

## GENERAL INSTRUCTIONS FOR SUBMITTING MODIFICATIONS TO THE UC IRB

### Getting Started

The Researcher's Gateway portal <http://researchgateway.uc.edu> is the starting point for all electronic submissions to the IRB. The system allows you to submit electronic documents for any protocol of which you are associated.

1. After logging into the Gateway, select My Protocols.
2. Under Human Subjects Protocols, select Submit a Modification.
3. The first screen after logging into the system lists each protocol relevant to you. The list includes the IRB #, title, PI name and initial approval date.
4. The action options are listed under each protocol: Protocol Progress Reports, Modifications, Adverse Events, or Correspondence.



The red banner at the top of the page shows where you are within the system (Protocol Viewer: Modifications). On the left hand side of the red bar, there are links for Contact Us, Protocol Viewer, Home and Logout. "Home" takes you back to your original list of protocols.

Once you select an action option (modifications, progress reports, etc), use the right-hand menu to navigate. You will use the right-hand menu to navigate throughout the application. The red arrow indicates the section where you are currently located. The right-hand menu will update as you customize the function in which you are working.



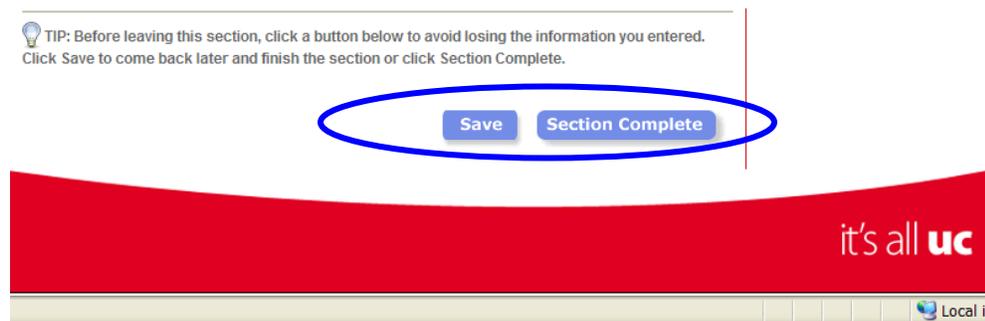
**Note:** Depending on where you are working on the screen, you may need to scroll up in order to see the right-hand menu.

## **Modifications**

1. Under the appropriate protocol, click on Modification OR
2. Choose to add a modification or select a pending modification to edit. 
3. Follow the on screen instructions.



**TIP: In each section that you enter or modify data, you MUST save the information in order for it to be stored. Click on the **Save** or **Section Complete** button at the bottom of each section / sub-section.**



### **Add Modification**

1. Read each statement and question on the page and ensure that all the appropriate information has been captured.
2. In the box just under short summary, enter a label for the modification that will allow you to distinguish it from any other modifications for this protocol. Example: Amendment #1, dated 04/01/07, version 3 dated 4/23/07.
3. Click to place a check mark in the box adjacent to the sections which require updating and press "Enter". This creates a customized modification. As you move forward you will only see those sections that you checked rather than all the available options. You can return here at any time to modify the short summary or add or subtract sections from your customized modification.
4. The sections you selected now appear in the right-hand menu. To move from one section to the next, click on the section on the right-hand menu.
5. You may complete the sections in any order you wish. You may work on a portion of a section, save the page, leave, and return later to complete it or you can simply move between the sections until all sections are completed.
6. As you progress through the modification process you may select sub-sections of sections. Whenever you select a section or sub-section, the title will appear on the right-hand menu. Remember to click on the title from the right-hand menu in order to access the section or sub-section.
7. Once in the section or subsection, follow the on-screen instructions. In the text boxes provided, type in the description or explanation as requested for that section. You may cut and paste information from another document.

### **Edit a Modification**

The "Modification" page, which lists all the modifications associated with the protocol, lists the most recently submitted modification first. The table includes the short description of the modification, the status of the modification and the date it was approved. You may only update modifications with a status of "Pending IRB Submission".

1. Click on the Edit icon  in the Action column to access what was previously created.
2. You may now move through the modification and add, change or delete information as necessary.

## Attachments

1. A number of documents may need to be attached to the modification. This section is used to a) indicate what you are attaching and b) attach or delete an attachment. You may go to this section at any time throughout the process.
2. Check off each type of attachment you will be including. Click Enter.
3. For each category of attachment press the "View/Update" button to upload or remove an attachment for that category.
4. To add an attachment click on Upload. This will give you the ability to browse your computer/server to add a document. Make sure to include a title for that specific document (such as "COI for Dr. Jones" or "Updated Protocol Document - Amendment 1"). Press "upload" and the document will now be attached to the modification submission. Repeat for each category as needed.

**NOTE:** The View/Upload button turns from green to red once a document has been attached. The column to the right of the View/Upload button shows how many documents have been attached for that category.

5. Ensure you attach the required documents. All modification documents must be submitted with the request in order to have your modification reviewed.
6. Attach a copy of the updated protocol.
7. Attach a copy of the list of changes to the updated protocol (if available). If not available, please provide a copy of the updated sections of the protocol, which clearly show what language has been added and/or removed (such as bolding and strikethroughs).
8. Attach a bolded copy of the updated informed consent(s) (when applicable). This copy should bold any information added to the consent. Information that is removed should be struck through. This consent will be stamped and used to re-consent participants already on the study who are affected by the changes.
9. Attach a clean copy of the updated informed consent(s) (when applicable). This copy will be stamped and used when consenting new participants into the study after the modification has been approved.
10. Attach a copy of any other documents being changed with this modification, such as questionnaires, investigator brochures, PI changes, COI forms, etc.
11. If there is other documentation stating reasons for changes (such as the VA's R&D Committee, Children's Hospital IRB's request for changes, or a letter from the sponsor), please be sure to attach this as well.
12. To remove an attachment (before submitting to the IRB), go to the Attachments Checklist page. Select View/Upload next to the attachment category. On the Modification: Attachments page, click on Remove next to the title of the attachment to be removed.

## Review and Print

This section displays a list of all the sections you elected to include in your customized modification. It also displays a list of the attachments. The on-screen instructions tell you how to interpret the information displayed. This is where you go to print a copy of the modification, if you require a hard copy.

**NOTE:** The Attachments Checklist page lists the documents which have been uploaded, by category. The Review and Print page lists all attachments uploaded for the entire modification.



**TIP:** When you select the **Printer Friendly View** option a separate window opens. You may need to close or minimize this window in order to see the Review and Print screen and continue navigating via the right-hand menu.

## [Route to PI / Contact](#)

This section allows you to route the modification to the PI or anyone who is set up on the protocol as a contact person. You may route the modification as many times as necessary to gather information. A textbox is available for including a comment.

## [Submit to IRB.](#)

***IMPORTANT:*** The PI **MUST** submit the modification to the IRB. The study contact personnel may prepare the modification, but the final version must be submitted by the PI. This step constitutes an electronic signature. If anyone other than the PI of record attempts to submit the modification, an error message will display. The IRB **will not** receive the modification for review.

1. Select this category once all sections are completed, attachments added and you are ready for the IRB to review and approve your modification. Once you submit the modification to the IRB the information is locked, you may not go back and directly change the information you have provided.
2. You are now at the same point in the overall modification approval process as if you had prepared the hard copy form and dropped it off at the IRB office. The steps for the IRB Board approval of the modification remain the same.
3. Logout of the Researcher's Gateway (located in the red banner near the top of the page – right hand side).