This guide shows the Kuali system steps to create and submit an Amendment Request for a Converted (Migrated) Protocol.

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IMPORTANT: For converted (migrated) protocols, as noted on the Amendment Request form, changes beyond personnel changes will require you to complete the entire Kuali IRB application form in order to fully capture the details of the study into the Kuali system. The completion of the full Kuali form will only need to be done one time upon the first amendment request (beyond study personnel). Future amendments will allow you to directly update the Kuali form sections.

Access Previously Approved Documents

Submitting the Amendment Request as PI

Routing to Principal Investigator/Faculty Advisor

Personnel ONLY Changes Amendment Requests

Submitting Amendment After Receiving Notification to Submit

Updating Study Personnel

### Sections in this guide:

- Access Kuali Protocols
- Locate Existing Approved Protocol
- **Create an Amendment**
- Fill Out the Amendment Form
- Update the Protocol
- Unlocking Protocol Sections

### Access Kuali Protocols

• Direct Link:

https://ucr.kuali.co/protocols/portal/protocols You will be prompted to enter your UCR NetID and password.

PLEASE NOTE: The Amendment Request can be filled out by students or other members of the research team. However, formal submission to the IRB must be done by the listed Principal Investigator or Faculty Advisor.

### Locate Existing Approved Protocol

Once logged in, you will be directed to the 'Manage Protocols' page.

Your existing IRB and IACUC (AUP) protocols, if any, will be listed on this page.

Locate the IRB protocol you would like to amend. The 'Status' must either be 'Approved' or 'Exempt'.









Click on the **Title**.



### **Create an Amendment**

In the right-side menu, you will have the actions available for this protocol.

Click on 'Amend'.

NOTE: You are also able to request an amendment when submitting your renewal by clicking on '**Renew &** Amend'. Please note that because these requests, Renewal and Amendment, are submitted together, approval must also be processed together. Therefore, any delays in reviewing one request, such as the amendment, will result in delays for approving the renewal.

If selecting 'Renew & Amend', the Amendment procedures outlined in this guide still apply in addition to completing questions for the Renewal.

An **Amendment Creation** window will pop up.

The sections available are limited to what is currently available in the limited converted record.

← Back Manage Prot	ocols $ ightarrow$ IRB: #300	16 Converted Protoco	Example		
	Protocol Reporta	able Events Activity Log	Permissions		
Jump to:	IRB: #30016	Converted Protoco	l Example		Amend
Project Basics       General Information       Study Personnel	Selected Version: 1   Initial   Approved			×	<ul> <li>Renew &amp; Amend</li> <li>Action Items Summary</li> <li>Admin Notes &amp; Files</li> </ul>
Supporting Information 🗸 Data Conversion Fields	Protocol Inform	ation		Show Less 🔨	→ Request Close □ Duplicate as New
Administrative Details	Review Type <b>Expedited</b>	Status Approved	Approval Date Jul 20, 2023	Continuing Review Date	🖶 Print
Determinations	Expiration Date	Initial Approval Date	Initial Review Type		•

Amendment Creation	1	
	Which sections would you like to amend?	
	To prevent other people in the system from making changes while you are, please sections you need to amend.	select the
	<ul> <li>Project Basics / Study Personnel</li> <li>General Information</li> </ul>	
DO NOT SELEC	<ul> <li>Supporting Information</li> <li>Data Conversion Fields</li> </ul>	
	Cancel	Done



If you will be making changes to beyond personnel changes, please check the 3 sections: Project **Basics/Study Personnel, General** Information and Supporting Information.

**Do not** select Data Conversion Fields.

Click 'Done'.



For <b>Personnel <u>Only</u> changes</b> , select	Amendment Creation
' <b>Project Basics / Study Personnel</b> '. <b>Do not</b> select Data Conversion Fields. Click ' <b>Done'</b> .	Which sections would you like to amend? To prevent other people in the system from making changes while you are, please select the sections you need to amend.
For the remaining steps in Personnel Only Amendment Requests, skip to the <u>'Personnel</u> <u>Only Amendment' section</u> .	<ul> <li>Project Basics / Study Personnel</li> <li>General Information</li> <li>Supporting Information</li> <li>Data Conversion Fields</li> </ul>
	Cancel Done



A new protocol version will be created for the Amendment.

NOTE: These protocol versions will continue accumulate as actions are taken on the protocol (e.g., additional amendments, renewals). When making future amendments, you want to ensure you are selecting the latest approved version of the protocol to update.

Back Manage Prote	$0$ cois $\rightarrow$ IRB: #30016 Converte	a Protocol Example				
	Protocol Reportable Events A	ctivity Log Permissions				
Jump to: Amendment Project Basics	IRB: #30016 Converted Selected Version: 2   Amendment   In Progress (Project Basi	Protocol Example	ig Information)	🗲 Active 👻		Add/Remove Section Notify PI To Submit Admin Notes & Files Abandon
General Information						 ▲ Submit
Study Personnel 😯	Protocol Information			Show Less 🔨	(	Duplicate as New
Data Conversion Fields	Submission Type Amendment	Status In Progress	Approval Date	Continuing Review Date		
Administrative Details Determinations	Expiration Date	Initial Approval Date Jul 20, 2023	Initial Review Type Expedited			
	Amendment					
		UCR AMENDMEN	T REQUEST FORM			
	All changes to an approved research immediate, apparent hazard to a stud	study must be submitted and approved by the y participant.	IRB prior to implementation, except when the	ose changes are necessary to avoid an		
	PLEASE NOTE: For changes beyond p for the system to fully capture all the	personnel changes in a converted (migrated) p details of the study.	rotocol, you will be required to complete the	entire Kuali application form in order		
	Researchers must complete the form original approved application as well	with the details of the currently approved pro as any approved amendments are readily avai	cedures, as well as the requested changes. I lable for your reference as you complete the	t is strongly recommended that the form.		
	For additional information and guida	nce on how to proceed with completing an am	endment on a converted (migrated) record, p	lease visit the Kuali IRB Training	-	

You can toggle through protocol versions using the drop down.

Click on the drop down arrow, and select the version you would like to view.

IRB: #30016 Converted Protocol Example	
Selected Version: 2   Amendment   In Progress (Project Basics, General Information, Study Personnel, Support 2   Amendment   In Progress (Project Basics, General Information, Study Personnel, Support	rting Information)
1   Initial   Approved	Show Less 🔨



The different sections of the form are listed on the left-side menu (highlighted in ORANGE). Using the left-side menu, you can navigate to each section by click on its name.

The body of the form (highlighted in GREEN) allows you to scroll through the entire form.

In the right-hand menu (highlighted in BLUE) researchers will have access to the functions:

- Notify PI to Submit available if the submitter is not the listed PI or Faculty Advisor
- Submit official submission to the IRB office; only available to the listed PI or Faculty Advisor
- Abandon Cancels the submission. Protocols • that are abandoned before submission cannot be edited, but can be viewed as read-only.
- Duplicate as New Create a copy of the ٠ protocol to use as a new submission
- Print •

← Back Manage P	rotocols $\rightarrow$ IF	RB: #30016 Convert	ed Protocol Example				
	Protocol	Reportable Events	Activity Log Permissions			_	
np to:	IRB: #	30016 Converted	d Protocol Example			Î	Add/Remove Section
mendment	Selected	Version:				ſ	Admin Notes & Files
roject Basics	2   Amend	ment   In Progress (Project Ba	sics, General Information, Study Personnel, Supporti	ing Information)	🗲 Active 👻	•	Abandon
eneral Information						1	Submit
tudy Personnel	Drotooo	Information			Chaw Loop A	ſ	Duplicate as New
Supporting Information	FIOLOCO	information			Show Less X	ē	Print
Data Conversion Fields	Submissio	on Type	Status	Approval Date	Continuing Review Date	15	
		incirc.	III Flogicoo				
ministrative Details	Expiration	Date	Initial Approval Date	Initial Review Type			
Determinations	-		Jul 20, 2023	Expedited			
	Amend	ment					
			UCR AMENDMEN	IT REQUEST FORM			
	All chan immedia	ges to an approved researcl ate, apparent hazard to a stu	h study must be submitted and approved by the udy participant.	e IRB prior to implementation, except when th	hose changes are necessary to avoid an	L	
	PLEASE for the s	NOTE: For changes beyond system to fully capture all th	personnel changes in a converted (migrated) ne details of the study.	protocol, you will be required to complete th	e entire Kuali application form in order		
	Researd original	hers must complete the for approved application as we	m with the details of the currently approved pr Il as any approved amendments are readily ava	ocedures, as well as the requested changes. ailable for your reference as you complete th	It is strongly recommended that the ne form.		
	For add	tional information and guid	ance on how to proceed with completing an an	nendment on a converted (migrated) record,	please visit the Kuali IRB Training	-	



### Fill out the Amendment Form

The Amendment Request Form will appear as the first section.

**IMPORTANT:** For converted (migrated) protocols, as noted on the Amendment Request form, changes beyond personnel changes will require you to complete the entire Kuali IRB application form in order to fully capture the details of the study into the Kuali system. The completion of the full Kuali form will only need to be done **one time** upon the first amendment request (beyond study personnel). Future amendments will allow you to directly update the Kuali form sections.

As you fill out the form, the system will auto save. You will see a 'Save Complete' pop up.

**IMPORTANT:** If you plan to exit out of the protocol before submitting to the IRB, please be sure that 'Save Complete' pop up appears on your latest edit before exiting.

		Protocol Reportable Events Activity Log Permissions
ump to:		Amendment
Amendment		UCR AMENDMENT REQUEST FORM
Project Basics	0	All changes to an approved research study must be submitted and approved by the IRB prior to implementation, except when those changes are necessary to avoid an
General Information	0	immediate, apparent hazard to a study participant.
Study Personnel	0	PLEASE NOTE: For changes beyond personnel changes in a converted (migrated) protocol, you will be required to complete the entire Kuali application form in order for the system to fully capture all the details of the study.
Supporting Information	0	Researchers must complete the form with the details of the currently approved procedures, as well as the requested changes. It is strongly recommended that the original approved application as well as any approved amendments are readily available for your reference as you complete the form.
Data Conversion Fields		For additional information and guidance on how to proceed with completing an amendment on a converted (migrated) record, please visit the Kuali IRB Training Videos webpage. You can also submit any questions to irb@ucr.edu.
dministrative Details		
Determinations		Proposed Changes
Seteminations		Please check off only applicable proposed changes
		Changes to Project Roster/Study Personnel
		Changes to procedures or measures
		Changes to participant population
		Changes to recruitment methods
		Changes to compensation or reimbursement
		Change to consent process including changes to consent form document
		Changes to risk-benefit assessment
		Other (Describe below)
		Please provide a brief description of the study, and describe how this amendment is in line with the original aims of the study.
		Click Here to Add Text
		Describe the proposed changes, including the reason for the change. Append all revised documents with the changes bolded or tracked.
		Click Here to Add Text



Identify the proposed changes that will be included in this amendment by checking off the applicable changes.

Provide responses to the amendment questions and include your certification if you are completing the form as the listed Principal Investigator or Faculty Advisor.

### **IMPORTANT:**

For studies that will be led by a researcher who is **NOT** PI eligible, the Certification must be completed by the Faculty Advisor/Sponsor. Similarly, for submissions where a designate (e.g., administrator) is completing the form on behalf of the Principal Investigator, the Certification must be completed by the PI. The system will allow you to leave this check box **blank** as you will need to route the submission to the listed PI / Faculty Advisor.

#### Amendment

immediate, apparent hazard to a study participant.

PLEASE NOTE: For changes beyond personnel changes in a converted (migrated) protocol, you will be required to complete the entire Kuali application form in order for the system to fully capture all the details of the study.

Researchers must complete the form with the details of the currently approved procedures, as well as the requested changes. It is strongly recommended that the original approved application as well as any approved amendments are readily available for your reference as you complete the form.

For additional information and guidance on how to proceed with completing an amendment on a converted (migrated) record, please visit the Kuali IRB Training Videos webpage. You can also submit any questions to irb@ucr.edu.

Please	e check off only applicable proposed changes
$\checkmark$	Changes to Project Roster/Study Personnel
	Changes to procedures or measures
$\checkmark$	Changes to participant population
$\checkmark$	Changes to recruitment methods
	Changes to compensation or reimbursement
	Change to consent process including changes to consent form document
	Changes to risk-benefit assessment
	Other (Describe below)
Please	e provide a brief description of the study, and describe how this amendment is in line with the original aims of the study.
Examp	le description text for amendment
Descri	ibe the proposed changes, including the reason for the change. Append all revised documents with the changes bolded or tracked.
Examp	le description text for proposed changes

# Research and Econo Development

### Kuali IRB Protocols – Amending a Converted (Migrated) Protocol for the First Time

### Update the Protocol

Following the Amendment Certification, you will then be able to update the protocol sections.

**IMPORTANT:** The Project Basics section contains an option for you to indicate if you will be updating the protocol beyond personnel. Once selected, you cannot un-select it.

Once Selected, all sections of the full Kuali IRB Protocol Form will be available for you to complete.

Once selected, additional questions in the Project Basics section will appear, specifically, Submission Type.

Respond to all the new questions.

For Submission Type, select 'IRB Human Subjects Review'.

		Protocol Reportable Events Activity Log Pe	ermissions
Jump to:		Project Basics	0
Amendment	~	Study Title	
Project Basics	0	Converted Protocol Example	
General Information	0	Principal Investigator:	Lead Department:
Study Personnel	0	Greer, Charles E	(D01234) Research Compliance 🛞
Supporting Information	0		
Data Conversion Fields		form. Once selected, this cannot be undone.	dating more than personnel only. Once selected, you will be required to complete the entire Kuali IRB protocol
		○ I am updating my protocol for the first time in the Ku	uali Protocols system
Administrative Details			

Jump to:		Project Basics		Ø
Amendment	~	Study Title		
Project Basics	0	Converted Protocol Example		
General Information	0	Will this study be led by a researcher who is NOT a PI-elic	aible faculty member (e.g., student, postdoc, trainee, visiting professor)?	
Study Personnel	0	Yes	y , , , ,	
Funding		⊖ No		
Supporting Information	0	Principal Investigator:	Lead Department:	
Added Information - Op	otio	Greer, Charles E 🔕	(D01234) Research Compliance 🛞	
Assurance/Acknowled	~ ~			
Data Conversion Fields		The listed Principal Investigator is a PI-eligible UCR empl IMPORTANT: Lead researchers who do not have PI-eligib	loyee per UCR Policy 527-3. Solution in the second s	
		⊖ Yes		
Administrative Details		⊖ No		
Determinations		SUBMISSION TYPE		
		O Not Human Subjects Research (NHSR) Determination	(Formerly Determination of Activity or DOA)	
		IRB Human Subjects Review		
		<ul> <li>Request for External Reliance (i.e., UCR's IRB will rely of</li> </ul>	on another IRB)	
		O [DO NOT USE] Stem Cell Research Oversight (SCRO)		
		IMPORTANT: Only select the below option if you are upda form. Once selected, this cannot be undone.	ating more than personnel only. Once selected, you will be required to complete the entire Kuali IRB	protocol
		I am updating my protocol for the first time in the Kual	li Protocols system	



## When 'IRB Human Subjects Review' is selected, additional protocol sections will appear.

Jump to:		Project Basics	0
Amendment	~	Study Title	
Project Basics	0	Converted Protocol Example	
General Information	0	Will this study be led by a researcher who is NOT	a DLaligible faculty member (e.g. student postdoe trainee visiting professor)?
Study Personnel	0		a Prengible faculty member (e.g., student, postuoc, iranice, visiting professor):
Funding		No	
Study Population		Principal Investigator:	Lead Department:
Research Characteris	tics	Greer, Charles E	(D01234) Research Compliance 🔕
Participant Compensa	ation	The listed Driveinel Investigator is a DL aligible LL	OD ampleure and UOD Daliny 527.2
Screening/Recruitmen	nt	IMPORTANT: Lead researchers who do not have	PI-eligibility <u>must</u> have a UCR Faculty Advisor / Sponsor listed as the PI.
Risks & Benefits		Yes	
Privacy & Confidentia	lity	○ No	
Supporting Informatio	on 🕜	SUBMISSION TYPE	
Added Information - C	Optio	<ul> <li>Not Human Subjects Research (NHSR) Deterr</li> </ul>	mination (Formerly Determination of Activity or DOA)
Assurance/Acknowle	dge	RB Human Subjects Review	
Data Conversion Field	ds	Request for External Reliance (i.e., UCR's IRB)	will rely on another IRB)
		O [DO NOT USE] Stem Cell Research Oversight (	SCRO)
Administrative Details		IMPORTANT: Only select the below option if you form. Once selected, this cannot be undone.	are updating more than personnel only. Once selected, you will be required to complete the entire Kuali IRB protocol
Determinations		I am updating my protocol for the first time in	the Kuali Protocols system



### Unlocking Protocol Sections

As you scroll through the form to these new sections, you will note that they are not immediately available for you to edit.

You will need to unlock any new sections that appear that does not have a **Green Lightning** next to it.

To unlock a section, click on 'Add/Remove Section' in the right-side menu.

The 'Amendment Creation' window will appear with the new sections included.

Check all the sections except Data Conversion Fields.

Click on 'Done'.

Jump to:		Funding	1	Add/Remove Section
Amendment		Choose the option that describes the funding for this project.	Û, I	Notify PI To Submit
	•		0 /	Admin Notes & Files
Project Basics	0		8	Abandon
General Information	0	Study Population	<u></u>	Submit
Study Personnel	0		[] (	Duplicate as New
Funding		Indicate the projected number of participants expected to be enrolled (i.e. sign consent) or the projected number of existing records/data/biospecimens to be accessed/collected/received by UCR Study Team	ē P	Print
Study Population				
Research Characterist	ics	Indicate whether any of the following populations will be specifically recruited:		
		Select all that apply.		
Participant Compensa	tion	Describe the nanulation including all inclusion aritaria		
Screening/Recruitmen	t			
Risks & Benefits				
Privacy & Confidentiali	ty	Research Characteristics		
Supporting Information	n 🚯			
		The research will involve the following. Carefully review then select all that apply or "None of the Above."		





All the sections will now be available for editing (i.e., has a **Green Lightning** next to name).

IMPORTANT: Depending on your responses to certain questions, additional sections may appear, and you will need to unlock those new sections using the 'Add/Remove Section' button.

Complete the protocol ensuring that the details are consistent with the original approved IRB application and any applicable approved amendments.

Researchers are encouraged to have their original approved documents readily available for reference as they complete the Kuali protocol form.

Jump to:	Funding	0
Amendment	Choose the option that describes the funding for this project.	
Project Basics	External to UCR	
General Information	O Gift	
Study Personnel		
Funding	Internal to UCR (e.g. Departmental, Academic Senate)	
Study Population	Other (e.g. Personal Funds, Faculty Advisor Funds)	
Research Characteristi.	Link to Kuali Research Proposal or Award (Effective After July 1st 2023)	
Participant Compensat	None	
Screening/Recruitment		
Risks & Benefits	3	
Privacy & Confidentialit	Study Population	G
Supporting Information Added Information - 0	<ul> <li>Indicate the projected number of participants expected to be enrolled (i.e. sign consent) or the projected number of existing records/data/biospecimens to b accessed/collected/received by UCR Study Team</li> </ul>	e
Assurance/Acknowled.	Click Here to Add Number	
Data Conversion Fields	Indicate whether any of the following populations will be specifically recruited:	
	Select all that apply.	
Administrative Details	Not applicable - No direct contact with research participants	
Determinations	Participants 18 years old or older	
	Participants under the age of 18 (Minors)	
	Wards	
	Pregnant women/human fetuses	
	Neonates	
	Use of Fetal tissue	
	Individuals with Cognitive Impairments	



## Access Previously Approved Documents

Previously approved applications, amendments, and renewals will be uploaded to each migrated record.

You can access these documents by clicking on 'Admin Notes & Files' in the right-side menu of your protocol.

Click on the **file name** you would like to view.

NOTE: If your previously approved documents are not uploaded in the Admin Notes & Files, please contact the IRB Office (irb@ucr.edu). Add/Remove Section
Notify PI To Submit
Admin Notes & F... 1
Abandon
Submit
Duplicate as New
Print

Admin Notes & Files				×
File	Note	Date Added	Added By	
Example Previously Approved IRB Application HS XX-XXX.pdf	Original Approved IRB Application	Jul 27, 2023 12:28 AM	Castro, Lorraine Joy	

Click on 'View Attachment'.

View Note & File	
Example Previously App	roved IRB Application HS XX-XXX.pdf
• View Attachment	
Note	
Original Approved IRB A	oplication
4	



The file will display in a	Example Previously Approved IRB Application HS XX-XXX.pdf	×
document viewer that you can toggle through. You can also download a copy for your records.	<form><form><form><form><form><form><form><form></form></form></form></form></form></form></form></form>	
	← Previous Page Page 1 of Next Page →	► × Close



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### Updating Study Personnel

When updating the '**Study Personnel**' section for the very first time, please ensure that all personnel are listed in the table.

The initial conversion into the Kuali system only allowed the study PI, Lead Researcher and/or Faculty advisor to be listed in the table.

You will need to update the table to ensure that the personnel list matches the list under the Data Conversion Fields.

#### Study Personnel

- List all UCR affiliated personnel conducting the research and provide the requested information.
- Click + Add Line to insert additional personnel.
- 2. Click the Edit Pencil to edit/update personnel info.
- 3. To Change the visibility of the columns, click Columns and select the columns to appear in the table.
- 4. Those listed here should include: Principal Investigator/Faculty Advisor, Co-Investigators, Lead Researcher and Personnel the IRB will need to review who are responsible for research teams and/or will manage research activities at participating sites.
- 5. If a non-study personnel will be an Administrative Contact, please add them to the study by navigating to the Permissions tab at the top of the form.

					Columns + Add Line
		PERSON =	RESEARCHER ROLE	INVOLVED IN	IRB TRAINING =
-	I	Greer, Charles E	Principal Investigator/Faculty Advisor	Obtain consent and/or assent Interact with participants (e.g., administer survey, interview)	() Charles Greer has no training courses on file.
1		Vaughn, Robert Craig	Research Personnel	Obtain consent and/or assent Interact with participants (e.g., administer survey, interview)	Robert Vaughn has no training courses on file.
		Wicker, Monica M	Research Personnel	Obtain consent and/or assent Interact with participants (e.g., administer survey, interview)	Monica Wicker has no training courses on file.
4					

Data Conversion Fields
Converted Renewal Dates
11/28/07; 12/8/08, 12/2/09; 11/29/10; 11/29/11; 11\29/12, 11\29/13
Special Population Categories
None
Transnational?
No
Project Personnel
Vaughn, Robert Craig - 9/26/22 Wicker, Monica 10/4/22

## Research and Economic Development

### Kuali IRB Protocols – Amending a Converted (Migrated) Protocol for the First Time

# Submitting the Amendment as PI

Once the form is complete and you have verified its accuracy, as the listed PI of the protocol, ensure that you have provided your Certification as part of the Amendment Request Form and Assurance as part of the Protocol Form.

When you are ready to submit, click the '**Submit**' button in the right-side menu.

For submissions completed by students, designees, etc., please see the 'Routing to Principal Investigator / Faculty Advisor' section (next page).

After clicking 'Submit', you will remain in the Protocols form. Scroll up to the top and you will see the Status has changed from 'In Progress' to '**Submitted for Review'**.

rotocol	Reportable Events Activity Log Permissions	
Amendr	ment	
CI CI	changes to compensation or reimbursement	
CI CI	change to consent process including changes to consent form document	
CI CI	changes to risk-benefit assessment	
0	ther (Describe below)	
Provide y	your Certification Below	
🔽 A:	as the PRINCIPAL INVESTIGATOR / FACULTY ADVISOR, I confirm that the information within this form is accurate and complete.	
_		

	0	Admin Notes & F
submitting this IRR protocol as Principal Investigator	⊗	Abandon
• I certify that the information provided in this application is complete and correct.		Submit
<ul> <li>I confirm that this study has been designed to protect human participants.</li> </ul>		
· I accept ultimate responsibility for the conduct of this study, the ethical performance of the project, and the protection of the rights and welfare of the human participants who are		Duplicate as Nev
directly and indirectly involved in this project.		Delet
<ul> <li>I will comply with all policies and guidelines of UCR and affiliated institutions where this study will be conducted, as well as with all applicable federal, state and local laws regarding the protection of human subjects in research.</li> </ul>	•	Print
• I will ensure that all personnel performing this study are qualified, appropriately trained and will adhere to the provisions of the IRB approved protocol.		
• I will not modify the UCR IRB-approved protocol or any attached materials without first obtaining UCR IRB approval for an amendment to the previously approved protocol.		
I will provide all continuing review documentation to the IRB.		
<ul> <li>I further confirm that I am not in violation of UCR's conflict of interest policy while participating in this research.</li> </ul>		

IRB: #30016 Converted Protocol Example					
Selected Version: 2   Amendment   Submitted for Review (Project Basics, General Information, Study Personnel, Funding, Study Population, Research Characteristics, Behavioral Observations, Participant Compensation / O					
Protocol Information			Show Less 🔨		
Submission Type Amendment	Review Type 	Status Submitted for Review	Time in Current Status Since July 27 – a few seconds		
Approval Date	Continuing Review Date	Expiration Date	Initial Approval Date Jul 20, 2023		
Initial Review Type Expedited					



From here, click the "Back" button in the top left to return to the **Manage Protocols** page. You will now see your submitted protocol in the Protocol List and its current status.

The status change to '**Submitted for Review**' confirms your protocol has been submitted to the IRB office. You will also receive a confirmation email from the system.

↔ Hide Menu	Protocols						
🕼 Manage Protocols						_	
							ude all protoco
	Q Search						Advanced
							_
	Title	Number 👻	PI Name	Submission Type	Review Type	Status	
	Converted Protocol Example	30016	Greer, Charles E	Initial	Expedited	Approved	
	Converted Protocol Example	30016	Greer, Charles E	Amendment		Submitted for	r Review
	2 of 2 protocols						

### **Routing to Principal Investigator/Faculty Advisor**

For studies that will be led by a researcher who is NOT PI eligible, the Assurance must be completed by the Faculty Advisor/Sponsor.

Similarly, for submissions where a designate (e.g., administrator) is completing the form on behalf of the Principal Investigator, the Assurance must be completed by the PI.

The system will allow you to leave this check box **blank** as you will need to route the submission to the listed PI / Faculty Advisor.

When you are ready to route to the PI, click on '**Notify PI to Submit**' in the right-hand menu.

Assura	nce/Acknowledgement
By subr	nitting this IRB protocol as Faculty Advisor / Sponsor,
• 1	certify that the information provided in this application is complete and correct.
• 1	confirm that this study has been designed to protect human participants.
۰۱ d	accept ultimate responsibility for the conduct of this study, the ethical performance of the project, and the protection of the rights and welfare of the human participants who are irectly and indirectly involved in this project.
• I r	will comply with all policies and guidelines of UCR and affiliated institutions where this study will be conducted, as well as with all applicable federal, state and local laws
• 1	will ensure that all personnel performing this study are qualified, appropriately trained and will adhere to the provisions of the IRB approved protocol.
• 1	will not modify the UCR IRB-approved protocol or any attached materials without first obtaining UCR IRB approval for an amendment to the previously approved protocol.
• 1	will provide all continuing review documentation to the IRB.
• 1	further confirm that I am not in violation of UCR's conflict of interest policy while participating in this research.

Assurance/Acknowledgement		Notify PI To Subr
	ſ	) Admin Notes & F
By submitting this IRB protocol as Faculty Advisor / Sponsor, • I certify that the information provided in this application is complete and correct.	¢	Abandon
<ul> <li>I confirm that this study has been designed to protect human participants.</li> <li>I accept ultimate responsibility for the conduct of this study, the ethical performance of the project, and the protection of the rights and welfare of the human participants who are</li> </ul>	1	Submit
directly and indirectly involved in this project.	ſ	Duplicate as New
regarding the protection of human subjects in research.	e	Print
<ul> <li>I will ensure that all personnel performing this study are qualified, appropriately trained and will adhere to the provisions of the IRB approved protocol.</li> <li>I will not modify the UCR IRB-approved protocol or any attached materials without first obtaining UCR IRB approval for an amendment to the previously approved protocol.</li> </ul>		
I will provide all continuing review documentation to the IRB.		
I further confirm that I am not in violation of UCR's conflict of interest policy while participating in this research.		
□ Lattest to the above statements.		



As the Certification and Assurance sections were left blank, a pop up will appear notifying you of the incomplete field(s).

If additional fields are identified, you can choose to view the fields for verification that they should be left blank.

When you are ready to route to the PI / Faculty Advisor, click '**Notify PI Anyway**' in the pop up.

Once routed to the PI, a pop up will appear stating 'Principal Investigator was notified'.

**IMPORTANT:** After notifying the PI, you will still be in the protocol form, and the form will remain editable. Any changes you may make while the protocol is in the PI / Faculty advisor's queue will appear; however, the changes will **not** be tracked. Researchers must communicate with each other if there are any changes while the protocol is in the 'Notify PI to submit' status.

**PLEASE NOTE:** If you are listed as study personnel with Full Access in the protocol, you will receive the submission confirmation email once the PI / Advisor submits to the IRB.

	There is 1 incomplete required field	×
•	Go back to see the blank fields before sending and we'll Show You what's missing. If you intended to leave these blank, continue to Notify your Principal Investigator Show me Notify PI Anyw	ay

Men accumentation to the mb.

S

Success! Principal Investigator was notified



# Submitting Amendment after receiving Notification to Submit

As the listed Principal Investigator or Faculty Advisor, you will receive an email notification when a protocol submission requires your review and submission to the IRB. You can access the protocol directly using the link provided in the email notification.

**IMPORTANT**: If you do not receive the email notification from Kuali in your inbox, please check your Spam, Junk or Trash folders.

#### Hello Greer, Charles E,

You have been listed as the Principal Investigator on the below IRB protocol. Please use the below link to review/confirm the details of your protocol and submit to the IRB for review.

- Protocol Number: 30016
- Protocol Title: Converted Protocol Example
- Submission Type: Amendment
- Link to Protocol: ucr-stg.kuali.co/protocols/protocols/64c2168bbb30cc0028ea491d

If you have any questions, please contact our office at irb@ucr.edu.

\*\* Note this email is an automated system notification which is unable to receive replies. Please direct all questions and correspondence to irb@ucr.edu.

# The protocol will also be listed in your **Manage Protocols** page.

The status will show as '**In Progress**' as the protocol is not yet submitted.

Access the protocol by clicking on the title.

**NOTE:** For additional actions on an approved protocol (i.e., Amendments or Renewals), you will see all iterations of the protocol.

↔	Hide Menu	Protocols						
ß	Manage Protocols							
							Include all pro	ot
		Q Search					Advan	10
		Title	Number 👻	PI Name	Submission Type	Review Type	Status	
		Converted Protocol Example	30016	Greer, Charles E	Initial	Expedited	Approved	
		Converted Protocol Example	30016	Greer, Charles E	Amendment		😑 In Progress	
		2 of 2 protocols						



	← Back Mana	ge Proto	cols $\rightarrow$ IRB: #30016 Converted Pr	rotocol Example				
As the listed PI or			Protocol Reportable Events Activit	ty Log Permissions				
Faculty Advisor, you will have full editing	Jump to:		IRB: #30016 Converted Pro	otocol Example			*	Add/Remove Section
capabilities in the protocol form.	Amendment	<ul> <li></li> <li></li> </ul>	Selected Version: 2   Amendment   In Progress (Project Basics. Ge	neral Information. Study Personnel. Fundina. Study	v Population. Research Characteristics. Behavioral	Observations. Participant Compensation / Cos	sts. Scre	<ul> <li>Notify PI To Submit</li> <li>Admin Notes &amp; F 1</li> </ul>
	General Information	0		· · · · ·				<ul><li>Abandon</li><li>Submit</li></ul>
Review the	Study Personnel	0	Protocol Information			Show Less	~	Duplicate as New
Amendment Request	Funding	0						🖶 Print
form and completed	Study Population	0	Submission Type	Status	Approval Date	Continuing Review Date		
protocol for	Research Characterist	- 0	Pinonamon	in rogicos				
completeness and	Behavioral Observation	ns 🕜	Expiration Date	Initial Approval Date	Initial Review Type			
accuracy.	Participant Compensa	t <b>(</b> )		Jul 20, 2023	Expedited			
-	Screening/Recruitmen	t <b>()</b>						
	Informed Consent	G						
	Waiver of Signed Cons		Amendment					
	Risks & Benefits	G						
	Privacy & Confidentiali	ty 🕑	All changes to an approved research study	must be submitted and approved by the IRB	prior to implementation, except when those ch	hanges are necessary to avoid an		
	Supporting Information	0	immediate, apparent hazard to a study par					
	Added Information - O.	. 0	PLEASE NOTE: For changes beyond persor system to fully capture all the details of th	nnel changes in a converted (migrated) proto e study.	col, you will be required to complete the entire	e Kuali application form in order for the		
	Assurance/Acknowled	0	Researchers must complete the form with	the details of the currently approved procedu	ıres, as well as the requested changes. It is st	rongly recommended that the original		
	Data Conversion Fields	3	approved application as well as any approv					
	Administrative Details		For additional information and guidance or webpage. You can also submit any questio	n how to proceed with completing an amendn ons to irb@ucr.edu.	nent on a converted (migrated) record, please	visit the Kuali IRB Training Videos		
	Determinations		Proposed Changes Please check off only applicable proposed	changes				
			Changes to Project Roster/Study Perso	onnel				
			Changes to procedures or measures					
			Changes to participant population					

Provide your assurance by checking off the attestation in the Assurance/Acknowledgment section.

When you are ready to officially submit to the IRB office, click '**Submit'** in the right-side menu.

After clicking 'Submit', you will remain in the Protocols form. Scroll up to the top and you will see the Status has changed from 'In Progress' to '**Submitted for Review'**.

From here, click the "Back" button in the top left to return to the **Manage Protocols** page. You will now see your submitted protocol in the Protocol List and its current status.

The status change to '**Submitted for Review**' confirms your protocol has been submitted to the IRB office. You will also receive a confirmation email from the system.

Assurance/Acknowledgement		Notify PI To Submit
	0	Admin Notes & Files
By submitting this IRB protocol as Faculty Advisor / Sponsor,	8	Abandon
<ul> <li>I confirm that this study has been designed to protect human participants.</li> <li>I accept ultimate responsibility for the conduct of this study, the ethical performance of the project, and the protection of the rights and welfare of the</li> </ul>	<b>±</b>	Submit
human participants who are directly and indirectly involved in this project.	6	Duplicate as New
<ul> <li>I will contiply with all policies and guidelines of OCR and annated institutions where this study will be conducted, as well as with all applicable rederal, state and local laws regarding the protection of human subjects in research.</li> <li>I will ensure that all personnel performing this study are qualified, appropriately trained and will adhere to the provisions of the IRB approved protocol.</li> <li>I will not modify the UCR IRB-approved protocol or any attached materials without first obtaining UCR IRB approval for an amendment to the previously approved protocol.</li> <li>I will provide all continuing review documentation to the IRB.</li> <li>I will provide all continuing review documentation to the IRB.</li> </ul>	ē	Print
I attest to the above statements.		

IRB: #30016 Converted	Protocol Example		Compare Versions
Selected Version: 2   Amendment   Submitted for Review (Pr	roject Basics, General Information, Study Personnel, Fi	unding, Study Population, Research Characteristics, E	Behavioral Observations, Participant Compensation / (
Protocol Information			Show Less 🔨
Submission Type Amendment	Review Type	Status Submitted for Review	Time in Current Status Since July 27 – a few seconds
Approval Date	Continuing Review Date	Expiration Date	Initial Approval Date Jul 20, 2023
Initial Review Type Expedited			

↔	Hide Menu	Protocols						
ß	Manage Protocols							
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		Q Search						Advanced
		Title	Number 👻	PI Name	Submission Type	Review Type	Status	
		Converted Protocol Example	30016	Greer, Charles E	Initial	Expedited	<ul> <li>Approved</li> </ul>	
		Converted Protocol Example	30016	Greer, Charles E	Amendment		<ul> <li>Submitted for</li> </ul>	Review
		2 of 2 protocols						





## Personnel ONLY Changes Amendment Request

This portion of the guide shows the Kuali system steps to create and submit a Personnel ONLY Changes Amendment Request for a Converted (Migrated) Protocol.

Follow steps to Locate Existing	Amendment Creation
Amendment.	Which sections would you like to amend?
For Personnel Only changes, select ' <b>Project Basics / Study Personnel</b> '.	To prevent other people in the system from making changes while you are, please select the sections you need to amend.
<b>Do not</b> select Data Conversion Fields.	Project Basics / Study Personnel
Click ' <b>Done'</b> .	Supporting Information
	Data Conversion Fields
	Cancel Done



A new protocol version will be created for the Amendment.

**NOTE:** These protocol versions will continue accumulate as actions are taken on the protocol (e.g., additional amendments, renewals). When making future amendments, you want to ensure you are selecting the latest approved version of the protocol to update.

You can toggle through protocol versions using the drop down.

Click on the drop down arrow, and select the version you would like to view.

← Back Manage Proto	ocols $\rightarrow$ IRB: #30016 Converted P	rotocol Example				
	Protocol Reportable Events Activi	y Log Permissions				
Jump to: Amendment ✓ Project Basics ④ General Information ✓	IRB: #30016 Converted Pre Selected Version: 3   Amendment   In Progress (Project Basics, St	otocol Example		🗲 Active 👻	Add Adn Q Adn Sub	I/Remove Section Ify PI To Submit nin Notes & F 1 Indon mit
Study Personnel 📀	Protocol Information			Show Less 🔨	🗇 Dup	ilicate as New
Data Conversion Fields	Submission Type Amendment	Status In Progress	Approval Date	Continuing Review Date		
Administrative Details Determinations	Expiration Date	Initial Approval Date Jul 20, 2023	Initial Review Type Expedited			
	Amendment					
	All changes to an approved research study immediate, apparent hazard to a study par <b>PLEASE NOTE:</b> For changes beyond perso system to fully capture all the details of th Researchers must complete the form with approved application as well as any appro For additional information and guidance o webpage. You can also submit any questi	UCR AMENDMENT must be submitted and approved by the IRB p ticipant. anel changes in a converted (migrated) protoc e study. the details of the currently approved procedu ved amendments are readily available for you n how to proceed with completing an amendm ns to inb@ucr.edu.	REQUEST FORM prior to implementation, except when those c col, you will be required to complete the entir res, as well as the requested changes. It is so reference as you complete the form. tent on a converted (migrated) record, please	hanges are necessary to avoid an e Kuali application form in order for the trongly recommended that the original e visit the Kuali IRB Training Videos		

# IRB: #30016 Converted Protocol Example

Selected Version:	
3   Amendment   In Progress (Project Basics, Study Personnel	)
3   Amendment   In Progress (Project Basics, Study Personnel)	+ Active
2   Amendment   Abandoned (Project Basics, Study Personnel)	
1   Initial   Approved	

## Research and Econo Development

### Kuali IRB Protocols – Amending a Converted (Migrated) Protocol for the First Time



In the right-hand menu (highlighted in BLUE), researchers will have access to the functions:

- Notify PI to Submit available if the submitter is not the listed PI or Faculty Advisor
- **Submit** official submission to the IRB office; • only available to the listed PI or Faculty Advisor
- Abandon Cancels the submission. Protocols ٠ that are abandoned before submission cannot be edited, but can be viewed as read-only.
- Duplicate as New Create a copy of the • protocol to use as a new submission



	← Back Man	age Proto	ocols → IRB: #30016 Converted Protocol Example	
Fill out the Amendment			Protocol Reportable Events Activity Log Permissions	
Form				*
The Amendment Request Form	Jump to:		Amendment	
will appear as the first section.	Amendment		UCR AMENDMENT REQUEST FORM	
<b>IMPORTANT</b> : As noted on the	Project Basics	0	All changes to an approved research study must be submitted and approved by the IRB prior to implementation, except when those changes are necessary to avoid an	
Amendment Request form,	General Information	$\checkmark$	immediate, apparent hazard to a study participant.	
changes beyond personnel	Study Personnel	0	PLEASE NOTE: For changes beyond personnel changes in a converted (migrated) protocol, you will be required to complete the entire Kuali application form in order for the system to fully capture all the details of the study.	
changes will require you to	Supporting Informat	ion 🗸	Researchers must complete the form with the details of the currently approved procedures, as well as the requested changes. It is strongly recommended that the original	
complete the entire Kuali IRB	Data Conversion Fiel	lds	approved application as well as any approved amendments are readily available for your reference as you complete the form.	
application form in order to			For additional information and guidance on how to proceed with completing an amendment on a converted (migrated) record, please visit the Kuali IRB Training Videos webpage. You can also submit any questions to irb@ucr.edu.	
fully capture the details of the	Administrative Details			
study into the Kuali system.	Determinations		Proposed Changes	
	Determinations		Please check off only applicable proposed changes	
As you fill out the form, the			Changes to Project Roster/Study Personnel	
system will auto save. You will			Changes to procedures or measures	
see a 'Save Complete' pop up.			Changes to participant population	
IMPORTANT: If you plan to			Changes to recruitment methods	
exit out of the protocol before				
submitting to the IRB, please			Changes to compensation or reimpursement	
be sure that 'Save Complete'			Change to consent process including changes to consent form document	
pop up appears on your latest			Changes to risk-benefit assessment	
cut before exiting.			Other (Describe below)	
			Please provide a brief description of the study, and describe how this amendment is in line with the original aims of the study.	
			Click Here to Add Text	
			Describe the proposed changes, including the reason for the change. Append all revised documents with the changes bolded or tracked. Click Here to Add Text Save complete	



Identify the proposed changes that will be included in this amendment by checking off the applicable changes.

For Personnel ONLY changes, check the first option. Choosing this option, will remove any additional questions in the amendment form. That is, you do not have to describe what the changes are as you making only making personnel changes.

### **IMPORTANT:**

For studies that will be led by a researcher who is NOT PI eligible, the Certification must be completed by the Faculty Advisor/Sponsor. Similarly, for submissions where a designate (e.g., administrator) is completing the form on behalf of the Principal Investigator, the Certification must be completed by the PI. The system will allow you to leave this check box **blank** as you will need to route the submission to the listed PI / Faculty Advisor.

A	-	al sea	
AM	en	um	ent

#### UCR AMENDMENT REQUEST FORM

All changes to an approved research study must be submitted and approved by the IRB prior to implementation, except when those changes are necessary to avoid an immediate, apparent hazard to a study participant.

PLEASE NOTE: For changes beyond personnel changes in a converted (migrated) protocol, you will be required to complete the entire Kuali application form in order for the system to fully capture all the details of the study.

Researchers must complete the form with the details of the currently approved procedures, as well as the requested changes. It is strongly recommended that the original approved application as well as any approved amendments are readily available for your reference as you complete the form.

For additional information and guidance on how to proceed with completing an amendment on a converted (migrated) record, please visit the Kuali IRB Training Videos webpage. You can also submit any questions to irb@ucr.edu.

lease	Please check off only applicable proposed changes				
	Changes to Project Roster/Study Personnel				
	Changes to procedures or measures				
	Changes to participant population				
	Changes to recruitment methods				
	Changes to compensation or reimbursement				
	Change to consent process including changes to consent form document				
	Changes to risk-benefit assessment				
	Other (Describe below)				
rovid	e your Certification Below				



### Update the Protocol

Following the Amendment Certification, you will then be able to update the protocol sections.

**IMPORTANT:** The Project Basics section contains an option for you to indicate if you will be updating the protocol beyond personnel. Once selected, you cannot un-select it.

**DO NOT** select this option for personnel only changes.

### Leave this blank.

		Protocol Reportable Events Activity Log Per	rmissions
mp to:		Project Basics	
mendment		Study Title	
roject Basics	O	Converted Protocol Example	
eneral Information	$\checkmark$	Principal Investigator:	Lead Department:
udy Personnel	0	Greer, Charles E 🛞	(D01234) Research Compliance 🔕
pporting Information	n 🗸		
ata Conversion Field	S	IMPORTANT: Only select the below option if you are upo Once selected, this cannot be undone.	dating more than personnel only. Once selected, you will be required to complete the entire Kuali IRB protocol form.
		I am updating my protocol for the first time in the Kua	ali Protocols system
ministrative Details			

Project Basi	cs							0
Study Title								
Converted Prot	ocol Example							
Principal Inve	stigator:			Lea	ad Department:			
Greer, Charle	s E 🙁			0	D01234) Research Co	mpliance 🙁		
MPORTANT: form. Once se	Only select the below op elected, this cannot be un	ition if yo ndone.	u are updating more than pers	onnel only.	. Once selected, you	will be requir	red to complete the entire K	uali IRB protocol
I am updating my protocol for the first time in the Kuali Protocols system								
General Info	rmation							
General Info	rmation							6
General Info	rmation							0
General Info	rmation						<ul> <li>Columns</li> </ul>	+ Add Line
General Info	rmation	Ŧ	RESEARCHER ROLE		INVOLVED IN	Ţ	Columns IRB TRAINING	
General Info Study Perso	rmation nnel PERSON Greer, Charles E		RESEARCHER ROLE Principal Investigator/Faculty	च v Advisor	INVOLVED IN	Ŧ	Columns  IRB TRAINING  Charles Greer has no tra	

Navigate to the 'Study Personnel' section.

Updating Study Personnel	· · · · ·			Study Do	reannal						0
When updating the ' <b>Study</b> Personnel' section for the very	Amend	Iment		Study Pe	12011161					<ul> <li>Columns</li> </ul>	+ Add Line
first time, please ensure that all personnel are listed in the table	Project	i Basics Il Informati	on 🗸		PERSON	Ŧ	RESEARCHER ROLE		N Ŧ	IRB TRAINING	Ŧ
The initial conversion into the Kuali system only allowed the study PI, Lead Researcher and/or Faculty advisor to be listed in the table.	Study F Suppor Data Co Data	Personnel rting Inform onversion I Convers	ation  Fields	4	Greer, Charles E		Principal Investigator/Faculty Adviso	r		Charles Greer has no trainin	g courses on file.
You will need to update the table to ensure that the personnel list matches the list under the Data Conversion Fields.	Conve 11/28 Speci None	erted Ren 3/07; 12/8 ial Popula	ewal Dates 3/08, 12/2/09; 1 tion Categories	/29/10; 11/:	29/11; 11\29/12, 11\29/	3					
Click on <b>Pencil</b> icon to edit the personnel info.	Trans No	national?									
Click on ' <b>Add Line</b> ' to add additional personnel.	Projec Vaugl	ct Person hn, Rober	nel t Craig - 9/26/22	Wicker, Mor	nica 10/4/22						
	Stud	ly Persor	nel							G	
									Oclumns	+ Add Line	
			PERSON	Ŧ	RESEARCHER ROLE	Ŧ	INVOLVED IN	Ŧ	IRB TRAINING	₹	
	1		Greer, Charles	E	Principal Investigator/Fa Advisor	aculty	Obtain consent and/or assent		Charles Greer h     on file.	as no training courses	
	1	•	Vaughn, Robe	t Craig	Research Personnel		Obtain consent and/or assent Interact with participants (e.g., ac survey, interview)	lminister	Robert Vaughn     on file.	has no training courses	
	1	1	Wicker, Monic	a M	Research Personnel		Obtain consent and/or assent Interact with participants (e.g., ac survey, interview)	lminister	i Monica Wicker on file.	has no training courses	



# Submitting the Amendment as PI

Once the form is complete and you have verified its accuracy, as the listed PI of the protocol, ensure that you have provided your Certification as part of the Amendment Request Form.

When you are ready to submit, click the '**Submit**' button in the right-side menu.

For submissions completed by students, designees, etc., please see the 'Routing to Principal Investigator / Faculty Advisor' section (next page).

After clicking 'Submit', you will remain in the Protocols form. Scroll up to the top and you will see the Status has changed from 'In Progress' to '**Submitted for Review'**.

From here, click the "Back" button in the top left to return to the **Manage Protocols** page. You will now see your submitted protocol in the Protocol List and its current status.

The status change to '**Submitted for Review**' confirms your protocol has been submitted to the IRB office. You will also receive a confirmation email from the system.

Protocol Reportable Events Activity Log Permissions		
Amendment		Add/Remove Section
Changes to compensation or reimbursement		Notify PI To Submit
Change to consent process including changes to consent form document	0	Admin Notes & F 1
Changes to risk-benefit assessment	×	Abandon Submit
Cther (Describe below)		Duplicate as New
Provide your Certification Below	ē	Print
As the PRINCIPAL INVESTIGATOR / FACULTY ADVISOR, I confirm that the information within this form is accurate and complete.		

IRB: #30016 Converted Pro	Compare Versions							
Selected Version: 2   Amendment   Submitted for Review (Project Basics, General Information, Study Personnel, Funding, Study Population, Research Characteristics, Behavioral Observations, Participant Compensation / C								
Protocol Information			Show Less 🔨					
Submission Type Amendment	Review Type 	Status Submitted for Review	Time in Current Status Since July 27 – a few seconds					
Approval Date 	Continuing Review Date	Expiration Date	Initial Approval Date Jul 20, 2023					
Initial Review Type Expedited								

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ß	Manage Protocols								
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			Q Search						Advanced
			Title	Number 👻	PI Name	Submission Type	Review Type	Status	
			Converted Protocol Example	30016	Greer, Charles E	Initial	Expedited	Approved	
			Converted Protocol Example	30016	Greer, Charles E	Amendment		Submitted for R	eview
			2 of 2 protocols						



### **Routing to Principal Investigator/Faculty Advisor**

For studies that will be led by a researcher who is NOT PI eligible, the Certification must be completed by the Faculty Advisor/Sponsor.

Similarly, for submissions where a designate (e.g., administrator) is completing the form on behalf of the Principal Investigator, the Assurance must be completed by the PI.

The system will allow you to leave this check box **blank** as you will need to route the submission to the listed PI / Faculty Advisor.

When you are ready to route to the PI, click on '**Notify PI to Submit**' in the right-hand menu.

Protocol Reportable Events Activity Log Permissions
Amendment
Changes to compensation or reimbursement
Change to consent process including changes to consent form document
Changes to risk-benefit assessment
Other (Describe below)
Provide your Certification Below
As the PRINCIPAL INVESTIGATOR / FACULTY ADVISOR, I confirm that the information within this form is accurate and complete.

Protocol Reportable Events Activity Log Permissions		
Amendment		Add/Remove Section
Changes to compensation or reimbursement	Á	Notify PI To Submit
Change to consent process including changes to consent form document	Û	Admin Notes & F 1
Changes to risk-benefit assessment	8	Abandon
	1	Submit Duplicate as New
	ē	Print
Provide your Certification Below		
As the PRINCIPAL INVESTIGATOR / FACULTY ADVISOR, I confirm that the information within this form is accurate and complete.		



As the Assurance section was left blank, a pop up will appear notifying you of the incomplete field.

If additional fields are identified, you can choose to view the fields for verification that they should be left blank.

When you are ready to route to the PI / Faculty Advisor, click '**Notify PI Anyway**' in the pop up.



view documentation to the http:

s

Once routed to the PI, a pop up will appear stating 'Principal Investigator was notified'.

**IMPORTANT:** After notifying the PI, you will still be in the protocol form, and the form will remain editable. Any changes you may make while the protocol is in the PI / Faculty advisor's queue will appear; however, the changes will not be tracked. Researchers must communicate with each other if there are any changes while the protocol is in the 'Notify PI to submit' status.

**PLEASE NOTE:** If you are listed as study personnel with Full Access in the protocol, you will receive the submission confirmation email once the PI / Advisor submits to the IRB. ✓ Success! Principal Investigator was notified



# Submitting Amendment after receiving Notification to Submit

As the listed Principal Investigator or Faculty Advisor, you will receive an email notification when a protocol submission requires your review and submission to the IRB. You can access the protocol directly using the link provided in the email notification.

**IMPORTANT**: If you do not receive the email notification from Kuali in your inbox, please check your Spam, Junk or Trash folders.

#### Hello Greer, Charles E,

You have been listed as the Principal Investigator on the below IRB protocol. Please use the below link to review/confirm the details of your protocol and submit to the IRB for review.

- Protocol Number: 30016
- Protocol Title: Converted Protocol Example
- Submission Type: Amendment
- Link to Protocol: ucr-stg.kuali.co/protocols/protocols/64c2168bbb30cc0028ea491d

If you have any questions, please contact our office at irb@ucr.edu.

\*\* Note this email is an automated system notification which is unable to receive replies. Please direct all questions and correspondence to irb@ucr.edu.

# The protocol will also be listed in your **Manage Protocols** page.

The status will show as '**In Progress**' as the protocol is not yet submitted.

Access the protocol by clicking on the title.

**NOTE:** For additional actions on an approved protocol (i.e., Amendments or Renewals), you will see all iterations of the protocol.

↔ Hide Menu	Protocols					
🕼 Manage Protocols						
						Include all prot
	Q Search					Advanc
	Title	Number 🤜	PI Name	Submission Type	Review Type	Status
	Converted Protocol Example	30016	Greer, Charles E	Initial	Expedited	Approved
	Converted Protocol Example	30016	Greer, Charles E	Amendment		In Progress
	2 of 2 protocols					

## Research and Economic Development

## Kuali IRB Protocols – Amending a Converted (Migrated) Protocol for the First Time

	← Back Mana	ige Proto	cols $\rightarrow$ IRB: #30016 Converted Pr	rotocol Example							
As the listed PI or		Protocol Reportable Events Activity Log Permissions									
Faculty Advisor, you will have full editing	Jump to:		IRB: #30016 Converted Pro			Add/Remove Section					
protocol form.	Amendment	~	Selected Version:	di Burran D			Notify PI To Submit     Admin Notes & F				
	Project Basics General Information	<b>(</b> )	3   Amendment   in Progress (Project Basics, Stu	lay Personnei)		4 Active	Abandon     Submit				
Poviow the	Study Personnel	0	Protocol Information			Show Less 🔥	Duplicate as New				
Review the	Supporting Informatio	n 🗸					🖶 Print				
form and protocol for	Data Conversion Field	S	Submission Type Amendment	Status In Progress	Approval Date	Continuing Review Date					
completeness and accuracy.	Administrative Details Determinations		Expiration Date	Initial Approval Date Jul 20, 2023	Initial Review Type Expedited						
			Amendment								
				UCR AMENDMENT	REQUEST FORM						
			All changes to an approved research study immediate, apparent hazard to a study par	must be submitted and approved by the IRB p ticipant.	rior to implementation, except when those ch	nanges are necessary to avoid an					
			PLEASE NOTE: For changes beyond persor system to fully capture all the details of th	nnel changes in a converted (migrated) protoc e study.	ol, you will be required to complete the entire	e Kuali application form in order for the					
			Researchers must complete the form with approved application as well as any approv	the details of the currently approved procedur ved amendments are readily available for your	res, as well as the requested changes. It is st reference as you complete the form.	rongly recommended that the original					
			For additional information and guidance or webpage. You can also submit any question	n how to proceed with completing an amendm	ent on a converted (migrated) record, please	visit the Kuali IRB Training Videos					
			Proposed Changes								
			Please check off only applicable proposed	changes							
			Changes to Project Roster/Study Perso	nnel							
			Changes to procedures or measures								
			Changes to participant population								



Provide your Certification by checking off the confirmation in the Amendment Request form.

When you are ready to officially submit to the IRB office, click '**Submit'** in the right-side menu.

After clicking 'Submit', you will remain in the Protocols form. Scroll up to the top and you will see the Status has changed from 'In Progress' to '**Submitted for Review'**.

From here, click the "Back" button in the top left to return to the **Manage Protocols** page. You will now see your submitted protocol in the Protocol List and its current status.

The status change to '**Submitted for Review**' confirms your protocol has been submitted to the IRB office. You will also receive a confirmation email from the system.

Amendment	*	
	/	Add/Remove Section
Changes to risk-benefit assessment		Notify PI To Submit
Other (Describe below)	l	) Admin Notes & F 1
	6	Abandon
Provide your Certification Below		▶ Submit
As the PRINCIPAL INVESTIGATOR / FACULTY ADVISOR, I confirm that the information within this form is accurate and complete.		Duplicate as New
	- e	Print

RB: #30016 Conve	erted Protocol Example		Compare Versions
Selected Version:			
2   Amendment   Submitted for R	eview (Project Basics, General Information, Study Perso	nnel, Funding, Study Population, Research Characte	eristics, Behavioral Observations, Participant Compensation /
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			Jul 20, 2023
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		Converted Protocol Example	30016	Greer, Charles E	Initial	Expedited	Approved	
		Converted Protocol Example	30016	Greer, Charles E	Amendment		Submitted for	Review
		2 of 2 protocols						