated persons, providing that the study presents no more than minimal risk and no more than inconvenience to the participants;
   - ☐ c) a study of conditions, particularly affecting prisoners as a class of people (e.g., research on diseases that are much more prevalent in prisons than elsewhere, such as hepatitis; research on social and psychological problems, such as alcoholism, drug addiction, and sexual assaults)
   - ☐ d) a study of practices (both innovative and accepted) that have the intent and reasonable probability of improving the health or well-being of the participants.
   - ☐ e) an epidemiologic study (e.g., related to chronic diseases, injuries, or environmental health) that meets ALL of the following conditions:
     - ☐ The research presents no more than minimal risk for prisoners-participants;
     - ☐ Prisoners are not a particular focus of the research;
     - ☐ The sole purpose of the research is either to describe the prevalence or incidence of a disease by identifying all cases or to study potential risk factor associations for a disease.

   NOTE: for categories c, d, and e, research conducted or sponsored by DHHS may proceed only after the DHHS Secretary has consulted with appropriate experts including experts in penology, medicine, and ethics, and published notice in the Fedreal Register of his/her intent to approve the research.

2. **Name of the penal institution:**
   Penal institution location:
   Type of facility (e.g. local, state, federal, etc.):

3. **Describe the possible advantages to participating prisoners (i.e., compared to general living conditions, medical care, quality of food, amenities, and opportunity for earnings in the prison):**

4. **Describe any additional steps that will be taken to avoid undue influence (considering the limited choice environment of prison):**

5. **Explain how the risks involved in the research are similar to the risks that would be accepted by non-prisoner volunteers:**

6. **Explain how prisoners will be selected for the study and/or assigned to treatment groups:**

   NOTE: The selection of participants within the prison and procedures for assignment to various groups within the research (e.g., experimental vs. control groups) should be designed to be fair to all prisoners and immune from arbitrary intervention by prison authorities or prisoners.If the study uses non-prisioners, as well, the prisoners should have a separate consent form.

   a. Describe the safeguards in place to provide assurances that parole boards will not take into account a prisoner's participation in the research when making decisions regarding parole:

   NOTE: Prisoners must be clearly informed in advance that participation in the research will have no effect on their parole. This must be clearly stated in the informed consent document.

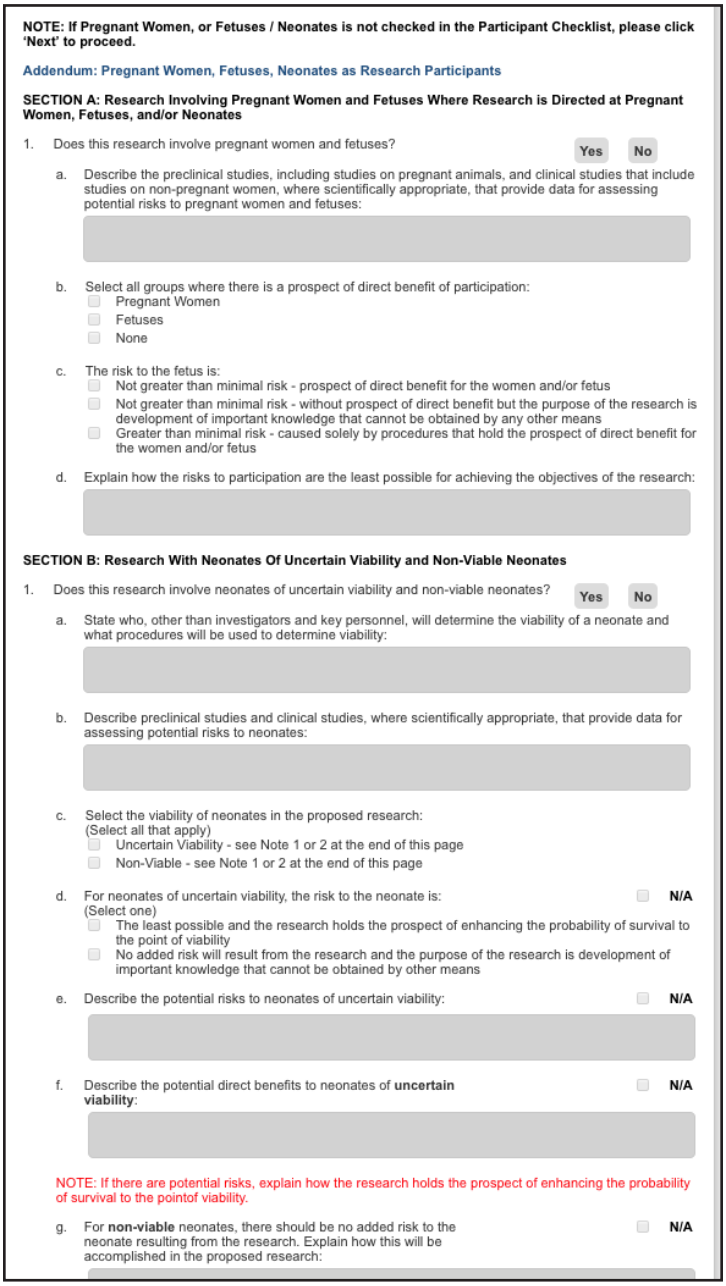
7. **Describe follow-up examinations or care of participants to be provided after their participation has ended (including frequency and duration that will be available), as applicable, taking into account the varying lengths of individual prisoner's sentences:**

8. **Describe where the copy of the informed consent form and/or information sheet will be kept (e.g., arrangements made with prison warden):**

Figure 5.18

Pregnant Women, Fetuses and Neonates as Research Participants
[FIGURE 5.19]

This tab is to gather additional information when the protocol involves pregnant women, fetuses, and neonates. Users will answer the following questions by using a series of check boxes, Yes/No buttons, single-line data fields, and multi-line data fields. If needed, appropriate documents can be uploaded to the Protocol Information tab in the blue menu on the left of the screen.



NOTE: If Pregnant Women, or Fetuses / Neonates is not checked in the Participant Checklist, please click 'Next' to proceed.

Addendum: Pregnant Women, Fetuses, Neonates as Research Participants

SECTION A: Research Involving Pregnant Women and Fetuses Where Research is Directed at Pregnant Women, Fetuses, and/or Neonates

1. Does this research involve pregnant women and fetuses? Yes No

a. Describe the preclinical studies, including studies on pregnant animals, and clinical studies that include studies on non-pregnant women, where scientifically appropriate, that provide data for assessing potential risks to pregnant women and fetuses:

b. Select all groups where there is a prospect of direct benefit of participation:
- Pregnant Women
- Fetuses
- None

c. The risk to the fetus is:
- Not greater than minimal risk - prospect of direct benefit for the women and/or fetus
- Not greater than minimal risk - without prospect of direct benefit but the purpose of the research is development of important knowledge that cannot be obtained by any other means
- Greater than minimal risk - caused solely by procedures that hold the prospect of direct benefit for the women and/or fetus

d. Explain how the risks to participation are the least possible for achieving the objectives of the research:

SECTION B: Research With Neonates Of Uncertain Viability and Non-Viable Neonates

1. Does this research involve neonates of uncertain viability and non-viable neonates? Yes No

a. State who, other than investigators and key personnel, will determine the viability of a neonate and what procedures will be used to determine viability:

b. Describe preclinical studies and clinical studies, where scientifically appropriate, that provide data for assessing potential risks to neonates:

c. Select the viability of neonates in the proposed research:
(Select all that apply)
- Uncertain Viability - see Note 1 or 2 at the end of this page
- Non-Viable - see Note 1 or 2 at the end of this page

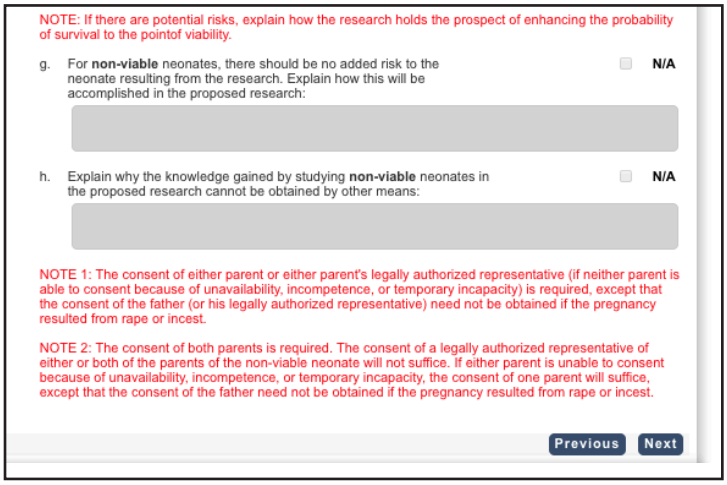
d. For neonates of uncertain viability, the risk to the neonate is: N/A
(Select one)
- The least possible and the research holds the prospect of enhancing the probability of survival to the point of viability
- No added risk will result from the research and the purpose of the research is development of important knowledge that cannot be obtained by other means

e. Describe the potential risks to neonates of uncertain viability: N/A

f. Describe the potential direct benefits to neonates of **uncertain viability**: N/A

NOTE: If there are potential risks, explain how the research holds the prospect of enhancing the probability of survival to the pointof viability.

g. For **non-viable** neonates, there should be no added risk to the neonate resulting from the research. Explain how this will be accomplished in the proposed research: N/A



NOTE: If there are potential risks, explain how the research holds the prospect of enhancing the probability of survival to the pointof viability.

g. For **non-viable** neonates, there should be no added risk to the neonate resulting from the research. Explain how this will be accomplished in the proposed research: N/A

h. Explain why the knowledge gained by studying **non-viable** neonates in the proposed research cannot be obtained by other means: N/A

NOTE 1: The consent of either parent or either parent's legally authorized representative (if neither parent is able to consent because of unavailability, incompetence, or temporary incapacity) is required, except that the consent of the father (or his legally authorized representative) need not be obtained if the pregnancy resulted from rape or incest.

NOTE 2: The consent of both parents is required. The consent of a legally authorized representative of either or both of the parents of the non-viable neonate will not suffice. If either parent is unable to consent because of unavailability, incompetence, or temporary incapacity, the consent of one parent will suffice, except that the consent of the father need not be obtained if the pregnancy resulted from rape or incest.

Previous Next

Figure 5.19

International Research

[FIGURE 5.20]

This tab is to gather additional information when the protocol involves research conducted outside of the United States. Users will answer the following questions by using a series of check boxes, single-line data fields, and multi-line data fields. If needed, appropriate documents can be uploaded to the Protocol Information tab in the blue menu on the left of the screen.

NOTE: In addition to completing the submission in eProtocol, appropriate documentation will need to be submitted to the Export Control Office

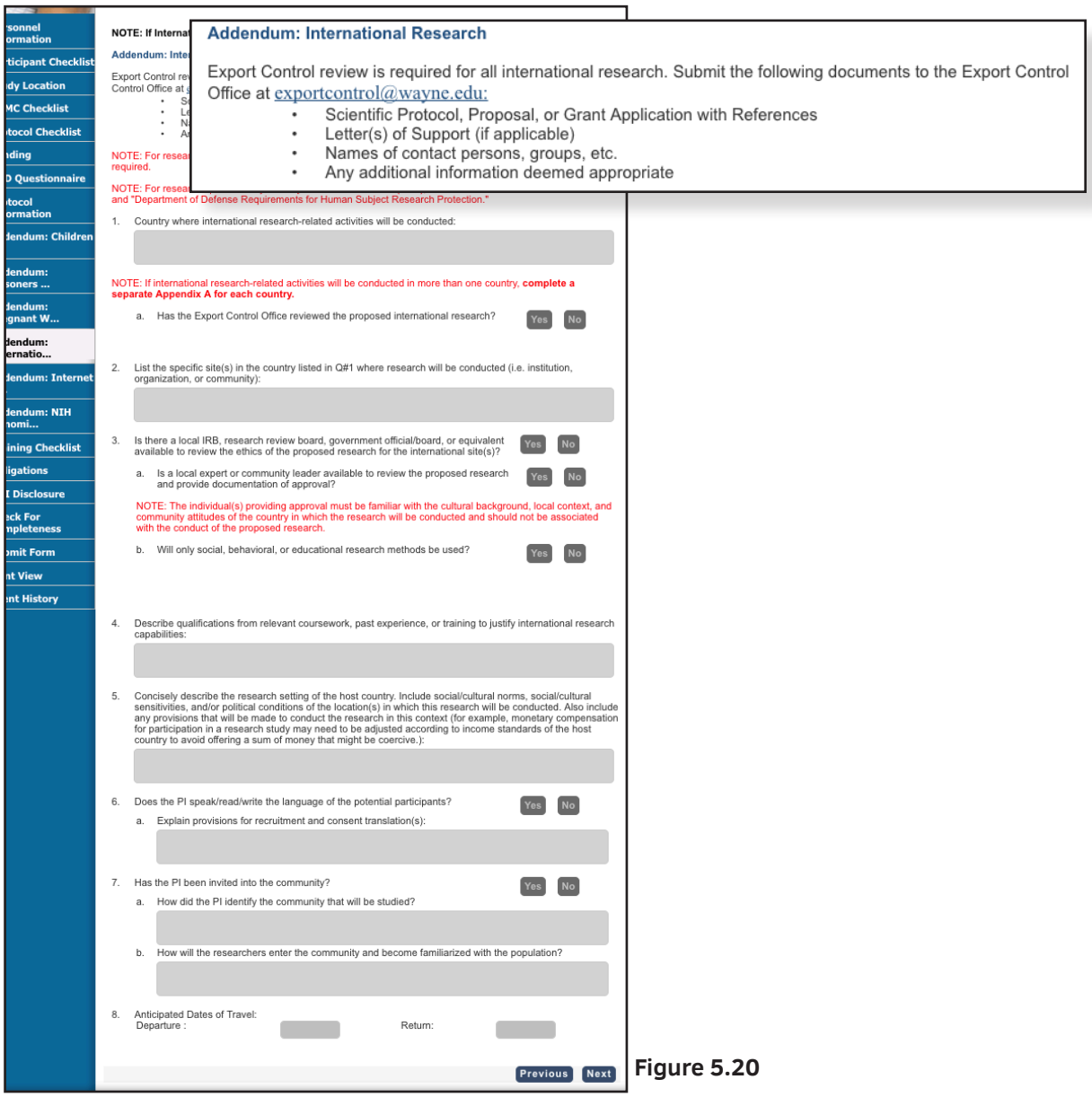


Figure 5.20

Internet Usage [FIGURE 5.21 and 5.22]

This tab is to gather additional information when the protocol involves internet usage. Users will answer the following questions by using a series of check boxes, Yes/No buttons, single-line data fields, and multi-line data fields. If needed, appropriate documents can be uploaded to Protocol Information tab in the blue menu on the left of the screen.

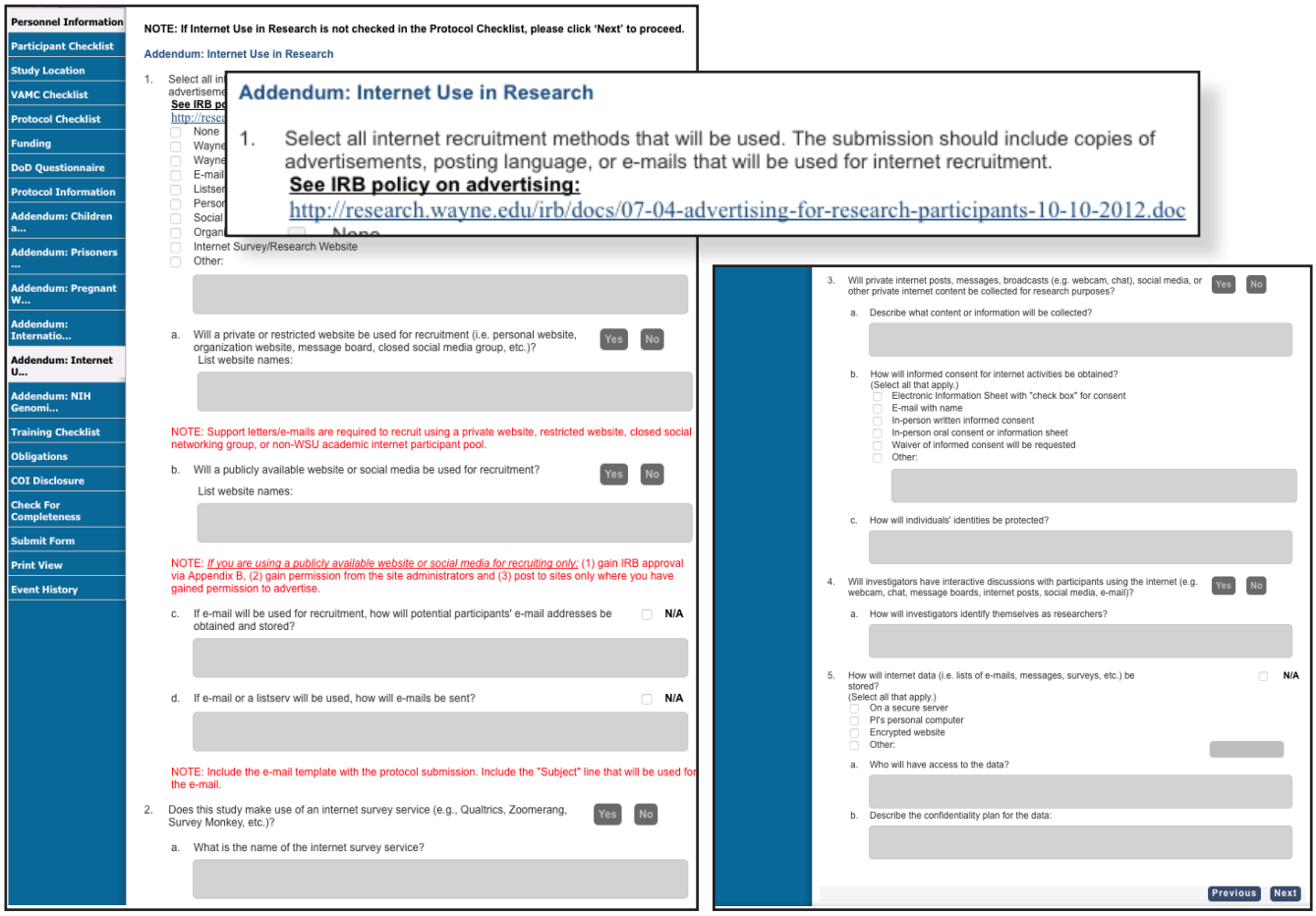


Figure 5.21

Figure 5.22

NIH Genomic Data Sharing [FIGURE 5.23]

This tab is to gather additional information when the protocol involves NIH Genomic Data Sharing. Users will answer the following questions by using a series of check boxes, Yes/No buttons, single-line data fields, and multi-line data fields. If needed, appropriate documents can be uploaded to the Protocol Information tab in the blue menu on the left of the screen.

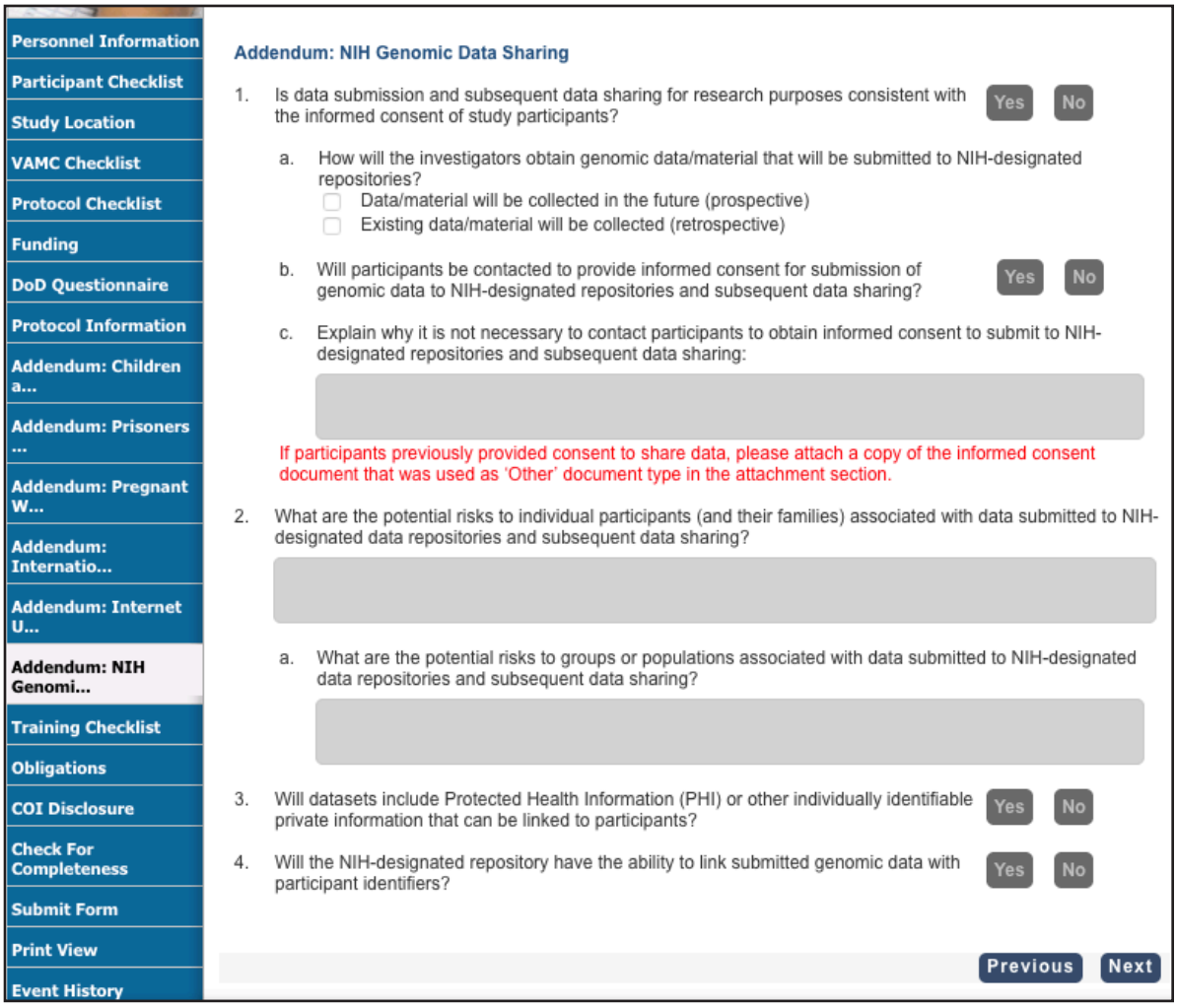


Figure 5.23

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 5.24] 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.

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.

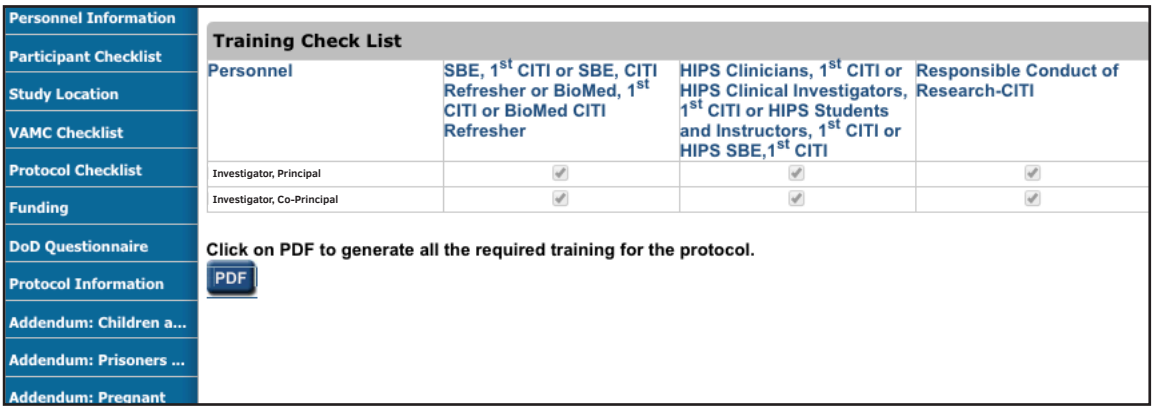


Figure 5.24

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 [Figure 5.25]. The list of the secondary tabs will appear upon clicking the **Protocol Information** menu tab. The new list of tabs are as follows: Study Details; Expedited Paragraphs; Summary & Purpose; Backgrounds, Rationale, Data Analysis, and Procedures; Participant Population; Recruitment Process, Participant Compensation, and Costs; Risks; Data Safety Monitoring Plan; Benefits; Procedures to Maintain Confidentiality; Consent Information; Assent Information; HIPPA; Drugs, Biologic Agents, Dietary Supplements and Devices; and Attachments. Depending on what module the user is working in will determine which tabs appear. For this manual, IRB tabs will be used as an example.

Figure 5.25

Figure 5.26

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 5.26].

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

The following tabs may require attachments: Background, Rationale, Data Analysis, and Procedures; Consent Information; Assent Information; Drugs and Devices; and Attachments. For this example, the Attachment tab is shown.

1. Click the **Add** button highlighted in the image below. A pop-up window will appear [Figure 5.27] 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.

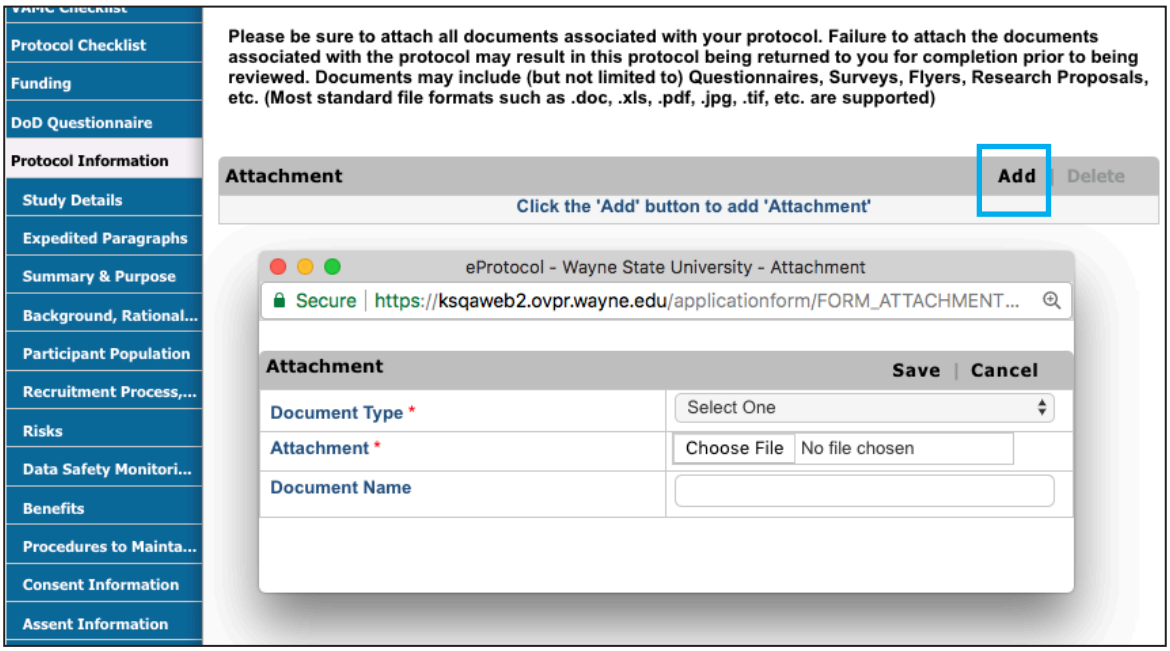


Figure 5.27

5.6 Obligations

The Obligations section is to ensure all study key personnel comply and will abide by regulations and guidelines pertaining to the study/protocol and research that is being performed. 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 obligations related to the protocol.

The Department Chairperson, Dean, Institute/Center Director, or other authorized signatory must sign off on the details listed under **Scientific Review**.

NOTE: Each person must individually open the protocol and check off their name. ONLY ONE USER CAN SIGN IN AT A TIME TO SIGN OFF ON THEIR OBLIGATIONS.

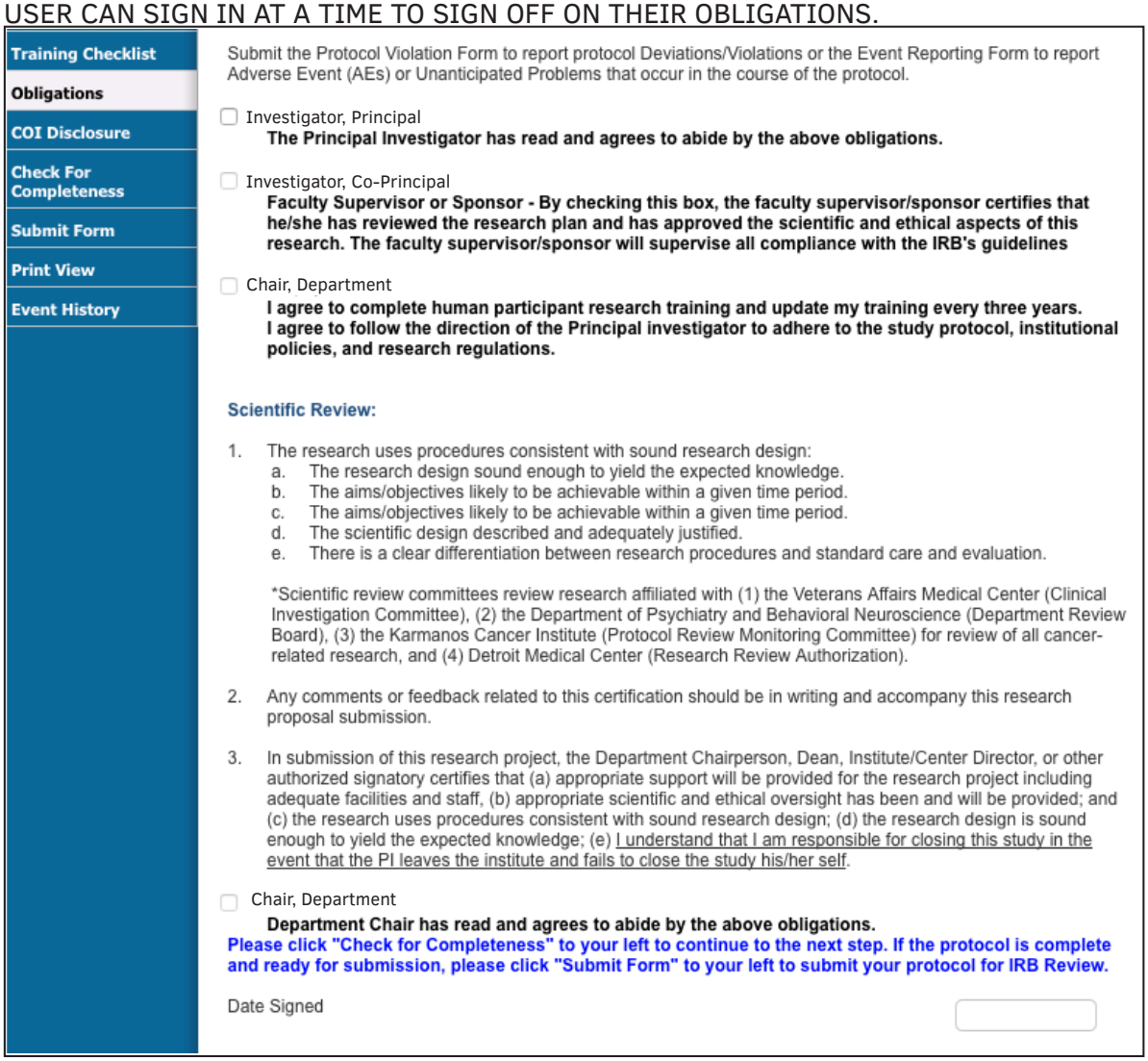


Figure 5.28

5.7 COI Disclosure

It is mandatory that the Principal Investigator and team members of the protocol sign and complete the COI Disclosure in order for a protocol to be approved. A Yes/No button is listed next to the names of all members on the research team. There is also a question relating to children and spouses of the research team. Check the Yes or No button next to your name. Do the same for the question regarding children and spouses.

NOTE: Each person must individually open the protocol and complete their own disclosure form. ONLY ONE USER CAN SIGN IN AT A TIME TO COMPLETE THEIR DISCLOSURE.

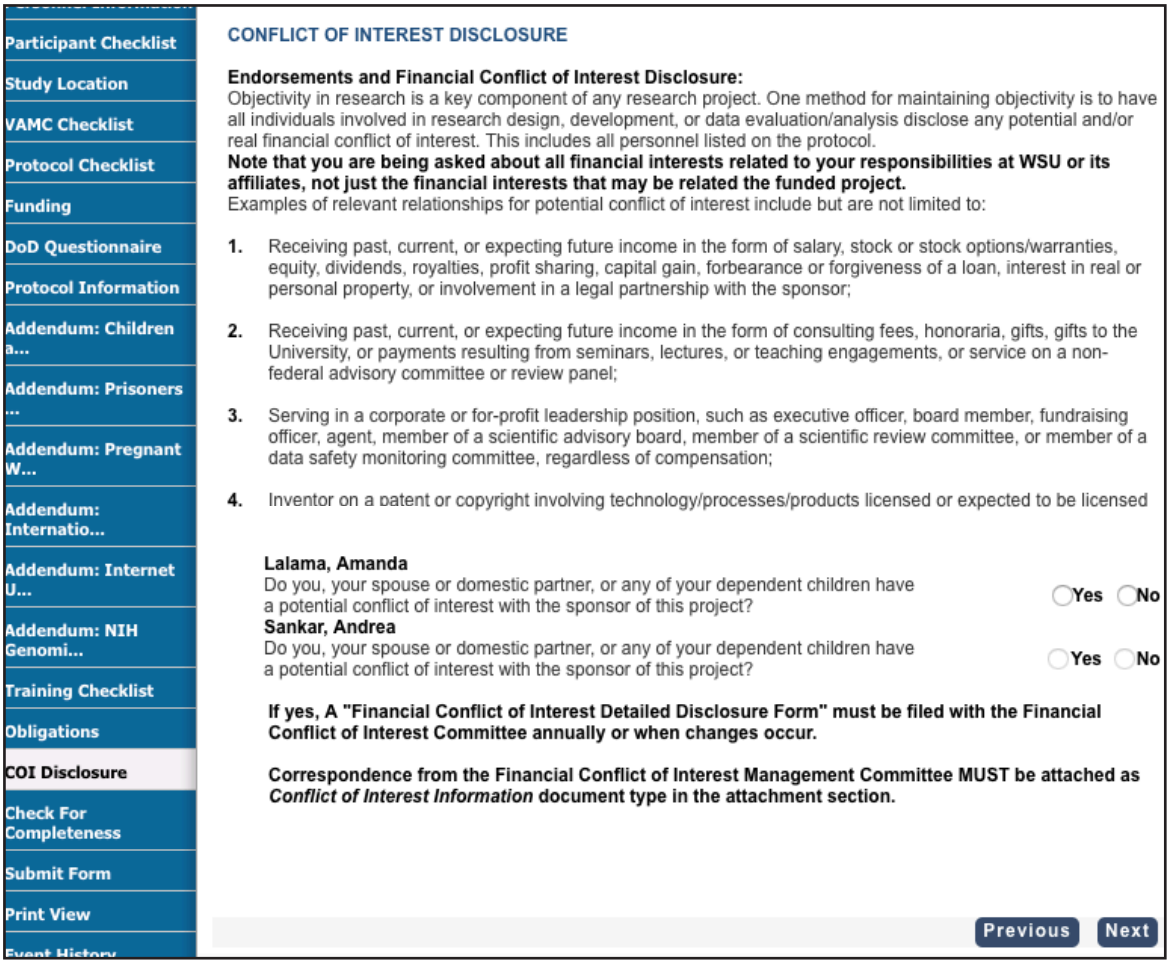
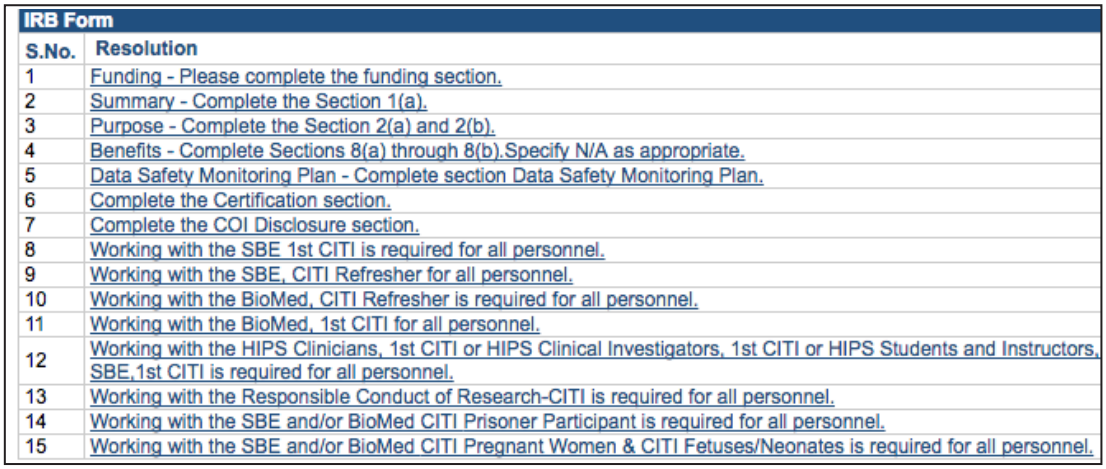


Figure 5.29

5.8 Check for Completeness

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.



IRB Form	
S.No.	**Resolution**
1	Funding - Please complete the funding section.
2	Summary - Complete the Section 1(a).
3	Purpose - Complete the Section 2(a) and 2(b).
4	Benefits - Complete Sections 8(a) through 8(b).Specify N/A as appropriate.
5	Data Safety Monitoring Plan - Complete section Data Safety Monitoring Plan.
6	Complete the Certification section.
7	Complete the COI Disclosure section.
8	Working with the SBE 1st CITI is required for all personnel.
9	Working with the SBE, CITI Refresher for all personnel.
10	Working with the BioMed, CITI Refresher is required for all personnel.
11	Working with the BioMed, 1st CITI for all personnel.
12	Working with the HIPS Clinicians, 1st CITI or HIPS Clinical Investigators, 1st CITI or HIPS Students and Instructors, SBE,1st CITI is required for all personnel.
13	Working with the Responsible Conduct of Research-CITI is required for all personnel.
14	Working with the SBE and/or BioMed CITI Prisoner Participant is required for all personnel.
15	Working with the SBE and/or BioMed CITI Pregnant Women & CITI Fetuses/Neonates is required for all personnel.

Figure 5.30

5.9 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 Obligations and COI Disclosure. 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 for Department Certification does not submit the form to the IRB. Once Department Certification is completed, an additional step is required to submit to the IRB.

Department Certification Process

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.

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 Obligations page and check the circle next to the user’s name to confirm they understand the Obligations of the protocol.

4. After confirming the obligations, go to the COI Disclosure page within the protocol. Check the Yes or No button next to the user’s name to indicate any financial conflict of interest the user (or children and/or spouses) may have with the protocol.

NOTE: The first of the two check-boxes shown below in Figure 5.31 will remain disabled until steps 3 and 4 have been completed.

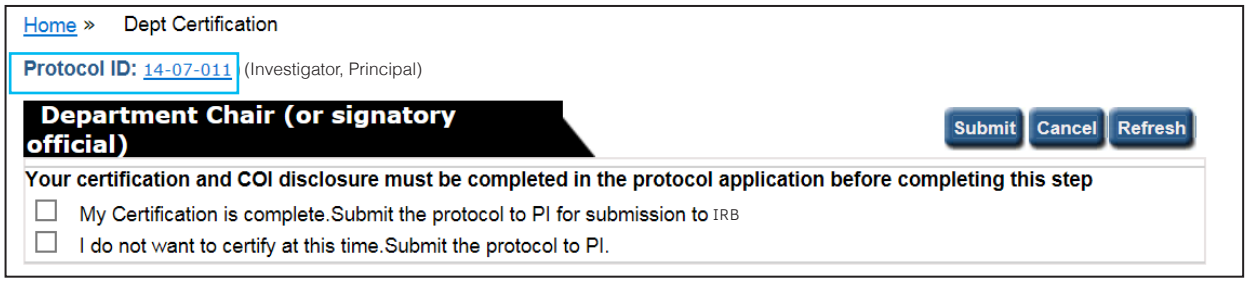


Figure 5.31

5. Save and close the changes in the protocol and return to the Department Certification pop-up window [Figure 5.22].

6. Click the **Refresh** button to update the window - enabling the first check box.

7. Choose to send off the certification by checking the appropriate box.

8. Click the **Submit** button to send the completed certification to the PI.

5.10 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 5.32. The user may then check which sections they would like to view and print, followed by the page orientation and whether or not they would like any comments within the protocol to be viewed. Click the **OK** action button to see the Print View PDF.

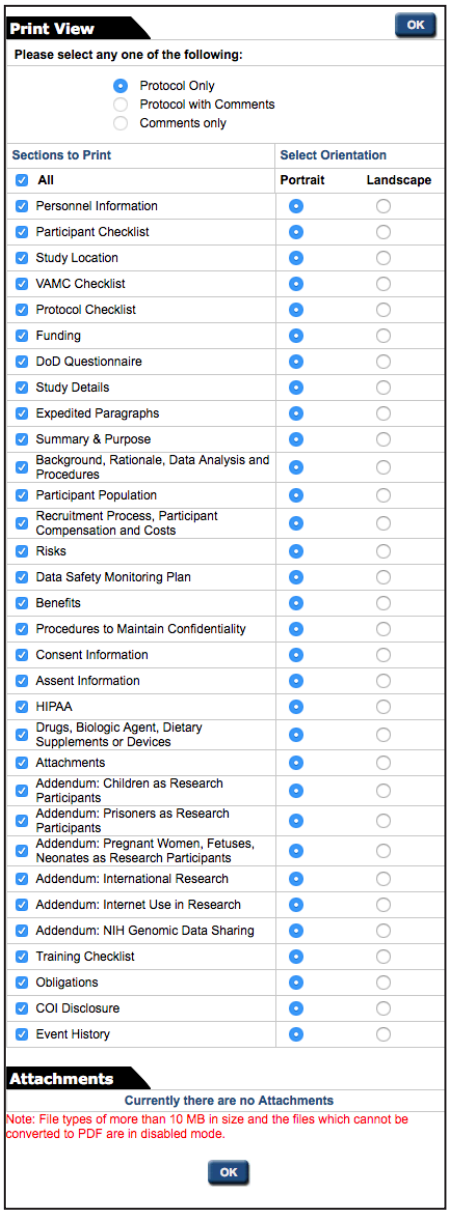
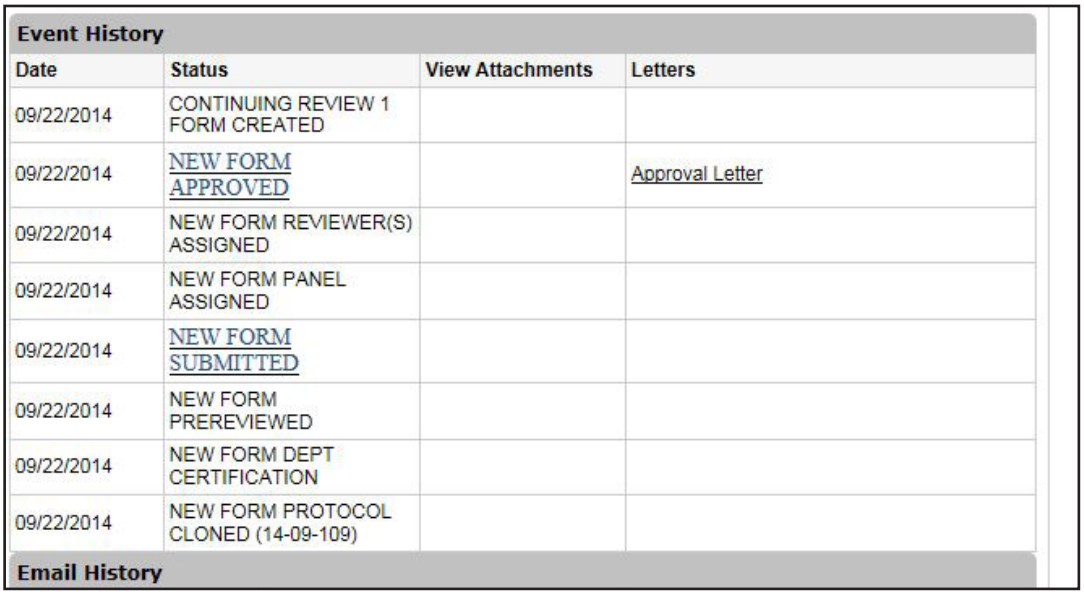


Figure 5.32

5.10 Event History

The Event History section of the protocol [Figure 5.33] 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 5.32], 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
09/22/2014	CONTINUING REVIEW 1 FORM CREATED		
09/22/2014	NEW FORM APPROVED		Approval Letter
09/22/2014	NEW FORM REVIEWER(S) ASSIGNED		
09/22/2014	NEW FORM PANEL ASSIGNED		
09/22/2014	NEW FORM SUBMITTED		
09/22/2014	NEW FORM PREREVIEWED		
09/22/2014	NEW FORM DEPT CERTIFICATION		
09/22/2014	NEW FORM PROTOCOL CLONED (14-09-109)		

Email History

Figure 5.33

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 5.34].

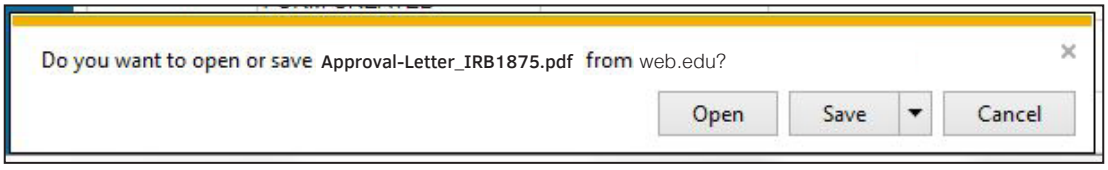


Figure 5.34

6 APPROVED PROTOCOLS

Whether proposing a change to an existing study, requesting a renewal, reporting safety information, or officially closing an Expedited/Full Board study, users may create another form or change an approved protocol. In order to do so, read pages 37 and 38 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.

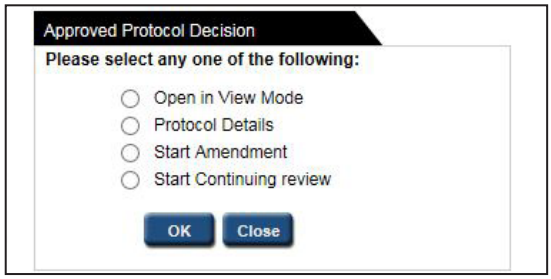


Figure 6.1

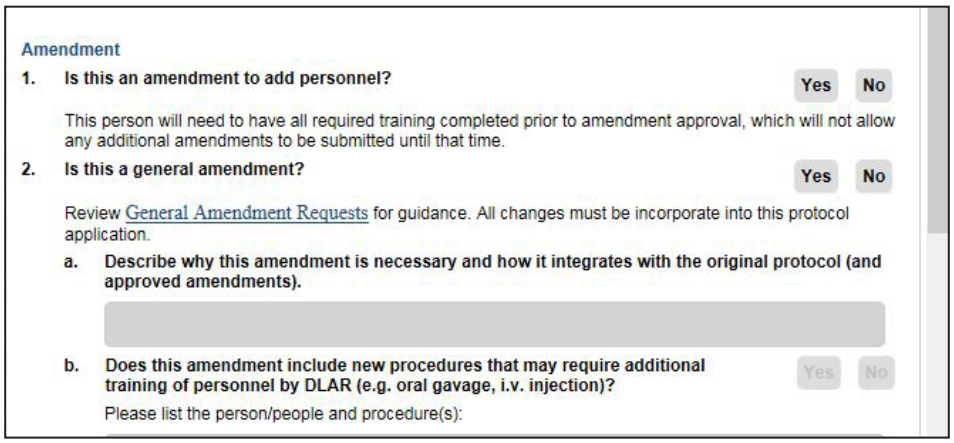


Figure 6.2

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. Please refer to your initial approval document for the protocol's expiration date.

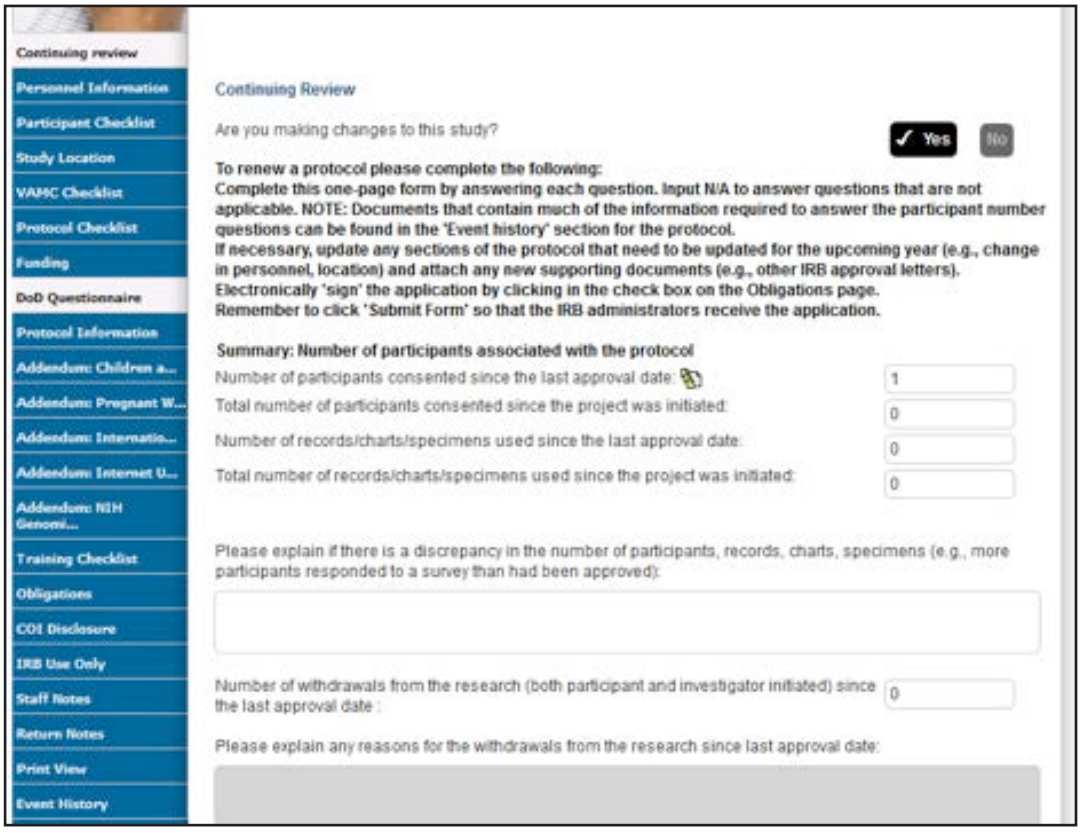


Figure 6.3

7 EDIT/CLONE/DELETE

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 study key personnel that can edit a protocol are study personnel listed within the Investigator or regulatory coordinator roles.

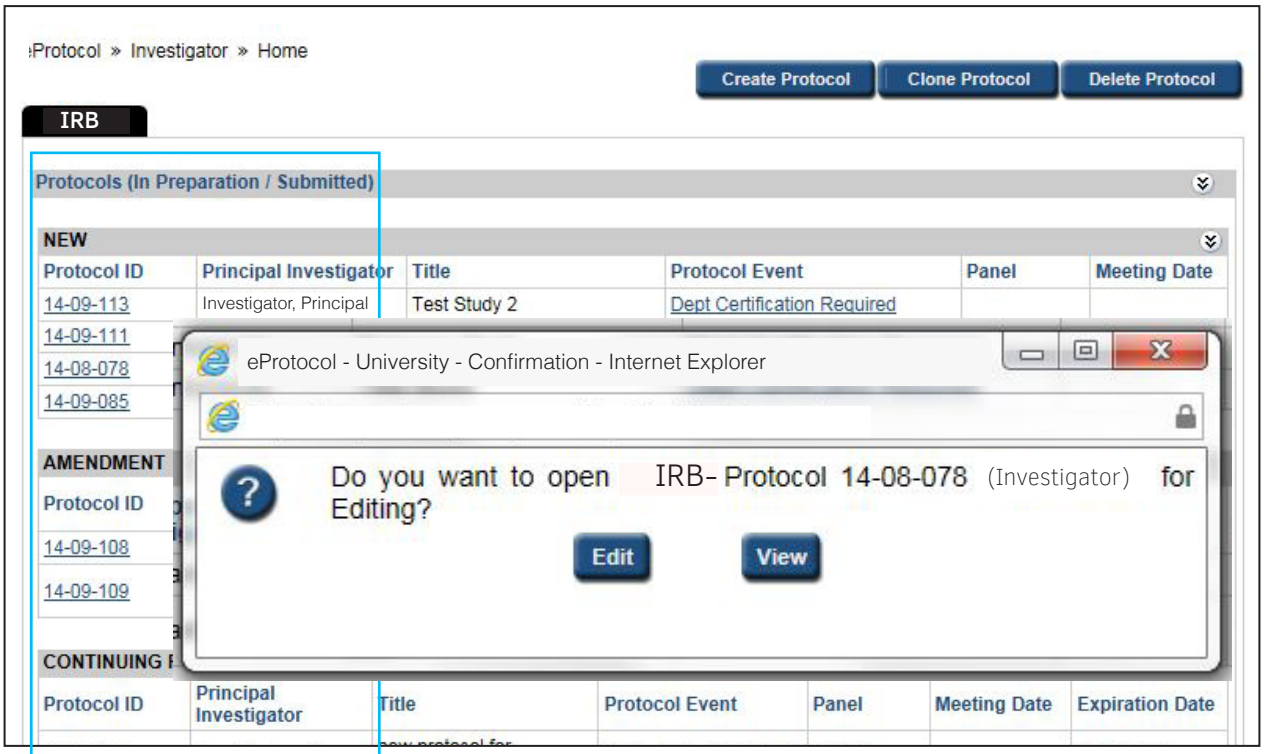


Figure 7.1

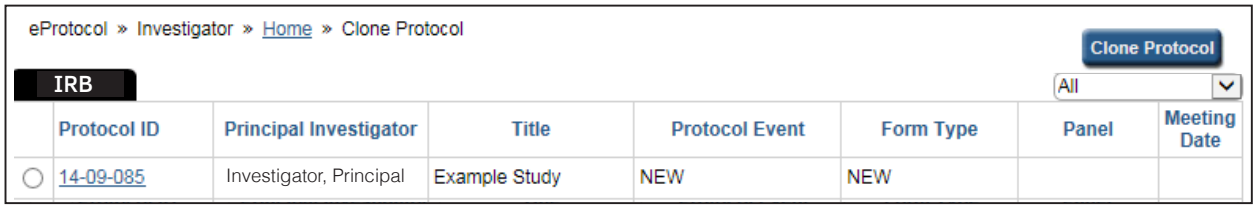


Figure 7.2

2 The **Clone Protocol** action button is used to duplicate a protocol. Clone Protocol can be used if resubmitting an expired protocol or submitting a new protocol that has a previous study's similar attributes. 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]. Please remember to change any information that may vary from the original protocol

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.

NOTE: Only protocols "In Preparation" can be deleted.

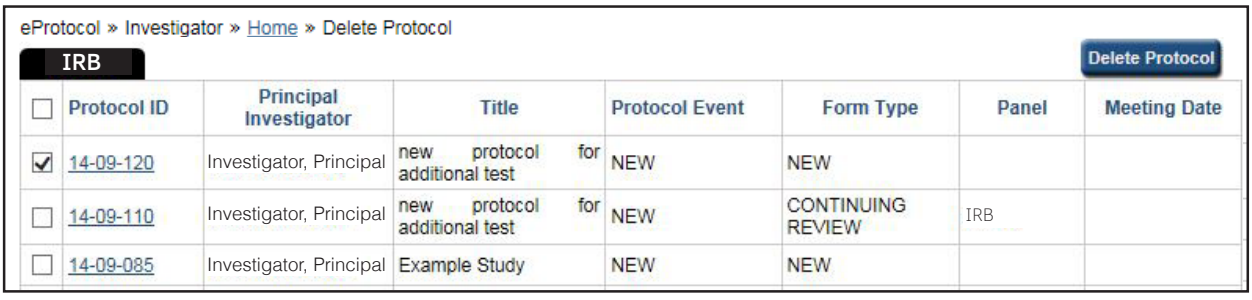


Figure 7.4

8 COMMENTS/RESPONSES

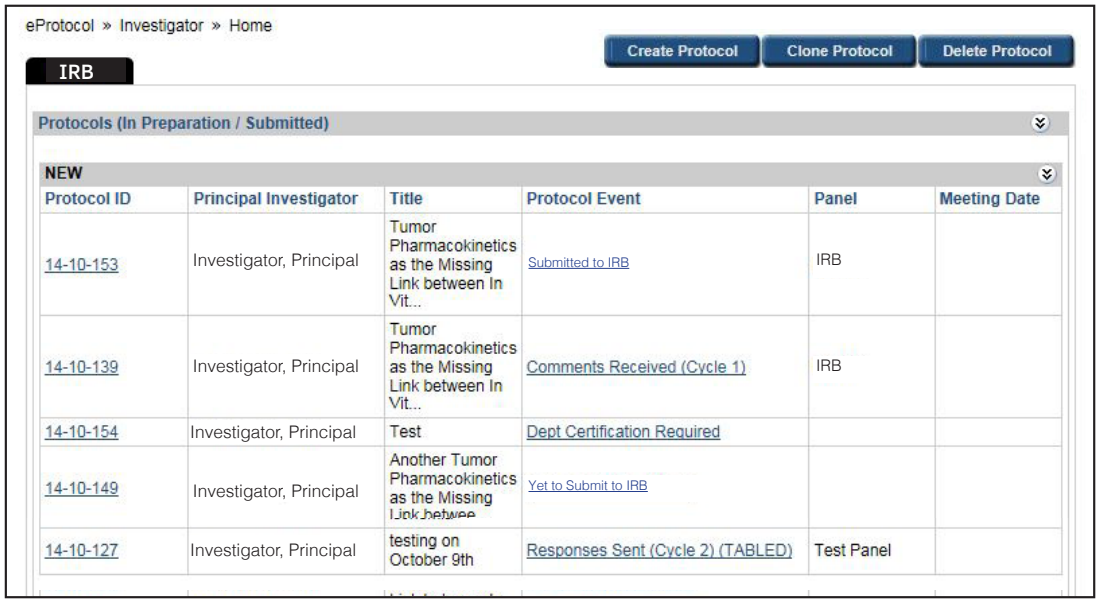


Figure 8.1

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 IRB action button to send off your response. The protocol event on your dashboard will now read "Responses Sent (Cycle 2)."

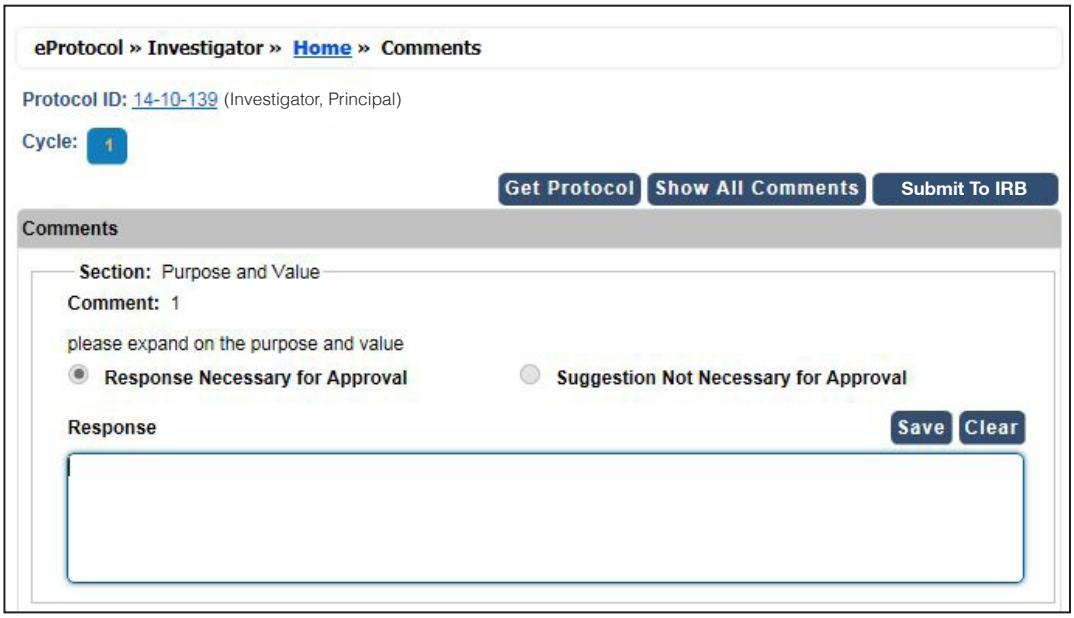


Figure 8.2

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 Research Compliance Administrators [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.

9 SEARCH PROTOCOL

Overview

No matter your role, all IRB eProtocol users have the ability to search a protocol. A user can access the Search Protocol page by first selecting the eProtocol menu on the top left 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.

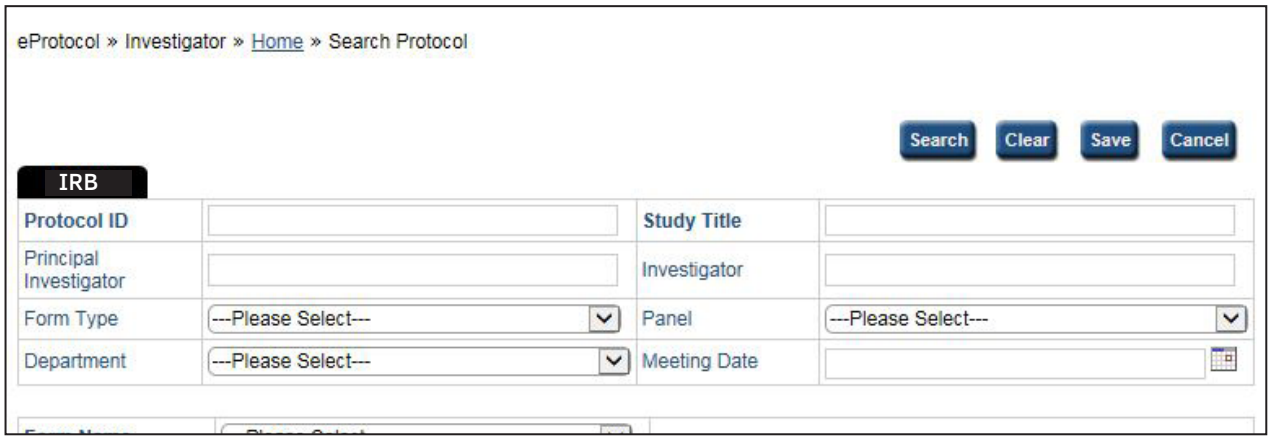


Figure 9.1

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.