Kuali Coeus Research Management (KCRM) User Guide: Create a Protocol Amendment, Renewal or Event

Version 1.0: February 2016

Purpose: To create an amendment, renewal or event on an existing IRB Protocol document.

Trigger / Timing / Frequency: When the CRC IRB office receives a protocol amendment, renewal or event application or form from a Researcher, the Administrator Coordinator updates the IRB Protocol Record in the KC system.

Prerequisites

- Individuals that are not paid BU employees to be named as PIs, COPIs or Study personnel on the protocol should be set up in KCRM.
- The Performing Organization or External Organization for the Protocol record should be set up in KCRM.

User Group Roles: IRB Administrator, IRB Reviewer, Protocol Viewer

Menu Path: Central Admin > Pre-Submission Compliance > Protocols > Human Participants

Tips and Tricks: It is important save your progress by clicking the Save button. Also progress can be saved by navigating to other tabs. When creating a Protocol Record, keep in mind that the available Protocol Actions that are available to you will vary based on the protocol status, as well as the previous action that was completed. Once the **Approve Actions** Protocol Action is submitted, the protocol status will change to *Active - Open to Enrollment* and the available Protocol Actions list will change allowing you to perform other actions on the Protocol Record that were not previously available such as: **Create Amendment** and **Create Renewal with Amendment**.

Results and Next Steps: As mentioned above available Protocol Actions on the protocol record will vary based on the protocol status. The administrative coordinator will be able to take the necessary action on the protocol record.The Administrative Coordinator, responsible for the creation of the initial protocol record, will so perform actions on the protocol records to match the findings of the IRB Analyst.

Process: There are two main actions related to the KC IRB Protocol: 1) A user can Create an IRB protocol record; 2) A user can update the IRB protocol record. This guide will focus on the updating of the IRB Protocols.

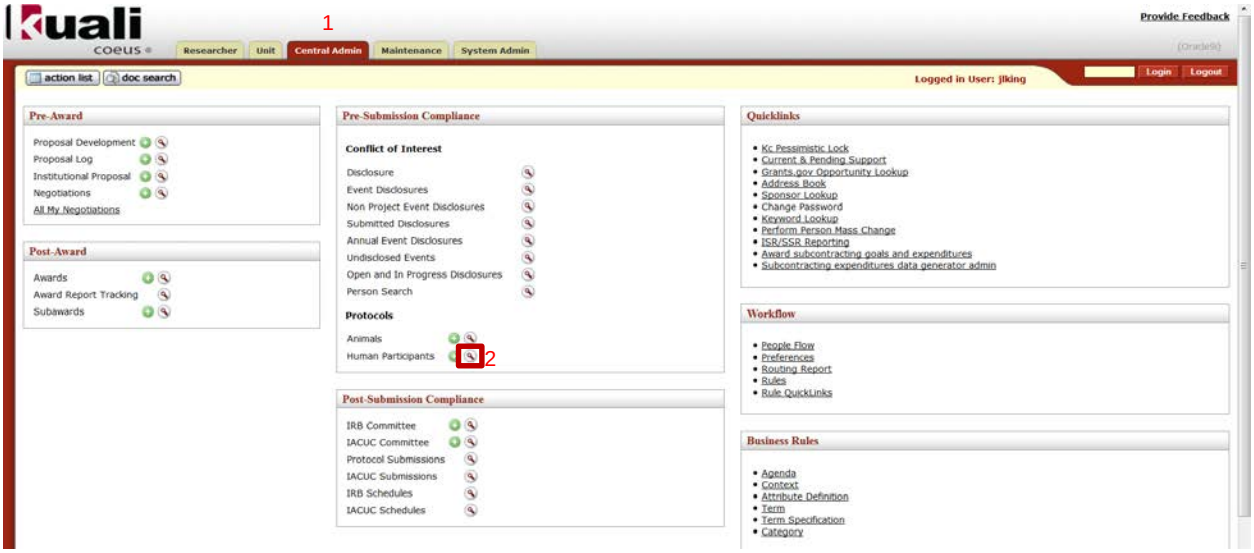
Contents

A. Create an Amendment 3
a. Find the protocol for which you'd like to create the amendment 3
b. Go to Protocol Actions tab 4
c. Create the amendment 4
d. Modify the protocol record based on the needs of the amendment 5
e. Submit amendment for review 6
B. Create a Renewal (Continuing Review) 7
b. Go to Protocol Actions tab 8
c. Create the Renewal 9
d. Submit renewal for review 10
C. Log an event 11
a. Find the protocol 11
b. Go to Protocol Actions tab 13
c. Notify IRB 13
d. IRB Acknowledgement 14
D. Reference - Available Actions Descriptions 15

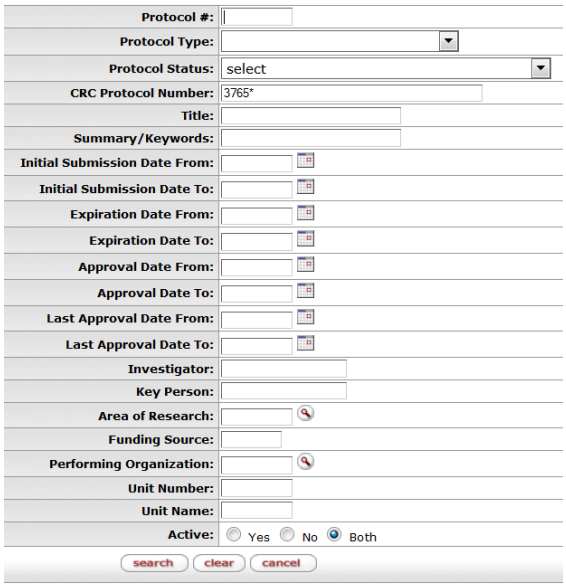
A. Create an Amendment

a. Find the protocol for which you'd like to create the amendment

Start the transaction in the Kuali Coeus Research Management portal and 1) navigate to the Central Admin Main Menu Tab. 2) Click the Search for Human Participants icon.



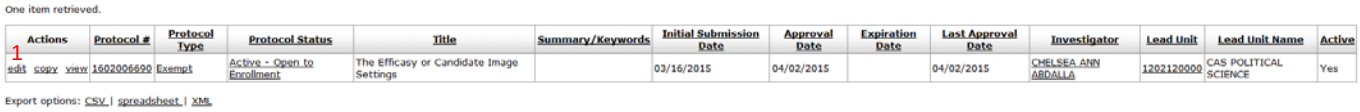
Use the search criteria to locate the protocol you're looking for.



Remember to use wildcards (*) before and after text items in your search to help locate the correct record.

When appropriate, be sure to search for both Active and Inactive records. The system treats the most recent base protocol and the most recent amendment or renewal as active. All other historical records are considered Inactive.

Your search will then return applicable values. Click on the **1)** Edit link to open the record to create an amendment.



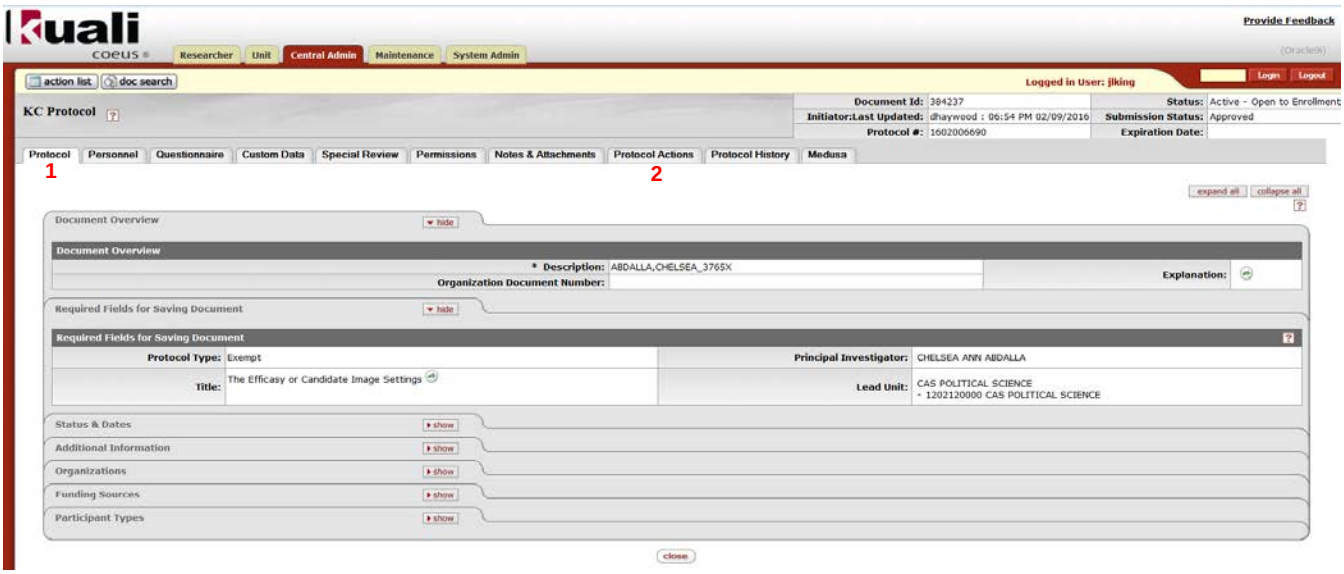
One item retrieved.

Actions	Protocol #	Protocol Type	Protocol Status	Title	Summary/Keywords	Initial Submission Date	Approval Date	Expiration Date	Last Approval Date	Investigator	Lead Unit	Lead Unit Name	Active
1 edit copy view	1602006690	Exempt	Active - Open to Enrollment	The Efficasy or Candidate Image Settings		03/16/2015	04/02/2015		04/02/2015	CHELSEA ANN ABDALLA	1202120000	CAS POLITICAL SCIENCE	Yes

Export options: CSV | spreadsheet | XML

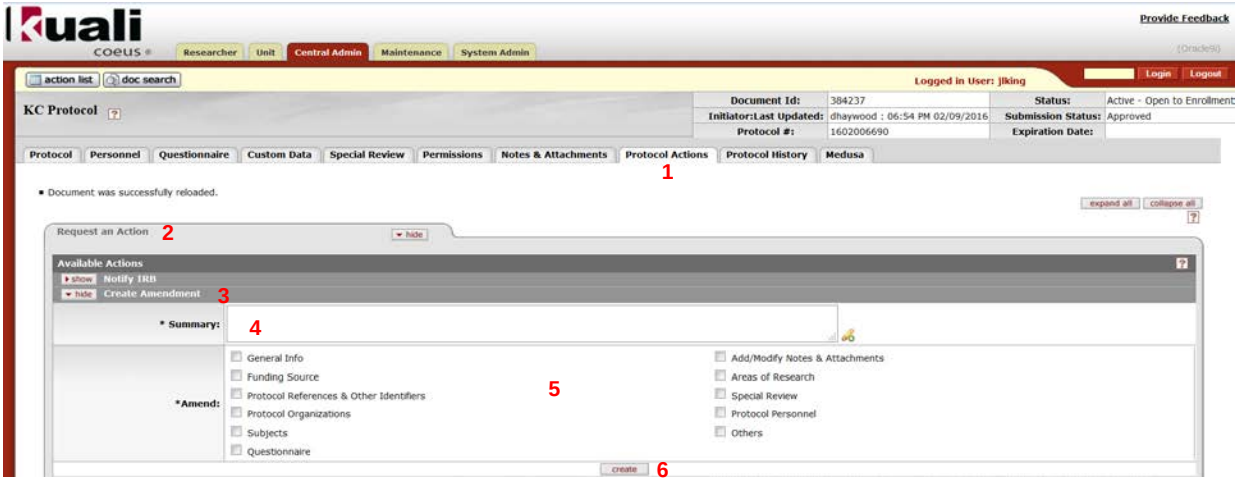
b. Go to Protocol Actions tab

The protocol record will open to the **1)** Protocol tab. Click the **2)** Protocol Actions tab.



c. Create the amendment

Once in the **1)** Protocol Action tab, click the show buttons to expand the **2)** Request an Action panel and **3)** Create Amendment sub-panel.



Data Quality	SOP Definition / Use	Required
4) Summary	Enter a description that describes why the amendment is being requested	Yes
5) Amend	Select at least one (but up to as many are needed) to reflect the changes that need to be made to the protocol as a result of the amendment. **Note: Always select "Others" as this will allow you to update the Custom Data tab to complete your tracking dates.**	Yes
6) Create	Clicking this button will create the amendment.	Yes

The Amendment Type values that are selected will drive the sections of the protocol that you are allowed to modify when you are processing the amendment. If you create the amendment and then need to adjust these values, you can do so by using the **Modify Amendment Sections** action.

Once the amendment is created, the system will display a message indicating success.

Upon create action for the amendment, the system creates an amendment protocol with a protocol number derived from protocol number of the protocol being amended followed by a suffix of A001 for the first amendment, A002 for the second amendment and so on.

d. Modify the protocol record based on the needs of the amendment

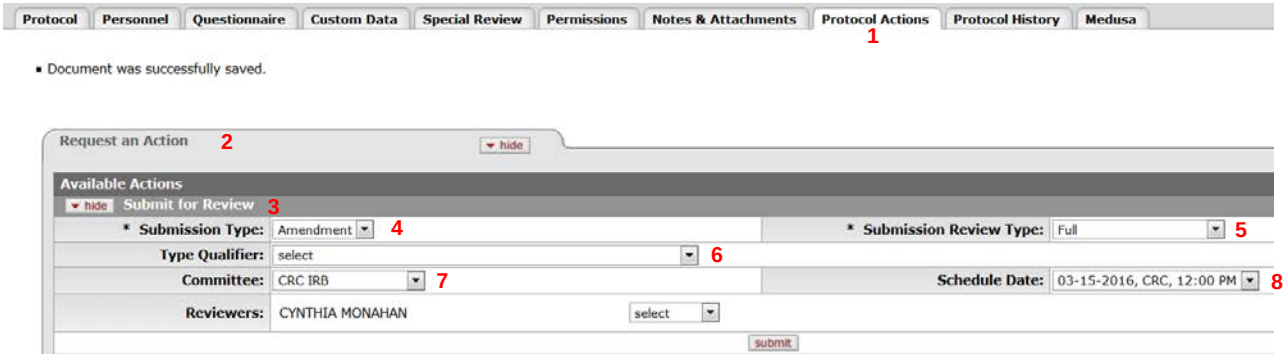
Based on the selections indicated above the Amendment Type section, certain parts of the protocol record will be available for edit.

Amendment Type	Protocol Sections available for Edit
General Info	Protocol > Required Fields for Saving Document panel
Funding Source	Protocol > Funding Source panel
Protocol References & Other Identifiers	Protocol > Additional Information > Additional Information panel, and Protocol > Additional Information > Other Identifiers panel
Protocol Organizations	Protocol > Organizations
Subjects	Protocol > Participant Types
Questionnaire	Questionnaire tab *(not applicable for our implementation)*
Add/Modify Notes & Attachments	Notes & Attachments tab
Areas of Research	Protocol > Additional Information > Areas of Research
Special Review	Special Review tab
Protocol Personnel	Personnel tab
Others	Custom Data tab

It is possible to have more than one amendment outstanding at the same time, but to avoid data collisions; KC does not allow two amendments of the same section of the protocol to be outstanding at the same time.

e. Submit amendment for review

Once all updates are applied on the protocol record, the amendment is ready for submission. Go to the **1)** Protocol Actions tab, **2)** Request an Action panel and **3)** Submit for Review.

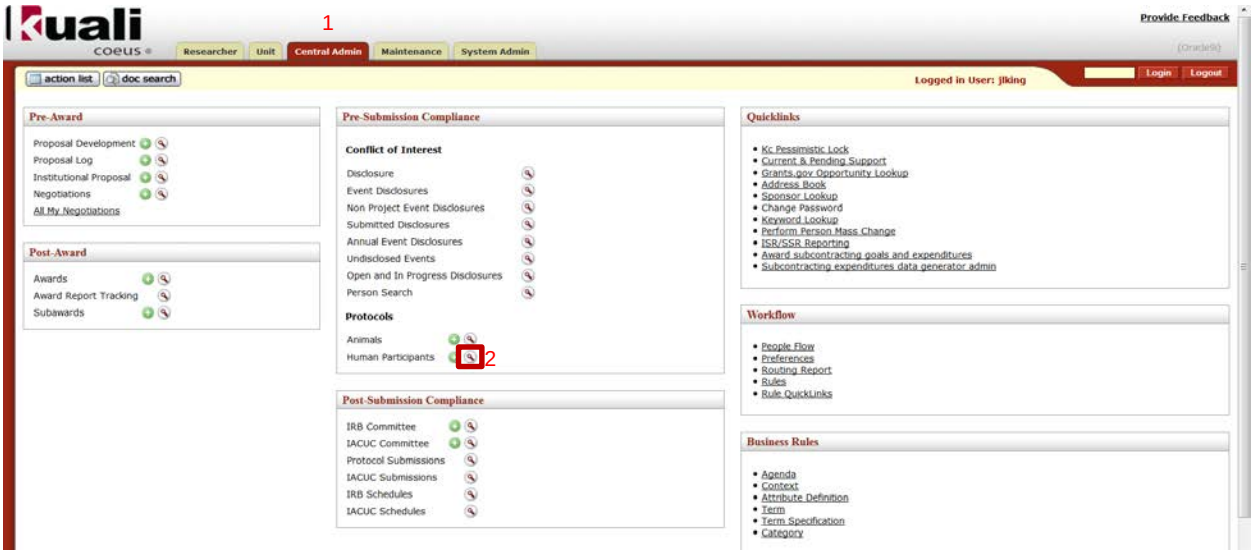


Data Quality	SOP Definition / Use	Required
4) Submission Type	This field will return from a list the available options for Submission Type.	Yes
5) Submission Review Type	This field will return from a list the available options for Submission Review Type.	Yes
6) Type Qualifier	This field will return from a list the available options for Type Qualifier. This field should be used to describe the type of 'event' that is taking place and only needs to be used if it's applicable.	
7) Committee	Although not required at this time, if the Committee that is being assigned is known, please select it from this list.	
8) Schedule Date	Based on the committee that is selected in (7), the applicable list of meeting dates will display and can be selected prior to submission.	

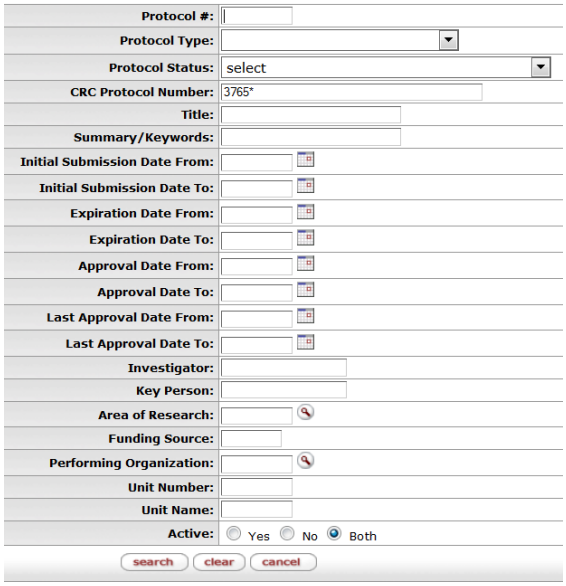
All submission steps here now follow the same as if it was a new protocol. Please refer to the **Create an IRB Protocol Userguide** (Section G) for more details.

B. Create a Renewal (Continuing Review)

a. Start the transaction in the Kuali Coeus Research Management portal and 1) navigate to the Central Admin Main Menu Tab. 2) Click the Search for Human Participants icon.



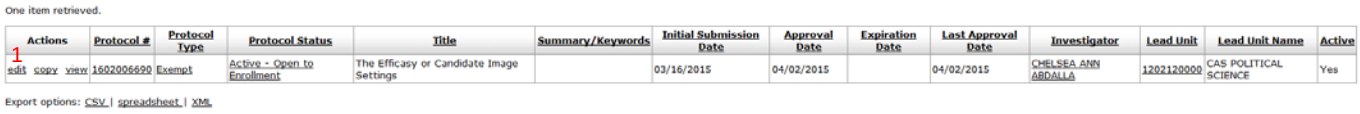
Use the search criteria to locate the protocol you're looking for.



Remember to use wildcards (*) before and after text items in your search to help locate the correct record.

When appropriate, be sure to search for both Active and Inactive records. The system treats the most recent base protocol and the most recent amendment or renewal as active. All other historical records are considered Inactive.

Your search will then return applicable values. Click on the **1)** Edit link to open the record to create a renewal.



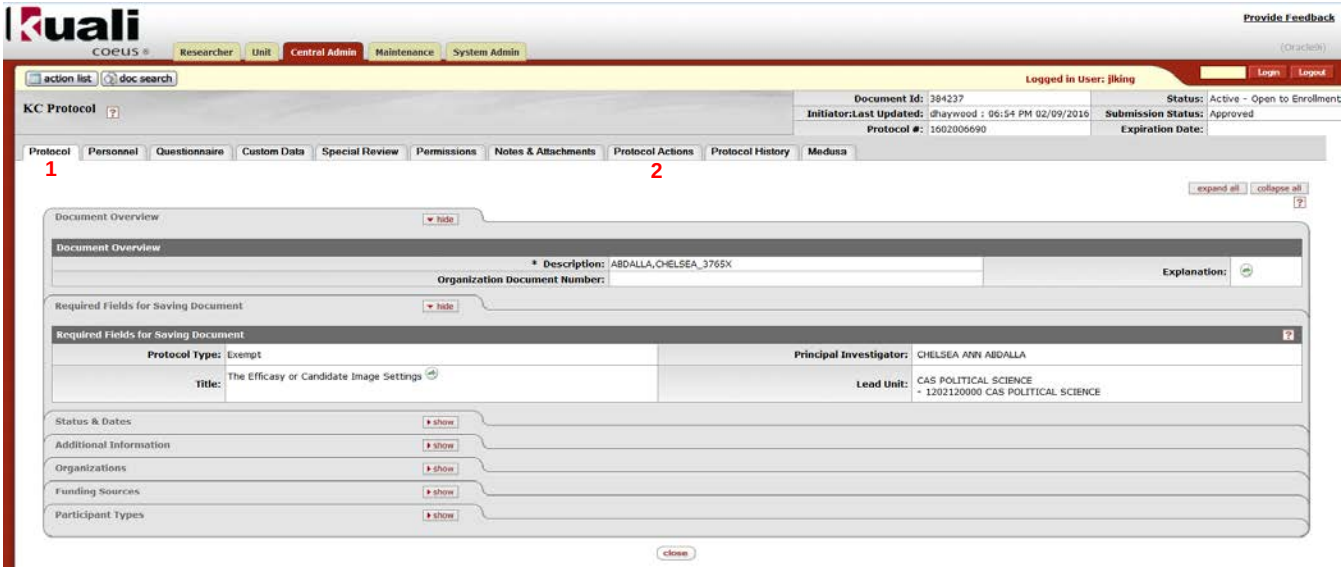
One item retrieved.

Actions	Protocol #	Protocol Type	Protocol Status	Title	Summary/Keywords	Initial Submission Date	Approval Date	Expiration Date	Last Approval Date	Investigator	Lead Unit	Lead Unit Name	Active
1 edit copy view	1602006690	Exempt	Active - Open to Enrollment	The Efficasy or Candidate Image Settings		03/16/2015	04/02/2015		04/02/2015	CHELSEA ANN ABDALLA	1202120000	CAS POLITICAL SCIENCE	Yes

Export options: CSV | spreadsheet | XML

b. Go to Protocol Actions tab

The protocol record will open to the **1)** Protocol tab. Click the **2)** Protocol Actions tab.



c. Create the Renewal

Once in the Protocol Action tab, click the ▸show buttons to expand the **1)** Request an Action panel and **2)** Create Renewal **<u>with Amendment</u>** sub-panel.

Note: While this Renewal may not have any changes, this selection is still required in order to update the Custom Data tab and update your dates.

Data Quality	SOP Definition / Use	Required
3) Summary	Enter a description that describes why the renewal is being requested	Yes

Data Quality	SOP Definition / Use	Required
4) Amend	Note: While this Renewal may not have any changes, this selection is still required in order to update the Custom Data tab and update your dates. **Note: Always select "Others" as this will allow you to update the Custom Data tab to complete your tracking dates.**	
5) Create	Clicking this button will create the amendment.	Yes

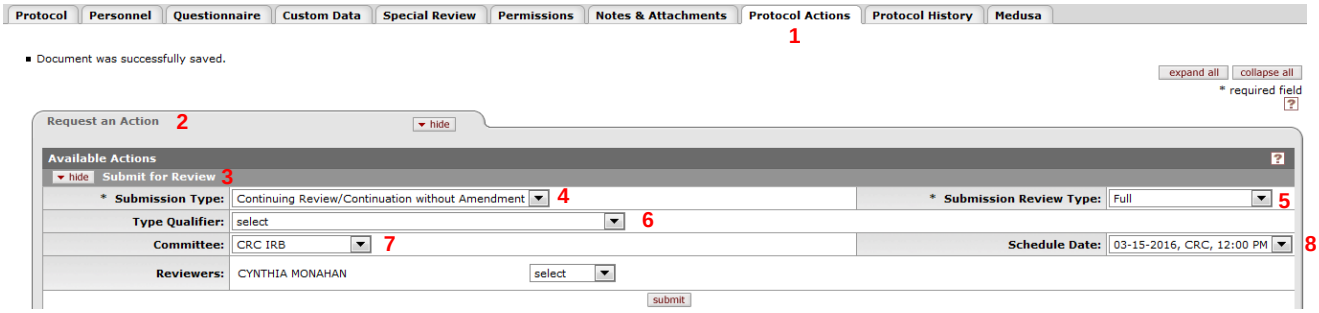
It is important for our business to always select Create Renewal with Amendment because that is how you will be able to go and edit the Custom Data tab to enter your dates. Renewals without amendments will not allow for any sections of the protocol to be edited.

Once the amendment is created, the system will display a message indicating success.

You will not be able to modify data elements in the Protocol document. Upon create action for the renewal without amendment, the system creates a renewal protocol with a protocol number derived from protocol number of the protocol being renewed followed by a suffix of R001 for the first renewal, R002 for the second renewal and so on.

d. Submit renewal for review

Once the renwal has been created, it is ready for submission. Go to the **1)** Protocol Actions tab, **2)** Request an Action panel and **3)** Submit for Review.



Data Quality	SOP Definition / Use	Required
4) Submission Type	This field will return from a list the available options for Submission Type.	Yes
5) Submission Review Type	This field will return from a list the available options for Submission Review Type.	Yes
6) Type Qualifier	This field will return from a list the available options for Type Qualifier. This field should be used to describe the type of 'event' that is taking place and only needs to be used if it's applicable.	
7) Committee	Although not required at this time, if the Committee that is being assigned is known, please select it from this list.	
8) Schedule Date	Based on the committee that is selected in (7), the applicable list of meeting dates will display and can be selected prior to submission.	

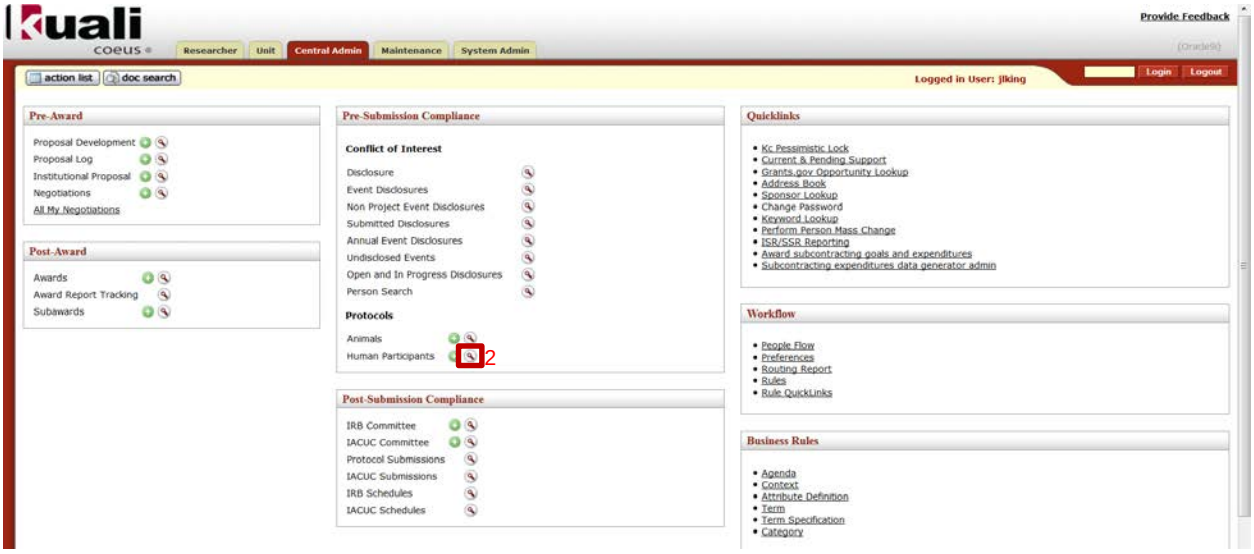
All submission steps here now follow the same as if it was a new protocol. Please refer to the **Create an IRB Protocol Userguide** (Section G) for more details.

C. Log an event

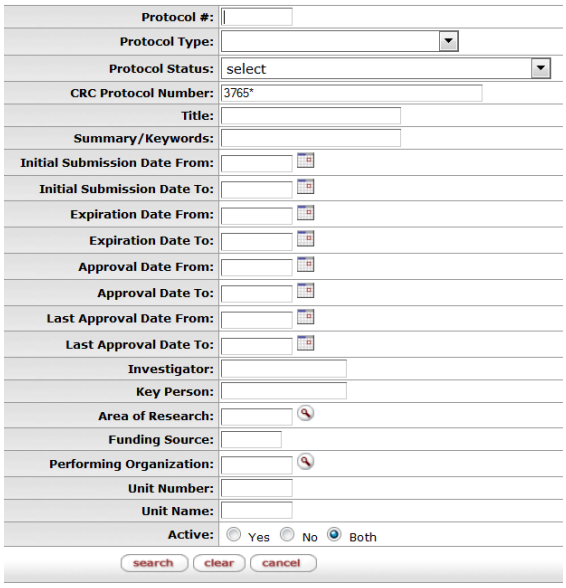
a. Find the protocol

Find the protocol that you'd like to log the event for by 1) navigating to the Central Admin Main Menu Tab. 2) Click the Search for Human Participants icon.

1



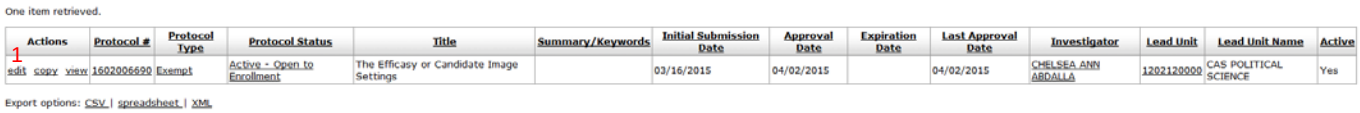
Use the search criteria to locate the protocol you're looking for.



Remember to use wildcards (*) before and after text items in your search to help locate the correct record.

When appropriate, be sure to search for both Active and Inactive records. The system treats the most recent base protocol and the most recent amendment or renewal as active. All other historical records are considered Inactive.

Your search will then return applicable values. Click on the **1)** Edit link to open the record to create a renewal.



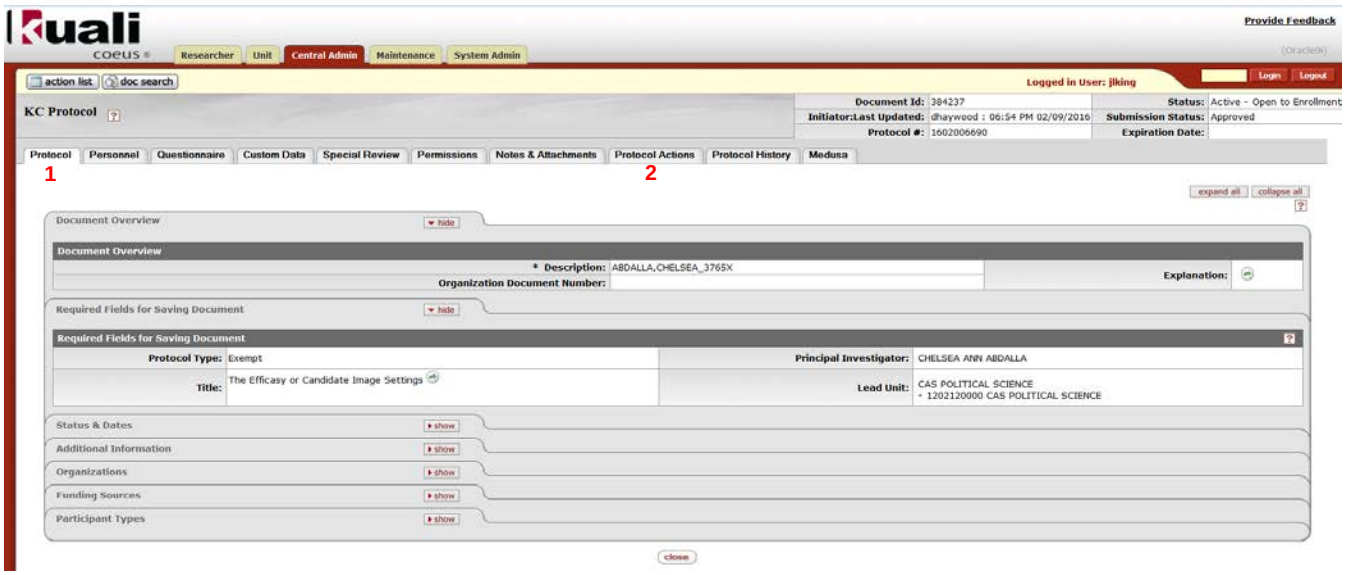
One item retrieved.

Actions	Protocol #	Protocol Type	Protocol Status	Title	Summary/Keywords	Initial Submission Date	Approval Date	Expiration Date	Last Approval Date	Investigator	Lead Unit	Lead Unit Name	Active
1 edit copy view	1602006690	Exempt	Active - Open to Enrollment	The Efficasy or Candidate Image Settings		03/16/2015	04/02/2015		04/02/2015	CHELSEA ANN ABDALLA	1202120000	CAS POLITICAL SCIENCE	Yes

Export options: CSV | spreadsheet | XML

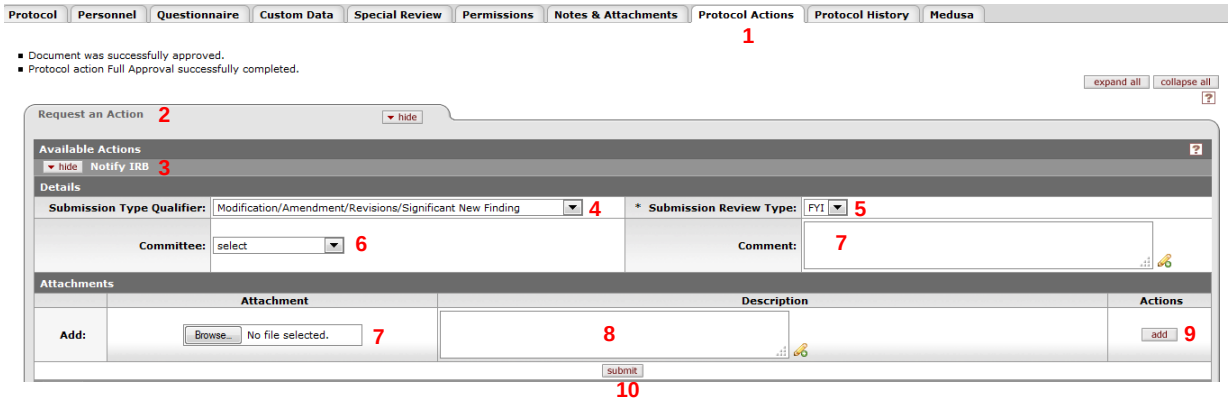
b. Go to Protocol Actions tab

The protocol record will open to the **1)** Protocol tab. Click the **2)** Protocol Actions tab.



c. Notify IRB

Once in the **1)** Protocol Action tab, click the buttons to expand the **2)** Request an Action panel and **3)** Notify IRB.

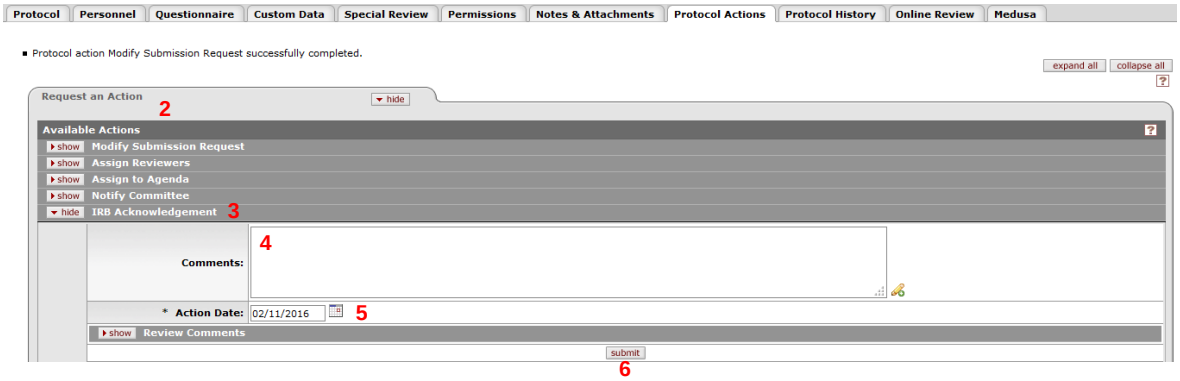


Data Quality	SOP Definition / Use	Required
4) Submission Type Qualifier	This field will return from a list the available options for Type Qualifier. This field should be used to describe the type of 'event' that is taking place.	
5) Submission Review Type	For Events, this will default to FYI.	Yes
6) Committee	Although not required at this time, if the Committee that is being assigned is known, please select it from this list.	
7) Comment	Enter in any relevant comments for the event.	
8) File Attachment	Upload any file(s) that are relevant for the event	
9) Description	Enter description for the file that is being uploaded	
10) Add	Click the add button to add the file and description to the submission	
11) Submit	Click Submit to log the event.	

d. IRB Acknowledgement

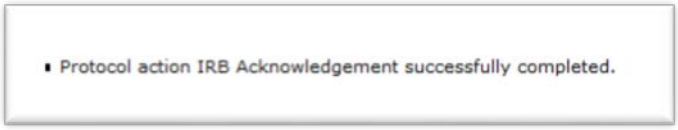
If the event can be easily approved, the action that should be taken is IRB Acknowledgement. Once in the **1)** Protocol Action tab, click the show buttons to expand the **2)** Request an Action panel and **3)** IRB Acknowledgement sub-panel.

1



Data Quality	SOP Definition / Use	Required
4) Comments	Enter in relevant comments as to why this event has been acknowledged/approved.	
5) Action Date	Enter date in which you'd like this to be effective.	Yes
6) Submit	Click Submit to log the IRB Acknowledgement/Approval.	

You will see a message indicating that the action has been successfully completed and the Submission Status will reflect "IRB Acknowledgement."



If the Event needs to go through a committee review, this can be done. All submission steps would follow the same as if it was a new protocol. Please refer to the **Create an IRB Protocol Userguide** (Section G) for more details.

D. Reference - Available Actions Descriptions

The actions that are available to you are based on previoiusly –performed actions, pending action requests, the role of the logged in user, and document status. Please see below for a summary of descriptions (as provided by Kuali) for all actions:

Available Actions Subsection	Summarized Usage Description
Approve	After recording a vote on a motion to approve, the IRB Administrator records the decision to grant approval, enters the approval date and comments. Expiration

Available Actions Subsection	Summarized Usage Description
	date will be generated based on approval date, but can be modified. Risk level can be recorded.
Assign Reviewers	Click the desired checkbox for each reviewer you want to select, choose either primary or secondary for each, then click the **submit** button.
Assign to Agenda	Click the Assign this protocol to an agenda checkbox, type to enter comments, select an Action Date as desired; optionally add Review comments, then click the **submit** button.
Close	Enter comments, review comments and an effective date.
Close Enrollment	This is the IRB Administrator's reaction to the Researcher's request to close enrollment of study participants by the PI and it changes the status of the document to Active – Closed for Enrollment. This action can also be taken by the IRB Administrator without a request from the Researcher.
Create Amendment	Type to enter text in Amendment Summary; select appropriate checkbox(es) for the portion of the Protocol document in need of amendment in Amend; then click the **create** button. A new Protocol document is created and you are taken to the selected portion. An amendment is a request by the researcher to make a change to a previously approved protocol. This change may be procedural or informational. Probably the most common amendment is a change to the personnel working on the project. For an amendment KC will allow changes to the data elements in the protocol in specific sections identified by the researcher. It is possible to have more than one amendment outstanding at the same time, but to avoid data collisions KC does not allow two amendments of the same section of the protocol to be outstanding at the same time.
Create Renewal with Amendment	Type to enter text in Amendment Summary; select appropriate checkbox(es) for the portion of the Protocol document in need of amendment in Amend; then click the **create** button. A new Protocol document is created and you are taken to the selected portion. Changes to the data elements and an extension of the expiration date will result upon approval.
Create Renewal without Amendment	Click the **create** button. A renewal (also referred to as a continuation) is a request (usually annually) to continue work on a previously approved project. A renewal would not include any change in process or information. It may require some sort of progress report or statement. The acceptance of the renewal by the IRB committee will generally extend the expiration date (default in KC is to extend by 1 year). For a renewal without amendment KC will not allow any data elements in the protocol to be modified.
Data Analysis Only	Response to Researcher request for Data Analysis Only, this action indicates that that the human participant portion of the study is complete and only data analysis remains to be completed. This action can also be taken by the IRB Administrator without a request from the Researcher.
Defer Action	Enter comments pertaining to the reason for deferment, specify an Action Date for the deferment action to become effective, optionally add Review Comments, then click the **submit** button.
Delete Protocol, Amendment, or Renewal	When the Protocol document has never been submitted, this allows you to delete it from the system.

Available Actions Subsection	Summarized Usage Description
Expedited Approval	IRB Administrator records decision to grant expedited approval. Enters the approval date and comments. Expiration date will be generated based on approval date, but can be modified. Risk level can be recorded.
Expire	Enter comments that summarize the reason for the expiration, then select an action date for the expiration to become effective.
Grant Exemption	Optionally enter review comments and action comments, modify action date, and add to a meeting agenda to grant an exemption to a previously-submitted Protocol document.
Make Administrative Correction	Type to enter comment text explaining the purpose for the correction, then click the edit button. Make corrections in the appropriate sections, then select Apply Administrative Correction checkbox and click the **submit** button.
Manage Review Comments	Enter review comments without performing any additional action on the protocol.
Modify Submission Request	Assign to Committee and select Schedule date through this panel. Select different options for Submission Type, Submission Review Type, Billable flag, and Type Qualifier, and then click the **submit** button.
Notify IRB	Select a Submission Type, Submission Review Type (required), and Committee; browse for and select a file for the File Name field, and type to enter a comment in the Comment field as desired; then click the **submit** button. This is used by the Researcher to inform the IRB of an event or new information about the protocol that does not require an amendment.
Request for Data Analysis Only	The Investigator submits a request to notify the Committee that the human participant portion of the study is complete and only data analysis remains to be completed. A comment is included, and a Protocol Submission record is created.
Request for Suspension	Investigator submits a request to suspend the study. A reason for the suspension is required. Creates protocol submission record.
Request for Termination	Type a reason for the termination request, then click the submit button.
Request to Close	Investigator submits a request to the IRB to close with a comment. Protocol will be submitted to the committee which approved the protocol.
Request to Close Enrollment	Investigator submits a request to close enrollment of participants into the study. A comment is included. Creates protocol submission record. The request to close enrollment requires action by IRB Administrator to close enrollment.
Response Approval	IRB Administrator records approval action resulting from a review of the Researcher's response to a previously-reviewed protocol that required revisions. Enters the approval date, risk level and comments. Expiration date will be generated based on approval date, but can be modified. Present approval letter for review and to mark final.
Submit for Review	Submit a new protocol/ Amendment/ Renewal/ Response to IRB office for review. Must select Submission type (New/Amendment/Renewal/Response) and Review type (Full/ Exempt/ Expedited). Entering committee, schedule and reviewers is optional. Checklist is required for exempt or expedited. Submission date set to current date.
Suspend	IRB Administrator marks protocol as suspended. Enter comments, reviewer comments and action date.

Available Actions Subsection	Summarized Usage Description
Suspend By DSMB	Protocol is suspended by Data Safety Monitoring Board (DSMB). IRB Administrator enters comments, reviewer comments and action date.
Terminate	Enter comments that summarize the reason for the termination, then select an action date for the termination to become effective.
Undo Last Action	Type to enter comments that summarize the purpose of undo-ing the last action, then click the submit button.
Withdraw Protocol	Type a textual reason for the withdrawal, then click the **submit** button to withdraw a Protocol application from review. The PI and any Correspondents are automatically notified.

KCRM Document Action Command Buttons Definitions

Save Allows the initiator of a document to save their work and close the document. The document may be retrieved from the initiator's Action List for completion and routing at a later time.

Reload Refreshes the page and displays the most recently saved information. Changes which are made but not saved prior to reloading a page are not maintained.

Close Signifies that you wish to exit the document. The system displays a message asking if you want to save the document before closing. No changes to Action Requests, Route Logs or document status occur as a result of a Close action. If you initiate a document and close it without saving, it is the same as canceling that document.