



Office of Sponsored Programs
and Research Integrity

UNIVERSITY OF COLORADO
COLORADO SPRINGS

User Manual for IRBManager

June 2019

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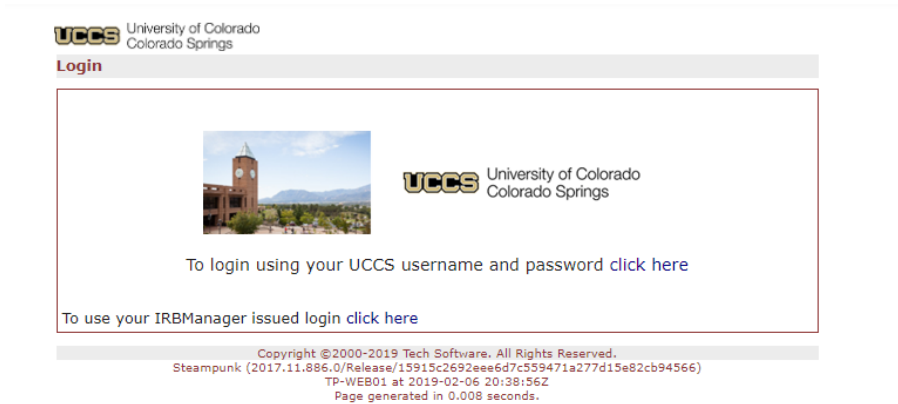
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Getting Started:

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

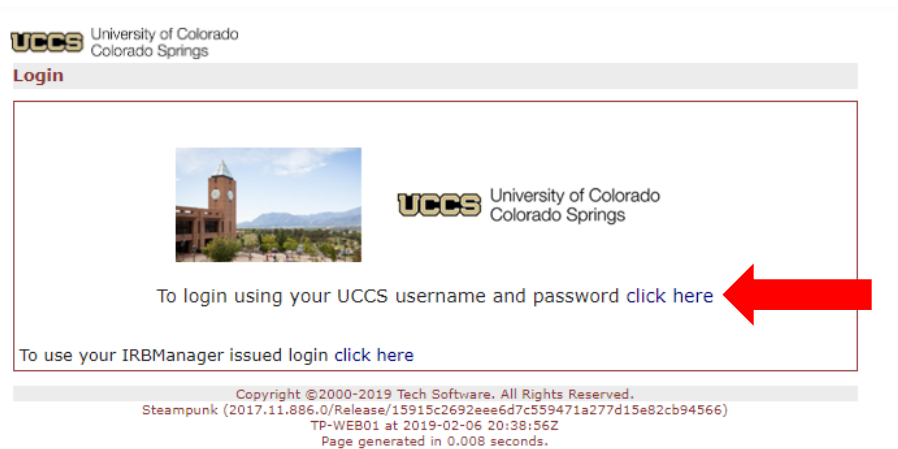
Open your web browser and go to <https://uccs.my.irbmanager.com/>

Once you click the link, you will be taken to the following screen:



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.

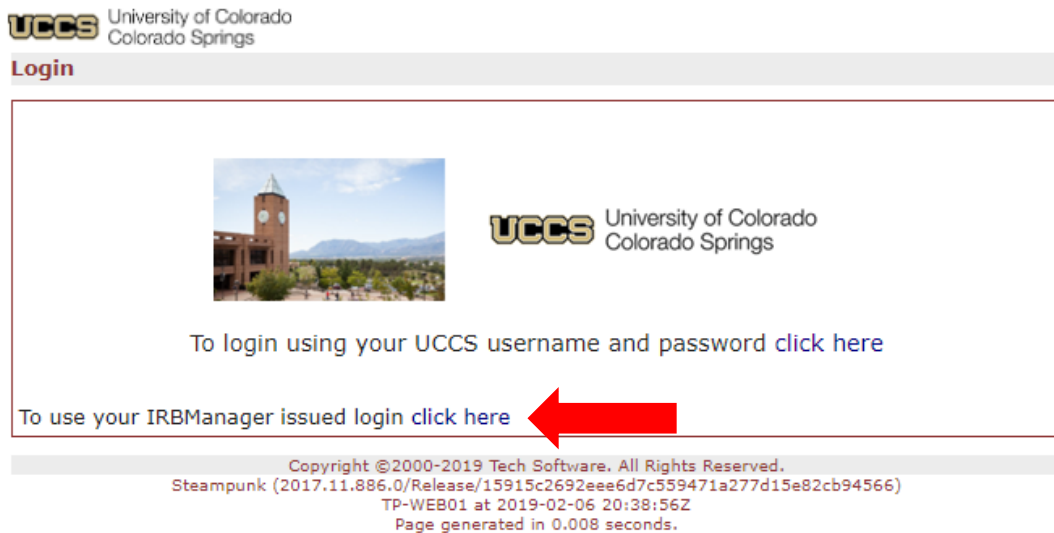


You will be taken to the UCCS authentication page, where you will enter your credentials.



If you do not have a UCCS email, please contact IRB@uccs.edu 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.

The screenshot shows the IRB Manager dashboard. On the left, there are navigation menus for 'Actions', 'Recent Items', 'Messages', and 'My Docs & xForms'. The main area displays 'My Projects (10 Active)' with a summary of active and total projects, xForms, and events. A table lists 10 active projects with columns for Project, Site, PI, Title, Expires, Status, and Reference Doc(s). A 'Notes' section in the top right provides help and contact information.

Project	Site	PI	Title	Expires	Status	Reference Doc(s)
2018-002-MAIN	Main Campus	Test Researcher Test Researcher	Protein vs chocolate milk for muscle recovery		New From PI	
2019-001-MAIN	Main Campus	Test Researcher Test Researcher	XVZ	Exempt	Open - Active	
2019-002-ONLINE	Online	Test Researcher Test Researcher	ABC		Open - Active	
2019-003-MAIN	Main Campus	Test Researcher Test Researcher	123	01/15/2020	Open - Active	
2019-004-LANE	Lane Center	Test Researcher Test Researcher	123		Open - Active	
2019-005-OI	Outside Institution	Test Researcher Test Researcher	1492		New From PI	
2019-007-OI	Outside Institution	Test Researcher Test Researcher	Red		New From PI	
2019-008-ONLINE	Online	Test Researcher Test Researcher	Blue	Exempt	Open - Active	
2019-009-ONLINE	Online	Test Researcher Test Researcher	Yellow		New From PI	
2019-010-OI	Outside Institution	Test Researcher Test Researcher	Green		New From PI	

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 [website](#)

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.

This image shows a close-up of the top navigation bar. The 'Home' button is highlighted with a red arrow, indicating its function to return the user to the dashboard.

For more detailed information about dashboard features, see the “[Detailed help for IRB Manager features](#)” section later in this guide.

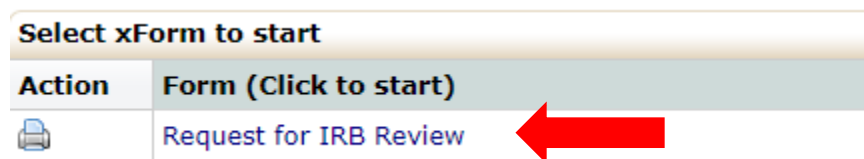
Creating new application:

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



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 “Study Details” page.

The screenshot shows the 'Study Details' page for the 'Request for IRB Review' form. The page header includes 'Collaborators', 'Study Details', and 'Page 1 of 6'. The main content area contains the following text:

UNIVERSITY OF COLORADO COLORADO SPRINGS
INSTITUTIONAL REVIEW BOARD (IRB) for Human Subjects
REQUEST FOR IRB REVIEW

Review application deadlines and meeting dates, listed at the beginning of each semester on the IRB meeting page, available here.
Please note the level of review is determined by the IRB.

ATTENTION: CITI human subjects research training is required for all personnel including PIs and Co-PIs involved in human subjects research. Faculty Advisors must also complete the training before submitting a protocol for review. All student requests for review must be submitted by a Faculty Advisor and human subjects CITI training must be complete PRIOR TO IRB REVIEW. If you have not completed CITI training at the time you submit your application, the processing of your application will be delayed.

Go to CITI and follow the instructions to complete the required IRB training.

To navigate between pages/sections of the application, use the drop down at the TOP of the page. Use this feature instead of the “Next” button to move to the following page when you have not answered all of the required fields. If you click “Next” before answering the required questions, it will highlight missing fields. Please note that additional pages may appear as you answer questions.

You may save the application at any time using the “save for later” button at the bottom of the page and return to the form at your convenience. The application cannot be submitted until all required questions are answered and accompanying documents are attached.

Additional information and clarification is provided for some questions either directly to the right of the question, or displayed when hovering over questions with your mouse (note, not all questions have additional information). If you need further clarification or examples, please click here for detailed application instructions.

* Denotes Required Field

Form Submitter View Audit

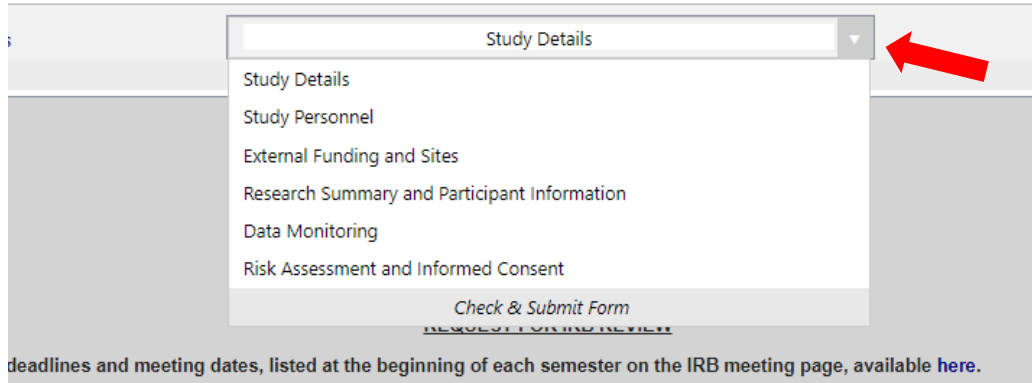
UCCS Test PI Test PI
Email: UCCSTestPI@gmail.com

Have you reviewed the researcher manual? (Required) View Audit

Yes
 No

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 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.

Collaborators Study Personnel Page 2 of 6

The following issues exist. Click on an issue to jump there.

- Human Subjects Training Complete - Required.
- Principal Investigator Name - Required.
- PI Affiliation - Required.
- Department/Center/Institute - Required.
- Student Personnel - Required.

Principal Investigator Information View Audit

==> Human Subjects Training Complete - Required.
==> Principal Investigator Name - Required.
==> PI Affiliation - Required.
==> Department/Center/Institute - Required.

Has the PI completed the required CITI training within the past three years? (Required) ?
 Yes
 No

Most Recent CITI Training Date

Enter the UCCS email address of the Principal Investigator. (Required)

PI Affiliation (Required)
 UCCS Faculty
 UCCS Staff
 Current UCCS Student

Department/Center/Institute (Required)

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

Collaborators Study Personnel

The following issues exist. Click on an issue to jump there.

- Human Subjects Training Complete - Required.
- Principal Investigator Name - Required.
- PI Affiliation - Required.
- Department/Center/Institute - Required.
- Student Personnel - Required.

Principal Investigator Information

==> Human Subjects Training Complete - Required.
==> Principal Investigator Name - Required.
==> PI Affiliation - Required.
==> Department/Center/Institute - Required.

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.

way (directly and purpose of te

[Show Help](#) [View Audit](#)

Note: Records should be kept for 3 years after the completion of the research or after the funding has ended, depending on which is longer.

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.

Request for Waiver of Written Documentation ?
Are you requesting a waiver of written documentation of informed consent (i.e., online survey where a signature is not possible)?
(Required)
 Yes
 No

Request for Alteration of Informed Consent ?
Are you requesting an alteration of informed consent?
 Yes
 No

Describe the consent process, including who will be involved in the process.

An IRB may waive the requirement for the investigator to obtain a signed form for some or all of the subjects if it finds either:

1. That the only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern; or
2. That the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context.

45 CFR 46-117(c)(1 or 2)

In cases in which the documentation requirement is waived, the IRB may require the investigator to provide subjects with a written statement regarding the research.

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.







Additional Personnel Detailed Information (Non-Student)				Show Help	View Audit
Additional Personnel Information					
Email Address*	Has this person completed the required CITI training?*	Most Recent CITI Training Date	Affiliation*	Action	
<input type="text"/>	<input type="radio"/> Yes <input type="radio"/> No	<input type="text"/>	<input type="text"/>	Save	

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.**

Co-Investigator(s) Detailed Information				Show Help	View Audit
Co-Investigator Information					
Email Address*	Has this person completed the required CITI training?*	Most Recent CITI Training Date	Affiliation*	Action	
Test Reviewer Test Reviewer Email: UCCSIRB@gmail.com	Yes	2/4/2019	UCCS Faculty		
<input type="text"/>	<input type="radio"/> Yes <input type="radio"/> No	<input type="text"/>	<input type="text"/>	Save	

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

Most Recent CITI Training Date	Affiliation*	Action
2/4/2019	UCCS Faculty	  
<input type="text"/>	<input type="text"/>	  

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




1 Save

Name of medical equipment to be used*

Describe how the equipment will be used*

Describe any known risks/safety concerns (if unknown, mark N/A)*

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.

1   

Name of medical equipment to be used Blood sugar monitor

Describe how the equipment will be used Test finger stick blood samples

Describe any known risks/safety concerns (if unknown, mark N/A) None


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.

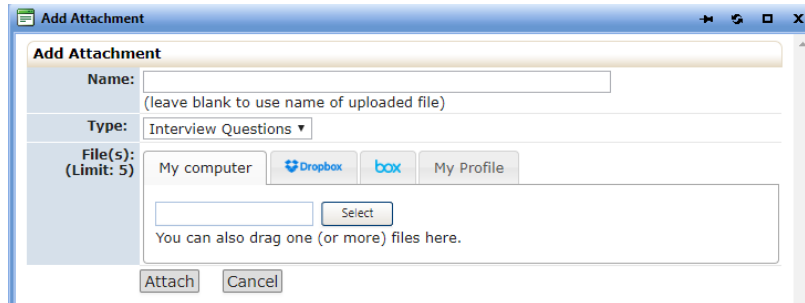
Check ALL of the different procedures planned for this study. One (Required)

- Audiotaping/videotaping
- Behavioral Observation
- Device
- Drug
- Focus Group
- In-person survey/questionnaire
- Interview
- Online survey
- Other Procedure not Listed
- Records Review/Biospecimens
- Social or behavioral intervention

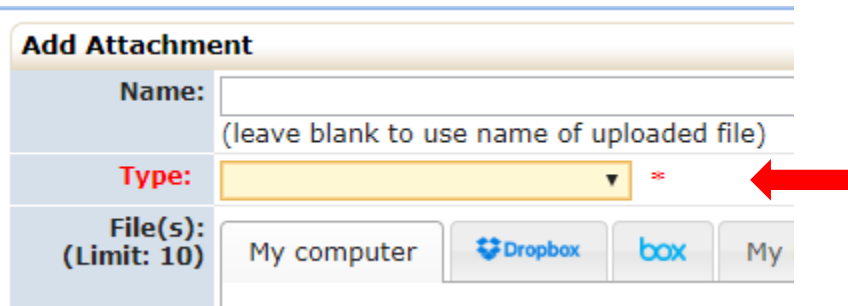
To satisfy regulatory requirements, the IRB needs an outline of the and/or sample questions that are planned. The IRB understands this information at the very least. Please attach. (Required)

Add Attachment 

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.

Add Attachment

Name:
(leave blank to use name of uploaded file)

Type: Interview Questions ▾

File(s): (Limit: 5)
My computer

You can also drag one (or more) files here

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

and/or sample questions that are planned. The 1KB under information at the very least. Please attach. (Required)

[Test survey.docx](#) Interview Questions

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

and/or sample questions that are planned. The 1KB under information at the very least. Please attach. (Required)

[Test survey.docx](#) Interview Questions

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

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.
 - 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.

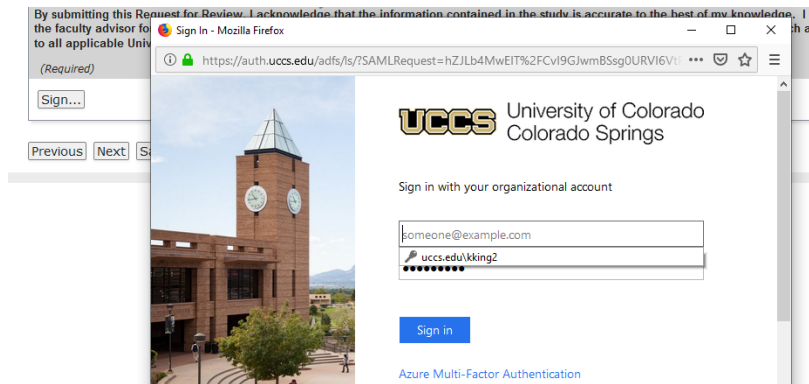
To sign the form, enter your password in the provided box. This will be the password as the credentials you used to log in to IRB Manager.

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



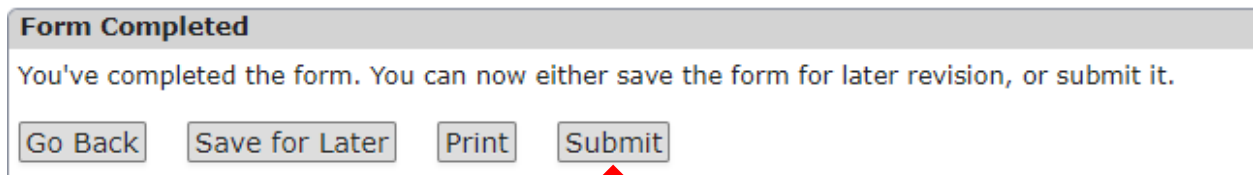
If this is the first time you have signed an application, a window will pop-up asking for your login credentials again. Enter your credentials and hit enter. If you have signed an application before, simply enter your password in the box.



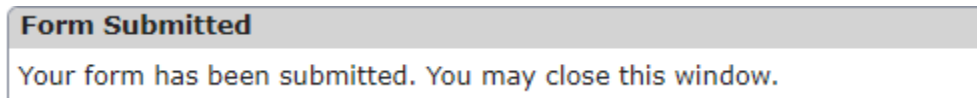
Entering your password will create a signature time/date stamp on the bottom of the page.



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.**



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

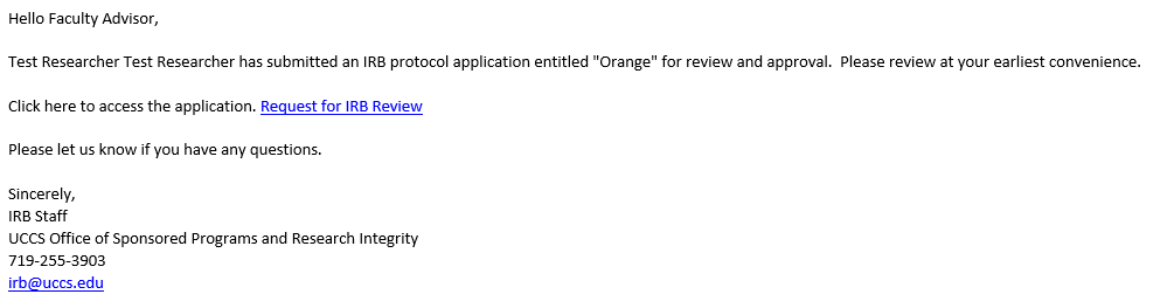
Student submissions:

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.

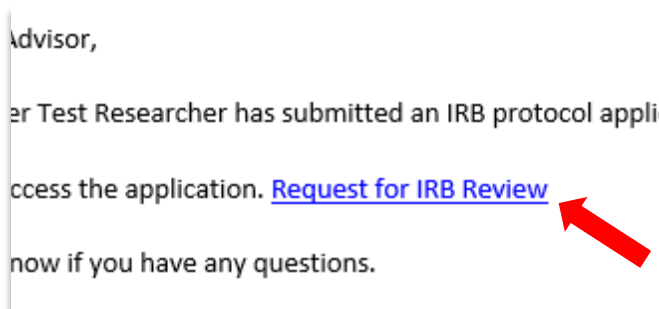
Once you have completed the information on the application, if you are a student, you will sign the form using your login credentials. Once you sign and click “Submit”, the application will be routed to your Faculty Advisor to review.

Faculty Advisor review and signature:

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

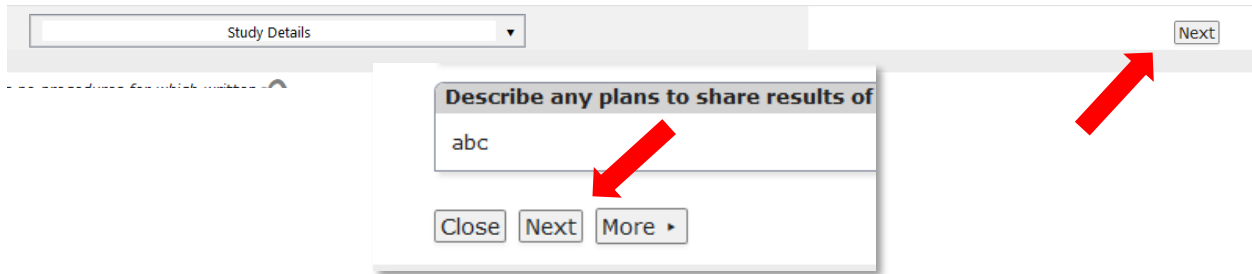


Click on the link provided in the email and it will take you to the protocol in IRB Manager (after being prompted to log in, if you are not already).



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:

Is the application ready to be forwarded to the IRB for review? (Required)

Yes
 No

Previous Next Save for Later More >

If there are no changes needed, click “Yes”.

The Faculty Advisor Acknowledgement section will appear.

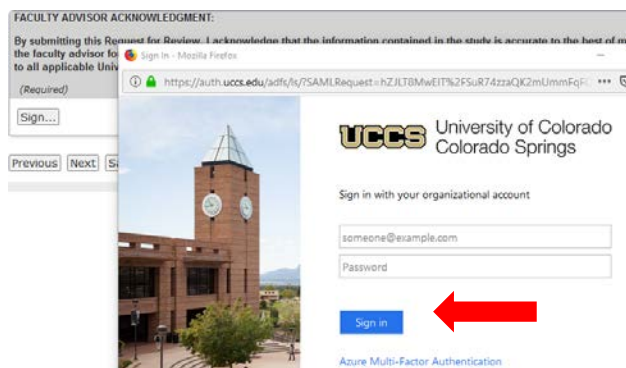
FACULTY ADVISOR ACKNOWLEDGMENT: [Add Note](#) [View Audit](#)

By submitting this Request for Review, I acknowledge that the information contained in the study is accurate to the best of my knowledge. I verify that I am the faculty advisor for the Principal Investigator for this study and that I shall be responsible for the oversight of the conduct of the research and adherence to all applicable University policies and procedures.

(Required)

Sign... ←

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 I am the faculty advisor for the Principal Investigator for this study and I agree to all applicable University policies and procedures.

(Required)

Signed Tuesday, March 26, 2019 11:33:21 AM ET by [Name]

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.**

Form Completed

You've completed the form. You can now either save the form for later revision, or submit it.

←

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

Is the application ready to be forwarded to the IRB for review? *(Required)*

Yes
 No ←

Please indicate changes required prior to IRB submission. *(Required)*

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.**

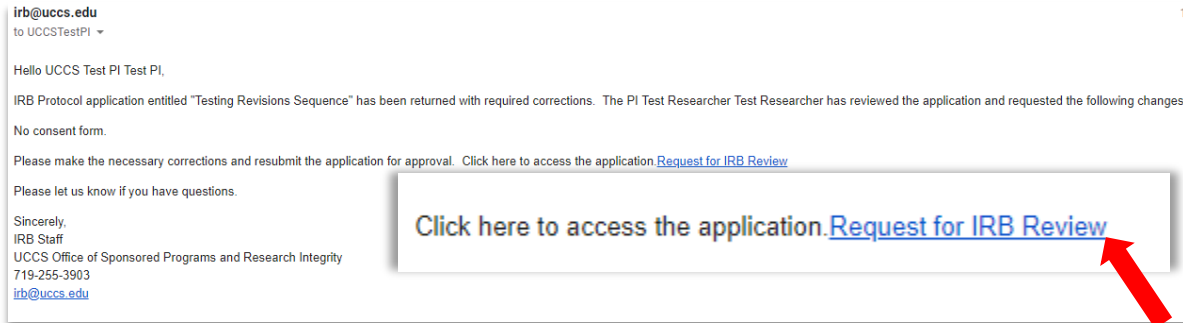
Form Completed

You've completed the form. You can now either save the form for later revision, or submit it.

←

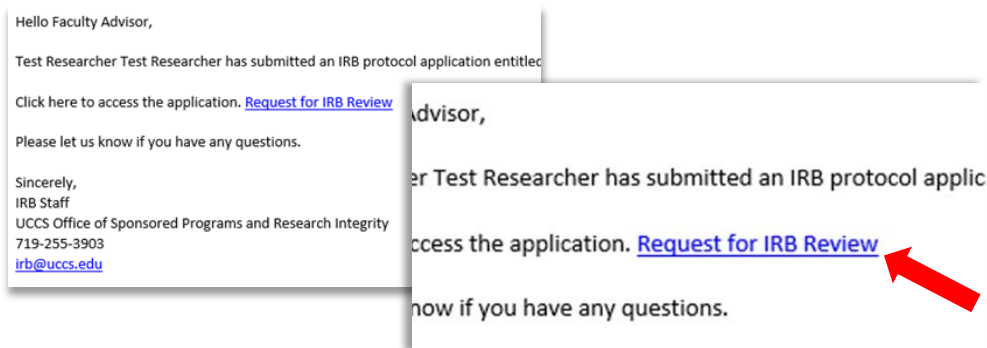
The student PI will then receive an email letting them know changes are needed. The FA's feedback will be in the body of the email.

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.

Informed Consent Information

Please attach your informed consent document(s) here.
 Test for consent form.docx Informed Consent

Request for Waiver of Written Documentation
An IRB may waive the requirement for the investigator to obtain a signed form for some or all of the subjects if it finds either:

1. That the only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern; or
2. That the research presents no more than minimal risk of

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

Study Details ▾

Highlight changes since: 3/26/2019 11:34:33 AM ▾

Previous stage result:

- 3/26/2019 Submitted
- 3/26/2019 Submitted

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.

Have you reviewed the researcher manual? (Required)

Yes
 No

[View Audit](#)

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

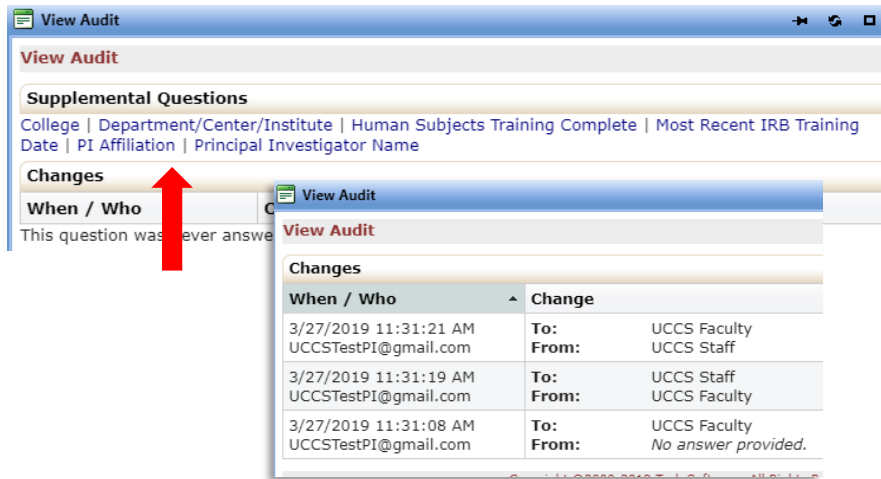
View Audit

View Audit

Changes

When / Who	Change
3/27/2019 11:27:44 AM UCCSTestPI@gmail.com	To: Yes From: No
3/27/2019 11:27:42 AM UCCSTestPI@gmail.com	To: No From: Yes
3/27/2019 11:27:39 AM UCCSTestPI@gmail.com	To: Yes From: No answer provided.

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 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 all of your applications by type, including those that have been approved.

My Projects

Projects (10 Active)

- You are associated with **10 active** Projects and **10 total** Projects.
- You are the PI for **10 active** and **10 total** Projects.

xForms (10 Active)

- You have **2 unsubmitted** xForms.
- You have **8 xForms** being processed at a later stage.

Events (8 Open)

Only show events where I am:


- You have **2 Continuing Review** events.
- You have **5 New Submission** events.
- You have **1 Request for Change** events.

You have **8 Total Open** events

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

My Projects (10 Active)							
Project	Site	PI	Title	Expires	Status	Reference Doc(s)	
2018-002-MAIN	Main Campus	Test Researcher Test Researcher	Protein vs chocolate milk for muscle recovery		New From PI		
2019-001-MAIN	Main Campus	Test Researcher Test Researcher	XYZ	Exempt	Open - Active		
2019-002-ONLINE	Online	Test Researcher Test Researcher	ABC	Exempt	Open - Active		
2019-003-MAIN	Main Campus	Test Researcher Test Researcher	123	01/15/2020	Open - Active		
2019-004-LANE	Lane Center	Test Researcher Test Researcher	123	01/15/2020	Open - Active		
2019-005-OI	Outside Institution	Test Researcher Test Researcher	1492		New From PI		
2019-007-OI	Outside Institution	Test Researcher Test Researcher	Red		New From PI		
2019-008-ONLINE	Online	Test Researcher Test Researcher	Blue	Exempt	Open - Active		
2019-009-ONLINE	Online	Test Researcher Test Researcher	Yellow		New From PI		
2019-010-OI	Outside Institution	Test Researcher Test Researcher	Green		New From PI		

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

My Projects (10 Active)	
Project	Site
2018-002-MAIN	Main Campus
2019-001-MAIN	Main Campus
2019-002-ONLINE	Online
2019-003-MAIN	Main Campus
 2019-004-LANE	Lane Center
2019-005-OI	Outside Institution
2019-007-OI	Outside Institution
2019-008-ONLINE	Online
2019-009-ONLINE	Online
2019-010-OI	Outside Institution

Project 2018-002-MAIN (IRB) Help Test Researcher's Settings Sign off

Project

Project: 2018-002	Sponsor(s): Department of Justice (Primary)
Committee: IRB	Sponsor Id:
College:	Grants:
Department: Anthropology	CRO:
Agent Types: Other Procedure not Listed	Year: 2018
Title: Protein vs chocolate milk for muscle recovery	Risk Level:
Applicable Regulations: Pre-2018 Common Rule	
Type of Review:	
Comments:	

Project Site

Site(s): MAIN - Main Campus and others	PI: Test Researcher Test Researcher
Status: New From PI	Additional: N
Approval:	Expiration:
Initial Approval:	Other Expirations:
Comments:	

Events (1)


Event	Att	FE	Instance/UDF	Start	Complete	Last Mtg
New Submission	0			12/20/2018		

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.

Initial Approval:

Comments:

Events (1)

Event	Att	FE	Instance/UDF
 New Submission	0		

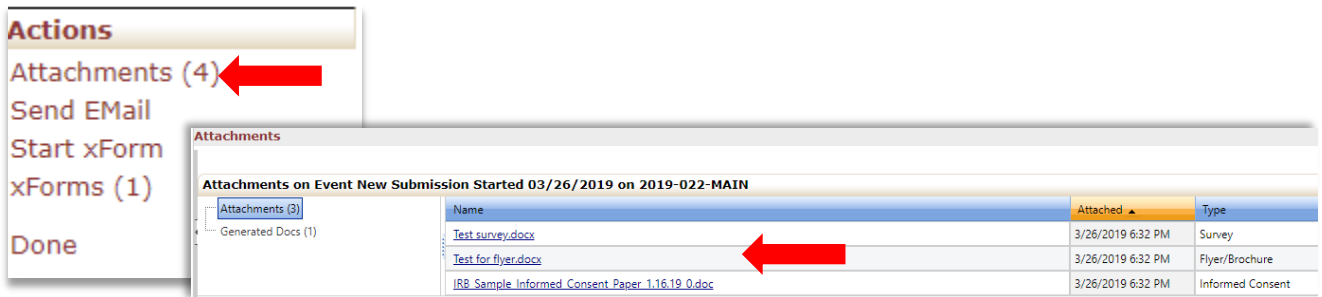
Event Details: New Submission on 2018-002-MAIN Help Test Researcher's Settings Sign

Project - Site	
Project: 2018-002-MAIN	Site: MAIN - Main Campus
Title: Protein vs chocolate milk for muscle recovery	Committee: IRB
PI: Test Researcher Test Researcher (was Kama King at time of event)	Sponsor Id:
Event	
Type: New Submission	Started: 12/20/2018
Instance:	Completed:
Committee: Inherited from Study	
Review Type:	
Application Addendums:	
▼ Emails (1)	
Subject	Date Del To/From
IRB 2018-002 Revisions Requested	01/02/2019 kking2@uccs.edu; kking2@uccs.edu
▼ Steps (10) Hide Skippe	
Step	Planned Actual Complete Minutes Micro Note
Receive new submission	
Administrative Review	12/20/2018 Yes
Assign Primary Reviewer	12/20/2018 Yes
Receive Review	12/21/2018 Yes
Notify PI	No
Approval Obtained	No

On this page you will find copies of any emails or other documents you were sent related to your review. To open, click on the title under “Subject”.

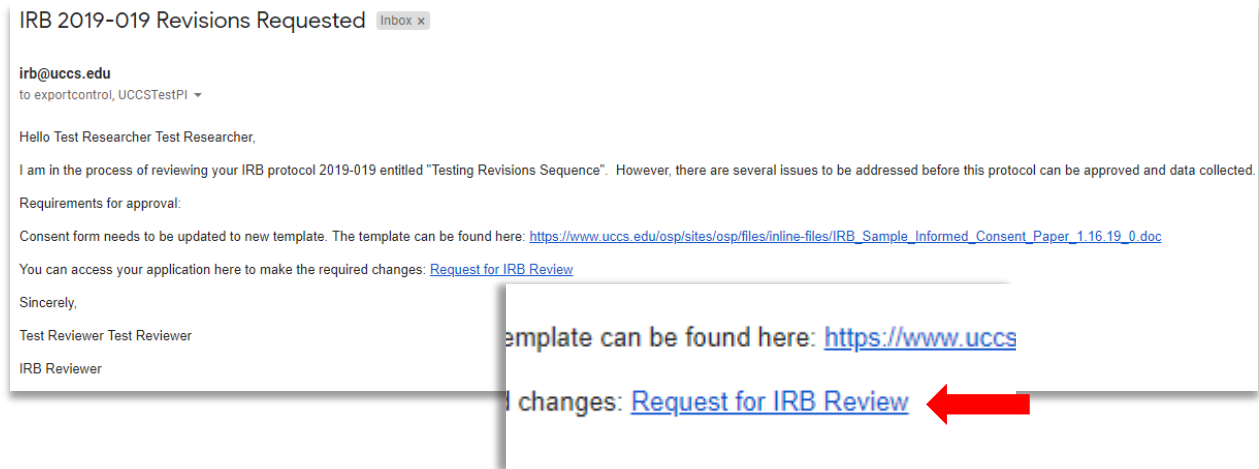


The file should download to wherever you have your browser set to save downloaded files. Any attachments originally sent with the email will still be attached. You can open attachments from there or from the left-hand “Actions” menu.



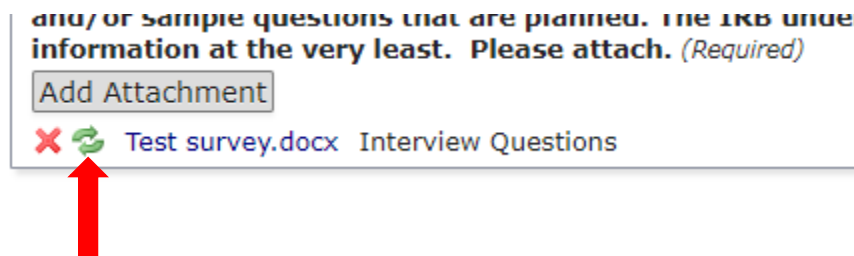
Revisions:

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.

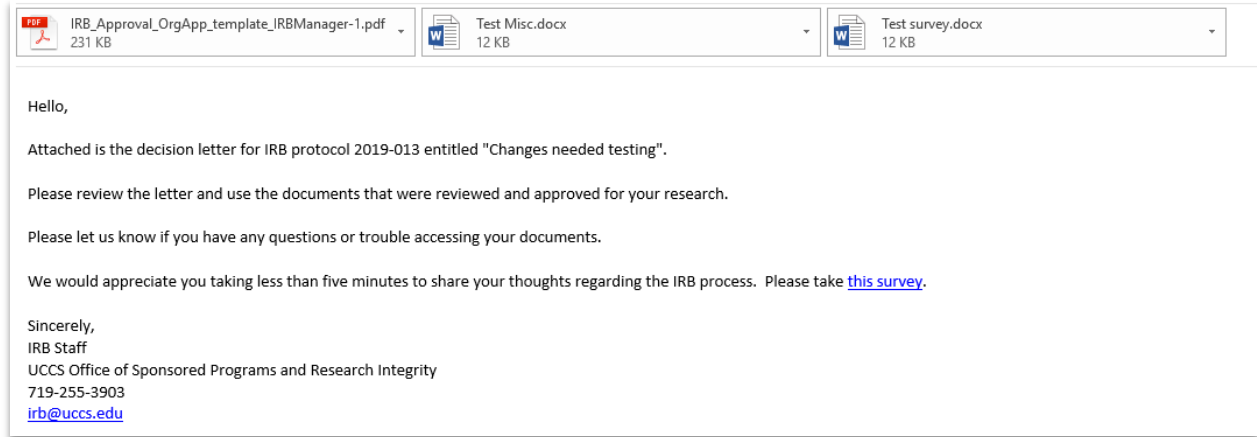


Once all revisions are complete, resubmit the form. If you are the PI, you will be asked to sign again. If you are a non-PI submitter, you will simply click "Submit". The application will then be routed as it was previously for signatures and review. Be aware you may be asked to make several rounds of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



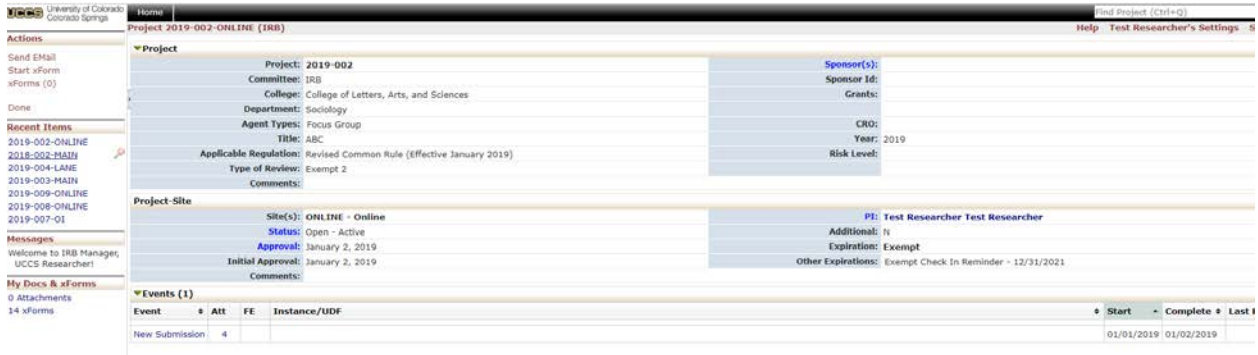
You can also access approved protocols and their accompanying documents and correspondence through your dashboard as described previously.

Starting a Request for Change or Continuing Review Application:

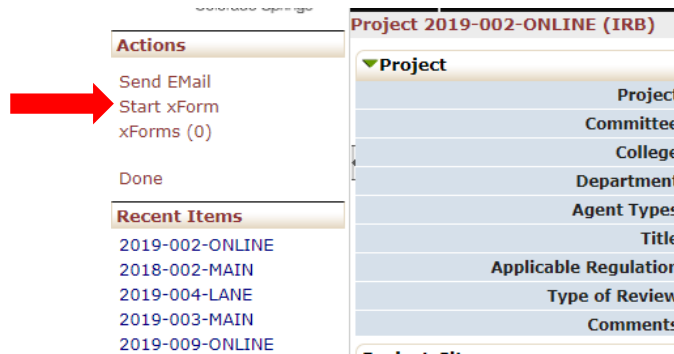
A Request for Change or Renewal (Continuing Review) application **can only be started** from an existing approved study. To start a request for change form, log in to your IRBManager dashboard. Locate the protocol for which you want to submit an application under “My Projects” and click on the Project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

My Projects (10 Active)		
Project	Site	PI
2018-002-MAIN	Main Campus	Test Researcher Test Researcher
2019-001-MAIN	Main Campus	Test Researcher Test Researcher
2019-002-ONLINE	Online	Test Researcher Test Researcher
2019-003-MAIN	Main Campus	Test Researcher Test Researcher
2019-004-LANE	Lane Center	Test Researcher Test Researcher
2019-005-OI	Outside Institution	Test Researcher Test Researcher
2019-007-OI	Outside Institution	Test Researcher Test Researcher
2019-008-ONLINE	Online	Test Researcher Test Researcher
2019-009-ONLINE	Online	Test Researcher Test Researcher
2019-010-OI	Outside Institution	Test Researcher Test Researcher

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.

Action	Form (Click to start)	Description
	Exempt and Non-Expiring Check-In	Exempt and Non-Expiring Check-In
	Request for Change	Use this form to request all changes for approved protocols.
	Request for Continuing Review	Request for Continuing Review
	Unanticipated Event/Deviation Form	Use this form for each incident of an unanticipated event OR protocol deviation.

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 [section](#).

Unanticipated Events and Deviations:

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

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.

The screenshot shows the IRBManager dashboard with the following sections:

- Actions:** Click Here to Start a New Request for IRB Review Form, Start xForm, Show Sponsor Ids
- My Projects (2 Active):**
 - Projects (2 Active): You are associated with 2 active Projects and 2 total Projects. You are the PI for 2 active and 2 total Projects.
 - xForms (1 Active): You have 1 unsubmitted xForms. You have 0 xForms being processed at a later stage.
 - Events (3 Open): Only show events where I am: [dropdown]. You have 1 Continuing Review events. You have 1 Repeatable Event events. You have 1 Request for Change events. You have 3 Total Open events.
- Recent Items:** 2019-022-MAIN, 2019-021-ONLINE
- Messages:** Welcome to IRB Manager, UCCS Researcher
- My Docs & xForms:** 0 Attachments, 7 xForms
- Notes:** For IRB Manager instructions, questions about UCCS IRB policies and procedures, or regulation information please visit our website. To start a New IRB Application click on "Start xForm" under 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.

Project	Site	PI	Title	Expires	Status	Reference Doc(s)
2019-021-ONLINE	Online	UCCS Test PI Test PI	Test for approval and then ROC and renewal apps	N/A	Open - Active	
2019-022-MAIN	Main Campus	UCCS Test PI Test PI	Test		Open - Active	

Actions:

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

Actions

[Click Here to Start a New Request for IRB Review Form](#)

[Start xForm](#)

[Show Sponsor Ids](#)

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".

Actions

[Click Here to Start a New Request for IRB Review Form](#)

[Start xForm](#)

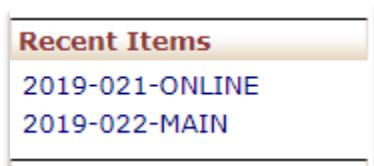
[Show Project Codes](#)

My Projects (2 Active)		
Project	Site	PI
2019-021-ONLINE	Online	UCCS Test PI Test PI
2019-022-MAIN	Main Campus	UCCS Test PI Test PI

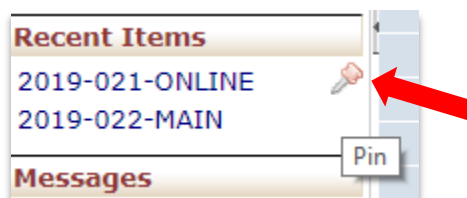
Two red arrows point from the "Show Project Codes" link in the Actions menu to the "Project" column of the My Projects table.

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.

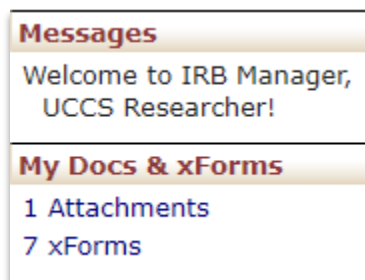


Messages:

There are no action items in the “Messages” menu.

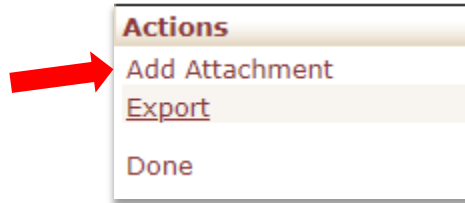
My Docs & xForms:

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.



 A screenshot of the 'Add Attachment' form. It has a title bar 'Add Attachment' and a sub-header 'Add Attachment to Yourself'. The form contains three main sections: 'Name' with a text input field and a note '(leave blank to use name of uploaded file)'; 'Type' with a dropdown menu currently set to 'Approval/Letter of Access'; and 'File' with a text input field, a 'Select' button, and a note 'You can also drag one (or more) files here.'. At the bottom of the form is an 'Attach' button. A red arrow points from the right towards the 'Attach' button.

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.

 A screenshot of the 'Attachments' page. At the top, there is a green banner with an information icon and the text 'What's this? These are attachments associated with you as a user of IRBManager. This is not a list of attachments for a specific protocol or event. Attachments here are not linked to any specific study or event.' Below this is a section titled 'Attachments on Yourself' which contains a table.

Action	Name	Attached	Type	Attached By
	IRB_Sample_Informed_Consent_Paper_1.16.19_0.doc	3/27/2019 12:32 PM	Informed Consent	UCCSTestPI@gmail.com
	Test for flyer.docx	3/27/2019 1:16 PM	Flyer/Brochure	UCCSTestPI@gmail.com

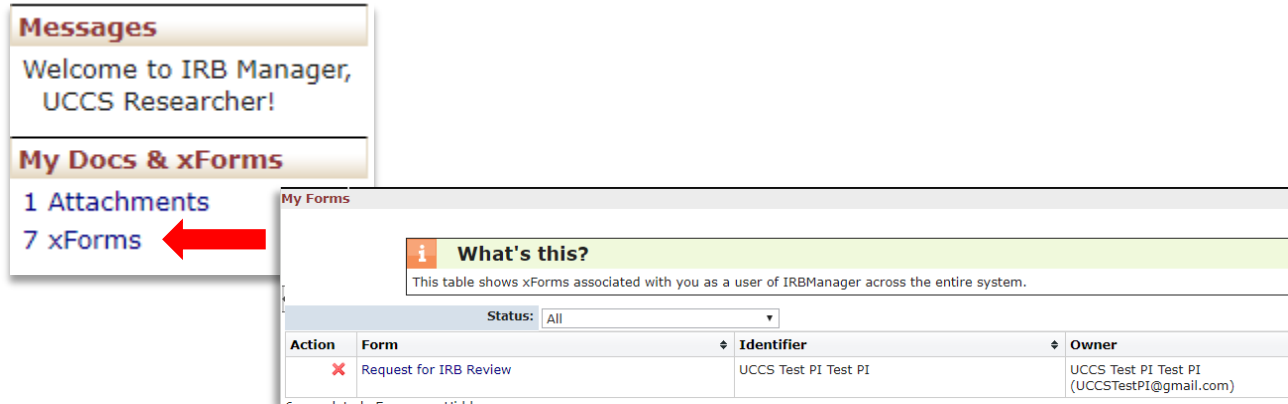
You can then attach these files on application questions. They will be under the “My Profile” tab in the attachment pop-up window.

 A screenshot of the 'Add Attachment' pop-up window. It has a title bar 'Add Attachment' and a sub-header 'Add Attachment'. The form contains three main sections: 'Name' with a text input field and a note '(leave blank to use name of uploaded file)'; 'Type' with a dropdown menu currently set to 'Informed Consent'; and 'File(s): (Limit: 10)' with four tabs: 'My computer', 'Dropbox', 'box', and 'My Profile'. A red arrow points from the right towards the 'My Profile' tab. Below the tabs is a table of selected files.

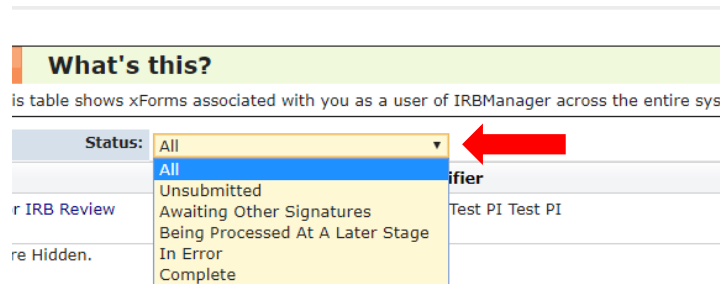
Name	Type
<input type="checkbox"/> IRB_Sample_Informed_Consent_Paper_1.16.19_0.doc	Informed Consent
<input type="checkbox"/> Test for flyer.docx	Flyer/Brochure

 At the bottom of the window are 'Attach' and 'Cancel' buttons.

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.

My Studies

Projects (2 Active)

Project	Site	Title
2019-021-ONLINE	Online	Test for approval and then ROC and renewal apps
2019-022-MAIN	Main Campus	Test

My Studies

Projects where I am the PI (2 Active)

Project	Site	Title
2019-021-ONLINE	Online	Test for approval and then ROC and renewal apps
2019-022-MAIN	Main Campus	Test

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.

xForms (1 Active)

- You have **1 unsubmitted** xForms.
- You have **0 xForms** being processed at a later stage.

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.

My Forms

What's this?
 This table shows xForms associated with you as a user of IRBManager across the entire system.

Status: Unsubmitted

Action	Form	Identifier	Owner
✘	Request for IRB Review	UCCS Test PI Test PI	UCCS Test PI Test PI (UCCSTestPI@gmail.com)

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

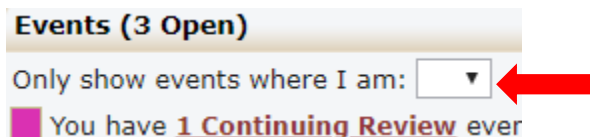
Events (3 Open)

Only show events where I am:

- You have **1 Continuing Review** events.
- You have **1 Reportable Event** events.
- You have **1 Request for Change** events.
- You have **3 Total Open** 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.

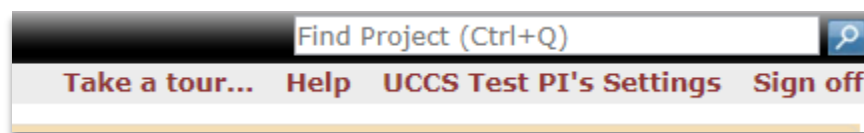
Project	Event	Started
2019-021-ONLINE	Continuing Review	03/19/2019

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.

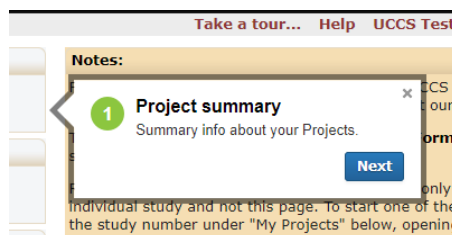


Other Dashboard Features:

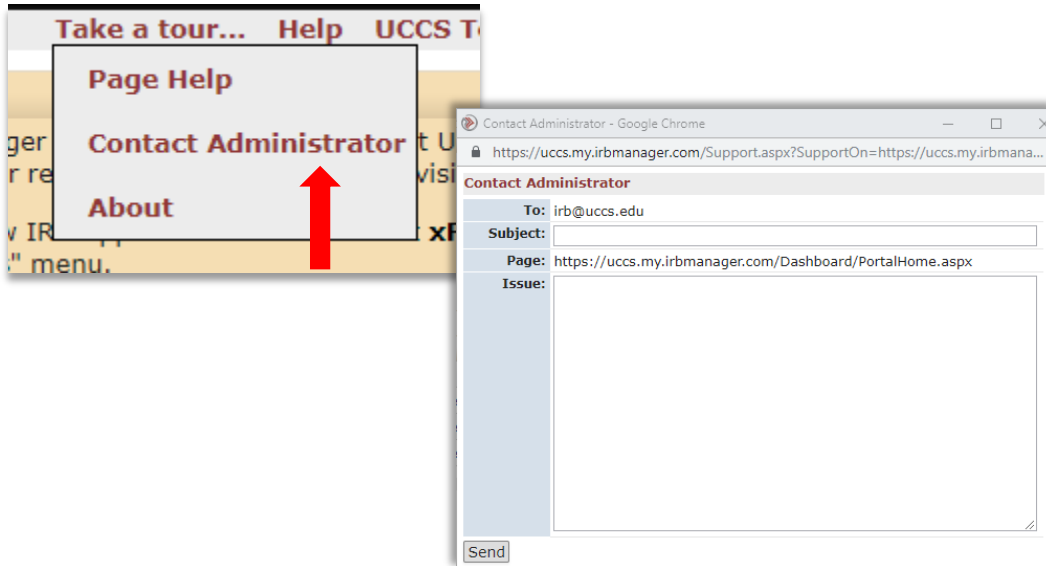
In the top right corner of the dashboard, there are several useful features.



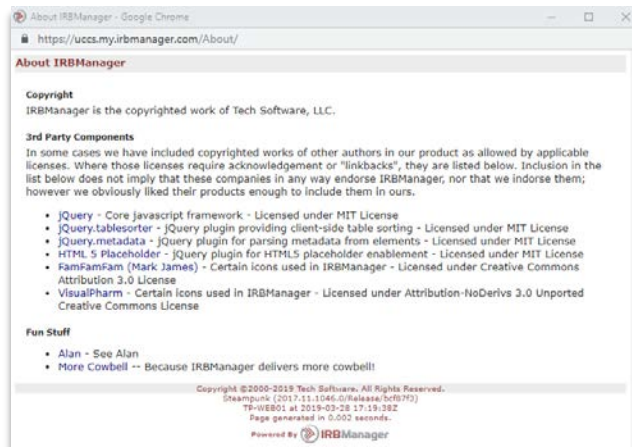
The “**Take a tour**” feature will give you a basic overview of features and links and can be helpful if you just need a quick reminder.



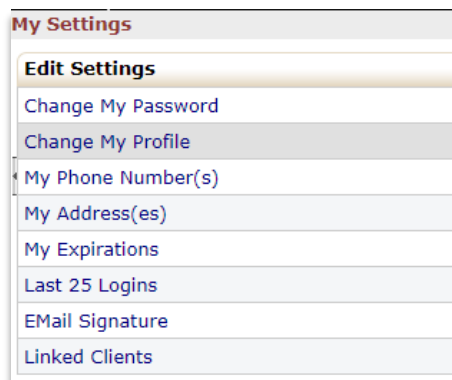
The “**Help**” feature is currently not active. Please see [OSPRI website](#) and guides. However, if you hover your mouse over the hyperlink, you can contact the IRB or get IRBManager version information. Clicking on “**Contact Administrator**” will open a new window where you can email us about any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



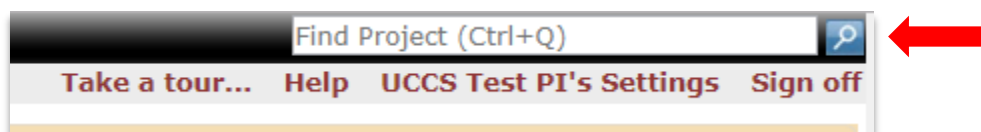
Hovering over “**Help**” and then clicking on “**About**” will open IRBManager information for those that are curious.



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.

Search Results		
2 matching Projects		
Project	Site	PI
2019-021-ONLINE	Online	UCCS Test PI Test PI
2019-022-MAIN	Main Campus	UCCS Test PI Test PI

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

Project 2019-021-ONLINE (IRB) Help UCCS Test PI's Settings Sign off

Project

<p>Project: 2019-021 Committee: IRB College: Other Center or Institute Department: Other Department/Office/Center or Institution Agent Types: Online survey Title: Test for approval and then ROC and renewal apps Applicable Regulation: Revised Common Rule (Effective January 2019) Risk Level: Minimal Comments:</p>	<p>Sponsor(s): Sponsor Id: Grants: CRO: Year: 2019 Renewal Risk Level: Minimal Type of Review: Expedited 7</p>
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Project-Site

<p>Site(s): ONLINE - Online Status: Open - Active Approval: March 22, 2019 Initial Approval: February 28, 2019 Comments:</p>	<p>PI: UCCS Test PI Test PI Additional: N Expiration: N/A Other Expirations:</p>
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Events (4)

Event	Att	FE	Instance/UDF	Start	Complete	Last Mtg
Reportable Event	0			03/19/2019		
Continuing Review	2			03/19/2019		
Request for Change	1		Additional Data Collection Sites	03/07/2019		
New Submission	5			02/28/2019	03/01/2019	

Emails (2)

Subject	Date	Del	To/From
Unanticipated Event/Deviation form for IRB 2019-021 has been submitted	03/19/2019 at 11:38 AM		irb@uccs.edu
Additional Information/Revisions Needed For IRB Continuing Review Application 2019-021	03/19/2019 at 11:11 AM		UCCSTestPI@gmail.com; UCCSTestPI@gmail.com

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.

Project 2019-021-ONLINE (IRB) Help UCCS Test PI's Settings Sign off

Project

<p>Project: 2019-021 Committee: IRB College: Other Center or Institute Department: Other Department/Office/Center or Institution Agent Types: Online survey Title: Test for approval and then ROC and renewal apps Applicable Regulation: Revised Common Rule (Effective January 2019) Risk Level: Minimal Comments:</p>	<p>Sponsor(s): Sponsor Id: Grants: CRO: Year: 2019 Renewal Risk Level: Minimal Type of Review: Expedited 7</p>
--	--

Project-Site

<p>Site(s): ONLINE - Online Status: Open - Active Approval: March 22, 2019 Initial Approval: February 28, 2019 Comments:</p>	<p>PI: UCCS Test PI Test PI Additional: N Expiration: N/A Other Expirations:</p>
--	--

Events (4)

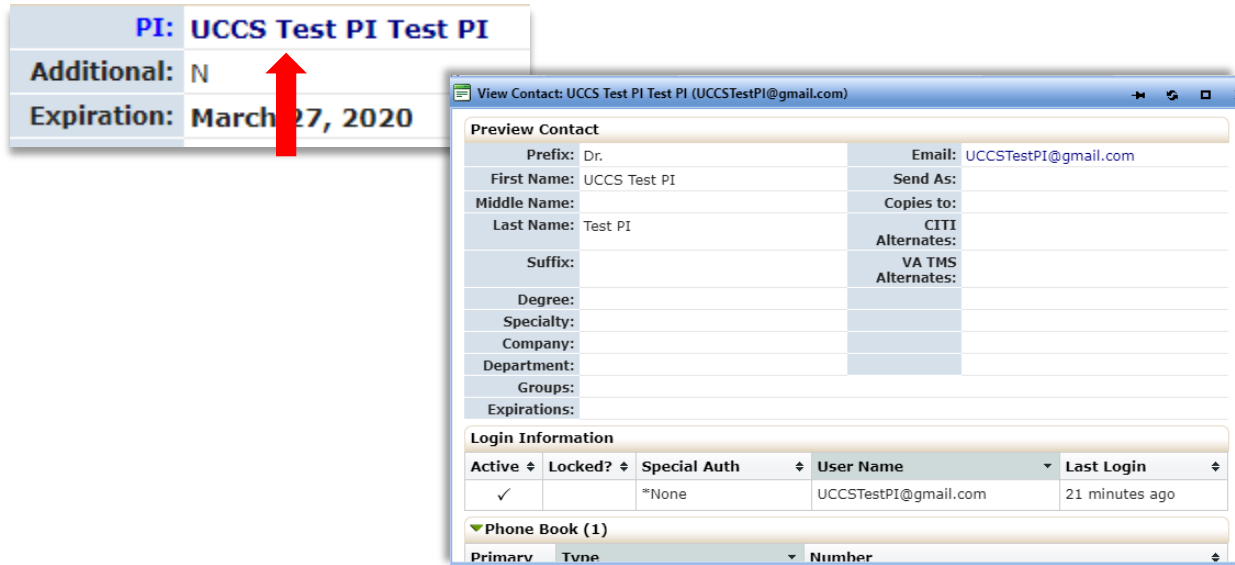
Event	Att	FE	Instance/UDF	Start	Complete	Last Mtg
Reportable Event	0			03/19/2019		
Continuing Review	2			03/19/2019		
Request for Change	1		Additional Data Collection Sites	03/07/2019		
New Submission	5			02/28/2019	03/01/2019	

Emails (2)

Subject	Date	Del	To/From
Unanticipated Event/Deviation form for IRB 2019-021 has been submitted	03/19/2019 at 11:38 AM		irb@uccs.edu
Additional Information/Revisions Needed For IRB Continuing Review Application 2019-021	03/19/2019 at 11:11 AM		UCCSTestPI@gmail.com; UCCSTestPI@gmail.com

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.

Event	Att	FE	Instance/UDF	Start	Complete
Reportable Event	0			03/19/2019	
Continuing Review	2			03/19/2019	
Request for Change	1		Additional Data Collection Sites	03/07/2019	
New Submission	5			02/28/2019	03/01/2019


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

Project-Site Contacts (1)	
Name	Role
Kama King	Faculty Advisor

▼ Events (1)

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.




▼ Events (4)			
Event	Att	FE	Instance/UDF
Reportable Event	0		
Continuing Review	2		
Request for Change	1		Additional Data Collection
New Submission	5		

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.

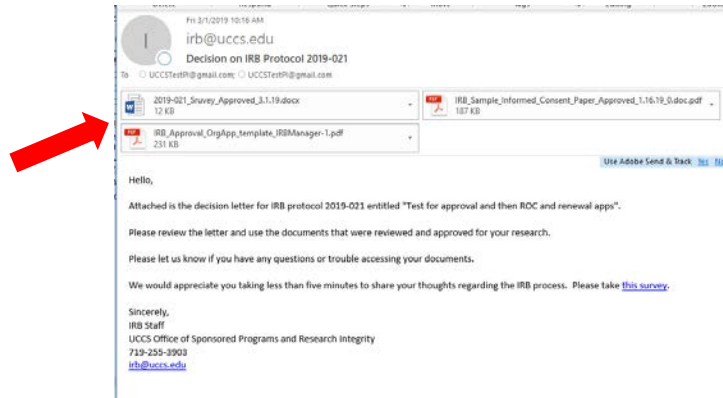
Event Details: New Submission on 2019-021-ONLINE			
Project-Site			
Project:	2019-021-ONLINE	Site:	ONLINE - Online
Title:	Test for approval and then ROC and renewal apps	Committee:	IRB
PI:	UCCS Test PI Test PI	Sponsor Id	
Event			
Type:	New Submission	Started:	02/28/2019
Instance:		Completed:	03/01/2019
Committee:	Inherited from Study		
Review Type:			
Application Addendums:			
▼ Emails (2)			
Subject	Date	Del	To/From
Decision on IRB Protocol 2019-021	03/01/2019 at 12:16 PM		UCCSTestPI@gmail.com; UCCSTestPI@gmail.com
IRB 2019-021 Revisions Requested	02/28/2019 at 6:24 PM		UCCSTestPI@gmail.com; UCCSTestPI@gmail.com
Steps (10)			
Step	Planned	Actual	Complete
Receive new submission		02/28/2019	Yes
Administrative Review		02/28/2019	Yes
Assign Primary Reviewer		02/28/2019	Yes
Receive Review		02/28/2019	Yes
Notify Board of Expedited Approval	03/01/2019		No
Notify PI		03/01/2019	Yes
Approval Obtained		03/01/2019	Yes

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.

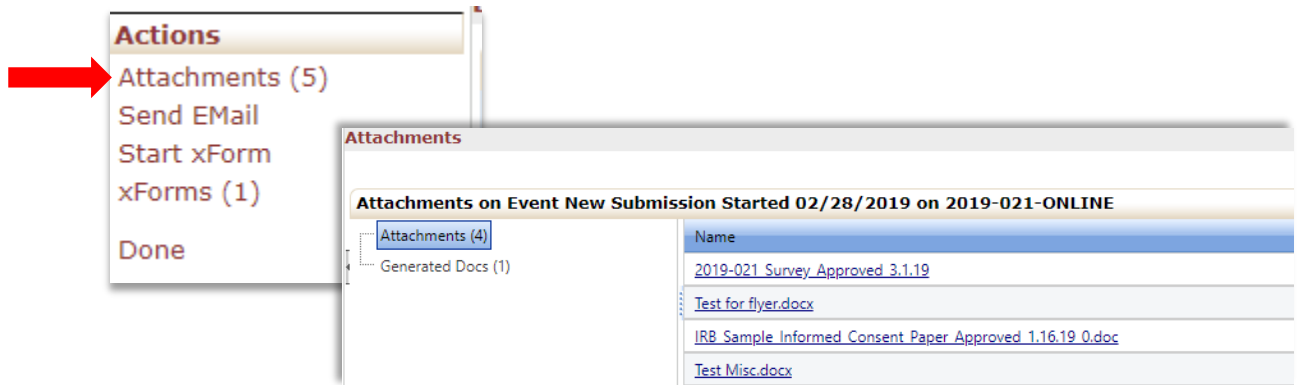
▼ Emails (2)			
Subject	Date	Del	To/From
Decision on IRB Protocol 2019-021	03/01/2019 at 12:16 PM		UCCSTestPI@gmail.com; UCCSTestPI@gmail.com
IRB 2019-021 Revisions Requested	02/28/2019 at 6:24 PM		UCCSTestPI@gmail.com; UCCSTestPI@gmail.com



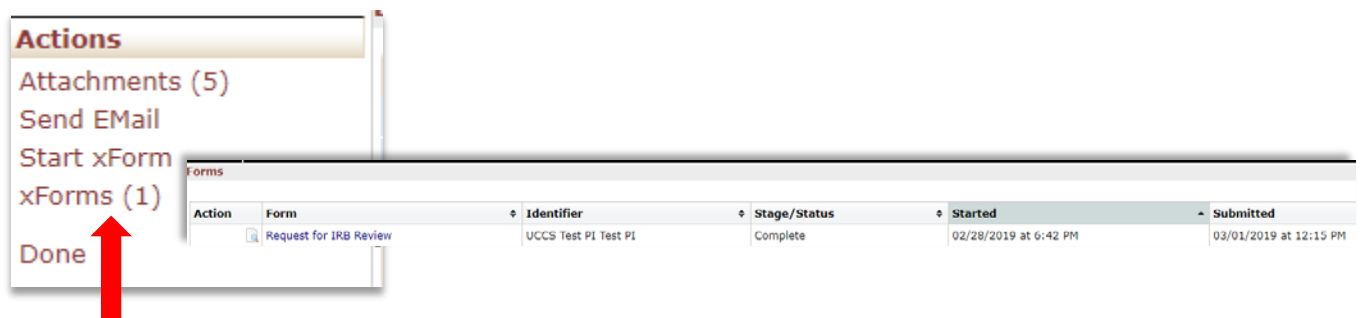
The emails will download to wherever you have your browser set to save files. Note, all attachments sent with the email originally will be attached.



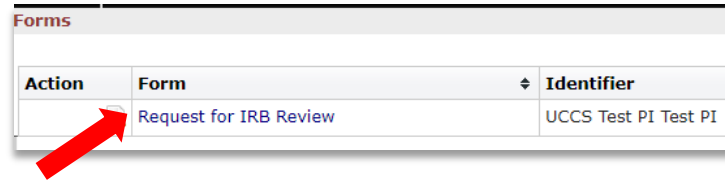
You can also view and download any attachments associated with your protocol via the left side "Actions" menu.



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.



Action	Form	Identifier
	Request for IRB Review	UCCS Test PI Test PI

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 IRB@uccs.edu or by phone at 719-255-3903.