

# User Manual for IRBManager



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#### **Getting Started:**

### IRBManager works best with Google Chrome. We recommend using this browser.

Open your web browser and go to <a href="https://uccs.my.irbmanager.com/">https://uccs.my.irbmanager.com/</a>

#### Logging in:

If you are a UCCS faculty, student, or staff member, you will click the link in the middle of the page and use your campus login credentials. If you have issues with your credentials, please contact IT at helpdesk@uccs.edu.



You will be taken to the UCCS authentication page, where you will enter your credentials.





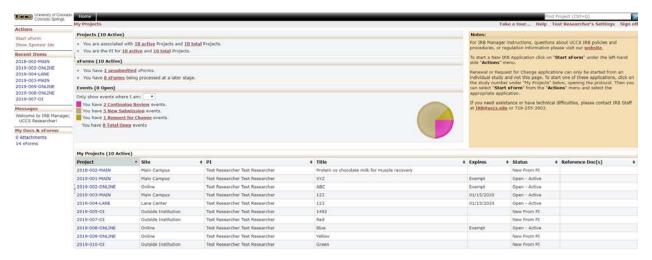
If you do not have a UCCS email, please contact <u>IRB@uccs.edu</u> to enable a login. Please allow 24-48 hours for your account to be created by IRB staff. You will be notified via email when the account is activated.

In this instance, you will use the "IRBManager issued login" at the bottom.



#### Your dashboard:

Once you are logged in, you will be taken to your "dashboard". This is where you will start forms, check the progress of applications, and find approved protocols.





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The "**Notes**" section at the top right has basic help, links, and contact information.

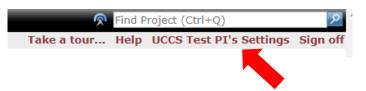
# Notes: IRBManager works best in Google Chrome. If you are having technical issues while using a different browser, please log out and open IRBManager in Chrome. If these issues still persist, please contact IRB Staff. For IRBManager instructions, questions about UCCS IRB policies and procedures, or regulation information please visit our <a href="weeksite">weeksite</a> Start a New IRB Application from the left-hand side "Actions" menu. Renewal or Request for Change applications can only be started from an individual study and not this page. To start one of these applications, click on the study number under "My Projects" below, opening the protocol. Then you can select "Start xForm" from the "Actions" menu and select the appropriate application. If you need assistance or have technical difficulties, please contact IRB Staff at IRB@uccs.edu or 719-255-3903.



Clicking the "Home" button on any page will bring you back to your dashboard.

#### Dark mode:

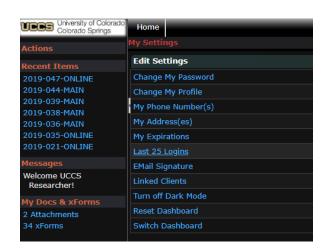
IRBManager has a dark mode option. To turn it on, go to "Settings" in the top right corner.



On the following page, you will se a list of settings. Click on "Turn on Dark Mode".



Your view should now look like this:





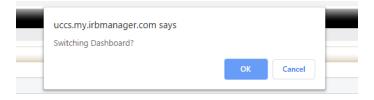
#### **Changing dashboard view:**

From the settings you can also change how your dashboard looks, engaging the "Bubble Dashboard".

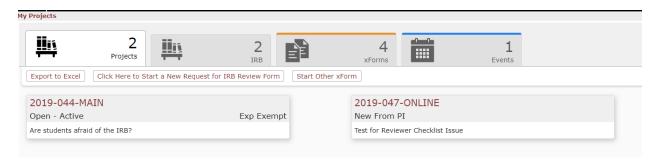
Click on "Switch Dashboard".



A pop-up will generate verifying that you wish to switch your view.



Click "Ok". Your view will now look like this.



You can switch it back at any time by clicking "Reset Dashboard" in "Settings".

For more detailed information about dashboard features, see the "Detailed help for IRB Manager features" section later in this guide.

#### **Creating new application:**

To begin your application, click on "Click Here to Start a New Request for IRB Review Form" in the top left corner under "Actions" from your dashboard.

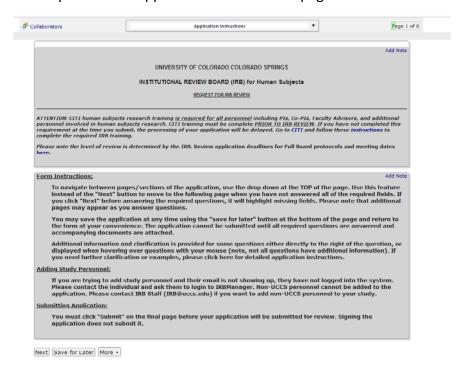


The application will open in a new browser tab.

You can also click on "Start xForm" just below that. If you do, a new tab will open, and you will need to click on "Request for IRB Review".

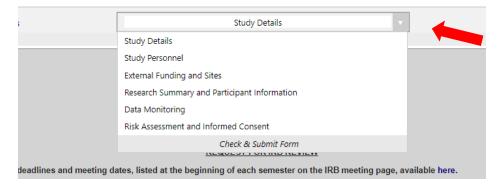


The application will open to the "Application Instructions" page.



#### **Navigating pages:**

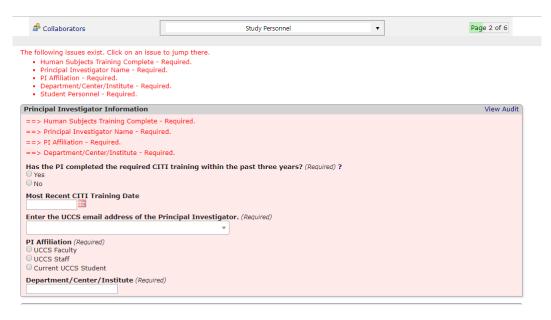
There are several pages to the application, and additional pages may be added based on your answers to individual questions. To skip to different application pages, use the drop-down box at the top of the page and select the page you want to skip to. Your changes will be automatically saved when you jump to a new page.



Answer each question on the page. Once you have completed ALL the answers click, "Next" at the bottom or top of the page. Your changes will be saved as you move to the next page.

You may also click "Save for Later" and return to the application at any time.

Please note that if you have not filled in all the required answers, when you click "Next", it will not advance to the next page. Instead sections with missing information will be highlighted (see example below). If you do not know the answers to those questions, use the page skip feature outlined above or click "Save for Later" and return to them at a later time.





You can click on the issues listed at the top of the page and jump to those questions, which saves time on longer pages.

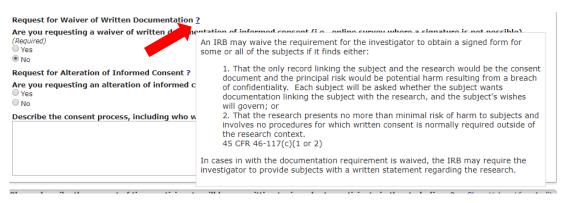


#### **Question Help:**

Many questions on the application have help text or notes. For most questions, this information is displayed by hovering your mouse over "Show Help" in the right-hand corner of the question.



For other supplemented questions, you will see a blue "?" next to the question. Hovering over this just like "Show Help" will reveal the help text.



For more detailed question help and answer examples, see the "Application Guide" on our website.



#### **Saving information in tables:**

For some needed information, such as additional personnel or participant information, there are tables where you will have to save information. These tables will allow you to add multiple iterations of similar details.



In these instances, you will enter the required information and then click "Save" on the right-hand side.

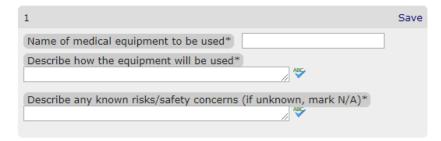
Once you have saved this information, a new row will appear and let you repeat the process. You must click "Save" before it will let you move on to the next page.



You can edit, duplicate, or delete entries by clicking on the icons under "Action" after a row has been saved.

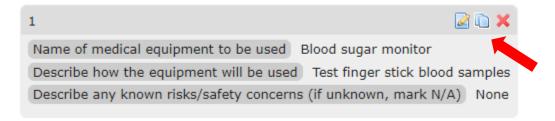


Similarly, in some places there are "cards" that function the same as a table.



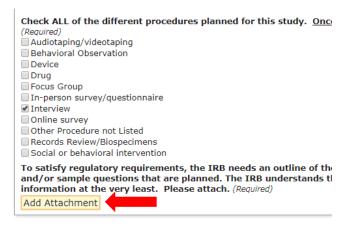


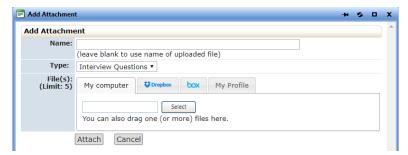
Complete the requested information and click "Save" just as with a regular table. You can add multiple entries; a new card will generate once you have saved the previous one. You can edit, duplicate, or delete entries by clicking on the icons in the top right corner after a row has been saved.



#### **Adding Attachments:**

In several places on the application, you will be asked to attach documents, such as consent forms, advertisements, etc. Simply click on the "Add Attachment" button.

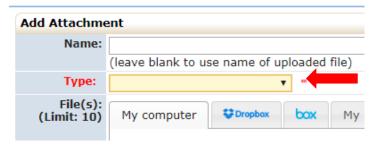




Once you have clicked the button, a window will pop-up allowing you to choose your file destination. Here you can select your file from various locations.



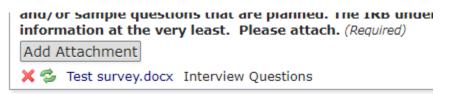
For some attachments you must choose a file type; where there is more than one type of document that might be uploaded IRBManager will not automatically choose one for you.



Once you have chosen and labeled your attachment, click "Attach" to upload.



After clicking "Attach", you will see a link to the attachment populate within the question.



You can remove or replace an attachment at any time using the icons on the left-hand side of the link.



When you are completing revisions, please replace the previous file with the updated version so that only the updated version is attached to the application.

#### Signing and submitting form:

Once you have filled out the form completely, it must be electronically signed before submitting. Please make sure to read and understand the entire section of Investigator Assurances and Acknowledgements before signing. Researchers and research personnel will be held accountable for these items.

#### **INVESTIGATOR'S CONTINUING RESPONSIBILITY TO IRB**

Add Note

Once the study has been approved, it is the Principal Investigator's (PI) responsibility to:

- · Ensure additional personnel take the CITI training and understand their responsibility when working with human participants.
- · Report all changes in research activity related to the study by submitting a Report of Change to the IRB.
- · Provide the IRB all study and consent form amendments and revisions.
  - IRB must approve these changes prior to their implementation.
  - All changes to advertisements recruiting study participants must also receive prior approval by the IRB.
- Promptly report any injury, adverse event, or detrimental incident experienced by a research participant that is or may be related to the research procedures.
- Renew study with the IRB at least ten business days prior to study expiration.
  - o All studies requiring continuing review must be reviewed at least annually.
  - Some studies will have the continuing review more frequently as determined in the initial review and approval.
  - Retro-active approval for lapsed studies is not allowed.
  - If the study approval lapses, you may be required to destroy any data collected or work completed during the lapsed time period.
- Inform the IRB if there is a newly identified Conflict of Interest or perceived Conflict of Interest.
- · Notify the IRB when the study is complete.

Failure to comply with these federally mandated responsibilities may result in suspension or termination of the study.

#### INVESTIGATOR ACKNOWLEDGMENT

- I have listed all potential Conflicts of Interest.
- I have read the definitions of Misconduct in Research.
- · I have read the Training requirements for IRB review.
- I have read the Investigator's Continuing Responsibilities to the IRB.
- I understand the definitions of Scientific Misconduct and Conflicts of Interest and my continuing responsibilities to the IRB.
- I understand submitting this application to the IRB does not constitute IRB approval, and that I will not proceed with my research (including recruitment initiation and obtaining participant informed consent) until I receive an approval letter from the IRB.
- By submitting this application, I attest to my agreement to conduct this research study in such a manner that acts of misconduct in research and conflicts of interest will not be committed and I will comply with the continuing responsibilities to the UCCS IRB.
- I will conduct my study in compliance with the UCCS IRB Standard Operation Procedures.

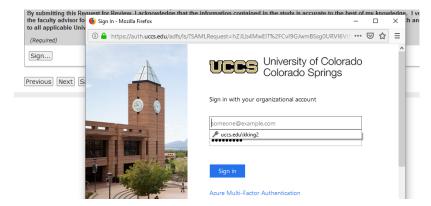
To sign the form, enter your password in the provided box. This will be the password as the credentials you used to log in to IRB Manager.

By submitting this form, as Principal Investigator, I hereby certify that to the best of my knowledge, Show Help Add Note View Audit the information furnished is true and complete, and that I have read and understand the Investigator Acknowledgement section. I understand that if found to be otherwise, it is sufficient cause for refusal or dismissal. I authorize representatives of the University of Colorado Colorado Springs to make any and all appropriate inquiries regarding the information listed in this supplement. I hereby release you or others from any liability or damage that may result from furnishing the information requested. (Required)

To sign, enter password for UCCSIRB@gmail.com



If this is the first time you have signed an application, a window will pop-up asking for your login credentials again. Enter your credentials and hit enter. If you have signed an application before, simply enter your password in the box.



Entering your password will create a signature time/date stamp on the bottom of the page.



Once you have signed and the signature stamp has populated, click "Next". You will be taken to a new page. You MUST click "Submit" on this page for your application to be sent for review.



Once your form has been successfully submitted, you will see the message below. **This will be the only notification you receive that your protocol was submitted.** 

## Form Submitted Your form has been submitted. You may close this window. Please contact the IRB (IRB@uccs.edu) if you have questions or have not been updated on your protocol within 10 business days.

You can then close the window and either exit IRB Manager or continue working on other forms.



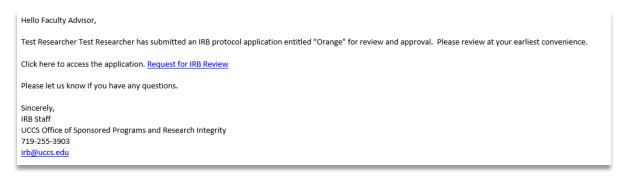
#### **Student submissions:**

Student submissions require Faculty Advisor approval. Make sure you have entered the correct information in the Faculty Advisor box on the "Study Personnel" page. If your Faculty Advisor's email is not an option, they do not have a contact in the system yet. Please contact them and ask them to log in using their UCCS credentials. Once they have logged in, you should be able to designate them as your Faculty Advisor.

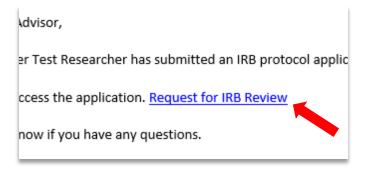
Once you have completed the information on the application, if you are a student, you will sign the form using your login credentials. Once you sign and click "Submit", the application will be routed to your Faculty Advisor to review.

#### **Faculty Advisor review and signature:**

Once your student has submitted their application, you will receive an email asking to review the application.



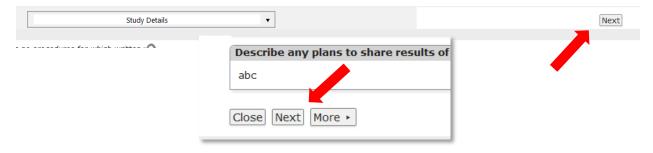
Click on the link provided in the email and it will take you to the protocol in IRB Manager (after being prompted to log in, if you are not already).



The link will open the completed application for your review. You can scroll through the application sections to verify all information provided is accurate. As the FA, you should thoroughly review the application before approving and signing.



Once you have reviewed the application, click "Next" at either the bottom or the top of the page.

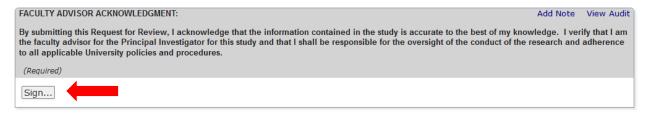


You will then see the following question:

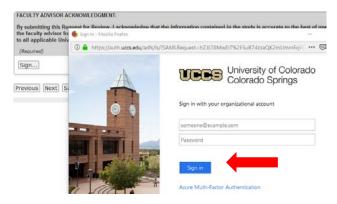


If there are no changes needed, click "Yes".

The Faculty Advisor Acknowledgement section will appear.



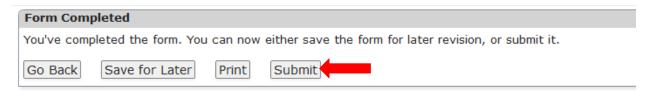
Review this section, and then click "Sign" to enter your password. Note that if this is your first time signing, a new window will open for you to enter your UCCS credentials. On subsequent signatures you will just enter your password in the box on the page.



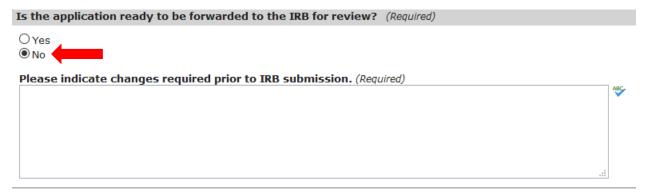
The signature time stamp will populate where the signature box was.

# FACULTY ADVISOR ACKNOWLEDGMENT: By submitting this Request for Review, I acknowledge that the faculty advisor for the Principal Investigator for this st to all applicable University policies and procedures. (Required) Signed Tuesday, March 26, 2019 11:33:21 AM ET by

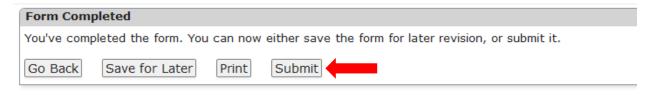
Then click "Next". You will be notified that your form is completed on the next page. Be sure to click "Submit". Your form will not move forward for processing unless you complete this step.



If there are revisions needed, click "No". A text box will appear.



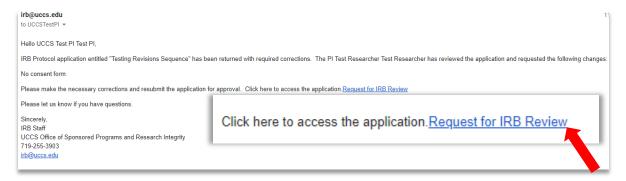
Explain the revisions needed in the provided text box. Once you are finished, click "Next". You will not be asked to sign this time, as the application is still incomplete. Instead, you will be taken to a page with the "Form Completed" message. Be sure to click "Submit" on this page or the application will not be routed back to the student PI for revisions.



The student PI will then receive an email letting them know changes are needed. The FA's feedback will be in the body of the email.

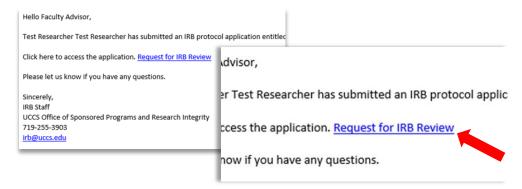


Click on the link in the email to access your application to make the requested changes.



The application will open (after you have logged in). The student PI can navigate the application just as during the initial submission to make the required changes. Changes will be highlighted in yellow for the FA (see below). Once all changes have been made, make sure to click "Submit" on the final page.

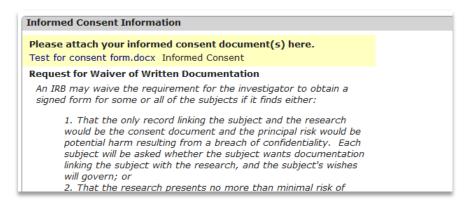
When the requisite changes have been made and the application is re-submitted, the FA will receive an email notification that the application is ready for their review and signature.



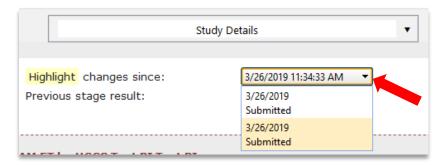
If they approve and sign, the application will move forward for review. If they require additional changes, the student PI will be notified and need to repeat this process again.



The email link will take the FA to a copy of the application. Changes made by the student PI will be highlighted. Review the changes and either approve or send back for further corrections, following the procedure above.



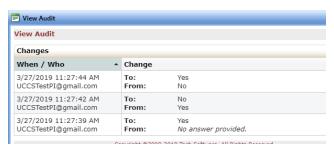
Previous changes can be viewed by using the drop down at the top of the page.



You can also view changes made to individual questions over the course of the app, by clicking on "View Audit" in the top right corner of each question.



A pop-up window will appear listing the changes made, who made those changes, and when they were made.





For supplemented questions, the pop-up will look slightly different, and you will have to click on each supplemental question to see the changes.



Once the FA is satisfied with all changes, they should sign and submit the form following the process outlined previously.

#### **Non-PI Submissions:**

Non-PI submissions follow similar procedures to student submissions. If the submitter is not the PI or CO-PI, they will click "Submit" on the final page of the form. There is **no signature page** for form submitters who are not the PI or CO-PI. Once the application has been submitted, it will be routed to the PI for approval and signature in the same manner as a student submission.

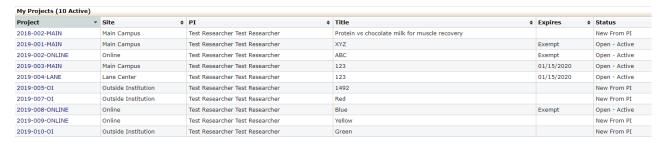
Please note that if you are trying to add a PI or other personnel and they are not showing up, it is because they are not a contact in the system yet. Please ask them to log in to IRBManager. Once they have logged in, you will be able to add them to the study.

#### **Checking on application progress:**

You can log back into your dashboard at anytime to check on the progress of your application. Your active projects (protocols) will be displayed in the center of the page. You can access approved protocols and those being reviewed under "Projects". Incomplete applications and those being reviewed currently can be accessed through the links under "xForms". Please be aware that it can take several minutes for your newly submitted application to show up here, it will not be instantaneous. The "Events" section will list your applications by type, including those that have been approved.



Also displayed at the bottom of this page, is a list of your active projects.

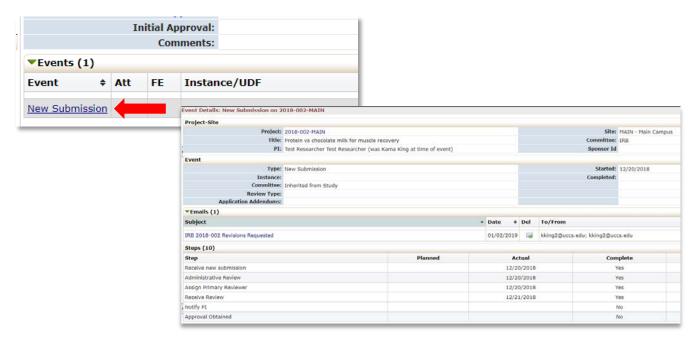


You can click on the project number on the right-hand side to accesss the details of that project.





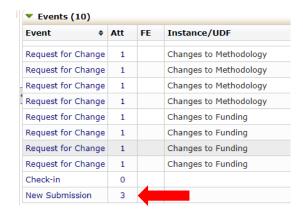
From this screen, you can check the detailed status history of your application to see where it is in the review process. In the bottom left-hand corner, click on the link under "Event". This may say a few different things based on if it is a new application, a renewal, or a request for change.



#### Accessing previous protocol documents and copies of application:

On the Event Details page of the application, you can access copies of your application, application documents, and copies of correspondence related to your review. (See previous section if you do not know how to navigate to the Event Details page.)

To open attachments, click on the number next to the associated application (e.g., New Submission, Request for Change).

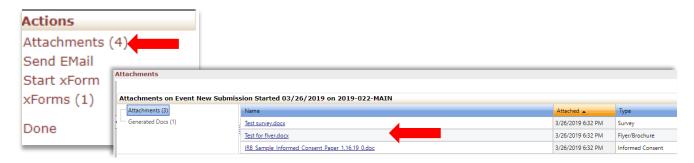


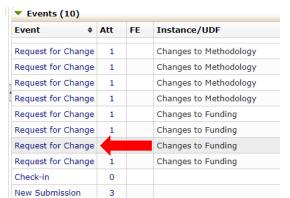


On the following page, you can click through and download your application attachments and approval letter. The approval letter is under "Generated Docs". The file should download to wherever you have your browser set to save downloaded files.



You can also open attachments from the left-hand "Actions" menu on the "Event Details" page.



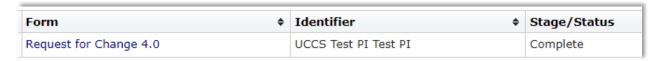


To access a PDF copy of your application, from the Project Page, click on the application you wish to access.

On the following page, click on "xForms" in the top left corner.



Click on the hyperlink to the application you would like a copy of. It will open in a new window where you can print or save to PDF.



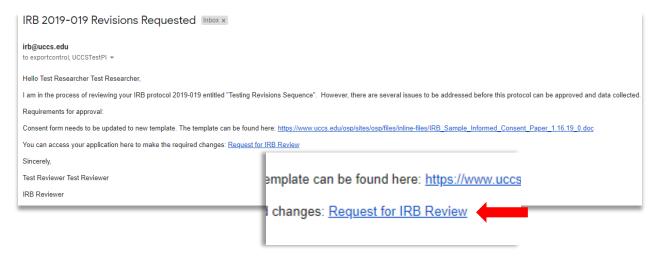


Under the "Actions" menu, you can also review email correspondence. To open, click on the title under "Subject". Any attachments originally sent with the email will still be attached.



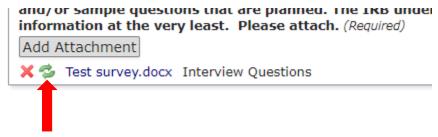
#### **Revisions:**

There may be instances that the application is returned for revisions by a reviewer, Faculty Advisor, PI, or the IRB office. If you are asked to make revisions, you will receive an email similar to the one below. Click on the link in the email and you will be taken to your application to make the requested changes. (Note: This email will go to the form submitter and the PI if the submitter is not the PI.)



The link will open the application (once you have logged in). You will be able to edit and navigate the application just as you did on the initial submission. Navigate through the pages and make the changes requested.

If you are attaching new versions of files, please use the replace feature. This will make it easier for your reviewer as they do not have to figure out which file is the new file.



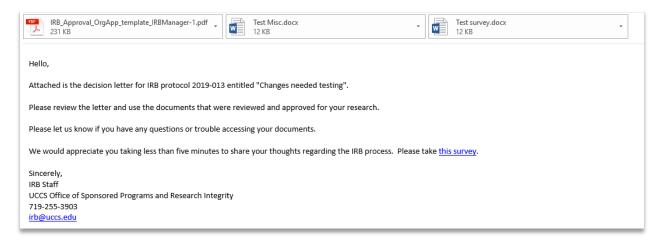


Once all revisions are complete, resubmit the form. If you are the PI, you will be asked to sign again. If you are a non-PI submitter, you will simply click "Submit". The application will then be routed as it was previously for signatures and review. Be aware you may be asked to make several rounds of revisions if necessary.

If review and signature by the FA or PI are necessary, they will be notified via email to review and sign the application (see "Faculty Advisor review and signature").

#### **Approvals:**

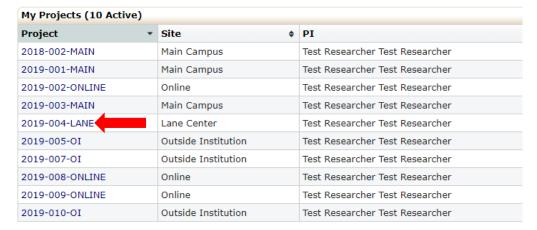
When your protocol has been approved, you will receive an email with an approval letter and all accompanying attachments you submitted.



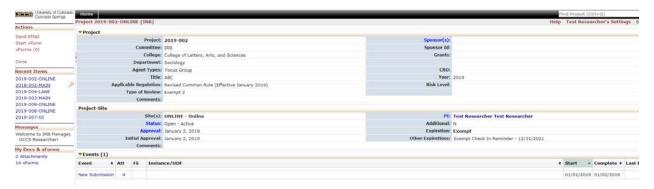
You can also access approved protocols and their accompanying documents and correspondence through your dashboard as described previously.

#### **Starting a Request for Change or Continuing Review Application:**

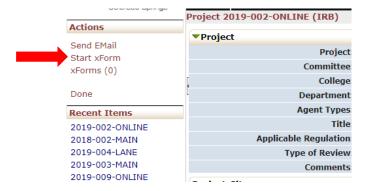
A Request for Change or Renewal (Continuing Review) application **can only be started** from an existing approved study. To start a request for change form, log in to your IRBManager dashboard. Locate the protocol for which you want to submit an application under "My Projects" and click on the Project number.



You'll be taken to the following study details screen.



#### On the left-hand side under "Actions" click "Start xForm"



A new tab will open, and you can select whichever application you need.



The functionality of these forms is the same as the original application.



#### **Exempt and Non-Expiring Check-In:**

For studies that do not have a formal expiration date, the IRB requests that you complete an Exempt and Non-Expiring Check-In. You will be notified via email 30 days before the check-in date. To access this form, see the previous <u>section</u>.

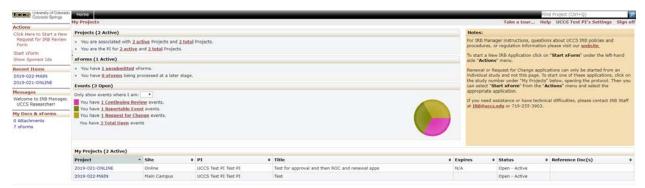
#### **Unanticipated Events and Deviations:**

Any deviation or unanticipated event from your approved protocol must be reported to the IRB (see the <u>IRB SOP's</u> for more information). To access the Unanticipated Event/Deviation form in IRBManager, see the previous <u>sections</u>.

#### **Detailed IRBManager features:**

#### Dashboard:

The dashboard is essentially your home page or control panel. You can start new applications, check on the status of applications, and access approved protocols and documents.



#### Actions:

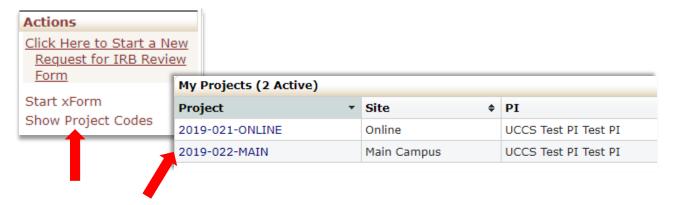
On the left-hand side of the page you will see the "Actions" menu.



This menu is where you will start a new application (see "Creating a new application").



Additionally, you will see "Show Sponsor Ids", which allows you to change how your studies are labeled. Clicking here will remove the Project number and replace with Sponsor Id's. Once selected, the menu item will change to "Show Project Codes". Clicking this will make the protocol number visible again under "My Projects".



#### Recent Items:

Below "Actions" on the left side, you will see "Recent Items". These will typically be the last protocols you worked on or accessed.



Hovering your mouse over these items will give you the option to pin them to this list, so that they always show up here. This can be useful if you have a large number of protocols and need quick access to certain ones.



#### Messages:

There are no action items in the "Messages" menu.

#### My Docs & xForms:

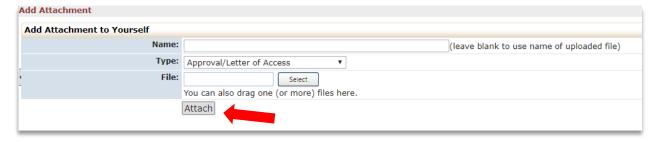
The last left-hand menu is "My Docs & xForms".



Clicking on "Attachments" will take you to your attachment page. Here you can upload files that are likely to use for multiple protocols, such as CITI certificates, survey instruments, etc. This is similar to a drop box or digital locker. Please be aware that the IRB cannot access these documents, so please be sure to add documents to specific protocols as they are needed. This is to serve as your own personal repository for convenience.

To upload an attachment, simply click on "Add Attachment" under the left-hand "Actions" menu.





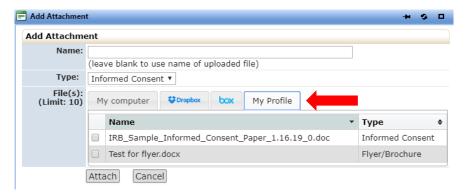
Select the file and file type, rename if necessary, and then click "Attach". Note that you can attach more than one file at a time.

Your files will then be uploaded to your profile.





You can then attach these files on application questions. They will be under the "My Profile" tab in the attachment pop-up window.



Clicking on "xForms" under the "My Docs & Forms" menu will take you to the "My Forms" page.



You can sort your forms using the drop down at the top of the page.



#### My Projects:

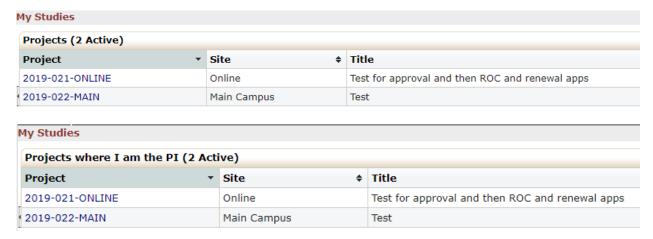
The "My Projects" section of the dashboard gives you a snapshot of your active and in progress protocols. It also allows you to quickly find protocols by type (ROC, Renewal, original application) and those that are still in progress.



Under "Projects", you can see how many active and total projects you are associated with. The first bullet links to all projects you are on, while the second includes only those that you are listed as the PI.



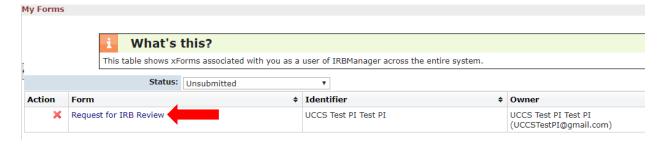
Clicking the hyperlinks will take you to the list of those studies.



The "xForms" section in the middle of the page shows you forms (applications) in progress. It will show you unsubmitted forms and those that are being processed.



Clicking on the hyperlink for unsubmitted xForms will take you to the "My Forms" page listing all of the unsubmitted applications. Click on the form name to open the incomplete application and continue working.

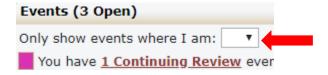




The "Events" section of the page shows the breakdown of events on approved protocols. These include Requests for Change, Renewals, and Unanticipated Events.



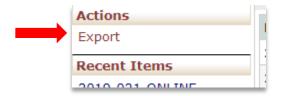
If you have multiple roles on various studies, you can sort by role using the drop down.



Clicking on any of the hyperlinks will take you to that study on the "My Events" page.

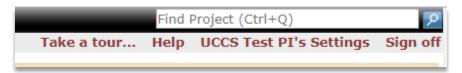


From this page, clicking on "Export" on the left side of the page will export an excel sheet of your studies for each event category. Note this file only exports basic information such as protocol number, event type, and PI.



#### Other Dashboard Features:

In the top right corner of the dashboard, there are several useful features.

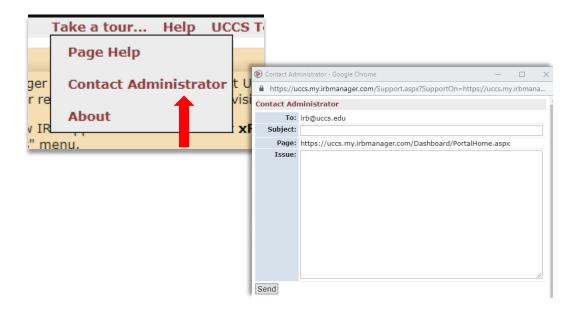


The "Take a tour" feature will give you a basic overview of features and links and can be helpful if you just need a quick reminder.

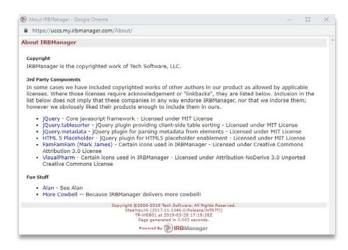




The "**Help**" feature is currently not active. Please see <u>OSPRI website</u> and guides. However, if you hover your mouse over the hyperlink, you can contact the IRB or get IRBManager version information. Clicking on "Contact Administrator" will open a new window where you can email us about any issues.



Hovering over "Help" and then clicking on "About" will open IRBManager information for those that are curious.

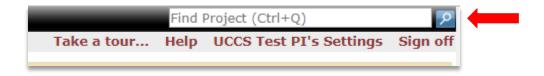




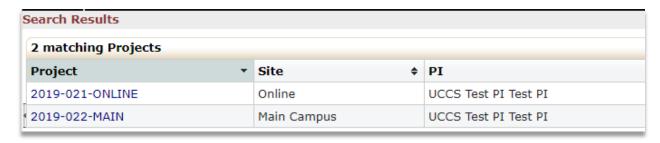
The "**Settings**" feature will be mostly non-functional for UCCS faculty, staff, and students due to your authentication through the UCCS system. For outside researchers who are issued a login, they may use these features to update their contact information and change their password.



The search bar in the top right allows you to quickly find protocols with minimal information. You can search by protocol number or project title. Be aware that if searching by number, you must input a complete protocol number or the beginning numbers. It will not search for incomplete secondary numbers. For example, protocols are typically titled by 4-digit year then protocol number, 2019-021. You can search for 2019 or 2019-021, but not 021.

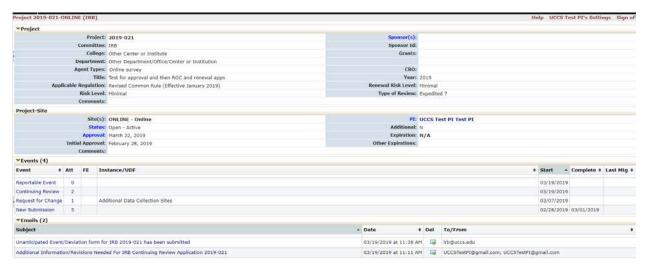


Searching using the leading digits will produce a list of protocols.



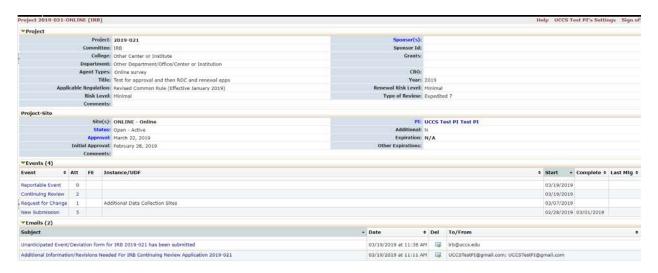


Searching using the complete protocol number will take you directly to that study's information page.



#### **Project pages:**

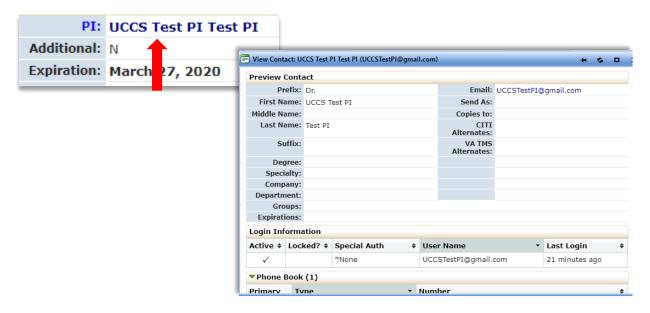
In IRBManager, protocols are referred to as "Projects". Every protocol will have a project page, which can be accessed from the dashboard and other access points.



This page details research personnel, approval information, submission and approval dates, events related to the study (ROCs, renewals, etc.), and all email correspondence generated during the review and approval process.



Some elements on the page allow you to click through to other information. For example, clicking on the PI name will take you to the PI's contact information. The text for clickable sections will be in blue.



The "Events" section toward the bottom lists events on the study. These include the original application, Requests for Change, Renewals, and Unanticipated Event forms.

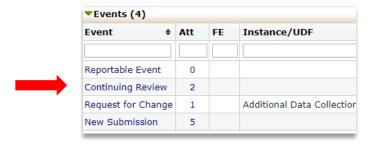


If there are additional personnel, such as a CO-PI or Faculty Advisor, they will be listed under "Project-Site Contacts".

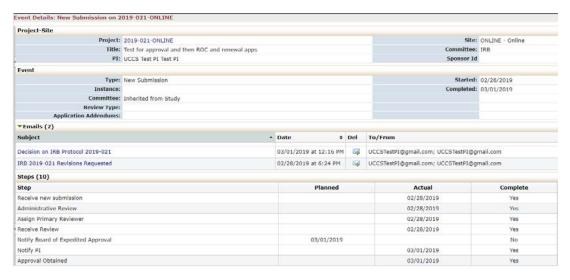


#### **Event details pages:**

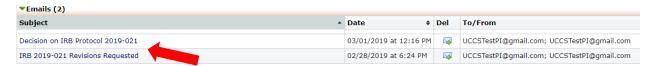
To access the event page, click on the hyperlink of the event you wish to view under "Event" on the project page.



The "Event Details" page looks similar to the project page, but it contains some additional information and allows you to access documents and correspondence associated with the protocol.



From this page, you can download and open emails sent to you during the review/approval process. Choose the email you wish to open from the "Subject" column under "Emails" in the center of the page.





The emails will download to wherever you have your browser set to save files. Note, all attachments sent with the email originally will be attached.



You can also view and download any attachments associated with your protocol via the left side "Actions" menu.



From the "Actions" menu, you can also view your approved application. Click on "xForms".





On the form page, click on the name of the form you wish to open. The completed form will open in a new tab.



The option "Start xForm" under the "Actions" menu is disabled on this screen. You can only start a new form such as, Requests of Change and Renewals, from the "Project" page. If you click this hyperlink, a new tab will open, but it will have no content.

Similarly, the "Send Email" option is not functional. Please do not use this feature to contact the IRB or fellow researchers.

#### Additional questions and technical issues:

While we have tried to make this guide as comprehensive as possible, you may have additional questions or experience technical issues. We would be glad to assist you with these. Please contact IRB staff via email <a href="IRB@uccs.edu">IRB@uccs.edu</a> or by phone at 719-255-3903.