COEUS® LITE IRB

COEUS 4.5.1_P3

USER GUIDE

Version: August 24, 2016

TABLE OF CONTENTS

A NOTE ABOUT THIS GUIDE

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

GETTING ACCESS TO COEUS LITE

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. 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.

PREPARING TO ENTER A PROTOCOL

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.
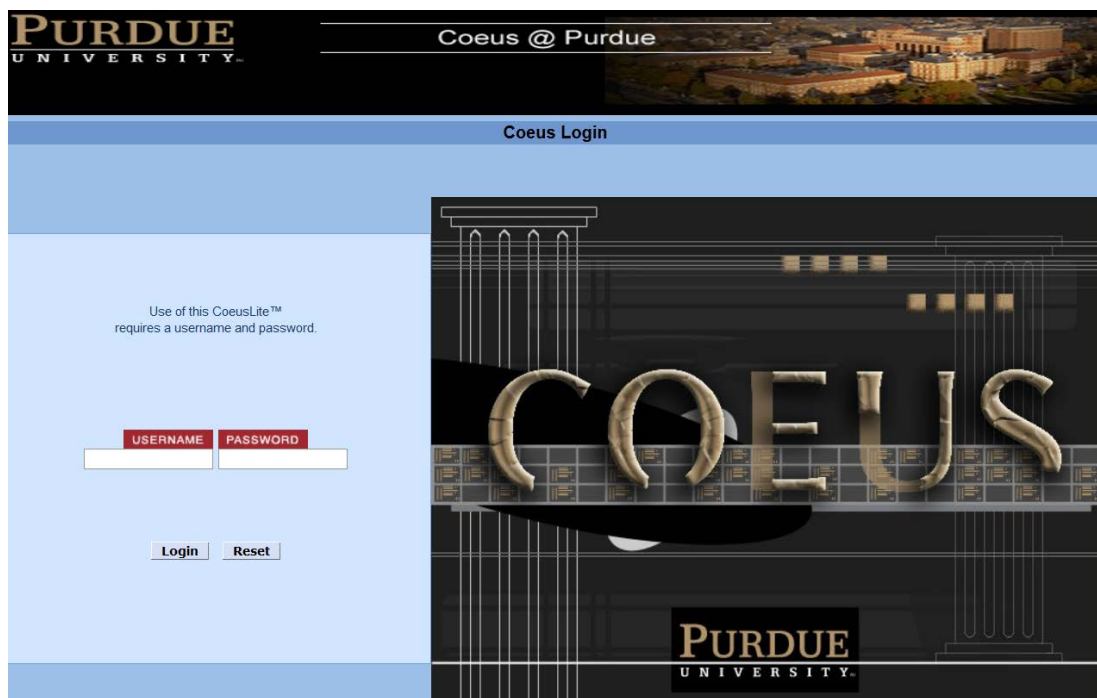
Here are a few questions to think about:

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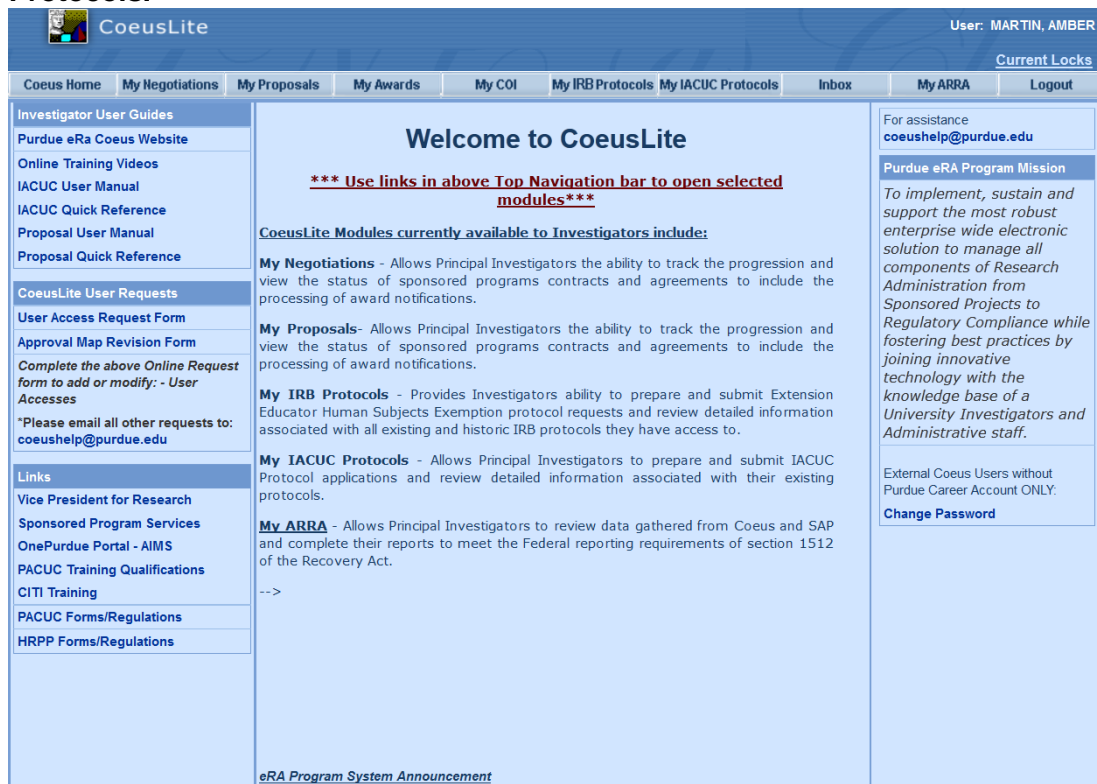
Log in to the Coeus application by entering your username and password. Click **Login**.

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

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.

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

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

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.

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.)*

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.

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 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.

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.

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

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.

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.

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.**

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

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.

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)**.

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: | ----Please Select---- ▼ |

| Comments: | |

| Save |

List of Correspondents

Type	Name	Comments		
Department Head	AGNEW, CHRISTOPHER R		View	Re
Sponsored Programs Regulatory Administrator	BRYANT-GAWTHROP, IANTHE N		View	Re
Psychological Sciences	PHEBUS, SUE ANN		View	Re
Psychological Sciences	WILLIAMS, LEANNE E		View	Re

FUNDING SOURCE

Researchers must provide <u>all</u> 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		Protocol #:	1504001451 (Pending/In Progress)	Expiration Date:
✓	*General Info	Investigator:	CAMPBELL, ELIZABETH K	Last Approval Date:
		Title:	Manual Production 4.30.15	
	*Investigators / Study	**Funding Source - (REQUIRED if applicable)**		
✓	Personnel	**Add Funding Source**		
✓	Correspondents			
	Funding Source >>	Type:	-----------Please Select----------- ▼	
	Subjects	Number/Code:		
	Notes	Name/Title:		
			Save	
2: Questionnaires		**List of Funding Source**		
	Human Subjects Research			

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

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.**

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

Click **Save.**

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

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.**

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.

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.

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.

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
This project is pending NSF funding.	MARTIN, AMBER L	2015-05-01 14:46:58.0	View

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

Comments - Mozilla Firefox

https://coeusbeta.itap.purdue.edu/coeus/coeuslite/mit/utils/dialogs/cwViewSpecialReview.jsp?va

Comments

This project is pending NSF funding.

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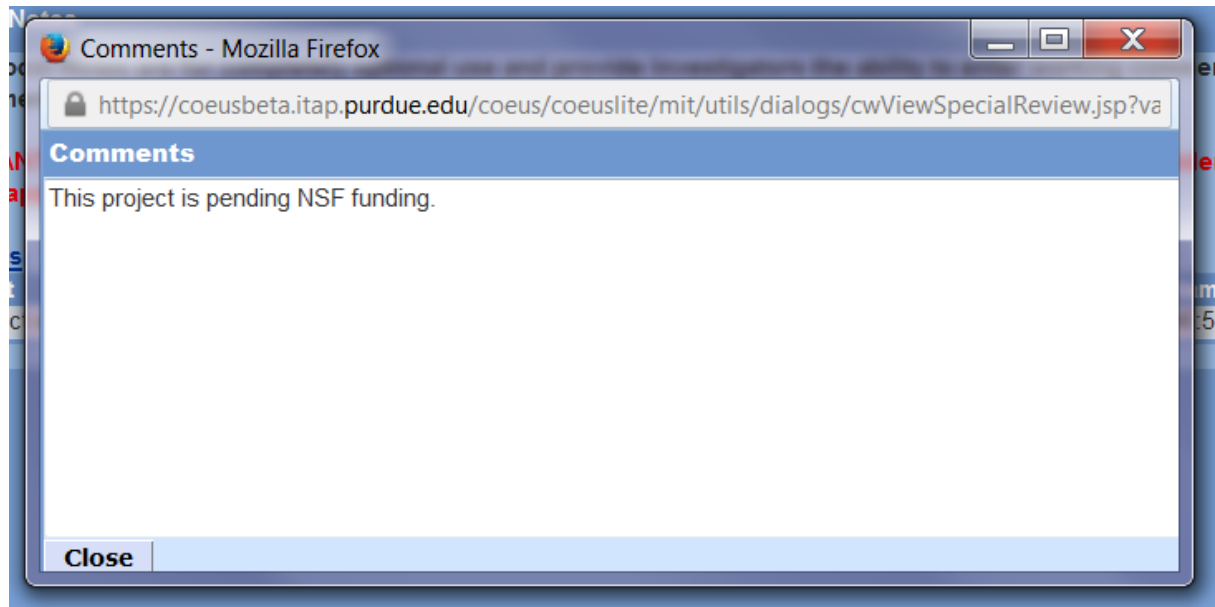
Note
Comments entered in this window are not modifiable nor can they be deleted.

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.

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

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

Add New Document

Document Type: ----Please Select----   ▼   Description: [   ]

File Name:
     ----Please Select----
     Study Description (Historical)
     Continuing Review/Closure Report
     Consent Documents
Save   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.

CoeusLite   User: MARTIN, AMBER L
                                                           Current Locks

| 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

Questionnaires
Human Subjects Research Determination

Attachment Uploads
Attachments   >>

Submit/Approve
Submit to IRB

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

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

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

Add New Document

Document Type: [Consent Documents   ▼]   Description: [Children's Assent Form, Ages 7 - 10, v.1]

File Name: [Choose File] No file chosen

    [Save]   [Cancel]

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.
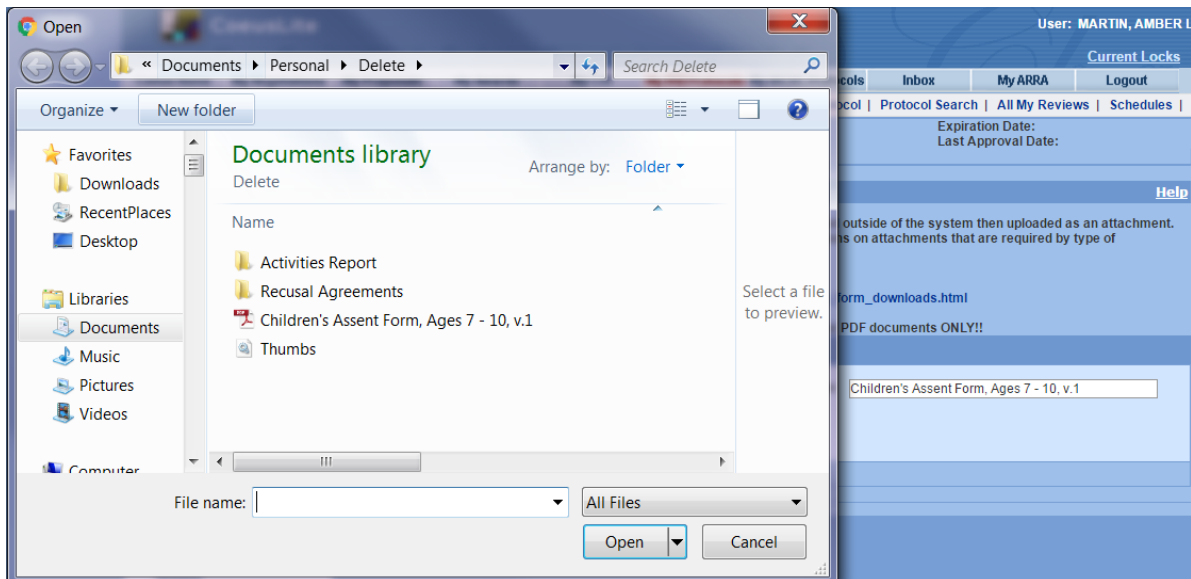
Note that when the document is brought into the application, it appears below the **File Name** line.
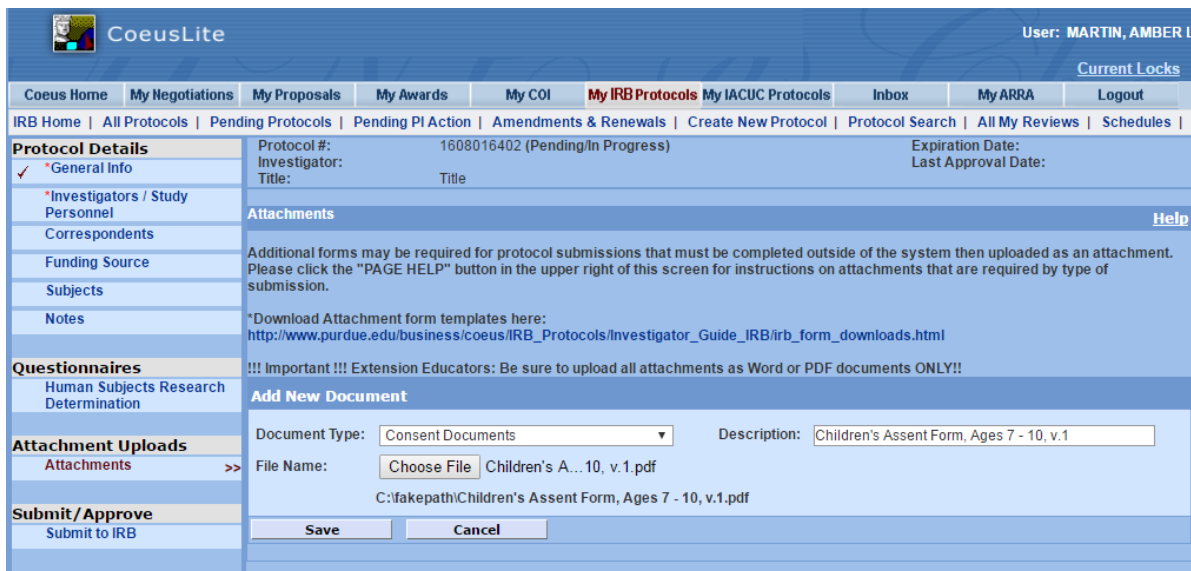
Click **Save** to build the list of attachments**.**

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:

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

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

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 instrucios 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
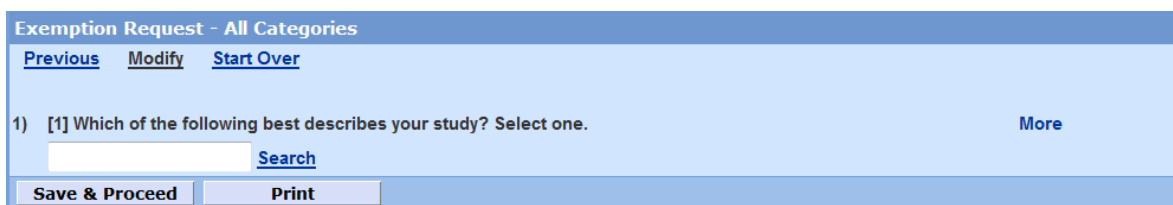
1)   Complete and submit this questionnaire when requesting approval for a non-exempt study. use this questionnaire for studies to be reviewed by either expedited or full board review. Incomplete questionnaires will be returned to   More
     the investigator without review. Select "Yes" to proceed.
     ○ Yes ○ No

  [Save & Proceed]   [Print]

You can click on "More" to get more information about how to answer a question.
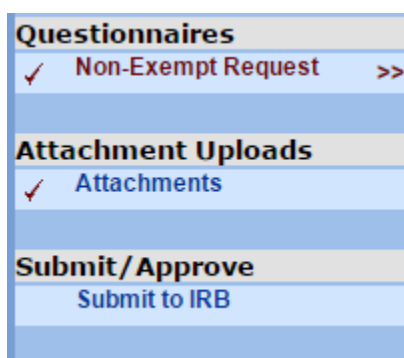
Answer the questions and click **Save & Proceed**. The next set of questions are displayed:

Exemption Request - All Categories
Previous   Modify   Start Over

1) [1] Which of the following best describes your study? Select one.   More
   _____   Search

| Save & Proceed | Print |

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

Questionnaire Completed for protocol 1504001451

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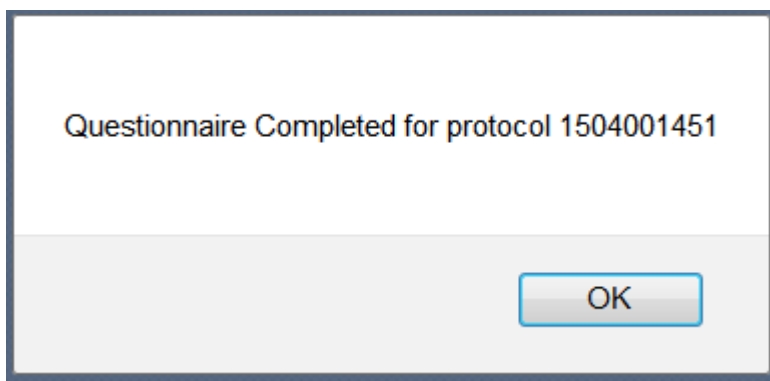
A check mark is now displayed in front of the Questionnaire:

Questionnaires
✓ Non-Exempt Request   >>

Attachment Uploads
✓ Attachments

Submit/Approve
   Submit to IRB

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 | 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 |

1: Protocol Details
✓ *General Info
✓ *Investigators / Study Personnel
✓ Correspondents
✓ Funding Source
✓ Subjects
✓ Notes

2: Questionnaires
Human Subjects Research Determination
✓ Exemption Request - All Categories

3: Attachment Uploads
✓ Attachments

Submit to IRB >>

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

Protocol Actions

You can perform following actions on this protocol.

Submit For Review   Submit to IRB for Review.

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.

Protocol Submission

!!! Protocol has not been Submitted. !!!
Please complete the below Mandatory fields and click "Submit" to complete submission into Routing for Academic Approvals.

* Indicates Mandatory Fields

Submission Details

| *Type: | Initial Protocol Application ▾ | *Review Type: | Pending IRB Determina ▾ |
| Type Qualifier: | New Submission to IRB ▾ | | |

Submit

The user will receive a message asking whether or not they wish to submit the protocol. Click **OK**.
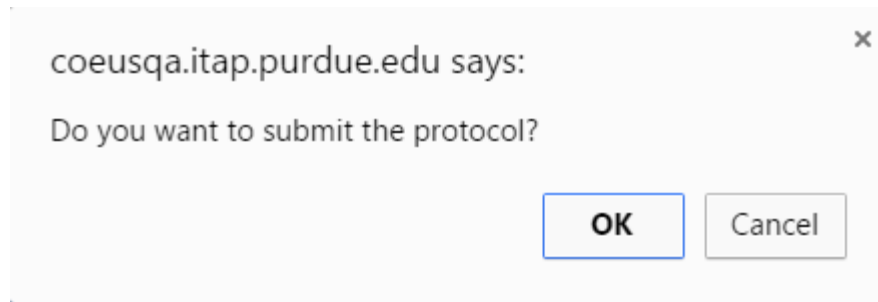
NOTE: CoeusLite is a dual submission system. After you have submitted through CoeusLite, the Principal Investigator will receive an email notification from Coeus-System@lists.purdue.edu asking for their approval. The Principal Investigator must follow the approval steps in order for the protocol submission 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.

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.

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 12th, thinking it will be received by the IRB in time for the meeting on the 21st. 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 14th. 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.

Protocol History

Amendments/Renewals History
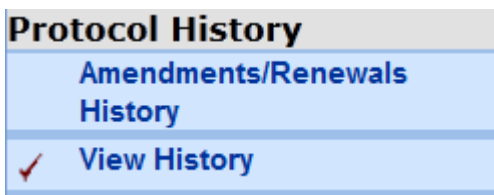
✓ **View History**

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	View
⊞ Protocol Created	04/30/2015	04/30/2015	Protocol Created	View

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	View

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	View

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.

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 20**08,** 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.