



OFFICE OF THE

VICE PRESIDENT FOR RESEARCH (OVPR)

UVMClick – IRB

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User Guides

DOCUMENTATION

For User Community
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<i>Step 1</i> ▶ <u><a href="#">How to Login (DOCX)</a></u>   <u><a href="#">(PDF)</a></u>
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<u><a href="#">How to Create and Submit a Continuing Review or Study Closure (DOCX)</a></u>   <u><a href="#">(PDF)</a></u>
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For User Community
<a href="#"><u>How to Request an Ancillary Review (DOCX)   (PDF)</u></a>
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<a href="#"><u>What Each Status Means (DOCX)   (PDF)</u></a>
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## Frequently Asked Questions

### What Happened to All of the IRB Forms?

A list of IRB Forms that have been replaced by the electronic SmartForm in UVMClick:

- Common Protocol Cover Form
- Amendment
- Change in PI or Key Personnel
- Continuing Review
- Waiver or Alteration of Consent and HIPAA
- Unanticipated Problem or Noncompliance
- New Safety Information

A complete protocol is still required. Researchers may submit an industry-sponsored (written by industry) protocol or use the Human Subjects Research Protocol which can be found under [IRB Forms](#).

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### How do I Prepare Documents?

We recommend that relevant IRB forms and additional supporting information be uploaded to the system as Microsoft Word Documents. This will allow for easier access to the content and the ability to view differences between document versions upload to the system.

The name of the document should describe what it is such as a questionnaire or a sponsor provided protocol.

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### How do I Access UVMClick and Navigate?

We recommend new users bookmark the [UVMClick Login Page \(opens in a new window\)](#).

If you experience problems with logging into UVMClick, it is likely that your password has expired. Please go to [UVM's Account Management page](#) for directions on how to reset your password.

Once you log into UVMClick, you will have access to "My Inbox" with relevant action items and the IRB tab to search for protocols. Select the IRB tab to view everything as a PI, Proxy or Guest. If you do not see anything, then this means that you have not been assigned to a protocol.

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#### What is a UVM Net ID and How do I get one?

- The [UVM Network ID should be 8 characters or less \(opens in a new window\)](#).
- If you haven't updated your password in the past year, you may need to go to [UVM's Account Management page \(opens in a new window\)](#) to change your Net ID password or reset a forgotten password.
- If you don't have an active UVM Net ID, you may complete the [Request for a UVM Net ID form](#) and submit it to the Research Protections Office.

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#### What are the Required Course(s) for IRB and Where can I find my Completions?

The Required Course(s) can be found on the CITI Program Training page under [Human Subjects & Good Clinical Practice Training \(IRB\)](#).

Please proceed to the [IRB Completion page](#) to view a complete list of individuals who have completed Human Subjects and Good Clinical Practice Training.

Starting December 2018, information about CITI will be listed under the "Training" tab in UVMClick.

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#### What to look for when Submitting a Protocol...

##### What is the purpose of the Short Title?

This is the Title that will be used on the UVMClick study workspace and your in-box.

##### Can I Exit before completing my submission and finish it later?

Yes, but be sure to click SAVE before clicking Exit. To return and continue editing, click on the grey Edit Study button in the left hand column of the applicable protocol.

##### Can I check for errors before completing the protocol submission?

Yes, to do so click on "Hide/Show Errors" in the navigation bar.

##### How can I make my "search" in any field easier?

Use a % sign as a wildcard before or after a word to help in your search.

##### What should I do if my Funding Source is not listed?

A request form will need to be completed to add a funding source. The form will be available fall 2018.

##### What should I do if the Drug under study is not listed?

Type in the name of the drug.

##### What if I do not have the IND number?

You need to find out what the IND number is by contacting the Sponsor or the FDA before submitting the protocol for IRB review. If PI initiated, you will need to apply for an IND with the FDA.

##### Where can I view all the protocol documents in one location?

You can access documents all in one place from the Documents tab.

##### How do I Upload and Submit Materials through UVMClick to RPO?

- First you must log into UVMClick to be brought to the "My Inbox" screen.
- Then select the "Create New Study" button on the left to begin a new protocol submission.
- The Smartform will then open to allow you to fill in the necessary information for a new protocol submission.

- Each section of the SmartForm has an attachment area at the bottom for IRB uploads. The red asterisk symbol (\*) next to a question indicates a required field. Once you have completed all the required fields in the SmartForm along with the uploads, then you will be able to select "Finish" to exit the Smartform. Do Not forget to hit the "Submit" button on the Main Study page.
- When you hit the "Submit" button the flowchart will change from "Pre-Submission to "Pre-Review." If you did not hit the button, then the flowchart will not change. The study will remain under the "Pre-Submission" area.
- Another way to see if a study has not yet been submitted is to go back to the "My Inbox" tab and check if the newly created study is listed there. If the study is no longer in the "My Inbox" area, then it has been successfully submitted to RPO.

### Where can I find My Study in UVMClick?

Once you log into UVMClick, select the "IRB" tab to view everything as a PI, Proxy or Guest. If you do not see anything, then this means that you have not been assigned to a protocol. This is what is called your "dashboard."

- Click on the "Active" tab in the middle of the page.
- Search by study ID number.
- When the study appears, click on the study name. This will take you into the main study workspace.

### What is a SmartForm?

A form on the web within UVMClick that you use to enter protocol information for Initial Applications, Modifications and Continuing Reviews.

### What Internet Browsers can I use?

You may use Internet Explorer, Microsoft Edge, Google Chrome or Mozilla Firefox. UVMClick will also work on mobile devices.

### What does each Protocol Status mean?

**Pre-Submission:** PI/Contact has started a new submission in UVMClick but has not submitted the request to RPO.

**Pre-Review:** The submission has been sent to RPO. RPO is currently processing the submission.

**Clarification Requested:** RPO or the Institutional Review Board has returned the submission to the PI/Contact for clarifications. The PI/Contact is expected to login to UVMClick and respond to clarifications.

**IRB Review:** The submission has been scheduled to an upcoming IRB meeting date (full) or is currently being reviewed by an IRB designated reviewer (exempt or expedited).

**Post-Review:** The IRB has made a decision on the submission. RPO may be in the process of communicating to the PI/Contact the decision or there may be other required approvals needed before RPO will approve the submission and release to the PI.

**Modifications Required:** The IRB determined that additional changes are required on the submissions. The PI/Contact is expected to login to UVMClick, make the required changes and re-submit back to RPO.

**Review Complete:** The review process has been completed for this submission.

### How do I find My Downloads from UVMClick?

Mozilla Firefox: [Where to find and manage downloaded files in Firefox](#)

Google Chrome: [Download a file](#)

Internet Explorer: [Download files from the web](#)

### What is a Proxy?Is this the same as a Delegate?

A Proxy in UVMClick is the same as a Delegate in InfoEd. Assigning a PI Proxy in UVMClick delegates authority to one or more alternate people on the study team who can then submit new studies and updates to existing studies on behalf of the PI. It is recommended that the designation of a proxy be documented in writing in the PI's records.

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### Who has Access to a Protocol?

All personnel listed on the study have view access. The PI and the Proxy can upload/submit materials. The Faculty Sponsor is considered a Proxy.

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### What is DUO Multi-Factor Authentication?

**[Vist the Enterprise Techonolgy Services Knowledge Base for information about this tool.](#)**

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### Do I need UVMClick Instruction?

Yes, we recommend all personnel review the User Guides prior to logging into UVMClick.

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### Why am I getting messages from UVMClick?

Pls, PI Proxies (designated staff who can submit on behalf of the PI), and Primary Contacts will receive email notifications related to these activities:

- Notifications that an item needs sign-off and submission
  - Reminders at 90, 60, and 30 days before expiration of study approval
  - Notification when study approval has lapsed (please note that if study approval lapses, you will need to re-submit the study as new research)
  - Requests for clarification or modifications required to secure approval for any submission
  - New comments were logged into the system
  - Determination letters sent by the IRB staff
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### How do I Close a Protocol in UVMClick?

You need to select "Create Modification/CR". You'll then see a screen that says "Modification/Continuing Review/Study Closure." Select "continuing review" and continue.

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### Can I Discard or Withdraw a submission? What is the difference?

You can discard a submission ONLY while it is in Pre-Submission. The "discard" activity will be available on the left hand side of the screen under "My Current Actions." If the PI or PI Proxy does not see the "discard" option, this means the transaction cannot be withdrawn.

You can withdraw a submission until the IRB has taken action (i.e. completed its review) on the submission. The withdraw activity will be available on the left hand side of the screen.

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### How do I find the Meeting Dates and Deadlines for new Protocol submissions?

This information can be found on the website maintained by the Research Protections Office. To view all events please visit the **[Calendar of Events](#)** page.

## FIND IT FAST

Committee on Human Research in Medical Sciences - **[CHRMS Meetings](#)**

Committee on Human Research in the Behavioral and Social Science - **[CHRBSS Meetings](#)**

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### Who's My Research Analyst?

In the IRB, studies are assigned to a particular research review analyst based upon the department of the protocol. Please visit the **[Human Subjects Research page to find out which IRB Research Analyst is assigned to your department.](#)**

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### Where can I find the Regulatory Information or the IRB Research Manual?

UVM applies the Common Rule to all human subject research. We encourage you to check the **[Regulatory Changes web page for updates.](#)**

The IRB Operating Procedures and the Researcher Manual have been combined into one set of **[Policies and Procedures.](#)**

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# UVMCLICK – LOGIN

## COMMITTEE LOGIN

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[UVMCLICK – IRB](#)

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[UVMCLICK – IACUC](#)

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[UVMCLICK – IBC](#)

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[UVMCLICK – FCOI](#)

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[UVMCLICK – GRANTS](#)

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[UVMCLICK – AGREEMENTS](#)

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### RECENT HEADLINES

11/09/2018

[UVMClick – IRB Update | Special Announcement](#)



10/26/2018

**COUNTDOWN TO UVMClick – IRB | Special Announcement**



10/05/2018

**UVMClick – IRB Update | Special Announcement**





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### Have a Question, Tech Issue or Suggestion?

Contact us at **802-656-5040** or

[Fill Out Our Feedback Form.](#)