

COEUS® LITE IRB

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**COEUS 4.5.1\_P3**

USER GUIDE

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Version: August 24, 2016

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## A NOTE ABOUT THIS GUIDE

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This user guide describes general functionality for using CoeusLite to submit and manage IRB protocols.

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## GETTING ACCESS TO COEUS LITE

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You can use a Mac or a PC and use Internet Explorer, Chrome or FireFox to run CoeusLite. Be sure to remove toolbars from your browser as they may contain pop up blockers within them that will prevent Coeus from launching.

To access to Purdue's CoeusLite submission system, please click on the link via the Purdue IRB's Main Web Page: [www.irb.purdue.edu](http://www.irb.purdue.edu). You will need a Purdue Career Account Username and Password established to access COEUS Lite through the log in screen.

Personnel who cannot be found when searching may not have a Coeus User Account. To request establishment of a new Coeus User Account: <https://www.purdue.edu/business/coeus/Requests/access.php>.

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## PREPARING TO ENTER A PROTOCOL

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To make the protocol submission process as smooth as possible, it's important to begin with the end in mind.

Here are a few questions to get you started on the right foot and to ensure that you have all the necessary information you need to successfully submit your protocols, amendments and renewals. The more complete the documentation upon submission, the quicker your protocols will be approved.

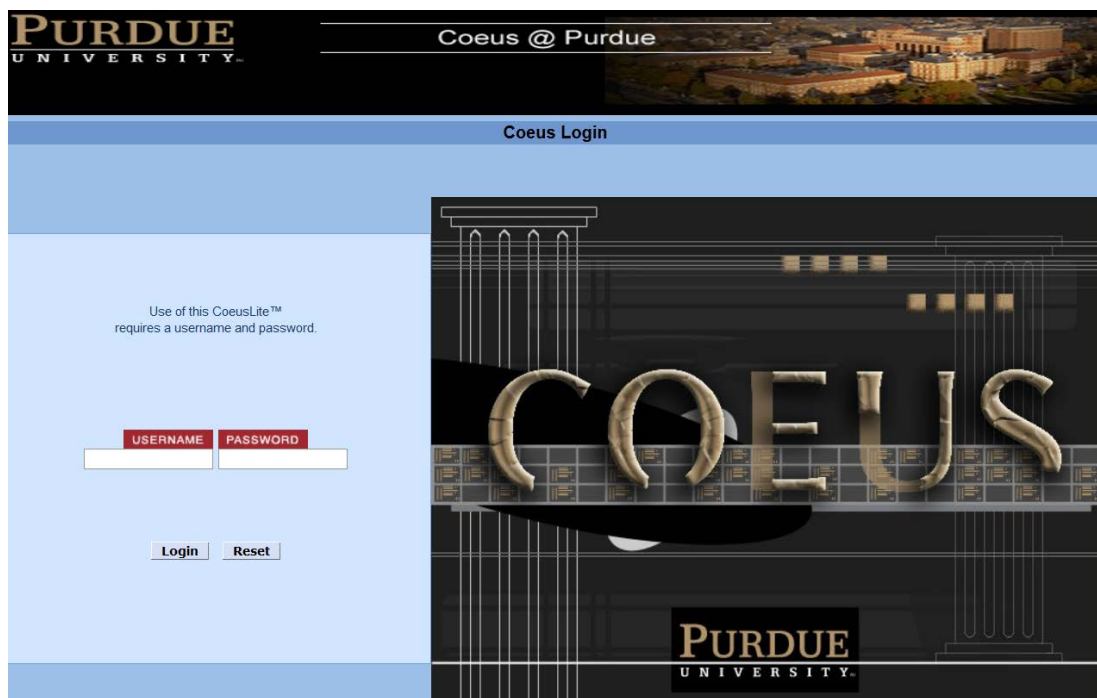
Here are a few questions to think about:

- Have you already completed all the paperwork and/or forms required by Purdue's IRB that must be electronically uploaded into Coeus to complete the type of submission that you have in mind? (Examples the study instruments, consent forms, surveys or interview protocols, etc.)
- Are the protocol-related documents saved on your local computer or a flash drive for easy access?

You'll see that the electronic process is meant to mirror the paper process with the exception that now your protocols will be routed electronically. You will need to ensure that all Investigators have completed all the required human research protection training before submission and have filed a protocol-specific conflict of interest disclosure when it's necessary to do so.

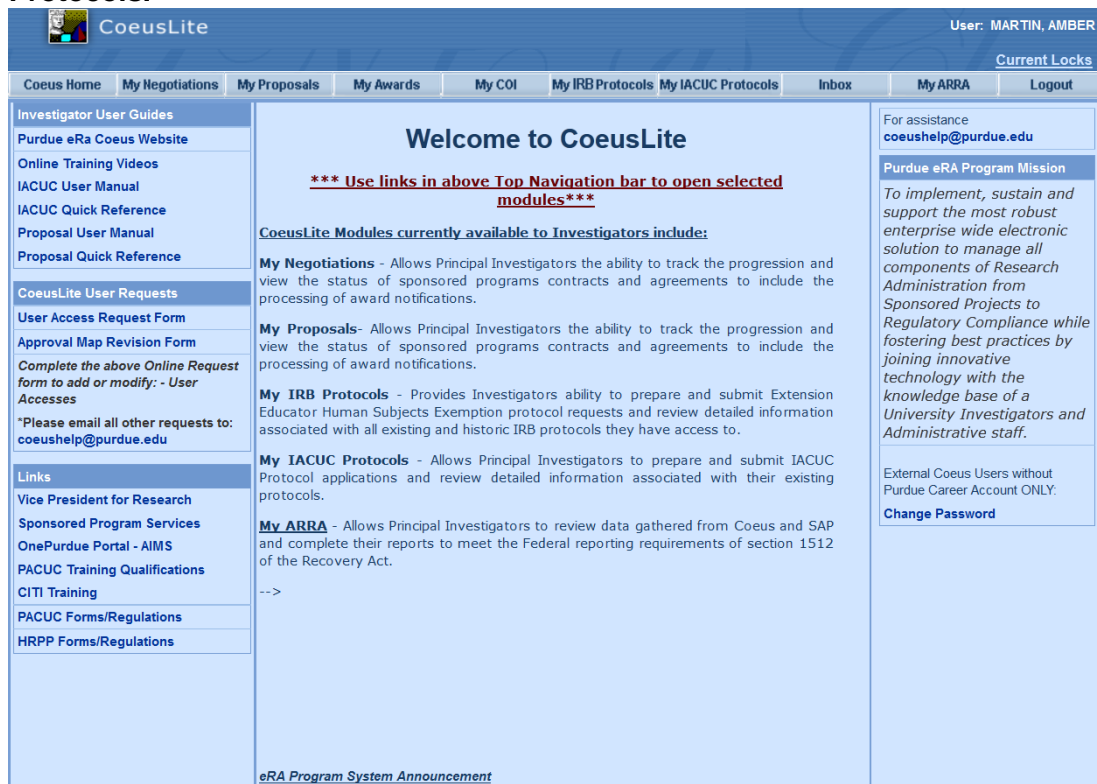
## GETTING STARTED: CREATING A NEW PROTOCOL

Log in to the Coeus application by entering your username and password. Click **Login**.



The image shows the Coeus @ Purdue login page. At the top left is the Purdue University logo. To its right is the text "Coeus @ Purdue". Below this is a banner image of a university campus. Under the banner is the text "Coeus Login". The main content area has a light blue background. On the left, it says "Use of this CoeusLite™ requires a username and password." Below this are two input fields labeled "USERNAME" and "PASSWORD". Below the fields are "Login" and "Reset" buttons. On the right, there is a large graphic with the word "COEUS" in large, stylized letters, and the Purdue University logo at the bottom.

After logging in, the **Welcome to Coeus Lite** window will launch. Click **My IRB Protocols**.



The image shows the CoeusLite "Welcome to CoeusLite" window. The top bar shows the user "User: MARTIN, AMBER L" and "Current Locks". Below the bar is a navigation menu with links: Coeus Home, My Negotiations, My Proposals, My Awards, My COI, My IRB Protocols, My IACUC Protocols, Inbox, My ARRA, and Logout. The main content area is titled "Welcome to CoeusLite" and contains the following text:   
**\*\*\* Use links in above Top Navigation bar to open selected modules\*\*\***  
CoeusLite Modules currently available to Investigators include:  
**My Negotiations** - Allows Principal Investigators the ability to track the progression and view the status of sponsored programs contracts and agreements to include the processing of award notifications.  
**My Proposals** - Allows Principal Investigators the ability to track the progression and view the status of sponsored programs contracts and agreements to include the processing of award notifications.  
**My IRB Protocols** - Provides Investigators ability to prepare and submit Extension Educator Human Subjects Exemption protocol requests and review detailed information associated with all existing and historic IRB protocols they have access to.  
**My IACUC Protocols** - Allows Principal Investigators to prepare and submit IACUC Protocol applications and review detailed information associated with their existing protocols.  
**My ARRA** - Allows Principal Investigators to review data gathered from Coeus and SAP and complete their reports to meet the Federal reporting requirements of section 1512 of the Recovery Act.  
-->  
At the bottom, there is a link for "eRA Program System Announcement". On the left side, there is a sidebar with links: Investigator User Guides, Purdue eRa Coeus Website, Online Training Videos, IACUC User Manual, IACUC Quick Reference, Proposal User Manual, Proposal Quick Reference, CoeusLite User Requests, User Access Request Form, Approval Map Revision Form, Complete the above Online Request form to add or modify: - User Accesses, \*Please email all other requests to: coeushelp@purdue.edu, Links, Vice President for Research, Sponsored Program Services, OnePurdue Portal - AIMS, PACUC Training Qualifications, CITI Training, PACUC Forms/Regulations, and HRPP Forms/Regulations. On the right side, there is a sidebar with links: For assistance coeushelp@purdue.edu, Purdue eRA Program Mission, To implement, sustain and support the most robust enterprise wide electronic solution to manage all components of Research Administration from Sponsored Projects to Regulatory Compliance while fostering best practices by joining innovative technology with the knowledge base of a University Investigators and Administrative staff, External Coeus Users without Purdue Career Account ONLY, and Change Password.

After clicking **My IRB Protocols**, the default view is the **IRB Home** page. This was a customization which gives Investigators immediate options and the buttons to initiate their submission, Create New Protocol/Amendment/Renewal buttons are front and center on the home page.

**CoeusLite** User: MARTIN, AMBER

[Coeus Home](#) | [My Negotiations](#) | [My Proposals](#) | [My Awards](#) | [My COI](#) | **[My IRB Protocols](#)** | [My IACUC Protocols](#) | [Inbox](#) | [My ARRA](#) | [Logout](#)

[IRB Home](#) | [All Protocols](#) | [Pending Protocols](#) | [Pending PI Action](#) | [Amendments & Renewals](#) | [Create New Protocol](#) | [Protocol Search](#) | [All My Reviews](#) | [Schedules](#)

### CoeusLite IRB PROTOCOL

[IRB Online User Manual](#) | [IRB Quick Reference Guides](#) | [IRB Video Tutorials](#) | [Download Attachment Templates](#)

**Manage IRB Protocol Submissions**  
Investigators may manage their existing IRB Protocols by clicking the desired links found in the top navigation menu. Protocol submissions may be saved after creation and completed at a later date. Clicking on Pending records will open them for editing and all other records will open in display.

- All Protocols* - Displays a list of all IRB protocol submissions regardless of current status
- Pending Protocols* - Displays a list of all Pending protocols submissions that are currently under development or have been submitted for Approval
- Pending PI Action* - Displays a list of protocols that have Requested Revisions or require Continuations/Renewals
- Amendments & Renewals* - Displays a list of all Amendments and Renewals for Approved IRB Protocols
- Protocol Search* - Allows Investigator to search for a specific protocol or submission

**Create New IRB Protocol Submission**

Create a New IRB Protocol submission or complete IRB Requested Revisions by clicking the appropriate link below.

<b>Create New Protocol</b>	- Click here to create a new initial protocol submission
<b>Complete IRB Requested Revisions</b>	- Click here to view and complete any IRB requested revisions
<b>Create New Amendment</b>	- Click here to view and complete an Amendment to a currently Active protocol
<b>Create New Renewal</b>	- Click here to create and complete a Renewal/Continuing Review on a currently Active protocol
<b>Notify IRB</b>	- Click here to submit additional information or documentation to include reports of Non-Compliance to IRB
<b>Request Protocol Status Change</b>	- Click here to request a status change to your currently Active protocol

To create a new protocol, click **Create New Protocol**.

**CoeusLite** User: MARTIN, AMBER

[Coeus Home](#) | [My Negotiations](#) | [My Proposals](#) | [My Awards](#) | [My COI](#) | **[My IRB Protocols](#)** | [My IACUC Protocols](#) | [Inbox](#) | [My ARRA](#) | [Logout](#)

[IRB Home](#) | [All Protocols](#) | [Pending Protocols](#) | [Pending PI Action](#) | [Amendments & Renewals](#) | [Create New Protocol](#) | [Protocol Search](#) | [All My Reviews](#) | [Schedules](#)

### CoeusLite IRB PROTOCOL

[IRB Online User Manual](#) | [IRB Quick Reference Guides](#) | [IRB Video Tutorials](#) | [Download Attachment Templates](#)

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<b>Create New Renewal</b>	- Click here to create and complete a Renewal/Continuing Review on a currently Active protocol
<b>Notify IRB</b>	- Click here to submit additional information or documentation to include reports of Non-Compliance to IRB
<b>Request Protocol Status Change</b>	- Click here to request a status change to your currently Active protocol

This will launch the **General Protocol Information** screen.

### ***Side Bar: Maneuvering in and Entering Information into the Protocol Screens***

The menu items (General Info, Investigators/Study Personnel, etc.) located in the left-hand column in all the protocol screens serve as tools for entering and uploading the specific information required to create a protocol record and submit the protocol to the appropriate oversight authorities and the IRB.

The menu items noted with an asterisk \* indicate that the field is mandatory.

Also note that as you work your way through the menu items a red check ✓ mark will appear noting that the particular screen or “page” of the application has data entered and saved. It does not necessarily mean that screen is complete. It may also denote when some information may be assumed and has therefore been populated into the system. This auto-populated information can be over-written by the user and is described in this document.

## **TO CREATE AN INITIAL PROTOCOL**

Utilizing the screens outlined below, you will enter pertinent information to create and prepare an initial protocol submission.

**Type:** Select the appropriate protocol type from the drop down menu. The mostly common types of protocols are “Request for Non-Exempt Approval” – or – “Request for Exemption”.

**Title:** Enter the title of the research protocol.

**Application Date:** Will default to today's date – the creation date of the protocol record.

**FDA Application No.:** Enter the alphanumeric information related to an Investigational New Drug (IND) or Investigational Devices (IDE or HDE) used in the protocol. Type *Pending* if an IND or IDE number has yet to be received.

Click **Save** when all information is entered.

General Protocol Information	
* Indicates Mandatory Fields	
Protocol Details	
*Type:	Request for Non-Exempt Approval
*Title:	Manual Production 4.30.15
Description:	
*Application Date:	04/30/2015
Reference Num 1:	
FDA Application No:	
<b>Save</b>	

Saving generates and **assigns the protocol number** and a **status of Pending/In Progress**. (At this time the record is saved and the investigator may proceed with completing the submission or save until a later time to complete.)

Protocol #:	1504001451 (Pending/In Progress)	Expiration Date:
Investigator:	CAMPBELL, ELIZABETH K	Last Approval Date:
Title:	Manual Production 4.30.15	Meeting Date:
General Protocol Information		
* Indicates Mandatory Fields		
Protocol Details		
*Type:	Request for Non-Exempt Approval	
*Title:	Manual Production 4.30.15	
Description:		
*Application Date:	04/30/2015	
Reference Num 1:		Reference Num 2:
FDA Application No:		
<b>Save</b>		



### Side Bar: Protocol Number

The number assigned to the protocol is generated by the Coeus database. This number will automatically populate the protocol record when the **General Information** screen of the protocol record is first saved.

*Coeus generates and assigns protocol numbers that consist of ten digits. The first four digits represent the year and month the initial protocol record was created. The last six digits represent the sequential order in which the protocol record was created.*

*Ex: 0801003756 - year 2008, month of January 01 and sequential number 003756.*

*Coeus also assigns a suffix to continuing review and amendment submissions... The renewals and amendments are numbered consecutively, with an "R" indicating a renewal and an "A" representing an amendment. Ex. R001, R002, and A001, A002, etc.*

## INVESTIGATORS/STUDY PERSONNEL

Click on **Investigators/Study Personnel** on the left side bar. This launches the **Investigators/Study Personnel Details** screen.

Select, "Add Investigators/Study Personnel". The default identifies the protocol creator as the Principal Investigator (PI) and provides an alert message that the PI information is not saved yet. The home unit of the protocol creator also defaults. If the creator is not the PI for the protocol or if a different unit will serve as the lead unit, do not save the information that defaulted.

The screenshot displays the CoeusLite web application interface. The top navigation bar includes tabs for 'Coeus Home', 'My Negotiations', 'My Proposals', 'My Awards', 'My COI', 'My IRB Protocols', 'My IACUC Protocols', 'Inbox', 'My ARRA', and 'Logout'. Below this, a sub-navigation bar provides links to various sections like 'IRB Home', 'All Protocols', 'Pending Protocols', 'Pending PI Action', 'Amendments & Renewals', 'Create New Protocol', 'Protocol Search', 'All My Reviews', and 'Schedules'. The main content area is organized into three primary sections: '1: Protocol Details', '2: Questionnaires', and '3: Attachment Uploads'. The '1: Protocol Details' section is further divided into sub-tabs: 'General Info', 'Investigators / Study Personnel' (which is currently selected), 'Correspondents', 'Funding Source', 'Subjects', and 'Notes'. The 'Investigators / Study Personnel' sub-tab shows a form for adding personnel. This form includes fields for Name (MARTIN, AMBER L), Email (MARTI652@PURDUE.EDU), Phone, Mobile, Fax, Unit (40701000), Protocol Role (Principal Investigator), Person Role, and Affiliation (Key Personnel). A message indicates that the PI information has not been saved yet and prompts the user to click the 'Save' button. Below the form are 'Save' and 'Cancel' buttons. At the bottom of the form, there is a table titled 'List of Investigators / Study Personnel:' with columns for Person Name, Department, Lead Unit, Role, Affiliate, and Training. A 'Send Notification' button is located to the right of this table.

To change the Principal Investigator or to find and add other investigators and study personnel, click on **Search/Add Person**. This will launch the Employee Search window.

### Side Bar: Non-Employee Search

Contact your Coeus administrator at [coeushelp@purdue.edu](mailto:coeushelp@purdue.edu) if someone not affiliated with Purdue is not available. In some instances it will be necessary to have these persons added to the person table or rolodex table in Coeus. Please request having those investigators added to the person table at that time by contacting [coeushelp@purdue.edu](mailto:coeushelp@purdue.edu).

The screenshot shows a web application interface. The top section is titled "Investigators / Study Personnel Details" and contains instructions: "Add all Personnel involved with this project below. Click the 'PAGE HELP' button to the right for instructions on how to complete." Below this is a red error message: "The PI information is not saved yet. Click the Save button to save the PI information". A yellow highlight is under the "Search/Add Person" link. The form fields include: Name (MARTIN, AMBER L), Email (MARTI652@PURDUE.EDU), Phone, Mobile, Fax, Unit (40701000), Vp For Research, Protocol Role (Principal Investigator), Person Role, and Affiliation (Key Personnel). There are "Save" and "Cancel" buttons. Overlaid on this is a "Employee Search - Mozilla Firefox" dialog box. The dialog box has a URL bar showing "https://coeusbeta.itap.purdue.edu/coeus/irbSearch.do?type=Employee Search&search=true&searchName=WEBPERSONSEARCH". Below the URL bar is a message: "Please enter search criteria of the form \*value\* or \*value\* or value\* in any of search fields." The search fields are: Last Name, First Name, Full Name, and User Name. There are "Search" and "Cancel" buttons at the bottom of the dialog box.

Enter the last name or other search criteria and click **Search**. Note: Not all search fields must be completed to search for an Employee. Do not forget to place "\*" before and after the name you are searching for in this field.

This screenshot shows the "Employee Search - Mozilla Firefox" dialog box with search criteria entered. The URL bar shows "https://coeusqa.itap.purdue.edu/coeus/irbSearch.do?type=Employee Search&search=true&searchName=WEBPERSONSEARCH". The message above the search fields is: "Please enter search criteria of the form \*value\* or in any of search fields. or \*value value\*". The search fields are: Last Name (\*campbell\*), First Name, Full Name, and User Name. There are "Search" and "Cancel" buttons at the bottom of the dialog box.

The **Person Search Result** window opens. The **Person Search Result** displays all investigators with the same last name (or other search criterion).

Name	ID	Email	Position
DREW M			
CAMPBELL DYLAN M	CAMPBELD 42901000	CAMPBELD@PURDUE.EDU	STUDENT SERVICE
CAMPBELL ELIZABETH K	EKCAMPBE 40701000	EKCAMPBE@PURDUE.EDU	
CAMPBELL ELIZABETH L	CAMPBEEL 40408000	CAMPBEEL@PURDUE.EDU	SECRETARY IV
CAMPBELL ERIC D	EDCAMPBE 43014000	EDCAMPBE@PURDUE.EDU	DEFAULT POSITION
CAMPBELL ERIC M	CAMPBEEM 41907000	CAMPBEEM@PURDUE.EDU	DEFAULT POSITION
CAMPBELL FVEI YN C	ECCAMPBE 42003000	ECCAMPBE@PURDUE.EDU	LIMITED TERM LECTURER

Select the investigator by clicking on the appropriate name.

The selected name, unit and contact information populate fields in the **Investigator/Study Personnel Details** window.

Note that the unit leading the research (lead unit) must also be designated and the field will automatically default to the home organization of the Principal Investigator. This can be over-written by the user by conducting a unit search.

**1: Protocol Details**

Protocol #: 1504001451 (Pending/In Progress)

Investigator: Manual Production 4.30.15

Expiration Date: Last Approval Date:

**\*Investigators / Study Personnel**

Investigators / Study Personnel Details

Add all Personnel involved with this project below. Click the "PAGE HELP" button to the right for instructions on how to complete.

**Search/Add Person**

Name: CAMPBELL, ELIZABETH K Email: EKCAMPBE@PURDUE.EDU Phone:

Mobile: Fax:

Unit: 40701000 Search Vp For Research

Protocol Role: ----Please Select---- Person Role: Affiliation: Key Personnel

Save Cancel

**List of Investigators / Study Personnel:**

Person Name	Department	Lead Unit	Role	Affiliate	Training
-------------	------------	-----------	------	-----------	----------

For each person added:

1. Enter the **Protocol Role** of the individual by clicking the drop down box. Choices are Principal Investigator, Co-Investigator or Study Personnel.
2. Select the individual's affiliation with Purdue by selecting from the **Affiliation** drop down box. Choices are Faculty, Non-Faculty, Key Personnel, Non-Key Personnel, Consultant, Extension Educator, Affiliate or Unaffiliated. NOTE: Anyone who is not listed as PI or Co-PI will require a Person Role to be entered.

**Search/Add Person**

Name: CAMPBELL, ELIZABETH K      Email: EKCAMPBE@PURDUE.EDU      Phone:      Mobile:      Fax:      Vp For Research

Unit: 40701000      [Search](#)

Protocol Role: Principal Investigator      Person Role:      Affiliation: **Affiliate**

Save      Cancel

**List of Investigators / Study Personnel:**

Person Name	Department	Lead Unit	Role
CAMPBELL, ELIZABETH K	• Vp For Research	<input checked="" type="checkbox"/>	Principal Investigator
MARTIN, AMBER L	• Vp For Research		Co-Investigator

---Please Select---  
 Faculty  
 Non-Faculty  
 Key Personnel  
 Non Key Personnel  
 Consultant  
 Extension Educator  
**Affiliate**  
 Unaffiliated

### Side Bar: Contact Information

The **Contact Information** brought in for each person comes from a central university source, usually a human resources system. Investigators and Correspondents must change their source information with the appropriate Human Resources or other central office if they want the appropriate contact information to appear in this window.

### Note

To override the system if a unit must be corrected or assigned, Click on **Search** which opens the **Unit Search** window.

A partial entry may be made, using an asterisk before, after or around the portion of the unit name. Click **Search**.

Unit Search - Mozilla Firefox

https://coeusbeta.itap.purdue.edu/coeus/irbSearch.do?type=Unit Search&search=true&searchName=WEBLEADUNITSEARCH

Please enter search criteria of the form \*value\* or \*value or value\* in any of search fields.

Unit Number:      Unit Name: \*vp for research\*

Search      Cancel

Unit Search - Mozilla Firefox

https://coeusbeta.itap.purdue.edu/coeus/irbSearch.do?type=+strType

**Unit SearchResult**

Search Again      Close Window

UNIT_NUMBER	UNIT_NAME	ADMINOFFICER	UNITHEAD	DEANVP	NOTIFY	ADMINTR
40701000	Vp For Research	-	-	-	-	-

Search Again      Close Window

Click on **Save** when completed. The information is saved in the **List of Investigators/Study Personnel**.

**Investigators / Study Personnel Details**

Add all Personnel involved with this project below. Click the "PAGE HELP" button to the right for instructions on how to complete.

[Search/Add Person](#)

Name: CAMPBELL, ELIZABETH K Email: EKCAMPBE@PURDUE.EDU Phone:   
 Unit: 40701000 Search Mobile: Vp For Research Fax:   
 Protocol Role: Principal Investigator Person Role: Affiliation: Affiliate

[Save](#) [Cancel](#)

**List of Investigators / Study Personnel:**

Person Name	Department	Lead Unit	Role	Affiliate	Training
CAMPBELL, ELIZABETH K	Vp For Research	<input checked="" type="checkbox"/>	Principal Investigator	Affiliate	<input checked="" type="checkbox"/> Remove
MARTIN, AMBER L	Vp For Research		Co-Investigator	Key Personnel	<input checked="" type="checkbox"/> Remove

## CORRESPONDENTS

This screen is populated with the names of persons who should receive notice of the IRB correspondence that is sent to the investigator. **Please note that this is an optional screen and is not required to be filled out.**

Click on the **Correspondents** button in the column on the left-hand side. This opens the **Correspondents** window. Add persons who should receive correspondence related to this protocol. Use the **Employee Search** or **Non Employee Search** to find and add correspondents, as described in the Investigator section.

**Investigators / Study Personnel**

**Correspondents** >>

Funding Source

Subjects

Notes

**2: Questionnaires**

Human Subjects Research Determination

**3: Attachment Uploads**

Attachments

Submit to IRB

**Correspondents - (OPTIONAL SCREEN)**

Correspondents are individuals who, in addition to the PI, should be copied on all PACUC communications and actions related to this protocol

"Click "Add Correspondents" and complete the listed field for each person."

**Add Correspondents**

[Employee Search](#) | [Non Employee Search](#)

Name:   
 Type: ----Please Select----   
 Comments:

[Save](#)

**List of Correspondents**

Type	Name	Comments
------	------	----------

Type: Select the **Type** of correspondent from the drop down menu (**Options are: Department Head, Sponsored Programs Regulatory Administrator, Psychological Sciences, Extension District Director, CES Director, EHSAC Coordinator, Study/Research Personnel**).

**Add Correspondents**

[Employee Search](#) | [Non Employee Search](#)

Name:   
 Type: ----Please Select----   
 Comments:

[Save](#)

**List of Corre**

Type	Name	Comments
------	------	----------

### Side Bar: Additional Information to Add

- Also add personnel from other institutions that are involved in the research study who may wish to receive notifications of renewal reminders, approvals, expired protocols, etc. These may include the Human Subject Protection Administrator at a collaborating institution or affiliate organizations. Note, however, that these persons must be set up as Coeus Users in your Coeus instance in order to access information such as IRB approval letters from the system. Please request having those investigators added to the person table at that time by contacting [coeushelp@purdue.edu](mailto:coeushelp@purdue.edu).

Click on **Save**. The selection is saved in the **List of Correspondents**. (Entries in the **Comments** section are optional.)

**Add Correspondents**

[Employee Search](#) | [Non Employee Search](#)

Name:

Type:

Comments:

**Save**

**List of Correspondents**

Type	Name	Comments		
Department Head	AGNEW, CHRISTOPHER R		<a href="#">View</a>	<a href="#">Re</a>
Sponsored Programs Regulatory Administrator	BRYANT-GAWTHROP, IANTHE N		<a href="#">View</a>	<a href="#">Re</a>
Psychological Sciences	PHEBUS, SUE ANN		<a href="#">View</a>	<a href="#">Re</a>
Psychological Sciences	WILLIAMS, LEANNE E		<a href="#">View</a>	<a href="#">Re</a>

## FUNDING SOURCE

Researchers must provide all sources of funding that support the conduct of the research project.

### Note

You can use this tab to provide the information necessary for the IRB to perform congruency reviews between sponsor proposals and the IRB protocols.

Select the **Funding Source** menu item from the column on the left-hand side of the screen.

**1: Protocol Details**

☒ **\*General Info**

☒ **\*Investigators / Study Personnel**

☒ **Correspondents**

**Funding Source** >>

**Subjects**

**Notes**

**2: Questionnaires**

**Human Subjects Research Determination**

Protocol #: 1504001451 (Pending/In Progress)

Investigator: CAMPBELL, ELIZABETH K

Title: Manual Production 4.30.15

Expiration Date:

Last Approval Date:

Funding Source - (REQUIRED if applicable)

**Add Funding Source**

Type:

Number/Code:

Name/Title:

**Save**

**List of Funding Source**



To search for the funding source for the protocol select **Type** from drop down menu.

**1: Protocol Details**

Protocol #: 1504001451 (Pending/In Progress)  
Investigator: CAMPBELL, ELIZABETH K  
Title: Manual Production 4.30.15

**Funding Source - (REQUIRED if applicable)**

**Add Funding Source**

Type: -----Please Select-----  
Number/Code: -----Please Select-----  
Name/Title: Sponsor-External Funding  
Departmental Funding  
Other-Self Funded

**Save**

**2: Questionnaires**

**List of Funding Source**

Select **Sponsor** when the protocol is fully or partially funded by an external entity. Select **Departmental Funding** to denote when the research is funded by departments *within Purdue University*. Click **Search**.

This **Sponsor Search** or Unit (Department) Search window opens up.

Enter the Sponsor or Department name, or number code, if known, using asterisks before, after or around partial names. Examples: \*National Institute of Health\* or \*Psychological\*. Coeus Lite will not recognize acronyms. If you cannot remember the entire sponsor's name, you may use a partial entry to begin the search. For example, using "Science" instead of "National Science Foundation". This will bring up any Sponsor in the system with "Science" in the name. Click on **Search**.

**Funding Source - (REQUIRED if applicable)**

**Add Funding Source**

Type: Departmental Funding  
Number/Code:  **Search**  
Name/Title:

**Save**

**Unit Search - Mozilla Firefox**

<https://coeusbeta.itap.purdue.edu/coeus/irbSearch.do?type=Unit Search&search=true&searchName=WEBLEADUNITSEAR>

Please enter search criteria of the form \*value\* or \*value or value\* in any of search fields.

Unit Number:  Unit Name: \*psychological\*

**Search** **Cancel**

The **Sponsor** or **Unit Search Result** window opens. Click on the appropriate sponsor to bring into the protocol record.

Unit SearchResult						
			Search Again	Close Window		
UNIT_NUMBER	UNIT_NAME	ADMINOFFICER	UNITHEAD	DEANVP	NOTIFY	ADMINTR
<a href="#">41311000</a>	<a href="#">Psychological Sci</a>	-	-	-	-	-
<a href="#">41713000</a>	<a href="#">Psychological Sci</a>	-	-	-	-	-
			Search Again	Close Window		

Click **Save**.

Funding Source - (REQUIRED if applicable)

**Add Funding Source**

Type: Departmental Funding

Number/Code: 41311000 [Search](#)

Name/Title: Psychological Sci

**Save**

The Sponsor is saved in the **List of Funding Source**.

**Add Funding Source**

Type: -----Please Select-----

Number/Code:

Name/Title:

**Save**

**List of Funding Source**

Type	Number/Code	Name/Title	
Departmental Funding	41311000	Psychological Sci	<a href="#">Remove</a>

Multiple funding sources for the protocol can be added.

### DATA ENTRY REQUIRED FOR CONGRUENCY BETWEEN PROPOSALS AND PROTOCOLS

To provide information about a pending proposal, first Search on the name of the Sponsor or Department and click **Save**. This will populate the name of the Sponsor or Department into the **List of Funding Sources**. To enter the Proposal Summary and Certification number (ProSum), from the drop down box, select **Other**. This opens the field for editing. Type in the abbreviation of the Sponsor or Department type Pending and then enter the ProSum (or M or C) number. Click **Save**.

**Add Funding Source**

Type: Other-Self Funded

Number/Code: PSY SCI Pending M09 23456

Name/Title:

**Save**

**List of Funding Source**

Type	Number/Code	Name/Title	
Departmental Funding	41311000	Psychological Sci	<a href="#">Remove</a>



**Add Funding Source**

Type:

Number/Code:

Name/Title:

**Save**

**List of Funding Source**

Type	Number/Code	Name/Title	
Departmental Funding	41311000	Psychological Sci	<a href="#">Remove</a>
Other-Self Funded	PSY SCI Pending M09 23456		<a href="#">Remove</a>

To enter the award number, first search on the name of the Sponsor and click **Save**. This will populate the name of the Sponsor into the **List of Funding Sources**. To enter the related number, from the drop down box, select **Other**. This opens the **Number/Code** field for editing. Type in **Sponsor** name abbreviation and the award number. Click **Save**.

If the proposal was submitted electronically to Purdue's research office then the researcher need not upload a copy of the proposal or award. However, copies of the proposal that was signed and dated by the authorized research office official must be uploaded with the protocol when the proposal was not submitted electronically to research office.

## NOTES

The **Notes** screen can be used to capture and track comments related to the protocol.

**\*Investigators / Study Personnel**

☒ **Correspondents**

☒ **Funding Source**

☒ **Subjects**

**Notes** >>

**2: Questionnaires**

**Human Subjects Research**

**Protocol Notes**

The protocol Notes are for completely optional use and provide Investigators the ability to enter working comments to assist with the development of the protocol submission. Entered notes cannot be modified or revised once saved.

**IMPORTANT: Any information entered on the Notes screen is for working purposes only and will NOT be considered part of the official protocol application.**

[Add Notes](#)

Comment	By	Posted Time Stamp	View
---------	----	-------------------	------

Click on **Add**. This opens the **Add Notes** window. Entries may be entered in the **Comment** window. For Example, if you have met with an Analyst prior to submission, you can communicate that to the IRB here. Click on **Save** when completed.

**Protocol Notes**

The protocol Notes are for completely optional use and provide Investigators the ability to enter working comments to assist with the development of the protocol submission. Entered notes cannot be modified or revised once saved.

**IMPORTANT: Any information entered on the Notes screen is for working purposes only and will NOT be considered part of the official protocol application.**

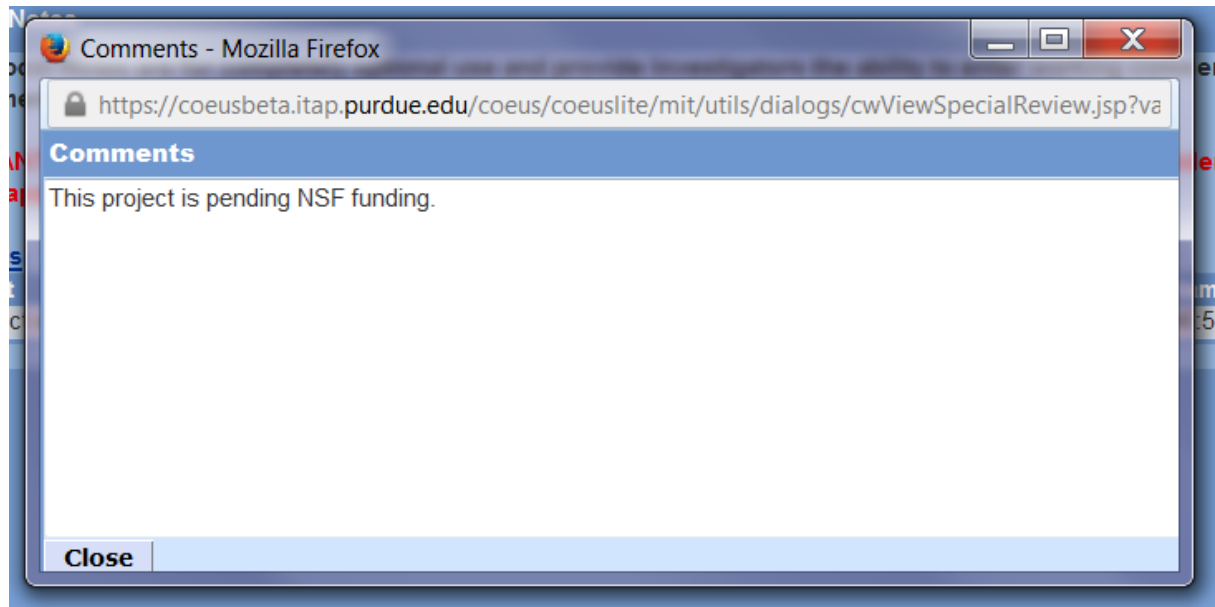
Comment:

**Save** **Cancel**

The comments appear in the **List of Protocol Notes**. Click on **View** to review the comment

Protocol Notes			
The protocol Notes are for completely optional use and provide Investigators the ability to enter working comments to assist with the development of the protocol submission. Entered notes cannot be modified or revised once saved.			
<b>IMPORTANT: Any information entered on the Notes screen is for working purposes only and will NOT be considered part of the official protocol application.</b>			
<a href="#">Add Notes</a>			
Comment	By	Posted Time Stamp	View
This project is pending NSF funding.	MARTIN, AMBER L	2015-05-01 14:46:58.0	<a href="#">View</a>

A **Comments** window launches to allow viewing of the entry.



### **Note**

Comments entered in this window are not modifiable nor can they be deleted.

## **ATTACHMENTS**

Once all data fields required for the protocol record and questionnaires are complete, it is time to upload the documents that the researcher must send to the IRB for review and approval.

The **Attachments** menu item is used by the researcher to upload such protocol-related documents.

Click on the **Attachments** menu item from the column on the left-hand side. This opens the **Attachments** window.

The researcher must select a **Document Type** from the drop down box for each item being uploaded for review by the IRB. Sample documents requiring upload include:

Document Type	Naming Conventions/Description
Exempt Research Request	Exempt Research Request Form
Continuing Review/Closure Report	Continuing Review or Closure Form
Personnel Amendment Table	Personnel Amendment Table
Amendment to Approved Study	Amendment to Approved Study Form
Consent Documents	Indicate the title of the form (Informed Consent, Information Sheet, Children's Assent, Parental Consent, Teacher's Consent, Etc.). Indicate Participant population or other unique identifiers such as ages, Healthy Controls, etc.
Recruitment Materials	Indicate advertisement type, Web postings, radio solicitations, flyers etc.
Application Narrative	Non-Exempt Application Narratives
Study Instruments/Surveys/Questionnaires	Materials used during the study (Examples: Interviews, Surveys, Questionnaires, Etc.).
Investigator Correspondences	Any communications from the Investigators that relate to the study.
Other Attachments	Use when there is no drop down document identifier. Describe the document that is being upload and the version date. Examples: HIPAA Research Authorization Form, Other Institutions IRB Approval Letters/Documents, Grant/Sponsor Proposal, Response to Revisions, Etc.
Appendix	Please disregard this document type.

[HELP](#)

Additional forms may be required for protocol submissions that must be completed outside of the system then uploaded as an attachment. Please click the "PAGE HELP" button in the upper right of this screen for instructions on attachments that are required by type of submission.

\*Download Attachment form templates here:  
[http://www.purdue.edu/business/coeus/IRB\\_Protocols/Investigator\\_Guide\\_IRB/irb\\_form\\_downloads.html](http://www.purdue.edu/business/coeus/IRB_Protocols/Investigator_Guide_IRB/irb_form_downloads.html)

!!! Important !!! Extension Educators: Be sure to upload all attachments as Word or PDF documents ONLY!!

### Add New Document

Document Type: ----Please Select----  
File Name: ----Please Select----

Description:

Study Description (Historical)  
Continuing Review/Closure Report  
Consent Documents  
Study Instruments/Survey Questionnaires  
Recruitment Materials  
Investigator Correspondences  
Appendix (Historical)  
Other Attachments  
Extension Educators Exemption Attachments  
Application Narrative  
Amendment to Approved Study  
Personnel Amendment Table  
Exempt Research Request

Type in the **Description** field the unique identifiers for this document. Please reference the CoeusLite Naming Conventions for Attachments document on the Forms & Templates page of Purdue's IRB website for more information.

### Side Bar

When uploading consent and assent forms, be sure to use the title referred to in the document and used commonly by the research team. This will help the research team to ensure that all documents are loaded prior to actually performing the submission.  
*Examples: Children's Assent Form, Ages 7-10, Children's Assent Form Ages 11 – 14, Children's Assent Form Ages 15-17.* It is also important to use version control when uploading documents. (eg: v.1, v.2, etc.)

Use the **Choose File** button to search your system files for the appropriate document to be uploaded.

User: MARTIN, AMBER L

[Coeus Home](#) | [My Negotiations](#) | [My Proposals](#) | [My Awards](#) | [My COI](#) | **[My IRB Protocols](#)** | [My IACUC Protocols](#) | [Inbox](#) | [My ARRA](#) | [Logout](#)

[IRB Home](#) | [All Protocols](#) | [Pending Protocols](#) | [Pending PI Action](#) | [Amendments & Renewals](#) | [Create New Protocol](#) | [Protocol Search](#) | [All My Reviews](#) | [Schedules](#)

**Protocol Details**  
☒ General Info  
☐ Investigators / Study Personnel  
☐ Correspondents  
☐ Funding Source  
☐ Subjects  
☐ Notes

Protocol #: 1608016402 (Pending/In Progress)  
Investigator: Title  
Expiration Date:  
Last Approval Date:

**Attachments** [Help](#)  
Additional forms may be required for protocol submissions that must be completed outside of the system then uploaded as an attachment. Please click the "PAGE HELP" button in the upper right of this screen for instructions on attachments that are required by type of submission.  
\*Download Attachment form templates here:  
[http://www.purdue.edu/business/coeus/IRB\\_Protocols/Investigator\\_Guide\\_IRB/irb\\_form\\_downloads.html](http://www.purdue.edu/business/coeus/IRB_Protocols/Investigator_Guide_IRB/irb_form_downloads.html)  
!!! Important !!! Extension Educators: Be sure to upload all attachments as Word or PDF documents ONLY!!

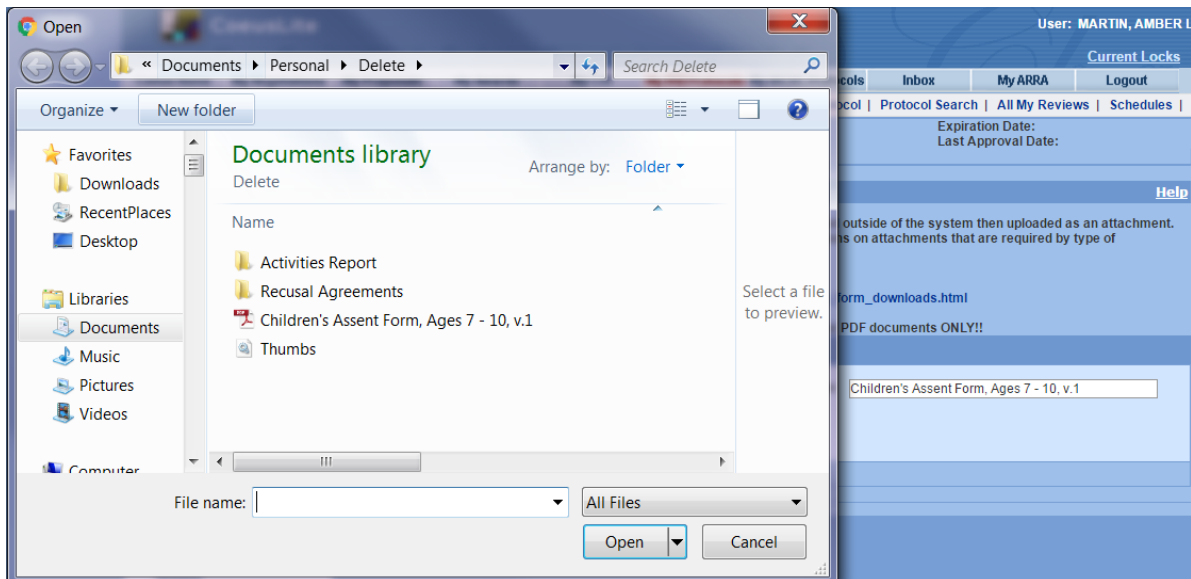
**Add New Document**  
Document Type: Consent Documents  
File Name: Choose File No file chosen  
Description: Children's Assent Form, Ages 7 - 10, v.1

**Questionnaires**  
Human Subjects Research Determination

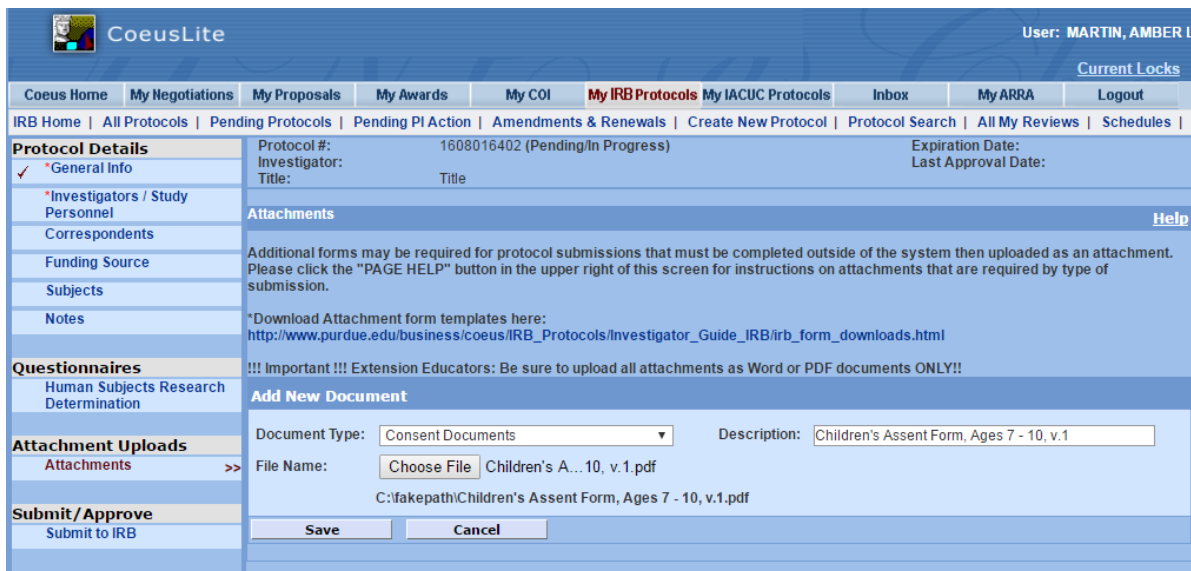
**Attachment Uploads**  
Attachments >>

**Submit/Approve**  
Submit to IRB

Highlight the document you wish to upload to the IRB and click **Open** or double click the file to bring the document into the **File Name** field.



Note that when the document is brought into the application, it appears below the **File Name** line.



Click **Save** to build the list of attachments.

Repeat as necessary until all documents required by the IRB for review are uploaded into the application.

## ACCESS PERMISSIONS

To give someone on the study aggregator access permission, please select the Access Permissions tab under Record Tools. An aggregator is someone who is allowed to create, modify and submit protocol applications through CoeusLite. The PI must be listed as an aggregator on all protocols. Any Key Personnel or Co-Investigators that the PI wishes to give aggregator access must be done by the PI through CoeusLite. These permissions can be added by using the Access Permissions menu item:

✓ <b>Access Permissions</b>
<b>Delete Protocol</b>
<b>Copy Protocol</b>
<b>Print/View Protocol</b>

Clicking on Access Permissions, brings up the list of protocol roles and users that have those roles for the protocol.

Protocol #:	1504001451 (Pending/In Progress)	Expiration Date:
Investigator:	CAMPBELL, ELIZABETH K	Last Approval Date:
Title:	Manual Production 4.30.15	

Protocol Roles		
Grant additional personnel access to edit or view this protocol submission. Personnel with current accesses are listed below. Click the "PAGE HELP" button to the right for instructions on how to complete.		
*Personnel who cannot be found when searching may not have a Coeus User Account. Request establishment of a new Coeus User Account: <a href="https://www.purdue.edu/business/coeus/Requests/access.php">https://www.purdue.edu/business/coeus/Requests/access.php</a>		
Protocol Aggregator <a href="#">Add User</a>		
User ID	User Name	Home Unit
MART1652	MARTIN, AMBER L	40701000: Vp For Research
Protocol Approver		
User ID	User Name	Home Unit
Protocol Viewer <a href="#">Add User</a>		
User ID	User Name	Home Unit

You can add users by clicking on "Add User".

Employee Search - Mozilla Firefox

<https://coeusbeta.itap.purdue.edu/coeus/irbSearch.do?type=Employee Search&search=true&searchName=USERSEARCH>

Please enter search criteria of the form \*value\* or \*value\* or value\* in any of search fields.

User ID:	<input type="text"/>	User Name:	<input type="text"/>
Non Employee:	<input type="text"/>	Unit Number:	<input type="text"/>
Unit Name:	<input type="text"/>	Status:	<input type="text"/>

Then you can search, select and save the user. In this case a protocol viewer was added.

**Protocol Roles**

Grant additional personnel access to edit or view this protocol submission. Personnel with current accesses are listed below. Click the "PAGE HELP" button to the right for instructions on how to complete.

\*Personnel who cannot be found when searching may not have a Coeus User Account.  
Request establishment of a new Coeus User Account: <https://www.purdue.edu/business/coeus/Requests/access.php>

**Protocol Aggregator** [Add User](#)

User ID	User Name	Home Unit
MARTI652	MARTIN, AMBER L	40701000: Vp For Research

**Protocol Approver**

User ID	User Name	Home Unit
---------	-----------	-----------

**Protocol Viewer** [Add User](#)

User ID	User Name	Home Unit
DLBELL	BELL, DIANNE L	40701000: Vp For Research

[Remove](#)

## QUESTIONNAIRES

You may be requested or required to complete a protocol questionnaire(s) prior to submitting a protocol. If questionnaires are available for a protocol submission, they are listed in the left-hand menu bar under the heading **"2: Questionnaires"**.

**Questionnaires**

[Non-Exempt Request](#)

**Attachment Uploads**

[✓ Attachments](#)

**Submit/Approve**

[Submit to IRB](#)

To fill out a questionnaire, click on the title of the questionnaire. The questions will appear:

**Non-Exempt Request**

[Previous](#) [Modify](#) [Start Over](#)

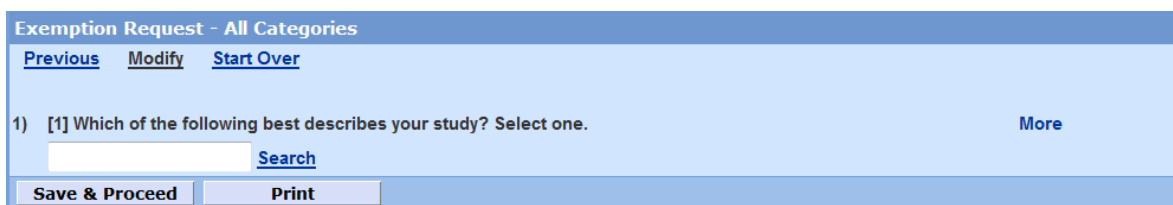
Complete and submit this questionnaire when requesting approval for a non-exempt study. use this questionnaire for studies to be reviewed by either expedited or full board review. Incomplete questionnaires will be returned to the investigator without review. Select "Yes" to proceed. [More](#)

☐ Yes ☐ No

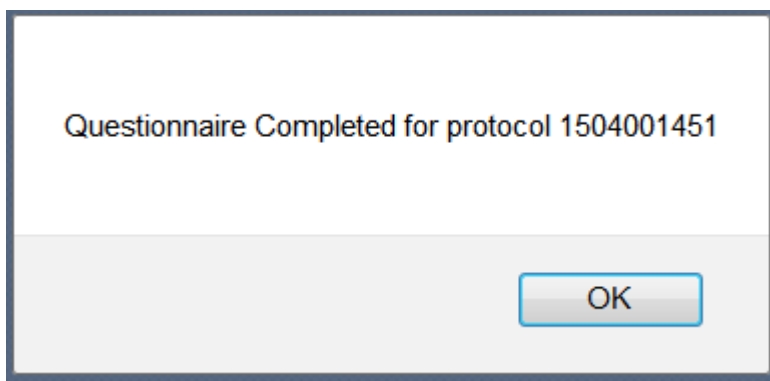
[Save & Proceed](#) [Print](#)

You can click on "More" to get more information about how to answer a question.

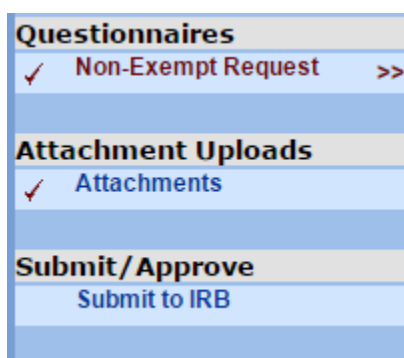
Answer the questions and click **Save & Proceed**. The next set of questions are displayed:



Continue until you complete the questionnaire. You will get a message when you are complete.



A check mark is now displayed in front of the Questionnaire:



To modify an answered Questionnaire, click on the Questionnaire. Select Modify or start over when the questions are displayed, and fill out and save the questions again.

### SUBMIT TO IRB

Once the protocol record is complete, all documents required by the IRB for review have been uploaded and all appropriate questionnaires have been completed, then the researcher is ready to submit the protocol.

To commence the submission process, click the **Submit to IRB** menu item from the column on the left-hand side. This will indicate the types of actions that can be performed on the protocol. For new applications, researchers can only **Submit to IRB**. The **Withdraw Submission** feature cannot be used until the protocol has already been received by the IRB.



Coeus Home	My Negotiations	My Proposals	My Awards	My COI	<b>My IRB Protocols</b>	My IACUC Protocols	Inbox	My ARRA	Logout
IRB Home	All Protocols	Pending Protocols	Pending PI Action	Amendments & Renewals	Create New Protocol	Protocol Search	All My Reviews	Schedules	
<b>1: Protocol Details</b>		Protocol #: 1504001451 (Pending/In Progress) Investigator: CAMPBELL, ELIZABETH K Title: Manual Production 4.30.15 Expiration Date: Last Approval Date:							
<input checked="" type="checkbox"/> General Info <input checked="" type="checkbox"/> Investigators / Study Personnel <input checked="" type="checkbox"/> Correspondents <input checked="" type="checkbox"/> Funding Source <input checked="" type="checkbox"/> Subjects <input checked="" type="checkbox"/> Notes		<b>Protocol Actions</b> You can perform following actions on this protocol. <a href="#">Submit For Review</a> Submit to IRB for Review.							
<b>2: Questionnaires</b>									
<input type="checkbox"/> Human Subjects Research Determination <input checked="" type="checkbox"/> Exemption Request - All Categories									
<b>3: Attachment Uploads</b>									
<input checked="" type="checkbox"/> Attachments <a href="#">Submit to IRB</a> >>									

Click on [Submit for Review](#) to submit the protocol. This function permits the user to identify the type of submission being sent to the IRB for review and approval.

**To Submit to the IRB:** Select the submission **Type** from the drop down box. Be sure to select **Initial Application** for a new protocol. Select a **Review Type** from the drop down box.

#### Note

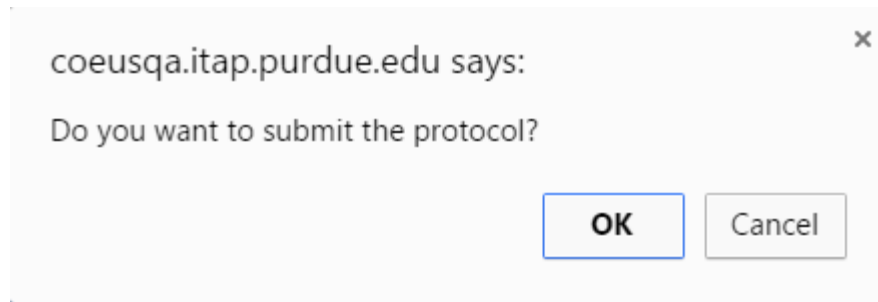
Federal guidance requires that someone other than the investigator determine whether or not a research study is exempt, therefore the only option to choose is Pending IRB Determination. Additionally, federal regulation and/or your institutions policy require the IRB office to determine the appropriate review type for each protocol. The IRB will override the selection to ensure compliance with federal regulations and institution policy regarding the appropriate review type when approved.

Select the **Type Qualifier** drop down box. For initial protocol submissions it should always be **Initial Protocol Application**.

Click the **Submit** button to submit for review.

<b>Protocol Submission</b>	
<p>!!! Protocol has not been Submitted. !!!</p> <p>Please complete the below Mandatory fields and click "Submit" to complete submission into Routing for Academic Approvals.</p>	
* Indicates Mandatory Fields	
<b>Submission Details</b>	
*Type:	Initial Protocol Application
*Review Type:	Pending IRB Determination
Type Qualifier:	New Submission to IRB
<input type="button" value="Submit"/>	


The user will receive a message asking whether or not they wish to submit the protocol. Click **OK**.



**NOTE: CoeusLite is a dual submission system. After you have submitted through CoeusLite, the Principal Investigator will receive an email notification from [Coeus-System@lists.purdue.edu](mailto:Coeus-System@lists.purdue.edu) asking for their approval. The Principal Investigator must follow the approval steps in order for the protocol submission to be routed to the HRPP-IRB.**

### CHECKING THE STATUS OF THE INITIAL SUBMISSION

Once the protocol is submitted, the user can view the status of the protocol in two ways.

- Open CoeusLite. Once logged in, the screen defaults to the **IRB Home Page**. Select **Pending Protocols**.
- Select the pink icon next to the protocol status  to launch a summary of the protocol status.

Protocol Submission Details		
Protocol #:	1409001366 (Submitted to IRB)	Expiration Date:
Investigator:	BELL, DIANNE L	Last Approval Date:
Title:	Cat 6 Testing 9.19.2014	
Submission Type : Initial Protocol Application		Review Type : Pending IRB Determination
Type Qualifier : New Submission to IRB		
Submission Status : Pending		
Date : 09/19/2014		Place :
Committee Id :	Schedule Id :	Schedule Date :
Committee Name :		
Close		

### CHECKING ON STATUS IN ROUTING

To view the status of an initial protocol, or when appropriate an amendment, that is being routed to the department chair for signature and other institutional Committees charged with research oversight click the **Approval Routing** menu item from the left hand column.

Coeus Home	My Negotiations	My Proposals	My Awards	My COI	<b>My IRB Protocols</b>	My IACUC Protocols
------------	-----------------	--------------	-----------	--------	-------------------------	--------------------

IRB Home | All Protocols | Pending Protocols | Pending PI Action | Amendments & Renewals | Create New Protocol | Prot

### 1: Protocol Details

✓ **\*General Info** >>

✓ \*Investigators / Study Personnel

✓ Correspondents

✓ Funding Source

✓ Subjects

✓ Notes

Protocol #: 1504001451 (Routing In Progress)

Investigator: CAMPBELL, ELIZABETH K

Title: Manual Production 4.30.15

**General Protocol Information**

**\* Indicates Mandatory Fields**

**Protocol Details**

\*Type: Request for Exemption

\*Title: Manual Production 4.30.15

Description:

\*Application Date: 04/30/2015

Reference Num 1:

FDA Application No:

### 2: Questionnaires

Human Subjects Research Determination

Exemption Request - All Categories

### 3: Attachment Uploads

✓ Attachments

**Approval Routing**

This will show all the routing steps that are involved in the review and approval of the submission based on the nature of the protocol and the home department of the principal investigator.

Coeus Home	My Negotiations	My Proposals	My Awards	My COI	<b>My IRB Protocols</b>	My IACUC Protocols	Inbox	My ARRA	Logout
------------	-----------------	--------------	-----------	--------	-------------------------	--------------------	-------	---------	--------

IRB Home | All Protocols | Pending Protocols | Pending PI Action | Amendments & Renewals | Create New Protocol | Protocol Search | All My Reviews | Schedules |

**APPROVE**

**REJECT**

**RECALL**

Protocol Summary

Protocol Details

**Department Required for Protocol Approval**

Comments and Attachments

Below is the list of the Approvers who are required to approve this protocol before it may be submitted to the committee.

(000001) IRB: HRPP Admin Map			Hide
	DECKER, SCHELLY D	To be submitted	
	DAVENPORT, MORGAN R	To be submitted	
	MARTIN, AMBER L	To be submitted	
	GASCHO, KIMBERLEY E	To be submitted	
	MUMMERT-BURNS, KIMBERLEY K	To be submitted	
(40701000) HRPP IRB: Dept Head Map			Hide
	MARTIN, AMBER L	To be submitted	
	DAVENPORT, MORGAN R	To be submitted	
(40701000) HRPP IRB: Principal Investigator Map			Add Approver Hide
	MARTIN, AMBER L	Waiting for approval	Add Alternate

Routed by Aggregator: MARTI652 2016-08-24 10:57:03.0

Recalled by Aggregator:

[Hierarchy](#)

[Hide Legend](#)

Primary Approver	Alternate Approver	Approved	Bypassed	Recalled
Approved by other	In progress	Passed	Rejected	
To be submitted	Waiting for approval	Delegated	Passed By Other	

Note that an approver in routing has the ability to **Approve the Protocol**, **Approve with Comments** or **Reject** the protocol submission. Approving the protocol or Approving the protocol with comments will move the submission up to the next step for approval.

Rejecting the protocol proposal will send the submission back to the investigator where further work must be performed on the submission prior to submitting it again for review.

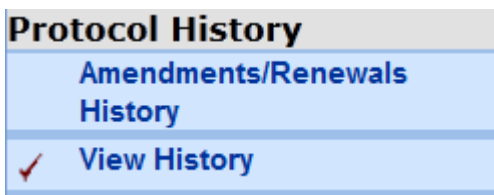
To view the Comments of the approver or any attachments that may have been uploaded, simply click on the **Comments and Attachments**.

Once the protocol has completed routing, it will be processed by the IRB Administrator. You will want to factor in the time for routing when you are submitting a protocol. For example:



*The IRB meeting may be scheduled for January 21, 2009, but the Submission Deadline is January 13, 2009. Thus an investigator “pushes” the submit button on January 12<sup>th</sup>, thinking it will be received by the IRB in time for the meeting on the 21<sup>st</sup>. However, via the electronic routing, it is waiting for the departmental Chair’s review and signature and doesn’t get approved by the Chair until January 14<sup>th</sup>. This causes the protocol to miss the deadline submission date. Thus, the protocol is scheduled for the next IRB meeting.*

## PROTOCOL HISTORY



You can track all protocol actions by using the View History menu item.



Throughout the life of the protocol, Coeus keeps the history of actions taken:

Protocol Action Details				
Description	Date	Action Date	Comments	
 Submitted to IRB	05/28/2015	05/28/2015	Submit to IRB	<a href="#">View</a>
 Protocol Created	04/30/2015	04/30/2015	Protocol Created	<a href="#">View</a>

Click the plus sign to see more details of an action.

Protocol Action Details				
Description	Date	Action Date	Comments	
 Submitted to IRB	05/28/2015	05/28/2015	Submit to IRB	<a href="#">View</a>
Submission Details				
Submission Type : Initial Protocol Application		Review Type : Pending IRB Determination		
Type Qualifier : New Submission to IRB				
Submission Status : Routing In Progress				
Date : 05/28/2015		Place :		
Committee Id :		Schedule Id :		Schedule Date :
Committee Name :				
 Protocol Created	04/30/2015	04/30/2015	Protocol Created	<a href="#">View</a>

## NOTIFY IRB

The **Notify IRB** functionality is used when a member of the research team needs to notify the IRB of a specific research activity or event. These may include:

- Adverse Events (Internal and External)
- DSMB or progress reports not associated with a request for renewal of approval
- External IRB Notices and Approvals (Populate in Special Review and can also store in References)

- FDA Notifications/Progress Reports
- Grant Certification
- Investigator Brochures
- Lost/ Stolen Laptops
- Quality Assurance Monitoring Visit reports,
- Protocol Deviation / Unanticipated Problems
- Publications
- QUACS Correspondence
- Responses to IRB QA/ Audit Findings
- Sponsor Close Out Visit
- Subject Complaint

Open up CoeusLite and select **My IRB Protocols** from the top navigation menu. Select **Notify IRB**.

This will bring up a list of all of your approved protocols. Select the protocol number you wish to submit the notification for.

PROTOCOL_NUMBER	TITLE	APPROVAL_DATE	EXPIRATION_DATE	PROTOCOL_STATUS_DESCRIPTION	PERSON_NAME
1506001464	Testing Approved Consent Forms	26/06/2015	25/06/2016	Active - Open to Enrollment	MARTIN, AMBER L
1504001442	Exempt Trial Test	03/04/2015		Exempt	MARTIN, AMBER L
1504001441	New Expedited App Test	03/04/2015	02/04/2016	Active - Open to Enrollment	MARTIN, AMBER L
1407001330	testing one...two...	01/08/2014		Exempt	MARTIN, AMBER L
1307001186A002	test	26/07/2013	25/07/2014	Withdrawn	MARTIN, AMBER L

Using the drop down box, select the appropriate **Notification Type**:

The **Action Date** will default to today's date.

Complete the description for the attachment and using **Choose File**, upload the document you wish to send to the IRB from your computer files. You can send multiple attachments with a Notify IRB. Click **Save** when finished uploading the documents. Then **Save Submission Details** to send it to the IRB for review. Select **Complete Submission** in the left-hand navigation and select **OK** to complete the submission. The user will receive a message indicating that the **Requested Action on the Protocol** was completed successfully.

## APPENDIX

The Appendix provides supplementary information for users regarding the Coeus application. It includes background information about each of the screens and their functions, important information about Areas of Research and a protocol routing table.

### EXPLANATION OF COEUS SCREENS/GLOSSARY

The following list provides descriptions of important fields when entering an initial submission.

**Protocol Number:** The number assigned to the protocol, generated by the Coeus database. This number will automatically populate the protocol record when the General Information screen of the protocol record is first saved. This number must be listed on all recruitment materials used by the Investigator.

*Coeus generates and assigns protocol numbers that consist of ten digits. The first four digits represent the year and month the initial protocol record was created. The last six digits represent the sequential order in which the protocol record was created.*

*Ex: 0801003756 - year 2008, month of January 01 and sequential number 003756.*

*Coeus also assigns a suffix to continuing review. The renewals and amendments are numbered consecutively, with an "R" indicating a renewal and an "A" representing an amendment. Ex. R001, R002, and A001, A002, etc.*

**Type:** Drop down list of protocol types; Request for Non-Exempt Approval, Request for Exemption, Request for IRB Review Not Required Determination. The investigator must select the type.

**Status:** The status of the protocol, which changes during the life of the protocol. The status changes automatically as the investigator or IRB take an action, e.g., Pending/In Progress, Submitted to the IRB, Specific Minor Revisions, Active Open to Enrollment, Closed by Investigator, etc.

**Title:** The title of the protocol. This must be entered by the research team member when creating the protocol record and submission.

**Application Date:** The date the protocol was created and the number generated. It will automatically default to reflect the current date that the record is initiated.

**Approval Date:** This date will automatically populate on the day that the IRB initially approves the application.

**Expiration Date:** The date the current approval of the protocol expires. The date is updated by the IRB with the approval of each renewal/continuing review.

**FDA Application No.:** This box allows for alphanumeric entry of information related to Investigational New Drugs (INDs) or Investigational Devices (IDE). This must be entered by the research team member when creating the protocol record and submission and can include the purpose of the study and/or the listing of all drugs used in the research study to facilitate easy searches when required. It can also indicate a Pending status by the investigator/research team member typing in Pending.

**Reference Num 1:** Institution defined. Space in this field is limited to 50 characters.

**Reference Num 2:** Institution defined. Space in this field is limited to 50 characters.

**Investigator Tab:** The investigator/research team member completing the online protocol record must add all names of the investigators who are involved in the design or conduct of the research on the protocol. The roles and affiliation must also be completed for each person.

The unit leading the research (lead unit) must also be designated and the field will automatically default to the home organization of the Principal Investigator. This can be over written by the user.

**Study Personnel:** The investigator/research team member must add or remove study personnel on the protocol. Select the roles for each of these individuals.

**Correspondent:** Add or remove the names of protocol correspondent(s).

Also add personnel from other institutions that are involved in the research study who may wish to receive notifications of renewal reminders, approvals, expired protocols, etc. These may include the Human Subject Protection Administrator at a collaborating institution.

**Funding Source:** Identify the funding source/sponsor of the protocol. This table is shared with the sponsored programs module. Be sure to query on Sponsor when the protocol is fully or partially funded by an external entity. Use Unit to denote when the research is funded by departments within your institution.

**Subjects:** When approved, the Non-Exempt protocol in CoeusLite will indicate in the Subjects Tab how many subjects have been approved for the study. This tab is to be completed by the HRPP-IRB team for internal use only.

**Notes:** The Notes field allows for manual entry of information pertinent to the protocol.