

Kuali IRB Protocols – Create and Submit a New Protocol

This guide shows the Kuali system steps to create and submit a new IRB protocol.

Sections in this guide:

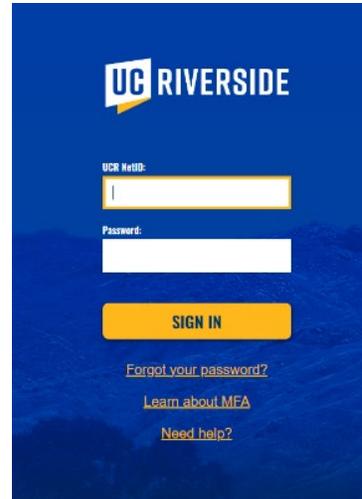
- [Access Kuali Protocols](#)
- [Create Protocol](#)
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- [Routing to Principal Investigator / Faculty Advisor to Submit](#)
- [Submitting Protocol after receiving Notification to Submit](#)

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 protocol form 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.



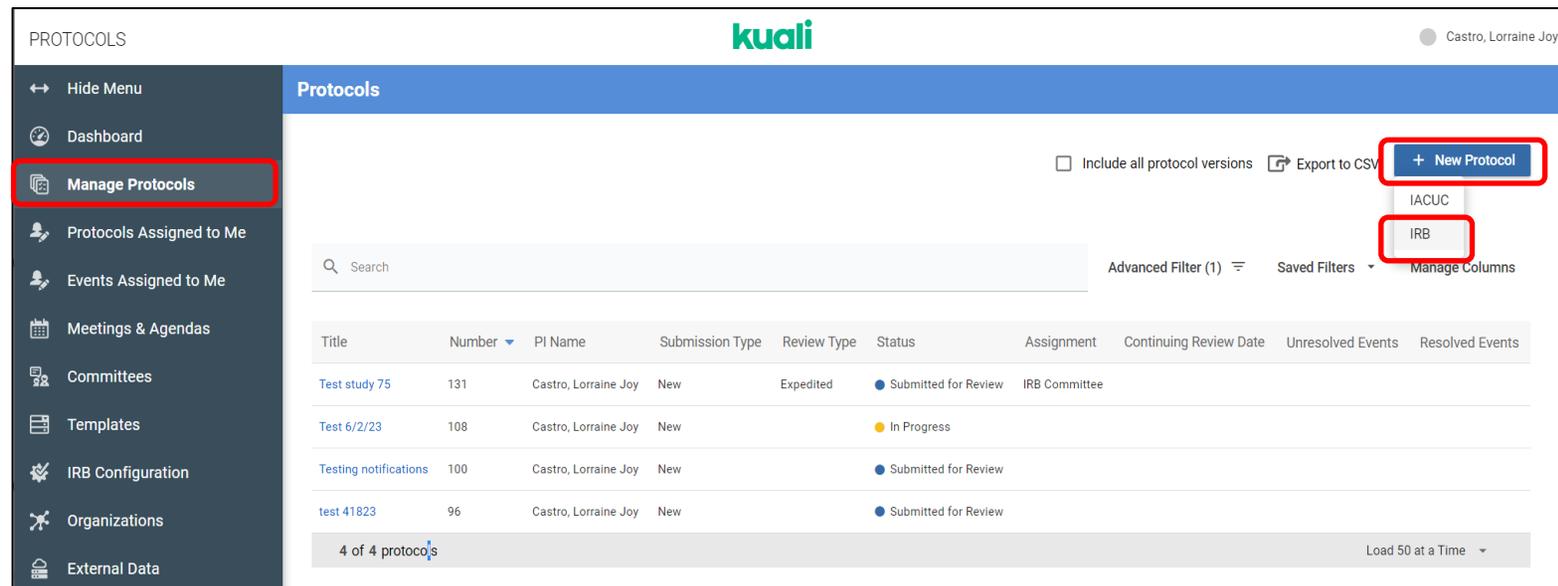
The image shows a login form for UCR Riverside. It features a blue background with the UCR Riverside logo at the top. Below the logo, there are two input fields: 'UCR NetID:' and 'Password:'. A yellow 'SIGN IN' button is positioned below the password field. At the bottom of the form, there are three links: 'Forgot your password?', 'Learn about MFA', and 'Need help?'.

Create Protocol

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

If you have any existing IRB or IACUC (AUP) protocols, they will be listed on this page.

To create a new IRB protocol, click on the blue '+ New Protocol' button at the top right, and select 'IRB'.



The screenshot displays the Kuali Protocols management interface. On the left is a dark sidebar menu with options: Hide Menu, Dashboard, Manage Protocols (highlighted with a red box), Protocols Assigned to Me, Events Assigned to Me, Meetings & Agendas, Committees, Templates, IRB Configuration, Organizations, and External Data. The main content area is titled 'Protocols' and includes a search bar, a table of protocols, and a '+ New Protocol' button (highlighted with a red box) in the top right corner. Below the '+ New Protocol' button, a dropdown menu is open, showing 'IACUC' and 'IRB' (both highlighted with red boxes). The table below contains the following data:

Title	Number	PI Name	Submission Type	Review Type	Status	Assignment	Continuing Review Date	Unresolved Events	Resolved Events
Test study 75	131	Castro, Lorraine Joy	New	Expedited	Submitted for Review	IRB Committee			
Test 6/2/23	108	Castro, Lorraine Joy	New		In Progress				
Testing notifications	100	Castro, Lorraine Joy	New		Submitted for Review				
test 41823	96	Castro, Lorraine Joy	New		Submitted for Review				

At the bottom of the table, it shows '4 of 4 protocols' and a 'Load 50 at a Time' dropdown menu.

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Fill Out Protocol Form

The first section to appear will be ‘General Information’.

Complete this section by providing the requested information.

To find the Principal Investigator or Faculty Advisor, start typing their name, and select the correct individual in the drop down that appears.

The Lead Department will auto-populate based on the listed investigator’s associated department.

Select a **Submission Type**.

NOTE: IRB Human Subjects Review covers submissions for Exempt, Expedited and Full Board review.

Click ‘**Next**’ to proceed to the next section.

IMPORTANT: If the study will be led by an individual who does not have PI eligibility (e.g., a student-led project), the second question should be ‘Yes’. This will change the title of ‘Principal Investigator’ to ‘Faculty Advisor’. Lead Researcher information will be added in the Study Personnel section later in the form.

IRB - General Information

Study Title
Protocol Submission Example

Will this study be led by a researcher who is NOT a [PI-eligible faculty member](#) (e.g., student, postdoc, trainee, visiting professor)?

Yes

No

Principal Investigator: Lead Department:

CASTRO, LOR

Castro, Lorraine Joy
 castrol@ucr.edu

The listed Principal Investigator is a PI-eligible UCR employee per [UCR Policy 527-3](#).
IMPORTANT: Lead researchers who do not have PI-eligibility must have a UCR Faculty Advisor / Sponsor listed as the PI.

Yes

No

SUBMISSION TYPE

Not Human Subjects Research (NHSR) Determination (Formerly Determination of Activity or DOA)

IRB Human Subjects Review

Request for External Reliance (i.e., UCR’s IRB will rely on another IRB)

[DO NOT USE] Stem Cell Research Oversight (SCRO)

✕ Cancel
→ Next

Will this study be led by a researcher who is NOT a [PI-eligible faculty member](#) (e.g., student, postdoc, trainee, visiting professor)?

Yes

No

Faculty Advisor: Lead Department:

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Complete this section by providing the requested information.

For sections requesting summaries, detailed information, etc., the text space will expand to accommodate longer texts.

PLEASE NOTE: Depending on your responses to the questions, additional questions may appear.

Once complete, click **'Next'** to proceed to the next section.

[← Back](#) **Manage Protocols** → IRB: #135 Protocol Submission Example [→ Next](#)

LAY LANGUAGE SUMMARY OF THE PROPOSED ACTIVITY
In non-technical, lay language, describe the purpose of the project, specify the problems and/or hypotheses to be addressed (Specific Aims):

[Click Here to Add Text](#)

Provide the scholarly rationale for this study and explain how it will contribute to existing knowledge.

[Click Here to Add Text](#)

LOCATION WHERE ACTIVITY(IES) WILL BE PERFORMED
Select all that apply.

- UCR Facilities or Sites (e.g., school, UCR Health clinics, etc.)
- Off-Campus (In California)
- Off-Campus (In USA outside of CA)
- International
- Web-based
- Other (specify below)

Provide a description of the location(s) including site name and location.

[Click Here to Add Text](#)

Is this a collaborative or multi-site study?

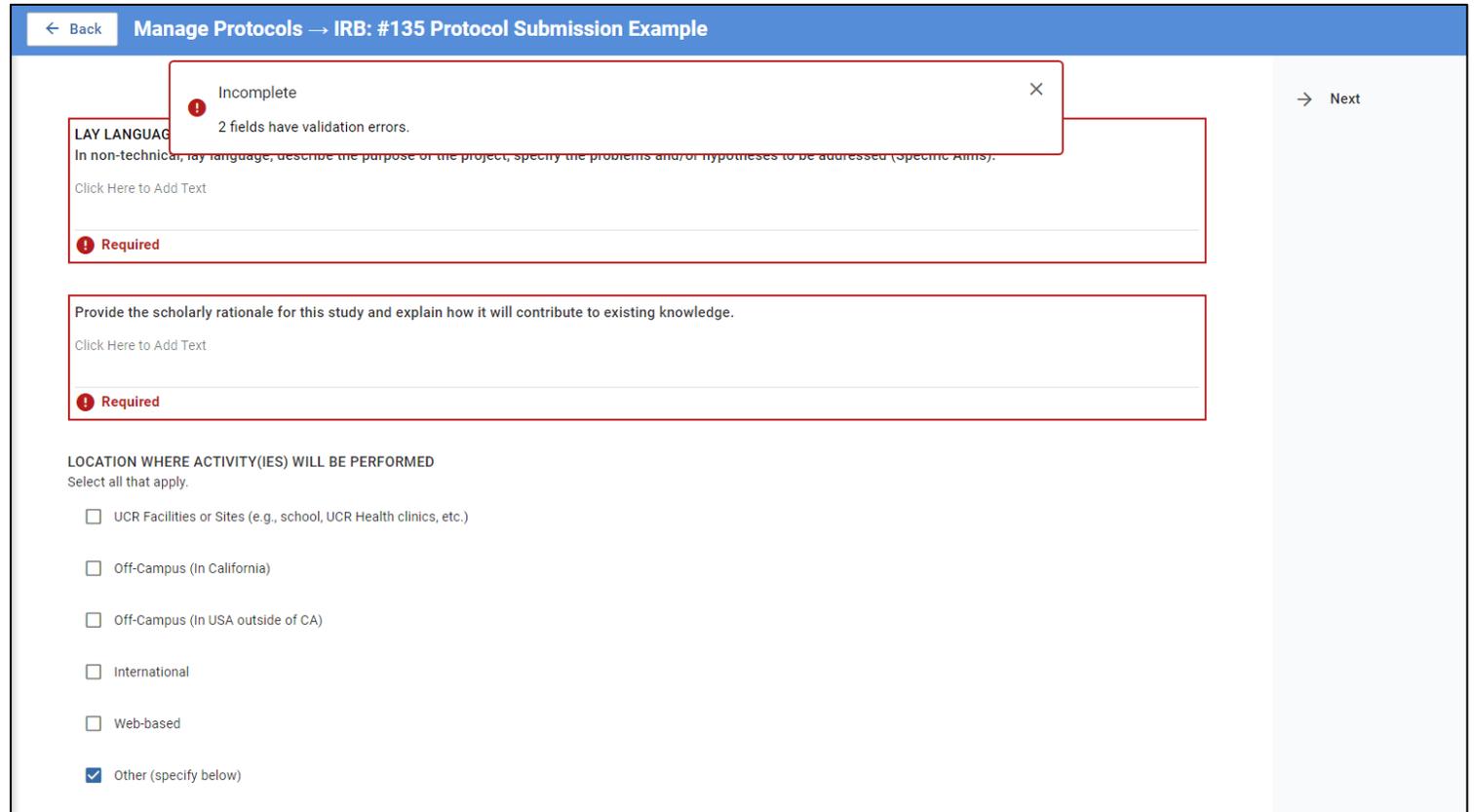
- Collaborative or cooperative studies involve investigators from two or more institutions working together to conduct a research project. Different research activities can occur at different sites or the study can be a single-site study that involves personnel from multiple institutions.
- Multi-site studies use the same research procedures outlined in a single protocol that is carried out at multiple institutions (e.g., a clinical trial where participants will be enrolled at each participating site, or an educational intervention implemented at each participating site).

Yes

No

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NOTE: If you try to move forward with the form without providing responses to required questions, the form will alert you of the incomplete information. You will not be able to move forward until the questions are answered.



The screenshot shows a web form titled "Manage Protocols → IRB: #135 Protocol Submission Example". A modal dialog box is open, displaying the message "Incomplete" and "2 fields have validation errors." The form contains several sections:

- LAY LANGUAGE:** A text area with the instruction "In non-technical, lay language, describe the purpose of the project, specify the problems and/or hypotheses to be addressed (Specific Aims)." and a "Click Here to Add Text" link. A red "Required" label is visible below the text area.
- Scholarly Rationale:** A text area with the instruction "Provide the scholarly rationale for this study and explain how it will contribute to existing knowledge." and a "Click Here to Add Text" link. A red "Required" label is visible below the text area.
- LOCATION WHERE ACTIVITY(IES) WILL BE PERFORMED:** A section with the instruction "Select all that apply." and a list of checkboxes:
 - UCR Facilities or Sites (e.g., school, UCR Health clinics, etc.)
 - Off-Campus (In California)
 - Off-Campus (In USA outside of CA)
 - International
 - Web-based
 - Other (specify below)

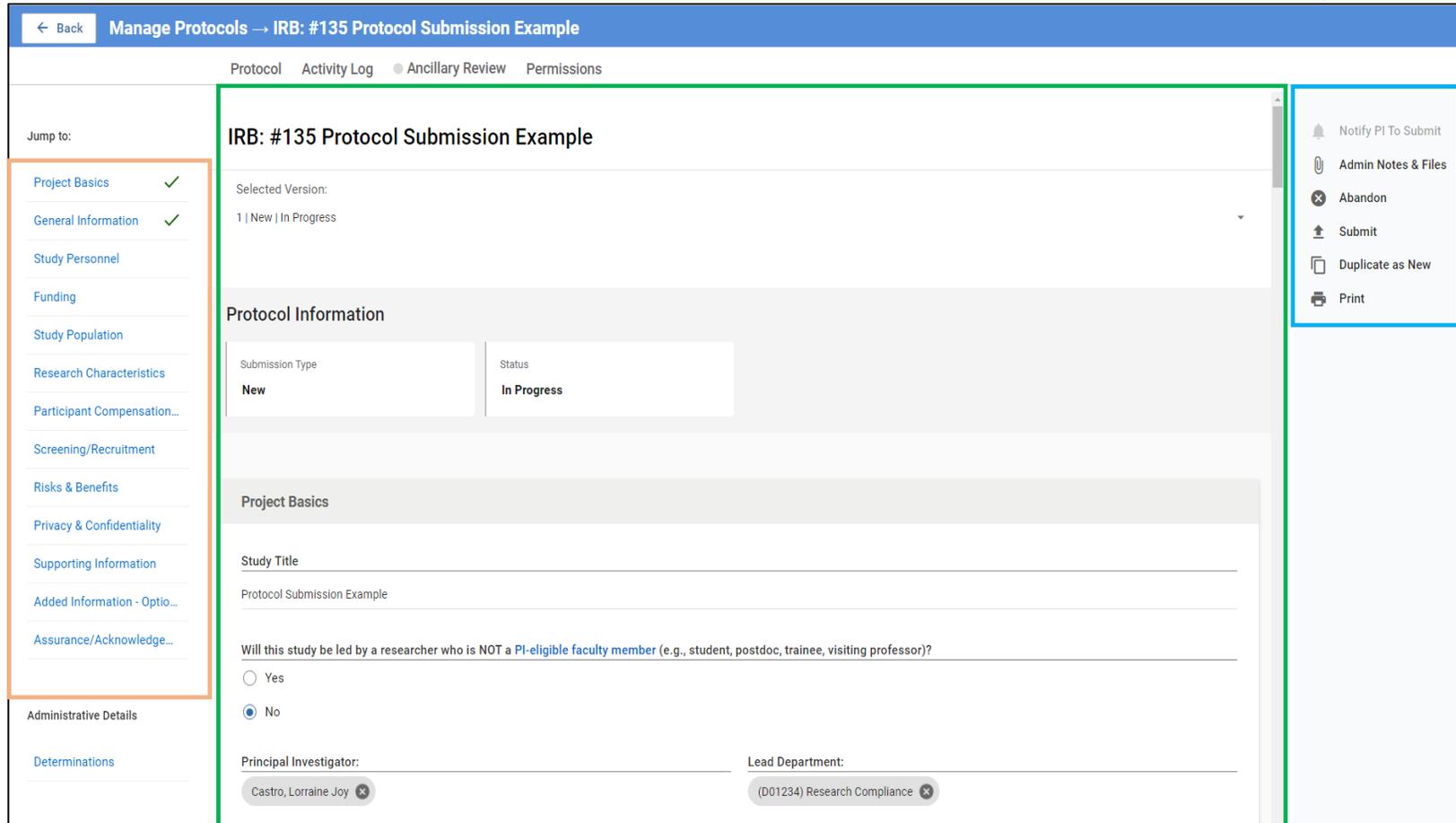
Navigation buttons include "Back" and "Next".

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Upon completing the initial sections, you will be directed to the full protocol form.

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.



The screenshot displays the 'Manage Protocols' interface for 'IRB: #135 Protocol Submission Example'. The top navigation bar includes a 'Back' button and tabs for 'Protocol', 'Activity Log', 'Ancillary Review', and 'Permissions'. The left sidebar, highlighted in orange, lists various sections: Project Basics (checked), General Information (checked), Study Personnel, Funding, Study Population, Research Characteristics, Participant Compensation..., Screening/Recruitment, Risks & Benefits, Privacy & Confidentiality, Supporting Information, Added Information - Optio..., Assurance/Acknowledge..., Administrative Details, and Determinations. The main content area, highlighted in green, shows the 'Protocol Information' section with 'Submission Type' set to 'New' and 'Status' set to 'In Progress'. Below this is the 'Project Basics' section, which includes a 'Study Title' field containing 'Protocol Submission Example' and a question: 'Will this study be led by a researcher who is NOT a PI-eligible faculty member (e.g., student, postdoc, trainee, visiting professor)?' with radio buttons for 'Yes' and 'No' (selected). At the bottom, there are fields for 'Principal Investigator' (Castro, Lorraine Joy) and 'Lead Department' ((D01234) Research Compliance). The right sidebar, highlighted in blue, contains a 'Notify PI To Submit' button, 'Admin Notes & Files', 'Abandon', 'Submit', 'Duplicate as New', and 'Print' options.

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 protocol to use as a new submission
- **Print**

Kuali IRB Protocols – Create and Submit a New Protocol

Fill out the reminder of the form.

As you complete each section, a Green Checkmark will appear next to the section name.

NOTE: The ‘Supporting Information’ and ‘Added Information’ sections will not show a Green checkmark.

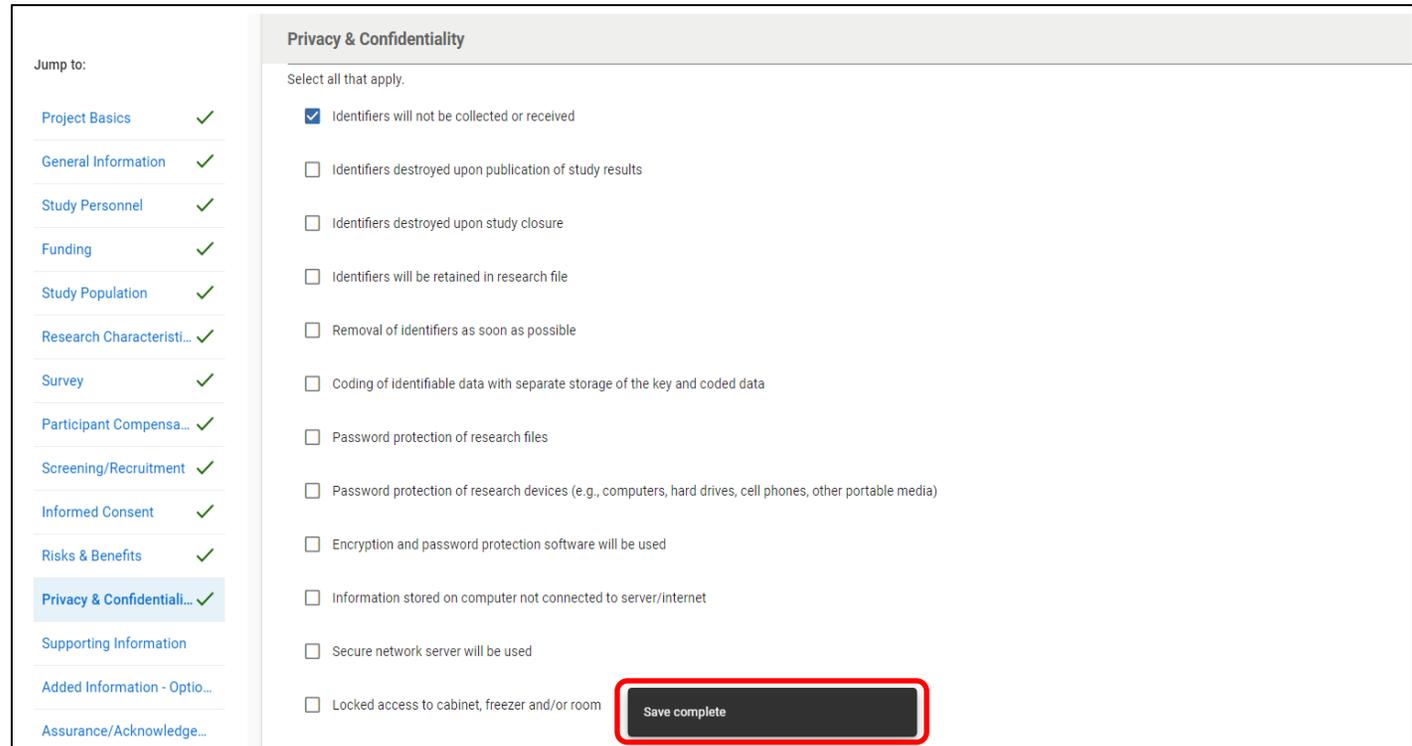
REMINDER: Depending on your responses, additional sections may appear in the left-side menu.

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.

Include all supplemental materials as ‘Supporting Information’ attachments.

NOTE: Depending on the procedures selected in the form, you may be prompted to attach specific materials. These will trigger an error if not included.

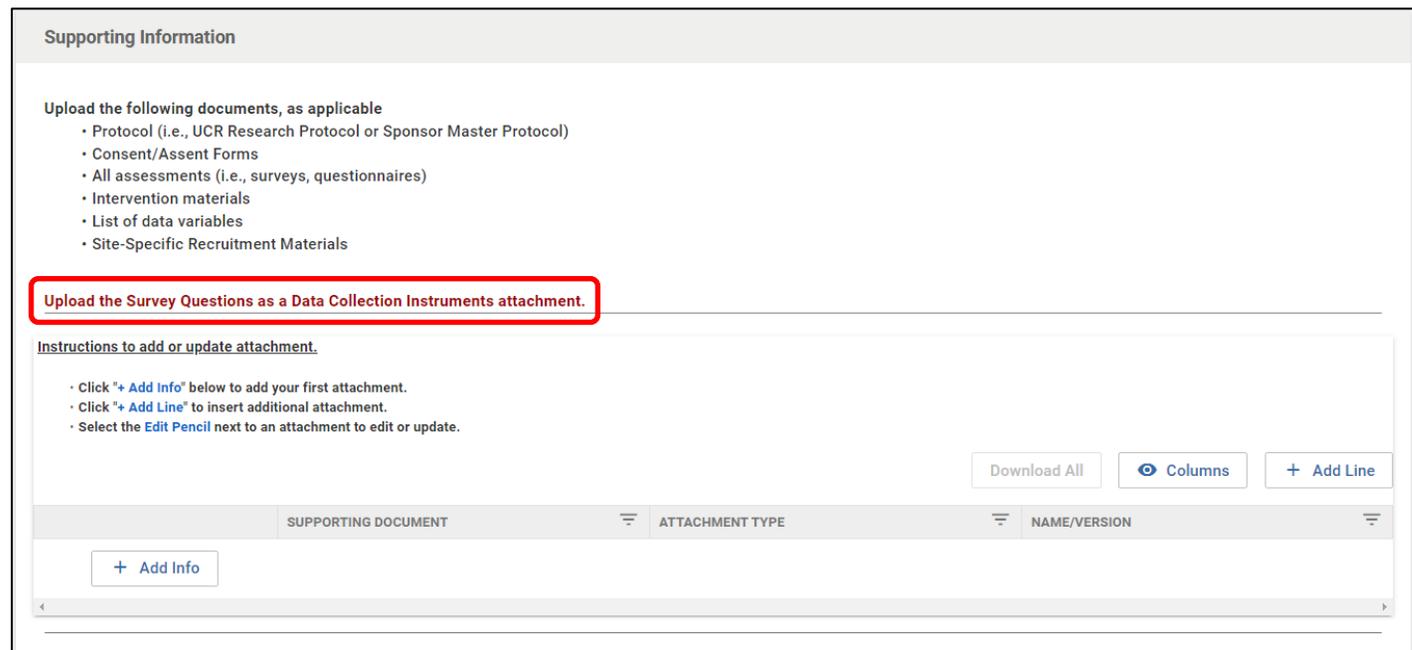


Privacy & Confidentiality

Select all that apply.

- Identifiers will not be collected or received
- Identifiers destroyed upon publication of study results
- Identifiers destroyed upon study closure
- Identifiers will be retained in research file
- Removal of identifiers as soon as possible
- Coding of identifiable data with separate storage of the key and coded data
- Password protection of research files
- Password protection of research devices (e.g., computers, hard drives, cell phones, other portable media)
- Encryption and password protection software will be used
- Information stored on computer not connected to server/internet
- Secure network server will be used
- Locked access to cabinet, freezer and/or room

Save complete



Supporting Information

Upload the following documents, as applicable

- Protocol (i.e., UCR Research Protocol or Sponsor Master Protocol)
- Consent/Assent Forms
- All assessments (i.e., surveys, questionnaires)
- Intervention materials
- List of data variables
- Site-Specific Recruitment Materials

Upload the Survey Questions as a Data Collection Instruments attachment.

Instructions to add or update attachment.

- Click "+ Add Info" below to add your first attachment.
- Click "+ Add Line" to insert additional attachment.
- Select the **Edit Pencil** next to an attachment to edit or update.

Download All Columns + Add Line

SUPPORTING DOCUMENT	ATTACHMENT TYPE	NAME/VERSION
+ Add Info		

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Submitting the Protocol

Once the form is complete and you have verified its accuracy, 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).

Assurance/Acknowledgement

By submitting this IRB protocol as Principal Investigator,

- I certify that the information provided in this application is complete and correct.
- I confirm that this study has been designed to protect human participants.
- 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 directly and indirectly involved in this project.
- 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.
- 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.
- I further confirm that I am not in violation of UCR's conflict of interest policy while participating in this research.

I attest to the above statements.

- Notify PI To Submit
- Admin Notes & Files
- Abandon
- Submit**
- Duplicate as New
- Print

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'**.

IRB: #135 Protocol Submission Example

Selected Version:
1 | New | Submitted for Review

Protocol Information

Submission Type New	Review Type --	Submitted for Review	Time in Current Status Since July 21 – a few seconds
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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.

PROTOCOLS


- Hide Menu
- Dashboard
- Manage Protocols**
- Protocols Assigned to Me
- Events Assigned to Me
- Meetings & Agendas
- Committees

Protocols
 Include all protocol versions

Advanced Filter (1)

Title	Number	PI Name	Submission Type	Review Type	Status	Assignment	Continuing Review Date
Protocol Submission Example	135	Castro, Lorraine Joy	New		Submitted for Review		

Kuali IRB Protocols – Create and Submit a New Protocol

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.

Assurance/Acknowledgement

By submitting this IRB protocol as Faculty Advisor / Sponsor,

- I certify that the information provided in this application is complete and correct.
- I confirm that this study has been designed to protect human participants.
- 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 directly and indirectly involved in this project.
- 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.
- 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.
- I further confirm that I am not in violation of UCR's conflict of interest policy while participating in this research.

I attest to the above statements.

Assurance/Acknowledgement

By submitting this IRB protocol as Faculty Advisor / Sponsor,

- I certify that the information provided in this application is complete and correct.
- I confirm that this study has been designed to protect human participants.
- 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 directly and indirectly involved in this project.
- 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.
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- 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.

I attest to the above statements.

 **Notify PI To Submit**

 Admin Notes & Files

 Abandon

 Submit

 Duplicate as New

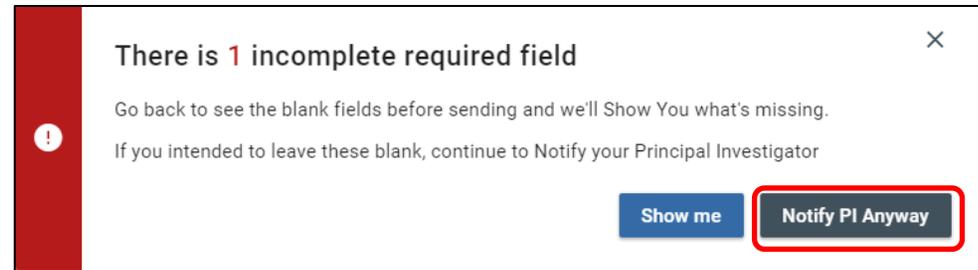
 Print

Kuali IRB Protocols – Create and Submit a New Protocol

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.



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.

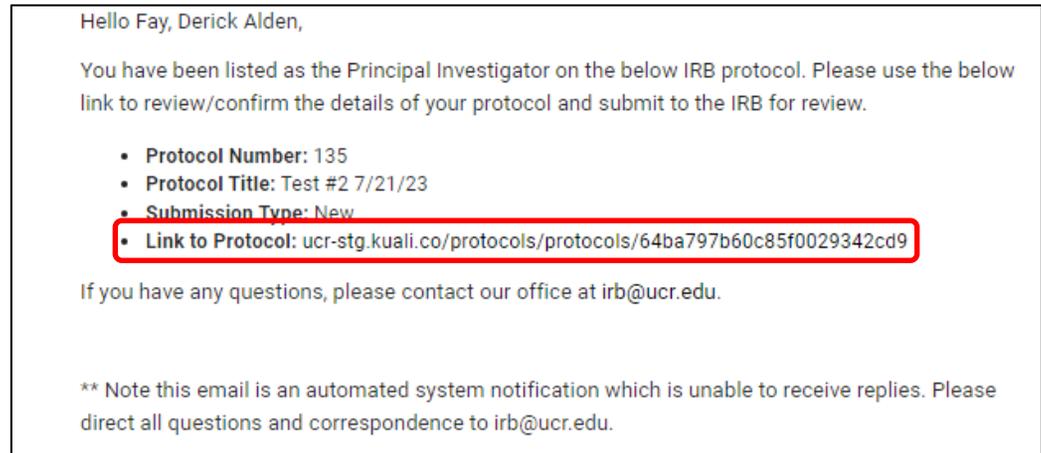
PLEASE NOTE: If you are listed as study personnel with Full Access in the protocol, you will receive the submission confirmation email once the PI / Advisor submits to the IRB.

Kuali IRB Protocols – Create and Submit a New Protocol

Submitting Protocol 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.



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.

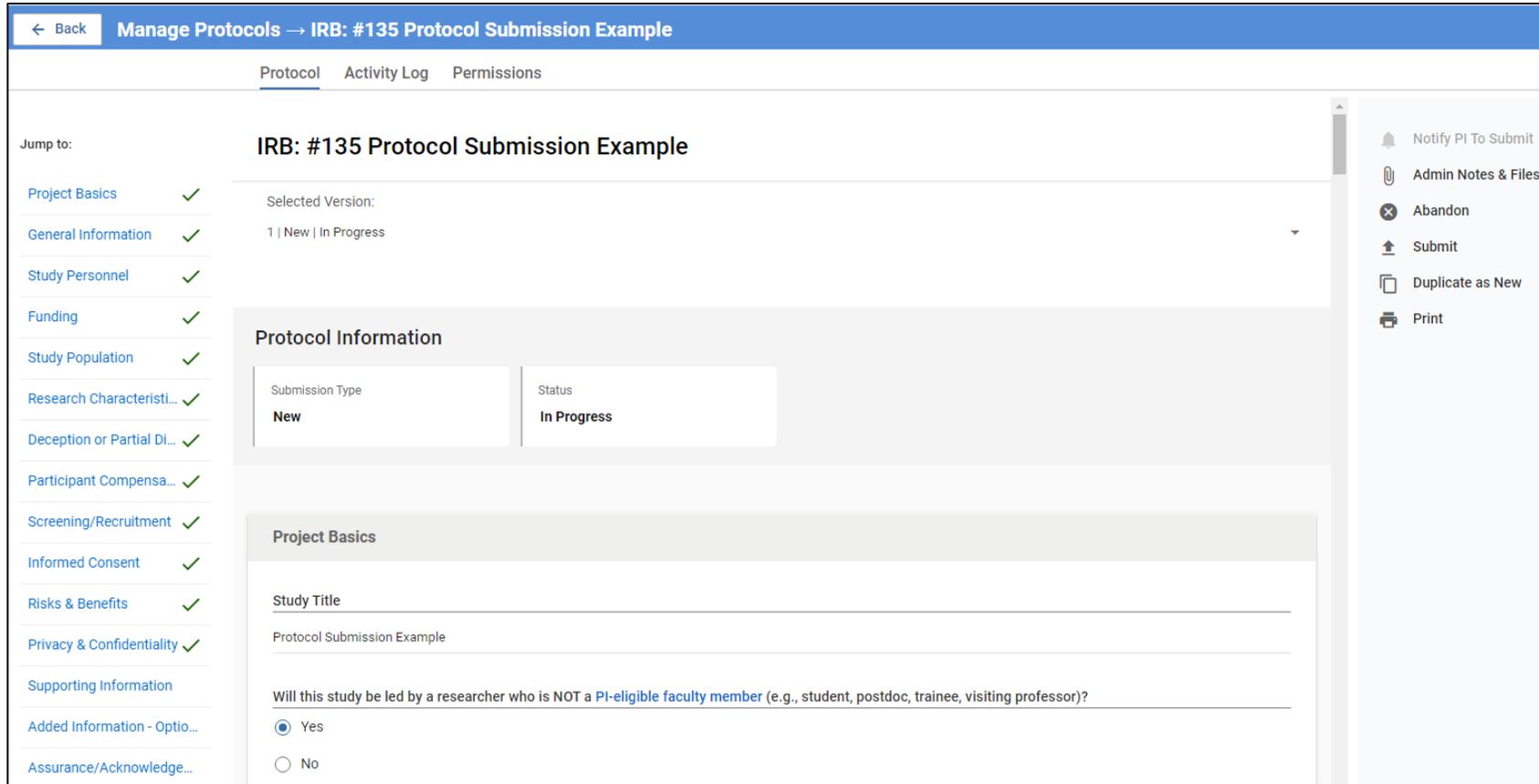
Access the protocol by clicking on the title.

Protocols							
<input type="checkbox"/> Include all protocol versions <input type="button" value="Export to CSV"/>							
<input type="text" value="Search"/> <input type="button" value="Advanced Filter"/> <input type="button" value="Saved Filters"/>							
Title ▲	Number	PI Name	Submission Type	Review Type	Status	Assignment	
Protocol Submission Example	135	Fay, Derick Alden	New		In Progress		
Test 7/21/23	134	Fay, Derick Alden	New		In Progress		

Kuali IRB Protocols – Create and Submit a New Protocol

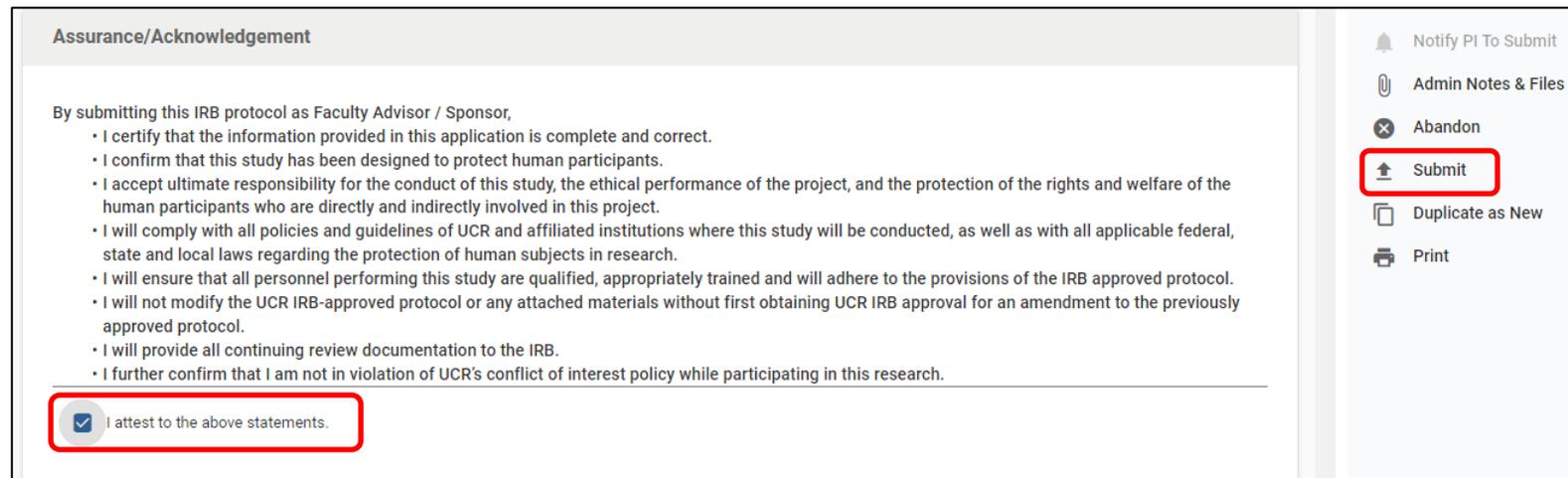
As the listed PI or Faculty Advisor, you will have full editing capabilities in the protocol form.

Review the protocol for completeness and accuracy.



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.



Kuali IRB Protocols – Create and Submit a New Protocol

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**'.

IRB: #135 Protocol Submission Example

Selected Version:
1 | New | Submitted for Review

Protocol Information

Submission Type New	Review Type --	Status Submitted for Review	Time in Current Status Since July 21 – a few seconds
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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.

Protocols

Hide Menu | Manage Protocols | Protocols Assigned to Me | Events Assigned to Me | Meetings & Agendas

Search | Advanced Filter | Include all protocol versions

Title	Number	PI Name	Submission Type	Review Type	Status
Protocol Submission Example	135	Fay, Derick Alden	New		Submitted for Review
Test 7/21/23	134	Fay, Derick Alden	New		In Progress