

**BROWN**

## IRB VIEW PROTOCOL GUIDE

## Table of Contents

<b>ABOUT COEUS</b> .....	1
o IRB Protocol Module Overview.....	1
o Logging into Coeus Lite .....	1
o Coeus Lite Interface .....	3
o Accessing IRB Protocols .....	3
o Navigating the Protocol Record .....	5
o Viewing the Irb Protocol Record.....	7
o Viewing Consent Documents.....	10
o Viewing Amendments/Renewals History .....	11
o Viewing Approval Memos.....	12

### **ABOUT COEUS**

Coeus is a research administration and grant management system developed by the Massachusetts Institute of Technology's Office of Sponsored Programs and implemented by the University in April 2006. The system centralizes stored information about proposals, protocols, awards, & subawards and is the system of record for all research activities for the University. In addition, it contains interfaces for proposal-development and IACUC protocol submissions that are electronically routed and approved within Coeus.

The following guide will introduce you to the **IRB Protocol Module** in Coeus Lite; providing instruction on how to access your IRB protocols, including currently approved consent documents.

#### **o IRB PROTOCOL MODULE OVERVIEW**

The IRB protocol module in Coeus has been designed to allow investigators and designated staff to view their approved protocols involving human participants. This view access includes currently approved consent documents, IRB approval memos, and other information for reference.

The use of Coeus IRB module supports the efforts of the office of the Institutional Review Board (IRB) to assist the Brown University research community with support and guidance to ensure consistency between research study activities and approved research protocols and procedures.

#### **o LOGGING INTO COEUS LITE**

1. To begin, use your internet browser to access the URL for the Coeus Lite homepage - <https://coeus.brown.edu/prod/userAuthAction.do>

Or go to

<https://coeus.brown.edu>

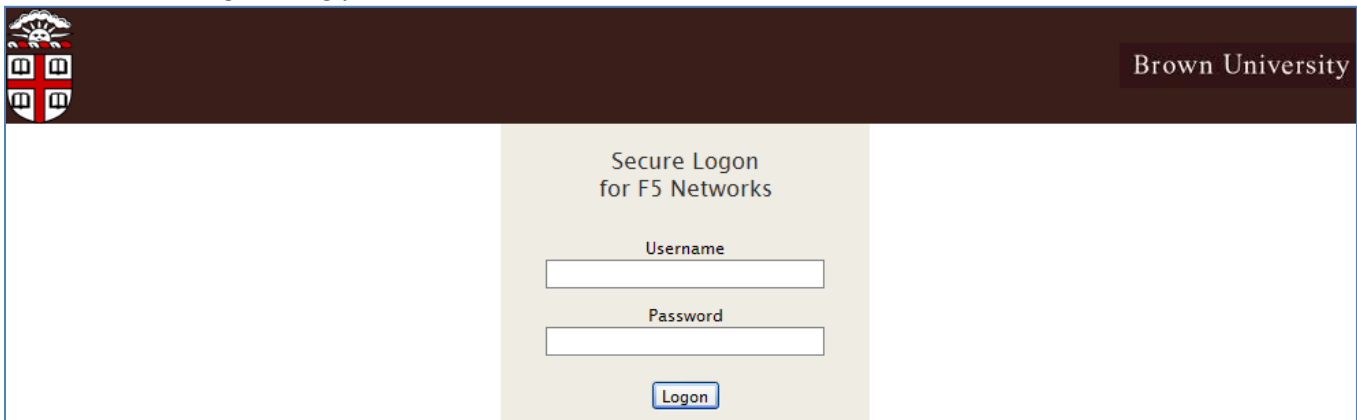
- **LAUNCH COEUS LITE** link

**\*NOTE\*** - When accessing Coeus Lite from “**off campus**,” you must be logged into SSL- VPN to access Brown’s servers.

Link to Brown WebVPN Service: <http://vpn.brown.edu>

For more information about the VPN system –  
[https://wiki.brown.edu/confluence/display/CISDOC/VPN+\(Virtual+Private+Network\)](https://wiki.brown.edu/confluence/display/CISDOC/VPN+(Virtual+Private+Network))

You will be asked to log in using your Brown Username and Password.



After logging into VPN, your browser may close once you are logged into VPN. There will be a red “F5” active in your system tray on the bottom right hand corner of your screen if you are connected to VPN.

If you try to access Coeus Lite from outside of Brown without being logged into VPN, you will receive the following message:

***"Network Timeout The server at coeus.brown.edu is taking too long to respond. The requested site did not respond to a connection request and the browser has stopped waiting for a reply."***



The Coeus application requires your Brown User Name and Password for login.

- Click in the **User Name** field and enter your **Brown User Name**.
- Click in the **Password** field and enter your **Brown Password**.
- Click on the **[LOGIN]** button

The **Coeus Lite Homepage** will open where you can access your protocols.

## ○ COEUS LITE INTERFACE

Once you have logged in to COEUS, the first screen you will see is the **Welcome to Coeus Lite** homepage.

**Welcome to Coeus Lite Page** contains the following links (**Links that are greyed out are currently not Used**):

<b>Coeus Home</b>	<b>Brings you back to the Coeus Lite Welcome Screen</b>
<b>My Negotiations</b>	Currently not used
<b>My Proposals</b>	Proposal Development Module
<b>My COI</b>	Currently not used
<b>My IRB Protocols</b>	IRB Module
<b>My IACUC Protocols</b>	IACUC Module
<b>Inbox</b>	Coeus Lite Inbox – stores the messages related to your Coeus Applications
<b>My AARA</b>	Currently not used
<b>Logout</b>	Use to logout of the system

## ○ ACCESSING IRB PROTOCOLS

1. Click on the **MY IRB PROTOCOLS** link to access the module and a new screen will open;

Protocol Number	Title	Status	Application Date	Approval Date	Expiration Date
1501001167	Test record for documentation	Active - Open to Enrollment	08/January/2015	19/February/2015	18/February/2016

The screen will default to a **List of Active Protocols**. All your active protocols will be listed here. Now that you are in the IRB Module - A second row of navigation links will also appear on this screen.



Link	Description
1 All Protocols	This screen lists <b>ALL</b> IRB Protocols on which you have a role, (this includes all active, expired or withdrawn protocols as well as amendments and renewals of active protocols)
2 Pending Protocols	Displays all non-approved protocol submissions
Pending PI Action	<i>Currently not used</i>
3 Amendments & Renewals	Lists all amendments and renewals that are not yet approved.
4 Protocol Search	Allows you to search for a specific protocol.
*All My Reviews	<i>Only visible to users who are committee member s– Currently Not Used by the IRB Committee</i>
*Schedules	<i>Only visible to user who are committee member – Currently Not Used by the IRB Committee</i>

Within the various “List” screens of your protocols, you will see consistent columns that identify the Protocol Number, Title, and Status. Dependent on which grouping of protocols you are viewing, you will see additional columns.

For example, the “List of Active Protocols” screen displays as follows:

Protocol Number	Title	Status	Application Date	Approval Date	Expiration Date
1501001167	Test record for documentation	Active - Open to Enrollment	08/January/2015	19/February/2015	18/February/2016

The unique number assigned the protocol by IRB

The title of the protocol as it was provided to IRB

This status of "Active-Open to Enrollment" indicates that the protocol is approved and active.

The date the protocol was submitted to IRB.

The date the protocol was approved by the IRB.

The date the protocol approval will expire.

To view/open a specific protocol, click on the protocol link via the Protocol Number or Title.

The screenshot shows the CoeusLite web application interface. At the top, there is a navigation menu with options like 'Coeus Home', 'My Negotiations', 'My Proposals', 'My CDI', 'My IRB Protocols', 'My IACUC Protocols', 'Inbox', 'My ARRA', and 'Logout'. Below this is a secondary menu with 'All Protocols', 'Pending Protocols', 'Pending PI Action', 'Amendments & Renewals', 'Create New Protocol', 'Protocol Search', 'All My Reviews', and 'Schedules'. The main content area is titled 'List of Active Protocols' and contains a table with columns for Protocol Number, Title, Status, Application Date, Approval Date, and Expiration Date. Two rows are visible, both for protocol 1501001167 with the title 'Test record for documentation'. An arrow points to the title link in the first row.

Protocol Number	Title	Status	Application Date	Approval Date	Expiration Date
1501001167	<a href="#">Test record for documentation</a>	Active - Open to Enrollment	08/January/2015	19/February/2015	18/February/2016
1501001166	<a href="#">Test record for documentation</a>	Active - Open to Enrollment	08/January/2015	19/February/2015	18/February/2016

The screen will open to the “General Info” screen.

The screenshot shows the 'General Info' screen for protocol 1501001167. On the left is a navigation panel with links for 'General Info', 'Organization', 'Investigators / Study Personnel', 'Correspondents', 'Areas of Research', 'Funding Source', 'Subjects', 'Special Review', and 'Other Identifiers'. The main content area displays protocol details: Protocol #: 1501001167 (Active - Open to Enrollment), Investigator: Provencal, Christiana, Title: Test record for documentation, Expiration Date: 02/18/2016, Last Approval Date: 02/19/2015, and Meeting Date: 02/19/2015. Below this is a section for 'Protocol Details' with a dropdown menu for 'Type' (set to 'Full Board') and a text area for 'Title' containing 'Test record for documentation' and 'Alcohol'.

Each screen within the Protocol Record will contain the main identifiers of the protocol record:

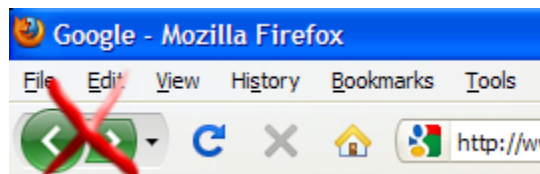
- Protocol #
- Investigator
- Title

Once in a record, you can navigate through different sections of the protocol by clicking on a link in the left hand navigation panel.

## ○ NAVIGATING THE PROTOCOL RECORD



**Use the Navigation Panel Links to navigate through your protocol. Do not use your Browser's “Back” or “Forward” buttons – these functions are not supported for use in navigation in Coeus Lite.**



Use the following Navigation Panel links to navigate your protocol:

✓ <b>*General Info</b> >>
✓ <b>*Organization</b>
<b>*Investigators / Study Personnel</b>
Correspondents
✓ <b>*Areas of Research</b>
Funding Source
Subjects
Special Review
Other Identifiers
Notes
Others
Attachments
Other Attachments
Validate
Submit to IRB
Amendments/Renewals History
✓ <b>View History</b>
New Renewal with Amendment
New Amendment
New Renewal
Send Email
✓ <b>Access Permissions</b>
Print Summary
Review Comments

<b>GENERAL INFO</b>	Displays basic information regarding your protocol. This panel will always be the first screen presented when a protocol is selected.
<b>ORGANIZATION</b>	Displays the contact information of organizations involved in the protocol. Brown University is the default performing organization.
<b>INVESTIGATORS/STUDY PERSONNEL</b>	Displays information about Investigators and advisors if applicable.
<b>CORRESPONDENTS</b>	Lists study staff or administrative individuals who are associated with the protocol and who may be contacted regarding protocol issues.
<b>AREAS OF RESEARCH</b>	Defaults to All Areas of Research.
<b>FUNDING SOURCE</b>	Contains information about the entity responsible for funding the protocol.
<b>SUBJECTS</b>	Displays the number of study participants approved by the IRB.
<b>SPECIAL REVIEW</b>	Identifies if there is an IAA (IRB Authorization Agreement) in place.
<b>OTHER IDENTIFIERS</b>	Currently Not Used
<b>NOTES</b>	Displays any comments noted by IRB office staff.
<b>OTHERS</b>	Displays countries (other than USA) in which the research is conducted, IRB review category and IRB keywords.
<b>ATTACHMENTS</b>	Currently not used
<b>OTHER ATTACHMENTS</b>	Contains approved informed consent documents uploaded by the RPO office.
<b>VALIDATE</b>	Currently Not Used
<b>SUBMIT TO IRB</b>	Currently Not Used
<b>AMENDMENT/RENEWALS HISTORY</b>	Lists all amendments and renewals that have been created for this protocol.
<b>VIEW HISTORY</b>	Lists all actions taken on the protocol, date, and system generated comments.
<b>NEW RENEWAL WITH AMENDMENT</b>	Currently Not Used
<b>NEW AMENDMENT</b>	Currently Not Used
<b>NEW RENEWAL</b>	Currently Not Used
<b>SEND EMAIL</b>	Currently Not Used
<b>ACCESS PERMISSIONS</b>	Identifies user access to your protocol.
<b>PRINT SUMMARY</b>	Allow users to generate the information in the protocol, including attachments into a PDF document.
<b>REVIEW COMMENTS</b>	Currently Not Used

## ○ VIEWING THE IRB PROTOCOL RECORD

- **General Info screen:**

The General Info screen contains basic attributes of the protocol. Type (Full Board, Expedited, Exempt), Title, Description (Keywords), Application Date (Date Coeus record was created), and Approval Date.

- **Organization screen:**

The **Organization** link displays the contact information of the submitting organization, performing organization and any additional site associated with the protocol such as recruiting sites.

- **Investigator/Study Personnel screen:**

The **Investigator/Study Personnel** screen will list all investigators identified on the project, their home unit and the role they have on the protocol.

Person Name	Department	Lead Unit	Role	Affiliate	Training
Provenca, Christiana	• Research Protections Office	<input checked="" type="checkbox"/>	Principal Investigator	Faculty	<input checked="" type="checkbox"/>
Quinn, Jennifer	• Cognitive Linguistic and Psychological Sciences		Co-Investigator	Faculty	<input checked="" type="checkbox"/>



- **Correspondents screen:**

The **Correspondents** screen lists study staff or administrative individuals who are associated with the protocol and who may be contacted regarding protocol issues.

Protocol #: 1501001167 (Active - Open to Enrollment)      Expiration Date: 02/18/2016  
Investigator: Provencal, Christiana      Last Approval Date:  
Title: Test record for documentation

Correspondents [Help](#)

List of Correspondents

Type	Name	Comments	
Cultural Consultant	Derby, Emily A.		<a href="#">View</a>

- **Areas of Research:**

The **Areas of Research** screen defaults to All Areas of Research.

Protocol #: 1501001167 (Active - Open to Enrollment)      Expiration Date: 02/18/2016  
Investigator: Provencal, Christiana      Last Approval Date:  
Title: Test record for documentation

Areas of Research [Help](#)

List of Areas of Research

Code	Description
000001	All Research Areas

- **Funding Source:**

List the Sponsors both Brown University and External Sponsors, along with any Institute Proposal record that is funding the protocol.

Protocol #: 1501001167 (Active - Open to Enrollment)      Expiration Date: 02/18/2016  
Investigator: Provencal, Christiana      Last Approval Date:  
Title: Test record for documentation

Funding Source [Help](#)

Add Funding Source

Type:

Number/Code:

Name/Title:

List of Funding Source

Type	Number/Code	Name/Title	
Sponsor	002141	Brown University	<a href="#">Remove</a>
Sponsor	000471	National Institute of Health	<a href="#">Remove</a>
Institute Proposal	15070721	Testing	<a href="#">Remove</a>

- **Subjects:**

The **Subjects** screen displays the approved number of study participants.

Protocol #: 1501001167 (Active - Open to Enrollment)      Expiration Date: 02/18/2016  
Investigator: Provencal, Christiana      Last Approval Date:  
Title: Test record for documentation

Subjects [Help](#)

Add Subjects

Description:

Count:

Subjects

Subject	Count
Children	100

- **Special Review:**

The **Special Review** screen identifies if there is an IAA (IRB Authorization Agreement) in place.

**Add Special Review**

Special Review :  Approval:

Protocol No:  Application Date:  Approval Date:

Comments:

**Save**

**List of Special Review**

Special Review	Approval	Protocol No	Application Date	Approval Date	Comments	
Other IRB	Approved					<a href="#">View</a> <a href="#">Remove</a>

- **Notes:**

The **Notes** screen displays a comment noted by the IRB.

**Protocol Notes** [Help](#)

[Add Notes](#)

Comment	By	Posted Time Stamp	View

- **Others**

The **Others** screen displays countries (other than USA) in which the research is conducted, IRB review category and IRB keywords.

**Others** [Help](#)

\*Indicates Mandatory Fields

**Other** [Miscellaneous](#)

Country 1  No International Collaboration

Country 2

Country 3

Country 4

## VIEWING CONSENT DOCUMENTS

The **Other Attachments** screen contains currently approved informed consent documents uploaded by the RPO office. The informed consent documents included here are in a PDF file format.

*\*For protocols that include multiple approved informed consent documents, they are combined within one PDF file.*

Type	Description	Timestamp	UpdateUser	
Informed Consent Document	Consent document	01/08/2015 10:07 AM	Derby, Emily A.	<a href="#">View</a>

To View your approved Consent Document: Click the **View** Link

Type	Description	Timestamp	UpdateUser	
Informed Consent Document	Consent document	01/08/2015 10:07 AM	Derby, Emily A.	<a href="#">View</a>

The PDF Document will open

Opening 15010011671.pdf

You have chosen to open:

**15010011671.pdf**  
which is: Adobe Acrobat Document (35.2 KB)  
from: https://coeus-qas.brown.edu

What should Firefox do with this file?

Open with Adobe Reader (default)

Save File

Do this automatically for files like this from now on.

Settings can be changed using the Applications tab in Firefox's Options.

OK Cancel

## ○ VIEWING AMENDMENTS/RENEWALS HISTORY

The **Amendments/Renewals History** screen lists all amendments and renewals that have been created for this protocol.

Type	Version No	Summary	Status	Created Date
Renewal	005	received 8/12/14	Approved	2014-08-14
Renewal	004	received 08/02/2013	Approved	2013-08-02
Renewal	003	received 8.10.2012	Approved	2012-08-10
Renewal	002	Received 08/17/2011 Renewal #2.	Approved	2011-08-18
Renewal	001	received 06/29/2010	Approved	2010-06-30

- **View History:**

The **View History** screen lists all actions taken on the protocol, date, and system generated comments.

Description	Date	Action Date	Comments
Administrative Correction	10/14/2014	10/14/2014	Add expedited review category to Other...
Expedited Approval	06/18/2014	06/17/2014	Renewal-005:
Submitted to IRB	06/18/2014	06/18/2014	Renewal-005: Submit to IRB
Renewal Created	06/13/2014	06/13/2014	Renewal-005 created
Expedited Approval	07/17/2013	07/15/2013	Renewal-004:
Submitted to IRB	07/17/2013	07/17/2013	Renewal-004: Submit to IRB
Renewal Created	06/20/2013	06/20/2013	Renewal-004 created
Expedited Approval	11/14/2012	11/14/2012	Amendment-003:
Submitted to IRB	11/14/2012	11/14/2012	Amendment-003: Submit to IRB
Amendment Created	11/05/2012	11/05/2012	Amendment-003 created
Expedited Approval	08/09/2012	08/09/2012	Amendment-002:
Submitted to IRB	08/09/2012	08/09/2012	Amendment-002: Submit to IRB
Administrative Correction	08/09/2012	08/09/2012	Change funding source from Healthcentr...
Amendment Created	07/27/2012	07/27/2012	Amendment-002 created
Expedited Approval	07/20/2012	07/20/2012	Renewal-003:
Submitted to IRB	07/20/2012	07/20/2012	Renewal-003: Submit to IRB
Renewal Created	07/05/2012	07/05/2012	Renewal-003 created
Expedited Approval	02/24/2012	02/24/2012	Amendment-001:
Submitted to IRB	02/24/2012	02/24/2012	Amendment-001: Submit to IRB
Amendment Created	01/31/2012	01/31/2012	Amendment-001 created

- **Access Permissions:**

The **Access Permissions** screen identifies user access to your protocol.

Protocol Roles			Help
Protocol Aggregator			Add User
User ID	User Name	Home Unit	
ederby	Derby, Emily A.	040569: PH - Ctr for Evidence-Based Medicine	
Protocol Approver			
User ID	User Name	Home Unit	
Protocol Viewer			Add User
User ID	User Name	Home Unit	

## ○ VIEWING APPROVAL MEMOS

Investigators can view the Coeus generated approval memos for their reference any time from within the protocol record. To view these documents, click on the **View History** link in the left hand navigation, the Protocol Actions details screen will open.

The screenshot shows the Coeus system interface. On the left is a navigation pane with various menu items. The 'View History' link is highlighted with a red box and a black arrow. The main area displays protocol details for Protocol # 1501001167 (Active - Open to Enrollment). The details include:
 

- Investigator: Provenal, Christiana
- Title: Test record for documentation
- Expiration Date: 02/18/2016
- Last Approval Date: 02/19/2015
- Meeting Date: 02/19/2015
- Type: Full Board
- Title: Test record for documentation
- Description: Alcohol
- Application Date: 01/08/2015
- Approval Date: 02/19/2015

Find the submission from the list and locate the “approval” in the example – Renewal #5 Expedited Approval Letter

Description	Date	Action Date	Comments
Administrative Correction	10/14/2014	10/14/2014	Add expedited review category to Other...
Expedited Approval	06/18/2014	06/17/2014	Renewal-005:
Submitted to IRB	06/18/2014	06/18/2014	Renewal-005: Submit to IRB
Renewal Created	06/13/2014	06/13/2014	Renewal-005 created
Expedited Approval	07/17/2013	07/15/2013	Renewal-004:
Submitted to IRB	07/17/2013	07/17/2013	Renewal-004: Submit to IRB
Renewal Created	06/20/2013	06/20/2013	Renewal-004 created
Expedited Approval	11/14/2012	11/14/2012	Amendment-003:

Click on the plus sign to open the line to view information.

Description	Date	Action Date	Comments
Administrative Correction	10/14/2014	10/14/2014	Add expedited review category to Other... <a href="#">View</a>
Expedited Approval	06/18/2014	06/17/2014	Renewal-005: <a href="#">View</a>

**Submission Details**

Submission Type : Continuing Review/Continuation      Review Type : Expedited

Type Qualifier :

Submission Status : Approved

Date : 06/18/2014      Place : Research Protections Office

Committee Id : Expedited      Schedule Id : 453      Schedule Date : 06/30/2014

Committee Name : Expedited

**Correspondences**

Protocol Status Letter      [View](#)

Submitted to IRB	06/18/2014	06/18/2014	Renewal-005: Submit to IRB <a href="#">View</a>
Renewal Created	06/13/2014	06/13/2014	Renewal-005 created <a href="#">View</a>

Then Click the **VIEW** link to open the Protocol Status Letter under Correspondences.

Protocol Action Details			
Description	Date	Action Date	Comments
Administrative Correction	10/14/2014	10/14/2014	Add expedited review category to Other... <a href="#">View</a>
Expedited Approval	06/18/2014	06/17/2014	Renewal-005: <a href="#">View</a>
Submission Details			
Submission Type : Continuing Review/Continuation		Review Type : Expedited	
Type Qualifier :			
Submission Status : Approved			
Date : 06/18/2014		Place : Research Protections Office	
Committee Id : Expedited		Schedule Id : 453      Schedule Date : 06/30/2014	
Committee Name :Expedited			
Correspondences			
Protocol Status Letter		<a href="#">View</a>	
Submitted to IRB	06/18/2014	06/18/2014	Renewal-005: Submit to IRB <a href="#">View</a>
Renewal Created	06/13/2014	06/13/2014	Renewal-005 created <a href="#">View</a>

The system generated PDF approval memo will open.