Coeus Lite Continuing Reviews

Coeus Lite website

- https://coeus.drexel.edu/coeus/userAuthAction.do
- Note that you must be on the Drexel University network to use the platform you can VPN in if you are not on the network

Login Information

- Username and password corresponds to other Drexel University credentials
 - Username example: abc123

Drexel	Coeus Web	
		Coeus Login
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My IRB Protocols

 Remember that all submissions needing HRP or IRB review and approval is submitted through the My IRB Protocols tab

Find Your Protocol

Principal Investigator or Co-Investigator

- Click All protocols tab
- Find protocol either through number or title

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Coeus Home	My Negotiations My Proposals My COI My IRB Protocols My IAC	CUC Protocols Inbox	My ARRA	Logout	
All Protoco	Is Pending Protocols Pending Pl Action Amendments & Renewals	Create New Protocol	Protocol Search	All My Reviews	Schedules
List of All Pro	stocols				
Protocol Number	Title	Status	Approv	val Date Expir	ation Date
1710005707	African Born Women seeking HIV Care in Philadelphia: Qu	Pending/In Progress	-		
1710005705	Post-operative pain management for routine general surg	Submitted to IRB			
1710005704	Adherence to PECARN criteria in trauma patients	Submitted to IRB			
1710005702	Weather influence on pediatric trauma	Submitted to IRB			
1710005700	Analysis of Post-Mortem Retrieved Devices and Tissues	Specific Minor Revisio	ns Required		
1710005698	Reinforcing Nursing/Family Education on the American Ac	Pending/In Progress			
1710005696	10 year epidemiological review of train injuries in Pen	Submitted to IRB			
1710005695	A Qualitative Study of Black Male Engineering Achieveme	Routing In Progress			
1710005694	Letter of Reliance for Mind the Gap Intervention Pilot	Routing In Progress			
1710005690	Small round blue cell tumors: An educational review	Submitted to IRB			
1710005689	Pediatric disparities in treatment of concussion	Submitted to IRB			
1710005688	Clinical and Microbiological Outcomes Associated with V	Pending/In Progress			

Study Personnel

- Click the Protocol Search tab
- In the search window, enter some identifier to find your protocol (such as protocol number, investigator, etc.)
 - Note that it is a best practice to use * when searching, so for my protocol, I typed *1710005674*
 - o This allows Coeus Lite to search for any possible keyword combinations

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CREATING A CONTINUING REVIEW OR FINAL REPORT (HRP 212)

Use this submission type to request a renewal (continuing review) or to close a protocol (final report) for a currently approved research protocol.

Click on My IRB Protocols.

Click on **All Protocols** to see the full listing of protocols that are already approved. Select the protocol you wish to work with. The information can be sorted by clicking on any one of the column headings. Example: Expiration dates may be sorted in ascending/descending order by clicking on the column heading **Expiration Date.**

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						<u>c</u>	urrent Locks
Coeus Home My	Negotiations My Proposals	My Awards	My COI	My IRB Protocols My IACUC Protocols	Inbox	My ARRA	Logout
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ist of All Protoco	ols Title			Status	Approval	Date Expira	tion Date
1606004506A001	Title of the Protocol II			Submitted to IRB	20/June/2	2016 <u>19/Jun</u>	0/2017
1606004506	Title of the Protocol II			Active - Open to Enrollment	20/June/2	2016 <u>19/Jun</u>	e/2017
1605004503	Standard Submission Test			Pending/In Progress			
1605004502	Case Report Case Study Te	st		Pending/In Progress			
1605004500	Title of the Protocol			Pending/In Progress			
1605004495	test protocol case study/ ca	se report		Routing In Progress			
1605004493	Testing Case Study / Case I	Report Questionnai	ire 05-24-16	Pending/In Progress			

Or you can select **Protocol Search** and search by using the base protocol number. A partial entry may be made, with an asterisk used as a wildcard when placed before or after the partial entry.

• Ex. *0123*

Click Search

		ments & Renewals	Create New Protocol	Protocol Search All My Reviews
	065 (Amondmont in Drogross)		Expiration Data:	
Protocol Search - Internet E	xpiorer	NAME AND ADDRESS.		
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Please enter search criteria of the f	orm *value* or *value or value*	in any of search fields.		
Protocol No: *1234*	×	Protocol Type:		✓
Title		Protocol Status:		~
Expiration Date:		Investigator:		
Funding Source:				
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Renewal/Final Report Application

Letter of Reliance Approved Protocols

• When Drexel University is not the IRB of Record, an electronic HRP-212 is not required to be submitted until study closure. Principal investigators need only provide the Drexel University HRP with a copy of the approved renewal documents (including the continuing review approval letter) provided by the IRB of Record.

Click the **New Renewal** button from the column on the left-hand side.

The Renewal summary window opens.

The **Renewal Summary** box is to include the type of continuing review request you are submitting for review and approval:

- Active and Open to Enrollment
- Continue for Data Analysis Only
- Continue for Follow Up of Subjects Only
 AND INCLUDE
- Progress report of what has happened with study since last approval

4	Amendments/Renewals History
*	View History
4	-
	New Renewal with Amendment
	New Amendment
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	Send Email
1	Access Permissions
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	Copy Protocol
	Print Summary
	Review Comments
E a -	
FOI	ms
1	Application Form - Standard and HUD
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Renewal Summary:	
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In January 2017, after IRB approval, the co-investigator contacted principals, teachers and students at Delanco Elementary, Holy Cross High School and University of Scranton to ask them to identify teachers in the core content areas who made innovations to their instruction. Principals from two of the three schools and the Director of Technology and Innovation responded with the names of 60 teachers. In April 2017, the researcher invited all 60 teachers to participate in the first phase of the research study by completing the demographics and background, innovation and mindset questionnaire via a link to <u>Qualtrics</u> . Those 45 teachers who completed the questionnaire were invited to participate in phase two of the research study: interviews. In August 2017, 21 teachers participated in either focus group or individual interviews. Data collection and data analysis has concluded.	~	
Save		

Click Save. The Renewal has been created.

Note an R00x suffix is applied to the protocol number. This refers to the sequential number of renewals for that particular protocol. The R suffix is dropped once the renewal is approved by the IRB.

Protocol #: Investigator: Title:	1710005674R001 (Penewal in Progress) Rivislie, Ralph J Test Protocol #4	Expiration Date: Last Approval Date:	10/15/2018
Protocol Organizat	lion		Help

Uploading A Document For Review

Select the **Attachments** tab from the left hand column. This opens the **Attachments** window to upload the required **clean copies (unstamped) of all previously stamped approval documents** (consent forms, advertisements/brochures, surveys, data collection tools, etc.)

• Clean copies are not required if the protocol is permanently closed to enrollment.

Coeus Home	My Negotiations	My Proposals	My Awards	My COI	My IRB Protocol	s My IACUC Protocols	Inbox	My ARRA	Logout		
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Others											

Click Add New Document to upload a new document. From the Document Type drop down box, select **HRP- 212 Continuing Review Progress Report Form**. Use the Description to indicate the document. For example, HRP 502 Consent Form (unstamped).

• <u>For any document attached with your renewal/final report, you must select HRP-212</u> Continuing Review Progress Report Form regardless of the actual document

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Renewal/Final Report Application

The renewal/final report application is at the bottom of the left hand column, in the Forms sections

o HRP 212, Continuing Review/Final Report

Application

- Complete the application answering yes or no to the questions
 - Depending on your response, you may receive more questions for clarification

Intendenent/Renewal Questionnaire			
Previous Modify Start Over I Has the study been updated in ClinicalTrials.Gov? More I Yes No Is this submission a Continuing Review ? More Yes No All must be applicable for a final report ; Research permanently closed to enrollment at this organization ; All subjects enrolled at this organization completed all research related interventions and interactions, including interventions and interactions related to collection of long-term follow-up data ; No additional identifiable private information about the subjects is being obtained by this organization completed all research related interventions and interactions. Including information is completed. (This is applicable even if a statistical center at another organization information at this organization completed. (This is applicable even if a statistical center at another organization is completed. (This is applicable even if a statistical center at another organization is completed. This is applicable even if a statistical center at another organization is completed. This is applicable even if a statistical center at another organization is completed. This is applicable even if a statistical center at another organization is completed. This is applicable even if a statistical center at another organization is completed at the organization is completed at the organization is completed for protocol 1710005674R001 Message from webpage V Image: Prove of subjects enrolled study wide? This is applicable when the Pl is enrolling or receiving data from multiple subsites. More Image: Prove of subjects approved for enrollment? More		P 212, Continuing Review/ Final Report endment/Renewal Questionnaire	
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Submit to IRB

- To submit for approval routing
- Click Submit to IRB in left hand column
- Then
 - o Submit for Review
 - o OK
 - o OK



Protocol Submission Window

- Once submission is initiated, the last window is the Protocol Submission window
- Type
 - o Continuing Review
- Review Type
 - To be determined
- Type Qualifier
 - o Standard
- Once you click Submit, Coeus Lite will ask you to confirm

Protocol #: Investigator: Title:	1710005674R001 (Renewal in Progress) Riviello, Ralph J Test Protocol #4	Expiration Date: Last Approval Date:	10/15/2018					
Protocol Submi	ssion		Help					
* Indicates Mandatory Fields Submission Details								
*Type: Type Qualifier:	CONTINUING REVIEW Standard	*Review Type: To be determined	∽					
Submit								

Approval Process

• You will know when your amendment has been submitted to the principal investigator for approval when your status changes to Routing in Progress

Protocol #: Investigator: Title:	1710005674R00 Riviello, Ralph J Test Protocol #4	Routing In Progress)		Expiration Date: Last Approval Date: Meeting Date:	10/15/2018				
General Protocol Information									
* Indicates Mandatory Fields									
Protocol Details						Help			
*Type:	Standard	×	2						
*Title:	Test Protocol #4				^				
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Description:	description.				0				
*Application Date:	10/06/2017			Approval Date:	10/16/2017				
Reference Num 1:				Reference Num 2:					
FDA Application No:									

- To check the approval status
 - You can click Approval Routing to see where your submission stands
 - Approval Routing will only show after you Submit to IRB
- If you are the principal investigator
 - You can click Approval Routing to approve
 - Options are
 - Approve
 - Reject

Renewals/final report need the principal investor and department chair or program director to approve

• Approver will receive an email alerting them that they have an approval waiting

Once the principal investigator and department chair or program director approves, HRP will received your request and begin the review process

