Kuali Coeus Research Management (KCRM) User Guide: Create an IRB Protocol

Version 1.1: March 2016

Purpose: To create an IRB Protocol document to be used for tracking new Human Subjects Research requests.

Trigger / Timing / Frequency: When the CRC IRB office receives a protocol application or form from a Researcher, the Administrator Coordinator the creates a new 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 or navigating to another tab. When creating a Protocol Record, keep in mind available Protocol Actions available to you will vary based on protocol status, as well as the previous action that was completed. Once the **Approve Actions** Protocol Action is submitted, 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 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) Create an IRB protocol record; 2) Update the IRB protocol record. This guide will focus on the the Create and IRB Protocol Record main action.
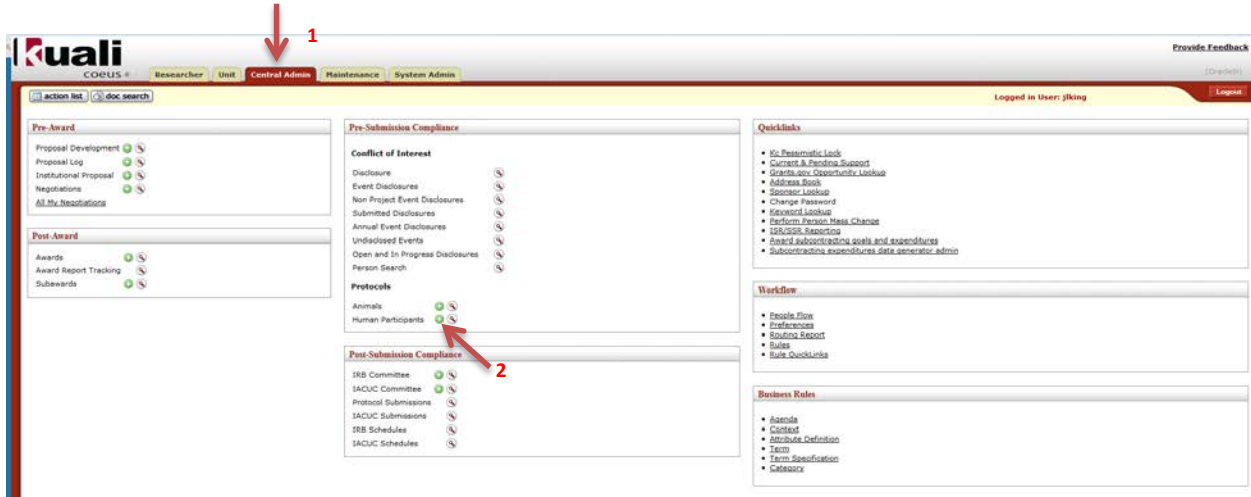
Contents

A. Create a new IRB Protocol record

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

The IRB Protocol document has several tabs, of which only the following tabs will be used: Protocol, Personnel, Custom Data, Special Review, Notes & Attachments, and Protocol Actions. In addition Protocol History and Medusa tabs will be available for viewing.
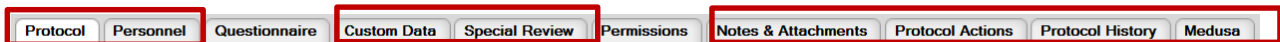
B. Protocol Tab
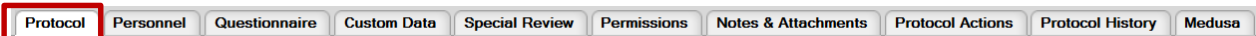
    a.   Complete the Document Overview

Enter Document Description in the Document Overview Panel for the protocol document using the following format: PI Last Name, PI First Name_IRB#.

The document description is a required field. There is a 30 character limit on this field.

b. Complete the Required Fields for Saving Document panel

All required fields on the Required Fields for Saving Document Panel must be completed before the
protocol document can be saved.

Data Quality	SOP Definition / Use	Required
1) Protocol Type	Used to select the type that best categorizes the protocol.	Yes
2) Principal Investigator (Employee)	This field is uses the lookup 🔍 to add the Principal Investigator. See below for further direction on using the 🔍 lookup function.	Yes
2) Principal Investigator (Non-Employee)	If the Principal Investigator is not an employee of BU, and is not available in the PI (Employee) selection field, the PI can be added to the system as a non-employee. To request that a non-employee be added, please submit a help ticket to the Kuali Coeus Support Team with the following information: *Name, Responsible Funds Center, Email, Organization (if not BU)*	Yes
3) Title	Enter the title of the protocol. If funded, the title should match the title of the proposal or award	Yes
4) Lead Unit	Look up and add the funds center or department affiliated with the protocol.	Yes

🔍 Using the lookup function to find an Employee record

On the KcPerson Lookup screen, 1) enter one or more criteria to narrow your results. Click the 2) Search
button to view results below the search criteria. To select a person click on 3) return value next to the
appropriate person.

c. Save Protocol Document

The protocol document can be saved after required fields from the Document Overview panel and Required Fields for Saving Document panel are completed. At the bottom of the Protocol Tab click the 1) **Save** button to save all progress on the newly created IRB Protocol record.

Note: Alternatively a user can click the 2) Personnel or other listed tabs to save the record. Once you have successfully saved the document the 3) Protocol #, located in the upper right-hand corner of the screen will be generated.

d. Additional Information

Additional information on the protocol may be added through the Additional Information panel.
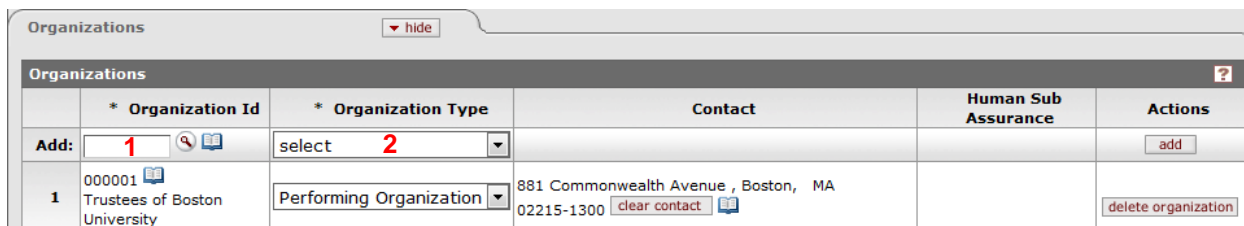
Data Quality	SOP Definition / Use	Required
1) FNA IND or IDE #	When applicable used to store the FNA IND # or the IDE#.	
2) CRC Protocol Number	Enter the number that the CRC uses to track the protocol.	
3) OHRP Categories	When applicable enter the OHRP Categories.	
4) Summary/Keywords	When applicable enter in the Name of Drug or Device associated to the protocol.	

e. Organizations
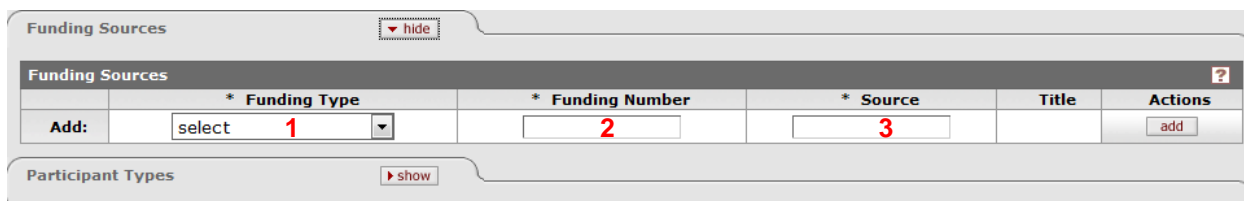
If there are other organizations involved in the protocol that need to be noted, add the Organization and the appropriate Organization Type. Note: By default, BU will be listed as the Performing Organization, but this can be deleted and/or updated.

Data Quality	SOP Definition / Use	Required
1) Organization ID	Look up the Organization by the Organization Id number.	Yes
2) Organization Type	Select the applicable Organization Type	Yes

f. Funding Sources

Select the applicable Funding Source leveraging the data entered on the protocol application. In order to search for the applicable Institutional Proposal or Award record in KC, use the PI name, Title, Sponsor Award ID. Multiple Funding Sources can be associated where needed.
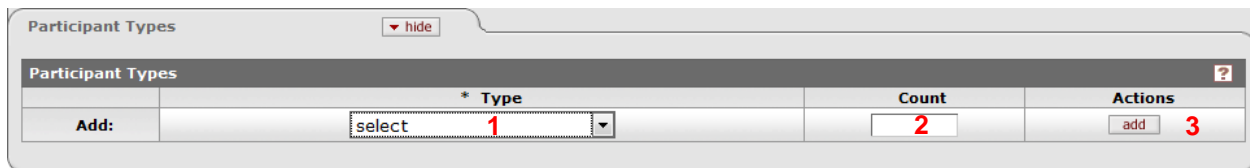
Data Quality	SOP Definition / Use	Required
1) Funding Type	Select the appropriate Funding Type.	Yes
2) Funding Number	Enter the Funding Name for the Funding Source.	Yes
3) Source	Enter the Source number for the Funding Source.	Yes

Note: When a Funding Type of Sponsor, Unit, Insititional Proposal or Award is selected, then **2)** Funding Number and **3)** Source will pre-populate. Otherwise, these fields will need to be completed.

g. Participant Types

Select and add data elements for Participant Types. Multiple Participant Types can be added as needed.

Data Quality	SOP Definition / Use	Required
1) Type	Select the applicable Participant Type	Yes
2) Count	Enter the number of participants for a specific participant type.	
3) ADD	Click the [add] button in order for the updates to be added to the record	Yes

C. Personnel Tab

a. Add Personnel

Personnel Affiliated with the protocol can be added to the protocol. By default the Principal Investigator will be loaded from the Protocol Tab. Additions or updates to personnel data can be made.

Data Quality	SOP Definition / Use	Required
1) Person	Look up the employee using the Employee Search or Non-Employee search. • *Employee Search* will list active BU employees. • *Non-employee Search* will return data for non-employees that have been manually entered into the database.	Yes
2) Protocol Role	Select the appropriate Protocol Role for each personnel added.	Yes

Whenever possible, please identify personnel using the Employee Search function prior to submitting a ticket to have a person added to the Non-Employee Address Book. Be sure to search for both Active and Inactive records.

b. Update Affiliation Data

Once individuals are added to the personnel area, the affiliation data can be updated. This is used to capture if the individual is a staff, faculty or student.

Data Quality	SOP Definition / Use	Required
1) Affiliation Type	Select the appropriate Affiliation Type for the individual listed	

D. Custom Data Tab

KC 5.2.1

| Protocol | Personnel | Questionnaire | Custom Data | Special Review | Permissions | Notes & Attachments | Protocol Actions | Protocol History | Medusa |

a. Enter Custom Data fields if applicable:

Dates ▼ hide

Dates

Full Group Name: Dates

Date Received:	1
Claim Date:	2
Determination Date:	3
Approval Date:	4
New Date of Expiration:	5
Date of Closure:	6
Authorization Date:	7

General ▼ hide

General

Full Group Name: General

Analyst:	8
Advisor:	9
Record Keeper Box#:	10

Modification Dates ▼ hide

Modification Dates

Full Group Name: Modification Dates

Req Mod Date 1:	11
Response Date 1:	12
Req Mod Date 2:	13
Response Date 2:	14
Req Mod Date 3:	15
Response Date 3:	16
Req Mod Date 4:	17
Response Date 4:	18
Req Mod Date 5:	19
Response Date 5:	20
Req Mod Date 6:	21
Response Date 6:	22

Data Quality	SOP Definition / Use	Required
1) Date Received	This custom field will be used to record the Date Received.	
2) Claim Date	This custom field will be used to record the Claim Date.	
3) Determination Date	This custom field will be used to record the Determination Date.	
4) Approval Date	This custom field will be used to record the Approval Date.	
5) New Date of Expiration	This custom field will be used to record the New Date of Expiration.	
6) Date of Closure	This custom field will be used to record the Date of Disclosure.	
7) Authorization Date	This custom field will be used to record the Authorization Date.	
8) Analyst	This custom field will be used to look up and/or enter an employee name.	
9) Advisor	This custom field will be used to record Advisor data from the Employee Lookup.	

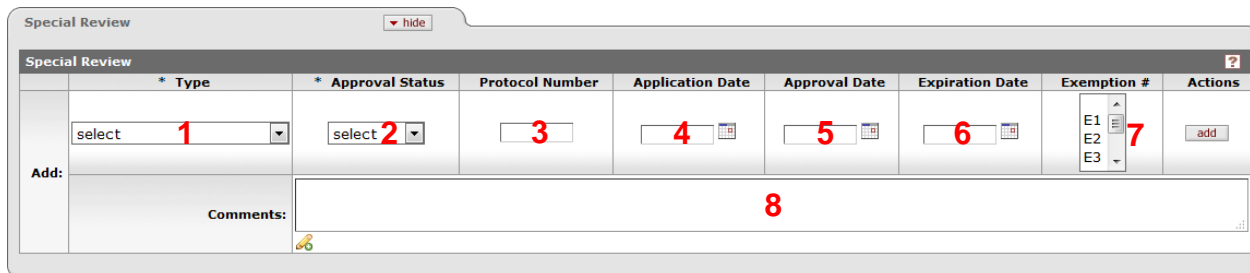| Data Quality	SOP Definition / Use	Required
10) Record Keeper Box#	This custom field will be used to record the Record Keeper Box#.	
11) Req Mod Date 1	This custom field will be used to record the Req Mod Date 1.	
12) Response Date 1	This custom field will be used to record the Response Date 1.	
13) Req Mod Date 2	This custom field will be used to record the Req Mod Date 2.	
14) Response Date 2	This custom field will be used to record the Response Date 2.	
15) Req Mod Date 3	This custom field will be used to record the Req Mod Date 3.	
16) Response Date 3	This custom field will be used to record the Response Date 3.	
17) Req Mod Date 4	This custom field will be used to record the Response Date 4.	
18) Response Date 4	This custom field will be used to record the Req Mod Date 4.	
19) Req Mod Date 5	This custom field will be used to record the Response Date 5.	
20) Response Date 5	This custom field will be used to record the Req Mod Date 5.	
21) Req Mod Date 6	This custom field will be used to record the Response Date 6.	
22) Response Date 6	This custom field will be used to record the Req Mod Date 6.	

| Protocol | Personnel | Questionnaire | Custom Data | **Special Review** | Permissions | Notes & Attachments | Protocol Actions | Protocol History | Medusa |
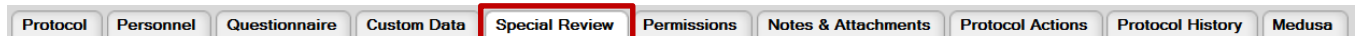
E. Special Review Tab
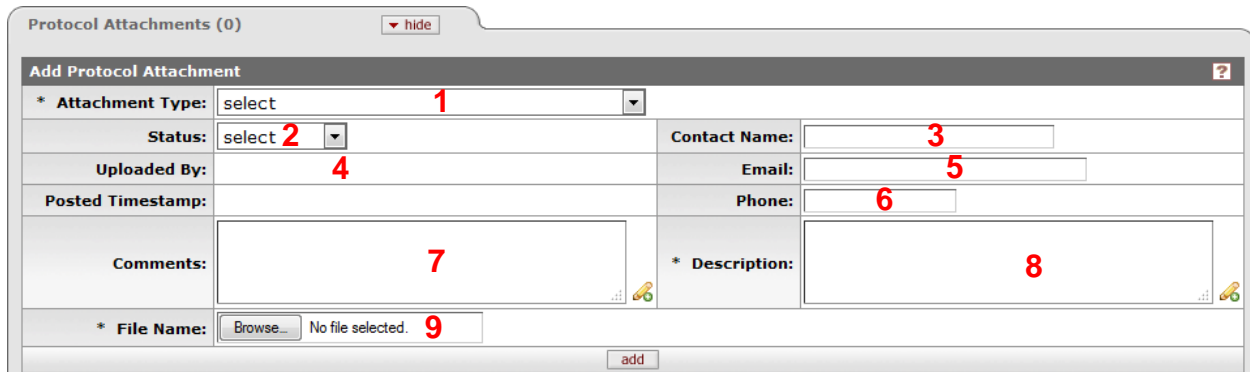
a. Enter Special Review, if needed for the protocol record.

Data Quality	SOP Definition / Use	Required
1) Type	Select the appropriate type of Special Review.	Yes
2) Approval Status	Select the appropriate approval types for the Special Review.	Yes
3) Protocol Number	Will capture the protocol number for the Special Review.	
4) Application Date	Will capture the Application Date for the Special Review.	
5) Approval Date	Will capture the Approval Date for the Special Review.	
6) Expiration Date	Will capture the Expiration Date for the Special Review.	
7) Exemption #	Will capture the Exemption number for the Special Review.	
8) Comments	Will capture comments for the Special Review.	

Protocol	Personnel	Questionnaire	Custom Data	Special Review	Permissions	Notes & Attachments	Protocol Actions	Protocol History	Medusa

F. Notes & Attachments Tab

    a. Enter and upload Attachments in this section as needed.
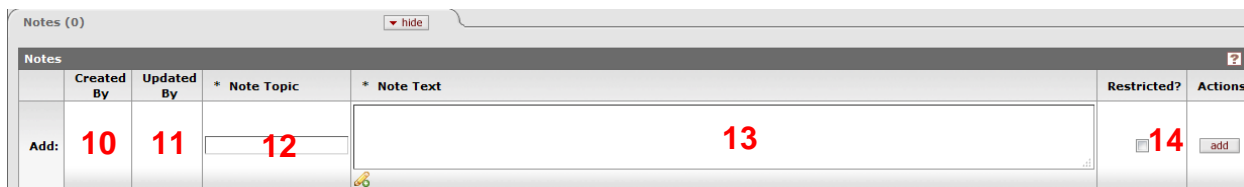
Data Quality	SOP Definition / Use	Required
1) Attachment Type	Required field to add the Attachment Type from a list to the protocol: 1. Informed Consent Document 2. Recruitment Brochure 3. Advertisement 4. Protocol Narrative 5. Investigator Brochure 6. Children's Assent Form 7. HIPAA Research Authorization Form 8. HIPAA Waiver of Research Authorization Form 9. Other 10. Adverse Event 11. Biography	Yes
2) Status	This field lists status for the Attachment: 1. Incomplete 2. Complete	
3) Contact Name	captures name of person to contact about the attachment.	
4) Uploaded By	Displays User ID of the user who uploaded the attachment.	
5) Email	Will be used to capture the email address of the person to contact about the attachment.	
6) Phone	Will be used to capture the phone number of the person to contact about the attachment.	

Data Quality	SOP Definition / Use	Required
7) Comments	Will be used to capture summary comments about the attachment.	
8) Description	Will be used to capture the description of the attachment.	Yes
9) File Name	Will be used to capture the name of the attachment file.	Yes

b. Enter Notes in this section as needed.

Data Quality	SOP Definition / Use	Required
10) Attachment Type	Required field to add the Attachment Type from a list to the protocol: 12. Informed Consent Document 13. Recruitment Brochure 14. Advertisement 15. Protocol Narrative 16. Investigator Brochure 17. Children's Assent Form 18. HIPAA Research Authorization Form 19. HIPAA Waiver of Research Authorization Form 20. Other 21. Adverse Event 22. Biography	Yes
11) Status	Will list the status for the Attachment: 3. Incomplete 4. Complete	
12) Contact Name	Will be used to capture the name of the person to contact about the attachment.	
13) Uploaded By	This field displays the User ID of the user who uploaded the attachment.	
14) Email	Will be used to capture the email address of the person to contact about the attachment.	
15) Phone	Will be used to capture the phone number of the person to contact about the attachment.	
16) Comments	Will be used to capture summary comments about the attachment.	

Data Quality	SOP Definition / Use	Required
17) Description	Will be used to capture the description of the attachment.	Yes
18) File Name	Will be used to capture the name of the attachment file.	Yes
19) Created By	The user name and the time and date the note was posted is set automatically by the system after clicking the add button.	
20) Updated By	The user name and the time and date an existing note was last updated is automatically populated by the system upon save action. For the initial creation of the note, the system populates the same user name and date time stamp in both the Created By and Updated By fields.	
21) Note Topic	Required field to add note, which briefly defines the nature of the note.	Yes
22) Note Text	Required field to add note, where details on the note are entered.	Yes
23) Restricted	This flag field allows you to indicate if the note is generally viewable (unchecked) or restricted to users with the right to view restricted notes.	

G. Protocol Actions Tab

After initial creation, each time the IRB record is updated, the Kuali Coeus system treats this as an **Action**. The available actions are based on previously performed actions, pending action requests, the role of the logged in user, and document status. The figure below illustrates a potential normal flow of protocol actions taken on a newly created Protocol Record.

Submit for Review → Assign to Agenda → Record Committee Decision → Approve Action

FULL BOARD REVIEW

   a.   Submit for Review – **Full Board**

Submit for Review → Assign to Agenda → Record Committee Decision → Approve Action

After the initial creation of the protocol, the first step is to Submit for Review. The following actions should be available:

Make selections for all applicable fields and then click the [submit] button.

Data Quality	SOP Definition / Use	Required
1) Submission Type	Will return from a list the available options for Submission Type.	Yes
2) Submission Review Type	Will return from a list the available options for Submission Review Type. Select Full.	Yes
3) Type Qualifier	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.	
4) Committee	Although not required at this time, if the Committee that is being assigned is known, please select it from this list.	
5) Schedule Date	Based on the committee that is selected in (4), the applicable list of meeting dates will display and can be selected prior to submission.	

Note: No reviewers need to be selected as part of your submission.

After the protocol is submitted, the Status will change to Submitted to IRB and the Submission Status will update to be Submitted to Committee. This can be viewed in the document header in the top right corner.

Status:	Submitted to IRB
Submission Status:	Submitted to Committee

b. Assign to Agenda – **Full Board**

Submit for Review	Assign to Agenda	Record Committee Decision	Approve Action

After the initial submission of the protocol, your available actions should be:

Available Actions

▶ show	**Withdraw Protocol**
▶ show	**Modify Submission Request**
▶ show	**Assign Reviewers**
▶ show	**Assign to Agenda**
▶ show	**Defer Action**
▶ show	**Notify Committee**
▶ show	**Make Administrative Correction**
▶ show	**Return To PI**
▶ show	**Manage Review Comments**
▶ show	**Manage Review Attachments**
▶ show	**Manage Notes (0)**

The Assign to Agenda action submits the protocol to the agenda of the Committee/Schedule in which the IRB Committee will review the protocol. Complete all applicable fields and then click the submit button.

Data Quality	SOP Definition / Use	Required
1) Committee ID, Committee Name, Schedule Date	These will all pre-populate from the Submission Request. If they need to be modified, then the **Modify Submission Request** action would need to be completed prior to this action being taken.	Yes
2) Comments	Open text field to add in any comments about the Agenda assignment	

Data Quality	SOP Definition / Use	Required
3) Action Date	This date pre-populates based on today's date. It should be used to reflect the date it was determined to assign this protocol to the agenda. It can be adjusted as needed	Yes
4) Standard Comment	Select and return a predefined comment from the Protocol Contingency Lookup screen. Click the **lookup** 🔍 icon to search for and return the value to populate the box automatically, or if known, type the value in the box.	
5) Comment	Open text field to provide any information you'd like to include as a Review Comment.	
6) Private	Flag the review comment action request to make it viewable only to the recipient. Click within the **checkbox** ✅ to select the item. A check mark appears within the checkbox to indicate the item is selected. Click within the checkbox again to clear the mark and deselect the item.	
7) Final	Flag the review comment as the last to be entered. Click within the **checkbox** ✅ to select the item. A check mark appears within the checkbox to indicate the item is selected. Click within the checkbox again to clear the mark and deselect the item.	
8) Action	Click the **add** [add] button to add your selection to as a row in the table below, which will become a numbered line item. Click the **delete** [delete] button to remove a previously added line item row from the table. Click the **up/down** arrow [▲] [▼] buttons as necessary to adjust the line item order.	

Note: If you did not select the Committee and Schedule date at the time of initial submission, you will need to go to the **Modify Submission Request** action to populate this information and submit the protocol again.

After the protocol is assigned to an agenda, the Status will remain to be Submitted to IRB and the Submission Status will update to be In Agenda. This can be viewed in the document header in the top right corner.

Status:	Submitted to IRB
Submission Status:	In Agenda

c. Record Committee Decision – **Full Board**

After assigning the protocol to an agenda, your available actions should be:

The Record Committee Decision action allows the IRB Administrator to record the decision of a full committee IRB review for an IRB protocol. The motion types that can be recorded are Approve, Disapprove, Specific Minor Revisions and Substantive Revisions Required. Based on the motion type selected within Record Committee Decision, the system will subsequently present an action panel for Approve, Disapprove, Specific Minor Revisions or Substantive Revisions Required.

Complete all applicable fields and then click the [submit] button.

Data Quality	SOP Definition / Use	Required
1) Motion Type	Will return from a list the available options for Motion Type (Approve, Disapprove, Specific Minor Revisions, Substantive Revisions Required). 💡 The system makes it mandatory to enter at least one review comment for motion types of Disapprove, Specific Minor Revisions or Substantive Revisions Required.	Yes
2) No/Yes counts	These fields can be leveraged to log committee votes.No values are required.	

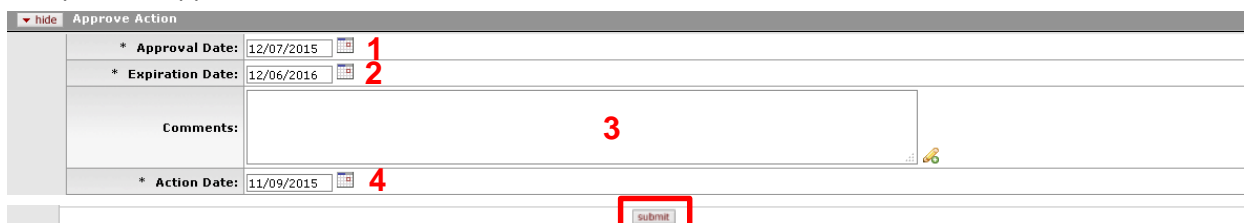| Data Quality	SOP Definition / Use	Required
3) Voting Comments	This is a free text field that can be used to capture comments about the voting.	

After the Record Committee Decision has been submitted for the protocol, the Status will remain "Submitted to IRB" and the Submission Status will remain "In Agenda". This can be viewed in the document header in the top right corner.

Status:	Submitted to IRB
Submission Status:	In Agenda

    d.   Next Action based on Previous Motion Type – **Full Board**

        1)   Approve Action

Complete all applicable fields and then click the [submit] button.

Data Quality	SOP Definition / Use	Required
1) Approval Date	Will be used to specify the date that you want the approval action to become effective. By default the field displays the current, which can be overwritten.	Yes
2) Expiration Date	Will be used to specify the date that the approval will expire. By default the field displays the current, which can be overwritten.	Yes
3) Comments	Will be used to enter textual information to describe this action.	
4) Action Date	Will be used to specify the date that you want this action to become effective.	Yes

After the Approve Action has been submitted for the protocol, the Status will update to "Active – Open to Enrollment" and the Submission Status will update to "Approved". This can be viewed in the document header in the top right corner.

Status:	Active - Open to Enrollment
Submission Status:	Approved

        2)   Disapprove Action

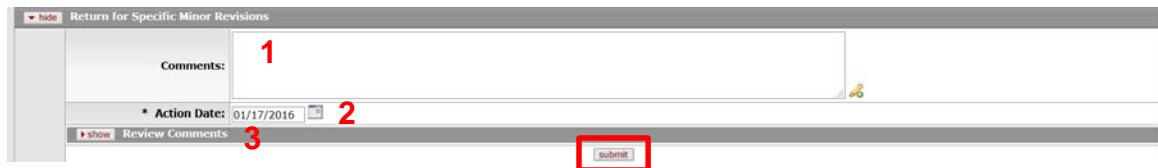Complete all applicable fields and then click the submit button.

Data Quality	SOP Definition / Use	Required
1) Comments	Will be used to enter textual information to describe this action.	
2) Action Date	Will be used to specify the date that you want this action to become effective.	Yes
3) Review Comments	💡 The system makes it mandatory enter at least one review comment for motion types of Disapprove, Specific Minor Revisions or Substantive Revisions Required.	Yes

After the Disapprove Action has been submitted for the protocol, the Status will update to "Disapproved" and Submission Status will update to "Disapproved". This can be viewed in the document header in the top right corner.

3) Specific Minor Revisions

Complete all applicable fields and then click the submit button.

Data Quality	SOP Definition / Use	Required
1) Comments	Will be used to enter textual information to describe this action.	
2) Action Date	Will be used to specify the date that you want this action to become effective.	Yes

Data Quality	SOP Definition / Use	Required
3) Review Comments	💡 The system makes it mandatory enter at least one review comment for motion types of Disapprove, Specific Minor Revisions or Substantive Revisions Required.	Yes

After the Return for Specific Minor Revisions action has been submitted for the protocol, the Status will update to "Specific Minor revisions Required" and Submission Status will update to "Specific Minor Revisions Requested". This can be viewed in the document header in the top right corner.

Status:	Specific Minor Revisions Required
Submission Status:	Specific Minor Revisions Requested

Note: If at least one review comment is included and the Status = Specific Minor Revisions Required, then the protocol will be in edit mode. Changes can be made and the protocol can be resubmitted for review.

4) Substantive Revisions Required

Complete all applicable fields and then click the submit button.

Data Quality	SOP Definition / Use	Required
1) Comments	Will be used to enter textual information to describe this action.	
2) Action Date	Will be used to specify the date that you want this action to become effective.	Yes
3) Review Comments	💡 The system makes it mandatory enter at least one review comment for motion types of Disapprove, Specific Minor Revisions or Substantive Revisions Required.	Yes

After the Approve Action has been submitted for the protocol, the Status will update to "Substantive Revisions Required" and Submission Status will update to "Substantive Revisions Required". This can be viewed in the document header in the top right corner.

Status:	Substantive Revisions Required
Submission Status:	Substantive Revisions Required

Note: If at least one review comment is included and the Status = Substantive Revisions Required, then the protocol will be in edit mode. Changes can be made and the protocol can be resubmitted for review.

EXEMPT

e. Submit for Review – **Exempt**

After the initial creation of the protocol, the first step is to Submit for Review. The following actions should be available:

Make selections for all applicable fields and then click the submit button.

Data Quality	SOP Definition / Use	Required
1) Submission Type	Will return from a list the available options for Submission Type.	Yes
2) Submission Review Type	Will return from a list the available options for Submission Review Type. Select **Exempt**.	Yes
3) Type Qualifier	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.	
4) Committee	Although not required at this time, if the Committee that is being assigned is known, please select it from this list.	

Data Quality	SOP Definition / Use	Required
5) Schedule Date	Based on the committee that is selected in (4), the applicable list of meeting dates will display and can be selected prior to submission.	
6) Checklist (Exempt)	Select one or more reasons as to why the protocol is considered to be Exempt.	Yes

Note: No reviewers need to be selected as part of your submission.

After the exempt protocol is submitted, the Status will change to "Submitted to IRB" and Submission Status will update to "Submitted to Committee". This can be viewed in the document header in the top right corner.

Status:	Submitted to IRB
Submission Status:	Submitted to Committee

f.   Grant Exemption – **Exempt**

After the submission of the exempt protocol, there is the opportunity to Grant Exemption. This action allows the IRB Administrator to grant exemption to submitted protocols that have a protocol review type of Exempt. This indicates that the research project does not have to go through an IRB review.

The following actions should be available:

Make selections for all applicable fields and then click the submit button.

Data Quality	SOP Definition / Use	Required
1) Approval Date	Will be used to specify the date that you want the approval action to become effective. By default the field displays the current, which can be overwritten.	Yes
2) Comments	Will be used to enter textual information to describe this action.	
3) Action Date	Will be used to specify the date that you want this action to become effective.	Yes
4) Review Comments	Optional area to include any review comments associated to the protocol review.	

After the Grant Exemption action is submitted, the Status will change to "Exempt" and Submission Status will update to "Exemption Granted". This can be viewed in the document header in the top right corner.

Note: If the Exempt protocol still needs to go through a Committee Review, follow the steps above b – d to Assign to Agenda, Record Committee Decision and Approve/Disapprove the protocol submission.

g. Submit for Review – **Expedited**

After the initial creation of the protocol, the first step is to Submit for Review. The following actions should be available:

Make selections for all applicable fields and then click the submit button.

Data Quality	SOP Definition / Use	Required
1) Submission Type	Will return from a list the available options for Submission Type.	Yes
2) Submission Review Type	Will return from a list the available options for Submission Review Type. Select **Expedited**.	Yes
3) Type Qualifier	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.	
4) Committee	Although not required at this time, if the Committee that is being assigned is known, please select it from this list.	
5) Schedule Date	Based on the committee that is selected in (4), the applicable list of meeting dates will display and can be selected prior to submission.	
6) Checklist (Expedited)	Select one or more reasons as to why the protocol is considered to be Expedited.	Yes

Note: No reviewers need to be selected as part of your submission.

After the expedited protocol is submitted, the Status will change to "Submitted to IRB" and the Submission Status will update to "Submitted to Committee". This can be viewed in the document header in the top right corner.

Status:	Submitted to IRB
Submission Status:	Submitted to Committee
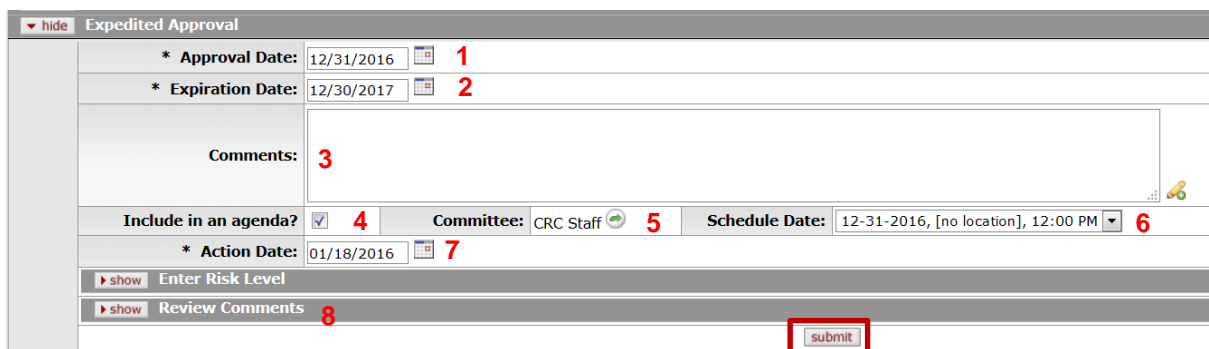
h. Expedited Approval – **Expedited**

After the submission of the expedited protocol, there is the opportunity to grant Expedited Approval in one step. This action allows approval of protocols of a review type Expedited. An expedited review of a protocol allows review of proposed human participant research by the IRB chair or a designated voting member or group of voting members rather than by the entire IRB.

The following actions should be available:

Make selections for all applicable fields and then click the submit button.

Data Quality	SOP Definition / Use	Required
1) Approval Date	Will be used to specify the date that you want the approval action to become effective. By default the field displays the current, which can be overwritten.	Yes

Data Quality	SOP Definition / Use	Required
2) Expiration Date	Will be used to specify the date that the approval will expire. By default the field displays the current, which can be overwritten.	Yes
3) Comments	Will be used to enter textual information to describe this action.	
4) Include in an agenda?	Check the box if you want the expedited protocol to be included within the agenda for an IRB full board review meeting. To remove it from the agenda, uncheck the box.	
5) Committee	The system auto-populates the committee that the protocol is assigned to. To perform expedited review the system requires assignment to a committee. This field is available in read-only mode. Note: In order to change the committee selection, you would need to perform the Modify Submission Request action prior to this submission.	
6) Schedule Date	Select the meeting date you want the expedited approval to be added to the meeting agenda.	
7) Action Date	Will be used to specify the date that you want this action to become effective.	Yes
8) Review Comments	Optional area to include any review comments associated to the protocol review.	

After the Expedited Approval action is submitted, the Status will change to Active – Open to Enrollment and the Submission Status will update to be Approved. This can be viewed in the document header in the top right corner.

Status:	Active - Open to Enrollment
Submission Status:	Approved

Note: If the Exempt protocol still needs to go through a Committee Review, follow the steps above b – d to Assign to Agenda, Record Committee Decision and Approve/Disapprove the protocol submission.

i.   Submit for Review – **Limited/Single Use**

After the initial creation of the protocol, the first step is to Submit for Review. The following actions should be available:

Make selections for all applicable fields and then click the submit button.

Data Quality	SOP Definition / Use	Required
1) Submission Type	Will return from a list the available options for Submission Type.	Yes
2) Submission Review Type	Will return from a list the available options for Submission Review Type. Select **Limited/Single Use**.	Yes
3) Type Qualifier	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.	
4) Committee	Although not required at this time, if the Committee that is being assigned is known, please select it from this list.	
5) Schedule Date	Based on the committee that is selected in (4), the applicable list of meeting dates will display and can be selected prior to submission.	

Note: No reviewers need to be selected as part of your submission.

After the Limited/Single Use is submitted, the Status will change to "Submitted to IRB" and the Submission Status will update to "Submitted to Committee". This can be viewed in the document header in the top right corner.

Note: Follow the steps above b – d to Assign to Agenda, Record Committee Decision and Approve/Disapprove the protocol submission.

j. Submit for Review – **IRB Review Not Required**

After the initial creation of the protocol, the first step is to Submit for Review. The following actions should be available:

Available Actions
- ▸show **Submit for Review**
- ▸show **Delete Protocol, Amendment, or Renewal**
- ▸show **Close**
- ▸show **Manage Notes (0)**

Make selections for all applicable fields and then click the submit button.

▾hide **Submit for Review**

* Submission Type:	Initial Protocol Application for Approval ▾ **1**	* Submission Review Type:	IRB Review not required ▾ **2**
Type Qualifier:	select ▾ **3**		
Committee:	CRC Staff ▾ **4**	Schedule Date:	12-31-2016, [no location], 12:00 PM ▾**5**
Reviewers:			

submit

Data Quality	SOP Definition / Use	Required
1) Submission Type	Will return from a list the available options for Submission Type.	Yes
2) Submission Review Type	Will return from a list the available options for Submission Review Type. Select **IRB Review not required**	Yes
3) Type Qualifier	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.	
4) Committee	Although not required at this time, if the Committee that is being assigned is known, please select it from this list.	
5) Schedule Date	Based on the committee that is selected in (4), the applicable list of meeting dates will display and can be selected prior to submission.	

Note: No reviewers need to be selected as part of your submission.

After the IRB Review Note Required is submitted, the Status will change to "Submitted to IRB" and the Submission Status will update to "Submitted to Committee". This can be viewed in the document header in the top right corner.
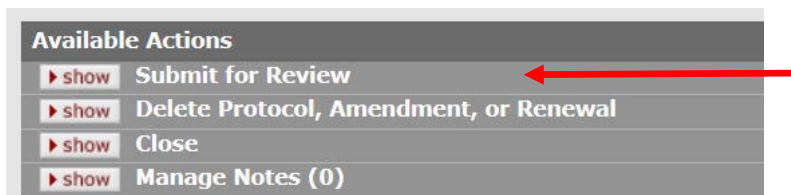
| Status:	Submitted to IRB
Submission Status:	Submitted to Committee

Note: Follow the steps above b – d to Assign to Agenda, Record Committee Decision and Approve/Disapprove the protocol submission.

k. Review Not Required – **IRB Review Not Required**

After the submission of the IRB Review Not Required protocol, there is the opportunity to grant note that Review is Not Required for the protocol in one step. This action allows the IRB Administrator to designate the IRB protocol to NOT require an IRB review. The nature of research is such that it does not constitute research with human subjects. Some investigators need documentation that the IRB office has evaluated and determined that a project does not need research with human subjects, and this option provides a method for such documentation.

The following actions should be available:

Available Actions

▸ show	**Withdraw Protocol**
▸ show	**Modify Submission Request**
▸ show	**Assign Reviewers**
▸ show	**Assign to Agenda**
▸ show	**Defer Action**
▸ show	**Notify Committee**
▸ show	**Make Administrative Correction**
▸ show	**Return To PI**
▸ show	**Review Not Required**
▸ show	**Manage Review Comments**
▸ show	**Manage Review Attachments**
▸ show	**Manage Notes (0)**
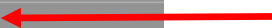
Make selections for all applicable fields and then click the [submit] button.

Data Quality	SOP Definition / Use	Required
1) Decision Date	Will be used to specify the date that you want the decision action to become effective. By default the field displays the current, which can be overwritten.	Yes
2) Comments	Will be used to enter textual information to describe this action.	
3) Action Date	Will be used to specify the date that you want this action to become effective.	Yes

After the Review Not Required action is submitted, the Status will change as show below in the document header top right corner.
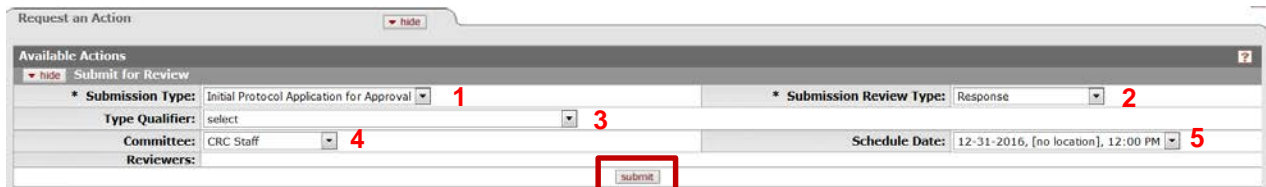

Note: If the Exempt protocol still needs to go through a Committee Review, follow the steps above b – d to Assign to Agenda, Record Committee Decision and Approve/Disapprove the protocol submission.

l.   Submit for Review – **Response**

After the initial creation of the protocol, the first step is to Submit for Review. The following actions should be available:

Make selections for all applicable fields and then click the [submit] button.

Data Quality	SOP Definition / Use	Required
1) Submission Type	Will return from a list the available options for Submission Type.	Yes
2) Submission Review Type	Will return from a list the available options for Submission Review Type. Select **Response**.	Yes
3) Type Qualifier	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.	
4) Committee	Although not required at this time, if the Committee that is being assigned is known, please select it from this list.	
5) Schedule Date	Based on the committee that is selected in (4), the applicable list of meeting dates will display and can be selected prior to submission.	

Note: No reviewers need to be selected as part of your submission.

After the Response is submitted, the Status will change as show below in the document header in the top right corner.

Status:	Submitted to IRB
Submission Status:	Submitted to Committee

m. Response Approved – **Response**

After the submission of the "Response" , there is the opportunity to Approve Response for the protocol in one step. This action allows the IRB Administrator to approve a protocol re-submission that is a response to revisions requested by the IRB office. When investigators make requested changes and re-submit a protocol an institution may decide that it does not require a full committee review again. The Response Approval action allows the IRB Administrator to grant an approval to the protocol in such a scenario.

Make selections for all applicable fields and then click the submit button.

Data Quality	SOP Definition / Use	Required
1) Approval Date	Will be used to specify the date that you want the approval action to become effective. By default the field displays the current, which can be overwritten.	Yes
2) Expiration Date	Will be used to specify the date that the approval will expire. By default the field displays the current, which can be overwritten.	Yes
3) Comments	Will be used to enter textual information to describe this action.	
4) Action Date	Will be used to specify the date that you want this action to become effective.	Yes

After the Response Approval has been submitted for the protocol, the Status will change as show below in the document header in the top right corner.

   n. Submit for Review – **FYI**

After the initial creation of the protocol, the first step is to Submit for Review. The following actions should be available:

Make selections for all applicable fields and then click the [submit] button.

Data Quality	SOP Definition / Use	Required
1) Submission Type	Will return from a list the available options for Submission Type.	Yes
2) Submission Review Type	Will return from a list the available options for Submission Review Type. Select **FYI**.	Yes
3) Type Qualifier	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.	
4) Committee	Although not required at this time, if the Committee that is being assigned is known, please select it from this list.	
5) Schedule Date	Based on the committee that is selected in (4), the applicable list of meeting dates will display and can be selected prior to submission.	

 Note: No reviewers need to be selected as part of your submission.

After the FYI is submitted, the Status will change as show below in the document header in the top right corner.

Status:	Submitted to IRB
Submission Status:	Submitted to Committee

Note: Follow the steps above b – d to Assign to Agenda, Record Committee Decision and Approve/Disapprove the protocol submission.

H. 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 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

Available Actions Subsection	Summarized Usage Description
	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.
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.

Available Actions Subsection	Summarized Usage Description
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.
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.