

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
a	•	Find the protocol for which you'd like to create the amendment
b		Go to Protocol Actions tab4
c	•	Create the amendment
d	•	Modify the protocol record based on the needs of the amendment
e	•	Submit amendment for review
B.	(Create a Renewal (Continuing Review)7
b		Go to Protocol Actions tab
c	•	Create the Renewal
d		Submit renewal for review10
C.]	Log an event11
a	•	Find the protocol
b		Go to Protocol Actions tab
c	•	Notify IRB
d	•	IRB Acknowledgement14
D.]	Reference - Available Actions Descriptions



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.

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COEUS COEUS COEUS COEUS	ait Central Admin Maintenance System Admin		(OracleS)
action list doc search		Logged in User: Jiking	Login Logou
Pre-Award	Pre-Submission Compliance	Quicklinks	
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	Animais Human Participantis Post.Submission Compliance	Propie Flow Professional Routine Report Subda Routine Seport Subda	
	IRB Committee S IACUC Committee S Protocol Submissions S IACUC Submissions S IRB Schedules S	Business Rules Agenda Context Automac Definition Attribute Definition Term Specification Context Context Context	

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

Protocol #:	
Protocol Type:	•
Protocol Status:	select
CRC Protocol Number:	3765*
Title:	
Summary/Keywords:	
Initial Submission Date From:	
Initial Submission Date To:	
Expiration Date From:	
Expiration Date To:	
Approval Date From:	
Approval Date To:	
Last Approval Date From:	
Last Approval Date To:	
Investigator:	
Key Person:	
Area of Research:	<u> </u>
Funding Source:	
Performing Organization:	۹
Unit Number:	
Unit Name:	
Active:	🔘 Yes 🔘 No 🖲 Both
search	ear cancel





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



One item retrieved.

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.

Action	. 1	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
edit copy	view 1	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 optic	Exoninem seconds Export options: CSV_1 spreadsheet, I XM_													

b. Go to Protocol Actions tab

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

action list						Logged in Use	er: jlking	Legin
Protocol 👔						Id: 384237 ed: dhaywood : 06:54 PM 02/09/2016 e: 1602006690		Active - Open to Approved
ocol Personnel Questionnaire Custom Data Special	Review Permissions	Notes & Attachments	Protocol Actions 2	Protocol History	Medusa		CAPITURE DUCE.	
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Required Fields for Saving Document Protocol Type: Exempt						CAS POLITICAL SCIENCE	28	E
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Required Fields for Saving Document Protocol Type: Title: The Efficasy or Candidate Im Status & Dates Additional Information	nage Settings 🔿					CAS POLITICAL SCIENCE	2	5

c. Create the amendment

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



uali								
COEUS # Research	er Unit Central Admin	Maintenance Syste	m Admin					/ (Oracle
action list						Logged in User	: jiking	Login Logi
Protocol					Document Id:	384237	Status:	Active - Open to Enrol
Protocol 👔						: dhaywood : 06:54 PM 02/09/2016		Approved
					Protocol #:	1602006690	Expiration Date:	
otocol Personnel Questionnair	Custom Data Special F	Review Permissions	Notes & Attachments	Protocol Actions	Protocol History	Medusa		
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Request an Action 2		- hide						11
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Available Actions		- Nde						2
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Available Actions		₩N0E	_		-		_	2
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Available Actions Psilow Notify IRB Notify IRB Net Amendment	4	• Nde		-	🗐 Add/Modify Notes 8			2
Available Actions Psilow Notify IRB Notify IRB Net Amendment	4 General Info	V NOC			Add/Modfy Notes 8			2 2 2
Available Actions Psilow Notify IRB Notify IRB Net Amendment	4 General Info Funding Source		5		Areas of Research		-	8
Available Actions b Store Kotify TRB while Create Amendment * Summary:	4 General Info		5		Areas of Research		-	17 17
Available Actions Psilow Notify IRB Notify IRB Net Amendment	4 General Info Funding Source Protocol References & Othe		5		Areas of Research Special Review		_	17 17
Available Actions b Store Kotify TRB while Create Amendment * Summary:	4 General Info Funding Source Protocol References & Othe Protocol Organizations		5		Areas of Research Special Review Protocol Personnel			
Available Actions b Store Kotify TRB while Create Amendment * Summary:	4 General Info Funding Source Protocol References & Othe		5		Areas of Research Special Review			2

Data Quality	SOP Definition / Use	Required
4) Summary	Enter a description that describes why the amendment is	Yes
	being requested	
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.	Yes
	Note: Always select "Others" as this will allow you to update the Custom Data tab to complete your tracking dates.	
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.

Protocol action Create Amendment successfully completed.

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 &	Protocol > Additional Information > Additional Information
Other Identifiers	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 &	Notes & Attachments tab
Attachments	
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.

otocol	Personnel (Juestionnaire	Custom Data	Special Review	Permissions	Notes & Attachments	Protocol Actions 1	Protocol Histor	/ Medusa	
Docum	nent was successf	ully saved.								
Req	uest an Action	2		✓ hide	2					
Avai	ilable Actions	_	_	_	_	_	_	_	_	_
Distances in the local distance in the local	hide Submit for	Review 3								
	* Submiss	ion Type: Am	nendment 💌 🕴 4				* Submission	Review Type:	Full	
	Туре	Qualifier: sel	ect			6				
	Co	mmittee: CR	C IRB	• 7			:	Schedule Date:	03-15-2016, C	RC, 12:00 PM
	D	eviewers: CY	NTHIA MONAHAN		6	select				
	150									



Data Q	uality	SOP Definition / Use	Required
4)	Submission Type	This field will return from a list the available options for	Yes
		Submission Type.	
5)	Submission	This field will return from a list the available options for	Yes
	Review Type	Submission Review Type.	
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.

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action list. (a) doc search Logged in User: jlking							
Pre-Award	Pre-Submission Compliance	Quicklinks					
Proposal Development	Conflict of Interest Disclosure Event Disclosure Non Project Event Disclosures Submitted Disclosures Annual Event Disclosures Undisclosed Events	KC: Pessimistic Lock Current. 8. Pending Support Ganta, or Opportunity Lockup Address. Book Spensor: Lockup Change Password Change Fassword Change Change Change Self Signal Lockup Second Lockup Lockup Second Lockup Lockup Second Lockup Lockup					
Awards O S Award Report Tracking S Subawards O S	Open and In Progress Disclosures S Person Search S Protocols	Subcontracting expenditures data generator admin Workflow					
	Animals Q Q Human Participants Q Q Post-Submission Compliance	People Flow Preferences Souting Report Suides Review Review Review					
	IRB Committee	Business Rules					
	IACUC Committee S Protocol Submissions S IACUC Submissions S IRB Schedules S	Agenda Context Agenda Context Attribute Definition Errm Term Specification					



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

Protocol #:	
Protocol Type:	•
Protocol Status:	select
CRC Protocol Number:	3765*
Title:	
Summary/Keywords:	
Initial Submission Date From:	
Initial Submission Date To:	
Expiration Date From:	
Expiration Date To:	
Approval Date From:	
Approval Date To:	
Last Approval Date From:	
Last Approval Date To:	
Investigator:	
Key Person:	
Area of Research:	<u> </u>
Funding Source:	
Performing Organization:	<u> </u>
Unit Number:	
Unit Name:	
Active:	🔍 Yes 🔍 No 🔍 Both
search	ear cancel



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 retrieve	e 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
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		CAS POLITICAL SCIENCE	Yes
Export options: C	SV spreads	heet XML											

b. Go to Protocol Actions tab

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



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action list () doc search						Logged in U	1	
Protocol						ant Id: 384237 dated: dhaywood : 06:54 PM 02/09/2016		Active - Open to E
						col #: 1602006690	Expiration Date:	Approved
ntocol Personnel Questionnaire Custom Data Special Review	Permissions	Notes & Attachments	Protocol Actions	Protocol History	Medusa			
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Required Fields for Saving Document Required Fields for Saving Document Protocol Type: Exempt Title: The Efficasy or Candidate Image Set Status & Dates Additional Information	trings * show show					AN CAS POLITICAL SCIENCE		

c. Create the Renewal

Once in the Protocol Action tab, click the **I** 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.

Request an Action 1 Available Actions Distant Notify IRI	• hite		
Show Create Amendment	dment <mark>2</mark>		
* Summary:	3	-6	
4 *Amend:	General Info Funding Source Protocol References & Other Identifiers Protocol organizations Subjects Questionnaire	Add/Modify Notes & Attachments Areas of Research Special Review Protocol Personnel Others	

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



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.

Protocol action Create Renewal with Amendment successfully completed

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.



Protocol Personnel Question	aire Custom Data	Special Review	Permissions	Notes & Attachments	Protocol Actions	Protocol History	Medusa	
					1			
 Document was successfully saved. 					•			
 Document was successfully saved. 								expand all collapse all
								* required field
								?
Request an Action 2		✓ hide	<u> </u>					
Available Actions								2
▼ hide Submit for Review 3								
* Submission Type:	Continuing Review/Cont	inuation without Ame	endment 💌 4			* Submi	ssion Review T	ype: Full 💌 5
Type Qualifier:	select			▼ 6				
Committee:	CRC IRB] 7					Schedule D	ate: 03-15-2016, CRC, 12:00 PM 🔻 8
Reviewers:	CYNTHIA MONAHAN		select	•				
				submit				

Data Q	uality	SOP Definition / Use	Required
4)	Submission Type	This field will return from a list the available options for	Yes
		Submission Type.	
5)	Submission	This field will return from a list the available options for	Yes
	Review Type	Submission Review Type.	
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



	t Central Admin Maintenance System Admin	(Orade)
action list () doc search		Logged in User: jiking
Pre-Award	Pre-Submission Compliance	Quicklinks
Proposal Development © S Proposal Log © S Institutional Proposal © S Negotations © S All My Negotations Post-Award Award Report Tracking S Subawards © S	Conflict of Interest Disclosure © Event Disclosures © Submitted Disclosures © Annuä Event Disclosures © Undisclosed Events © Open and In Progress Disclosures © Person Search © Protocols	Kc Pessimistic Lock Current & Amedian Support Grants apro Opportunity Lookup Address Book Sonoso: Lookup Change Password Kerword Lookup Perform Person Mass Change IsSVSSR Reporting Award subcontracting posts and expenditures Subcontracting expenditures data generator admin Workflow
	Animals Human Partsopants 2 Post-Submission Compliance	People.Flow Proferences Souting Report Subdis Subdis Subdis
	IRB Committee O S	
	IACUC Committee	Business Rules

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

Protocol #:	
Protocol Type:	-
Protocol Status:	select
CRC Protocol Number:	3765*
Title:	
Summary/Keywords:	
Initial Submission Date From:	
Initial Submission Date To:	
Expiration Date From:	
Expiration Date To:	
Approval Date From:	
Approval Date To:	
Last Approval Date From:	
Last Approval Date To:	
Investigator:	
Key Person:	
Area of Research:	<u> </u>
Funding Source:	
Performing Organization:	<u>()</u>
Unit Number:	
Unit Name:	
Active:	🔘 Yes 🔘 No 🔍 Both
search cle	ear cancel



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.

1 Jype Active Open to The Efficacy or Candidate Image Date Date Date Date Open CHELSEA ANN CAS POLITICAL	One item retrieve	item retrieved.												
set sopy view 1602006609 [Exempt] Active - Open to The Efficacy or Candidate Image 03/16/2015 04/02/200000000000000000000000000000000	Actions	Protocol #		Protocol Status	Title	Summary/Keywords					Investigator	Lead Unit	Lead Unit Name	Active
	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.

action list 💮 doc search								Logged in Use	er: ilking	Login L
							Documen	t Id: 394237		Active - Open to En
Protocol 🦷								ted: dhaywood : 06:54 PM 02/09/2016		
							Protoc	e: 1602006690	Expiration Date:	
tocol Personnel Questionnaire	Custom Data	Special Review	Permissions	Notes & Attachments	Protocol Actions	Protocol History	Medusa			
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Required Fields for Saving Docur Protocol Type:	nent Exempt	_	2000	<u>.</u>		_	Principal Investigator	CHELSEA ANN ABDALLA		Ð
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Required Fields for Saving Docur Protocol Type: Title:	nent Exempt	lidate Image Setting	Θ	L				CAS POLITICAL SCIENCE	2	8
Required Fields for Saving Docur Protocol Type: Title: Status & Dates	nent Exempt	lidate Image Setting	ys ⊕ → show					CAS POLITICAL SCIENCE	2	8
Required Fields for Saving Docur Protocol Type: Title: Status & Dates Additional Information	nent Exempt	lidate Image Setting	ps 🛞 + show + show					CAS POLITICAL SCIENCE	2	

c. Notify IRB

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



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

ocument was successfully ap otocol action Full Approval s					expand all collap:
Request an Action 2	▼ hide				
Available Actions					
▼hide Notify IRB 3					
Details					
Submission Type Qualif	ier: Modification/Amendment/Revisions/Sign	ificant New Finding 💽 🛃	* Submission Review Type:	FYI 💌 5	
Commit	tee: select 💌 6		Comment:	7	a i:.
Attachments					
	Attachment		Descriptio	n	Actions
Add:	Browse_ No file selected. 7	8	ه ^{بن}	8	add
			ubmit		
			10		

Data Quality	SOP Definition / Use	Required
4) Submission Type	This field will return from a list the available options for	
Qualifier	Type Qualifier. This field should be used to describe the	
	type of 'event' that is taking place.	
5) Submission	For Events, this will default to FYI.	Yes
Review Type		
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 **base** buttons to expand the 2) Request an Action panel and 3) IRB Acknowledgement sub-panel.

1



Protocol	Personnel	Questionnaire	Custom Data	Special Review	Permissions	Notes & Attachments	Protocol Actions	Protocol History	Online Review	Medusa
 Protocol 	action Modify	Submission Request	successfully comp	leted.						
										expand all collapse all
Reque	est an Action	_		▼ hide						
		2								
	able Actions									?
		bmission Reques								
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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
<mark>6)</mark> 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.