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 |
| | Use of this Cosuit.ife ^{ree} regulars a username and pactorine. | The definition of the second compliance Administration |



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

| 2 | CoeusLite | | | User: | Fuhrer, Adam |
|-------------------|--|------------------------|-----------------|----------------|--------------|
| 1/ | | | | <u>C</u> | urrent Locks |
| Coeus Home | My Negotiations My Proposals My COI My IRB Protocols My IACU | C 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 Pr | otocols | | | | |
| Dents and | | 00000 | | | |
| Number | Title | Status | Appro | val Date Expir | ration Date |
| 1710005707 | African Born Women seeking HIV Care in Philadelphia: Qu | Pending/In Progress | | | |
| <u>1710005705</u> | 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 | | | |
| <u>1710005694</u> | 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

| | Coel | usLite | | · | • | | | | | 1 | User: | Fuhrer, | Adam G |
|-------------------|------------|------------------|-----------------|-----------------|----------------------|-----------------------|----------|-----------|---------------------|----------|---------------|----------|-------------|
| 1/ | | | | | | | | | | | <u>Cı</u> | irrent L | <u>ocks</u> |
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| All Protoco | ls | Pending Protoc | ols Pend | ing PI Action | Amendments & F | tenewals Create | New Prot | tocol I | Protocol Search | All My R | eviews | Sched | lules |
| List of All Pro | otoco | ls | | | | | | | | | | | |
| Protocol | | | | | | | | | | | | | |
| Number | litt | https://coe | us.drexel.edu | ?type=Protocol | &search=true&sear | chName=ALL PROT | OCOL SEA | RCH&SU | JBHEADER ID - Inte. | | | X | ate |
| <u>1710005707</u> | Afr | Please enter | search criteria | of the form *va | lue* or *value or va | lue* in any of searc | fields | | | | | | |
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| 1710005704 | Mo | Protocol No | *17100056 | 74* | × | Protoco | Type: | | | | $\overline{}$ | | |
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| 1710005698 | Rei | Expiration Date | c 🗌 | | | Inves | igator: | | | | | | |
| 1710005696 | 10 | Funding Source | c | | | | | | | | | | |
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| 1709005671 | Eva | | | | | | | | | | | | |
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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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| Co | beusLite | | | | | | User: | Storino, Cheryl L |
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| Coeus Home | My Negotiations | My Proposals | My Awards | My COI | My IRB Protocols My IACUC Protocol | s Inbox | My ARRA | Logout |
| All Protoco | ols Pending | Protocols Pen | ding PI Action | Amendments & | Renewals Create New Protocol | Protocol Search | All My Reviews | Schedules |
| List of All Prot | ocols | | | | | | | |
| Drotocol Numb | or Title | | | | Status | Approval | Data Expir | ation Data |
| 1606004506A00 | 1 Title of the | Protocol II | | | | 20/June/ | 2016 19/ Ju | no/2017 |
| 1606004506 | Title of the | Protocol II | | | Active - Open to Enrollmer | t 20/.lune/ | 2016 19/.lu | ne/2017 |
| 1605004503 | Standard S | ubmission Test | | | Pending/In Progress | 20/04/16/ | 2010 13/04 | 110/2011 |
| 1605004502 | Case Repor | rt Case Study Tes | st | | Pending/In Progress | | | |
| 1605004500 | Title of the | Protocol | | | Pending/In Progress | | | |
| 1605004495 | test protoco | ol case study/ cas | se report | | Routing In Progress | | | |
| <u>1605004493</u> | Testing Cas | se Study / Case R | eport Questionn | aire 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

| All Protocols Pending Protoc | ols Pending Pl Action A | mendments & Renewals | Create New Protocol | Protocol Search All M | y Reviews |
|--------------------------------|------------------------------------|---------------------------------|---------------------|-------------------------|-----------|
| Protocol Search - Inte | rnet Explorer | arty Designa (See 1939) | | | |
| https://coeus.irttest | drexel.edu/coeus//protoco | lSearch.do?type=Proto | col&search=true&sea | archName=ALL_PROT | |
| Please enter search criteria | of the form *value* or *value or v | value* in any of search fields. | | | |
| Protocol No: *1234* |) , | < Protocol Type: | : | ~ | |
| Title: | | Protocol Status: | | ~ | |
| Expiration Date: | | Investigator | | | |
| Funding Source: | | | | | |
| | | Search Cancel | | | |

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 |
|-----|--|
| 4 | View History |
| | New Renewal with Amendment |
| | New Amendment |
| (| New Renewal |
| | Send Email |
| | |
| 4 | Access Permissions |
| | Copy Protocol |
| | Print Summary |
| | |
| | Review Comments |
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| For | ms |
| 1 | Application Form - Standard and HUD |

| Renewal Summary: | |
|------------------|--|
|------------------|--|

| 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 #: | 1710005674R001 (tenewal in Progress) Rivisile, Ralph d Test Protocol #4 | Expiration Date: Last Approval Date: | 10/15/2018 |
|-----------------------|---|---|------------|
| Protocol Organization | | | 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.

| | | \sim / | | T / | 1 | /// | 1 | M. | 2 | 1 | 1. 1 | Current Loc |
|--|----------------------------------|---------------|------------------------------|-------------------|---------------------------|--------------------|----------|------------|--------------------------|---------------------|----------------|-------------|
| Coeus | s Home My Negotiations | My Proposals | My Awards | My COI | My IRB Prote | ocols My IACUC Pro | tocols | Inbox | My ARRA | Logout | | |
| | | All Protocols | Pending Prot | ocols Pend | ing PI Action | Amendments & | Renewals | Create Net | w Protocol | Protocol Search | All My Reviews | Schedule |
| ✓ *G | General Info | | Protocol #: Investigator: | 160600 Storing | 04506R002 (Re Chervi I | newal in Progress) |) | | Expiration Last Appro | Date: oval Date: | 06/19/2017 | |
| ¥ *0 | Organization | | Title: | Title of | the Protocol II | | | | | | | |
| ✓ [*]Ir Pe | nvestigators / Study ersonnel | | Attachments | | | | | | | | | Help |
| 🖌 Co | orrespondents | | Add New Doo | ument | | | | | | | | |
| 🖌 *A | Areas of Research | | Attachments | in Oriei al F | rotocol | | | | | | | |
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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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| | CoeusLite | | | | | | | | | | User: | Storino, Cheryl L |
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| | | All Protocols | Pending Protoco | ols Pendin | g PI Action | Amendments & Ren | newals (| Create New I | Protocol | Protocol Search | All My Reviews | Schedules |
| | ✓ *General Info | | Protocol #: Investigator: | 1606004 Storino, 0 | 506R002 (Ren Cheryl L | newal in Progress) | | | Expiration Last Appro | Date: oval Date: | 06/19/2017 | |
| | *Organization | | Title: | Title of th | e Protocol II | | | | | | | |
| | *Investigators / Study ✓ Personnel | | Attachmente | | | | | | | | | Help |
| | Correspondents | | Add New Docur | nent | | | | | | | | |
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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

| HRP 212, Continuing Review/ Final Report Amendment/Renewal Questionnaire Previous Modify StartOver 1) Has the study been updated in ClinicalTrials.Gov? • Yes No 2) Is this submission a Continuing Review ? • 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 additute identifiable private information about the subjects is being obtained by this organization's investigator ¿ Analysis of private identifiable private information about the subjects is being obtained by this organization's investigator ¿ Analysis of private identifiable private information at this organization is complete. (This is applicable even if a statistical center at another organization Message from webpage 4 4 5 6 7 8 9 9 9 9 9 9 9 9 9 9 9 9 | | | |
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| acknowledge the following information must be completed for enrolled subjects of a vulnerable population at the more investigators site(s). | 10) | I acknowledge the following information must be completed for enrolled subjects of a vulnerable population at the investigators site(s). | More |
| • Yes ONO | | ● Yes ON0 | |



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 | | | | | | | | |
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| Submit | | | | | | | | |
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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 | | | | ^ | | | | |
| | | | | | \sim | | | | |
| 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

