User Manual for IRBManager

May 2019
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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 “Notes” section at the top right has basic help, links, and contact information.

Clicking the “Home” button on any page will bring you back to your 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.
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.
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.

<table>
<thead>
<tr>
<th>Most Recent CITI Training Date</th>
<th>Affiliation*</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>2/4/2019</td>
<td>UCCS Faculty</td>
<td>![Edit, Duplicate, Delete]</td>
</tr>
</tbody>
</table>

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

1

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.

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.

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.
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.

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**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.

Hello Faculty Advisor,

Test Researcher Test Researcher has submitted an IRB protocol application entitled “Orange” for review and approval. Please review at your earliest convenience.

Click here to access the application. [Request for IRB Review]

Please let us know if you have any questions.

Sincerely,

IRB Staff

UCCS Office of Sponsored Programs and Research Integrity

719-255-3903

irb@uccs.edu

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.

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 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.

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 access 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.
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.

Hello,

Attached is the decision letter for IRB protocol 2019-015 entitled “Changes needed testing”.

Please review the letter and use the documents that were reviewed and approved for your research.

Please let us know if you have any questions or trouble accessing your documents.

We would appreciate you taking less than five minutes to share your thoughts regarding the IRB process. Please take this survey.

Sincerely,
IRB Staff
UCCS Office of Sponsored Programs and Research Integrity
719-255-3903
irb@uccs.edu

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

Starting a request for change or renewal 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.
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.

```
Recent Items
2019-021-ONLINE
2019-022-MAIN
```

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.

```
Recent Items
2019-021-ONLINE
2019-022-MAIN
```

**Messages:**

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

**My Docs & xForms:**

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

```
Messages
Welcome to IRB Manager,
UCCS Researcher!

My Docs & xForms
1 Attachments
7 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.

<table>
<thead>
<tr>
<th>Project</th>
<th>Site</th>
<th>Title</th>
</tr>
</thead>
<tbody>
<tr>
<td>2019-021-ONLINE</td>
<td>Online</td>
<td>Test for approval and then ROC and renewal apps</td>
</tr>
<tr>
<td>2019-022 MAIN</td>
<td>Main Campus</td>
<td>Test</td>
</tr>
</tbody>
</table>

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.

- 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.

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 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.
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”.

<table>
<thead>
<tr>
<th>Event (s)</th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Reportable Event</td>
<td>0</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Continuing Review</td>
<td>2</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Request for Change</td>
<td>3</td>
<td>Additional Data Collection Sites</td>
<td></td>
<td></td>
</tr>
<tr>
<td>New Submission</td>
<td>4</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Events (1)</th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
</table>

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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”.

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