

UHCMC IRB – iRIS™ Frequently Asked Questions

- **What is iRIS™?**
- **How do I access iRIS™?**
- **What do I submit via iRIS™?**
- **Where can I receive more information about iRIS™ and how can I learn to use the system?**
- **What if I have a paper-based study that has been previously approved by the UHCMC IRB?**
- **How do I start a new protocol application?**
- **Do I need to fill out the electronic protocol application all in one sitting? Can I start it and go back to it later?**
- **Are you using the Dahms Clinical Research Unit or Investigational Drug Services (aka Investigational Pharmacy)?**
- **How do I get my Department Review Committee's signoff for my New protocol submission?**
- **How do I print a copy of my application in iRIS™?**
- **I filled out my electronic application but now my section numbers are starting over. Did I lose my answers?**
- **What type of documents can I upload and attach in iRIS™?**
- **I have a study document I want/need to attach but I wasn't asked for it when I was putting together my electronic submission packet?**
- **While filling out the protocol application, I can't put a figure into the rich text editor where I describe my background information, study procedures, etc.**

- **I routed a submission to my PI or the UHCMC IRB but I want to pull it back?**
- **Who do I contact with my questions re: an iRIS™ submission?**

What is iRIS™?

iRIS™ is the electronic submission and review system that is being implemented by the UHCMC IRB, Case's IACUC and the Case Cancer IRB.

iRIS™ is a web-based system that you can log into from any computer that has internet access.

Users will fill out their protocol submissions, route them for the necessary signatures and submissions will then be sent to the IRB. Submissions will be reviewed by the IRB within the system and approval documents will be issued within iRIS™.

How do I access iRIS™?

The link is: <https://cortex.case.edu>

You can log in with your UH or Case credentials (the username and password that gets you into your computer). Please let us know if you have trouble logging in so we can troubleshoot the problem.

If you do not have UH or Case credentials, please contact Meghan Kulaszewski (meghan.kulas@uhhospitals.org or 216-844-7388) and an iRIS™ account will be created for you.

What do I submit via iRIS™?

All new studies must be submitted to the UHCMC IRB via iRIS™. This includes New protocols, New Chart Review/ Discarded Tissue studies, New Requests for Exemption, New Requests for Determination of Human Subjects Research and Notifications of Emergency Use.

Once your study has been approved and established in iRIS™, all Amendments, Continuing Reviews, Adverse Events, etc for that study must be submitted using iRIS™.

Where can I receive more information about iRIS™ and how can I learn to use the system?

The UHCMC IRB's webpage now has a section dedicated to iRIS™. There you can find updates regarding the rollout as well as information and registration links for iRIS™ training sessions.

[UH IRB - iRIS™ Webpage](#)

Once you log into the iRIS™ system, there are user manuals available on various topics. You can access them by selecting the "HELP" link in the upper right corner of any iRIS™ screen.

What if I have a paper-based study that has been previously approved by the UHCMC IRB?

If you have a study that is paper-based and currently approved by the UHCMC IRB, you will need to register your study in iRIS™. There is a user manual available regarding registrations available in iRIS™ via the “HELP” link.

Once your registration has been submitted to and approved by the UHCMC IRB, you will then submit future forms (i.e. Amendments, AEs, Continuing Reviews) for this study electronically via iRIS™. You may not make changes to your study during the registration process. All studies are required to be registered by December 31, 2011.

How do I start a new protocol application?

On the left side of your iRIS™ homepage, there is a “Study Assistant” tab. Selecting the “Add a New Study” link will take you into the protocol application. No matter what type of new study you have (clinical trial, chart review, exemption request, etc.) you will “Add a New Study” and the protocol application will branch you to the appropriate questions, based on your answers.

Do I need to fill out the electronic protocol application all in one sitting? Can I start it and go back to it later?

You don’t have to complete the protocol application all in one sitting. You can start the protocol application and come back to it at another time, just be sure to select “save and continue” before you navigate away from a page. This will insure that the questions you have answered thus far are saved. Your incomplete submission will be in “draft” status and can be accessed by going to the “Study Assistant” tab (dark blue tab along the left) and then selecting “My Studies”.

Are you using the Dahms Clinical Research Unit or Investigational Drug Services (aka Investigational Pharmacy)?

If you are using either the Dahms Clinical Research Unit or Investigational Drug Services (aka Investigational Pharmacy) as part of your research, you need to add these areas as departments in Section 2 of your protocol application. You can do so by selecting “Add” and then finding these areas in the list of departments. The DCRU is listed as “Case – Dahms Clinical Research Unit” and Investigational Pharmacy is listed under “UH – Investigational Drug Services”.

How do I get my Department Review Committee’s signoff for my New protocol submission?

The Department Review Committees are being set up in iRIS™ throughout 2011 and 2012. As of right now, the department review committee process is still paper-based for most of the committees. Please contact your department review committee to ask them how they would like to receive your items – paper or electronically.

If your Department Review Committee has a formal review process (convened meetings, committee members, etc.) you will need to fill out the protocol application in iRIS™ but before you route to anyone to sign off in iRIS™, print out a copy of your protocol application and give it to your Department Review Committee. Once the committee has reviewed and approved your protocol, they will give you an approval letter. You can then scan and attach the Department Review Committee approval letter to your submission in iRIS™. You can attach it to the last section (“Study Documents”) of your electronic submission packet. You will then proceed with routing for PI signature and any other electronic signatures necessary.

If your department review process involves a single signoff (perhaps from the department chair) rather than a formal committee, you don’t need to print from iRIS™. You can fill out the electronic protocol application, assemble your electronic submission packet and then route for PI and department chair signoff in iRIS™.

If you route an electronic submission for signature (PI, department chair, etc.), once those signature are obtained, the submission will be sent the UHCMC IRB.

How do I print a copy of my application in iRIS™?

If you have the protocol application open for viewing, there is a “printer friendly” button in the upper right corner. You can then select the “print” option.

I filled out my electronic application but now my section numbers are starting over. Did I lose my answers?

As you are filling out the protocol application, the number of application sections grows. Once you finish answering the protocol application questions, you will be taken to a page that says “Submission Packet to the Review Board”, starting with Section 1.0. You will put together your packet by attaching various protocol documents as you are prompted to attach them. Your protocol application can be accessed in Section 2.0 of the submission packet. From there, you can still open the application and revise your answers. Be sure to “save and continue” before you navigate away from an application section you have revised.

What type of documents can I upload and attach in iRIS™?

iRIS™ accepts Microsoft Word, RTF, pdf and Excel files. Please upload/attach Office 2003 documents. University Hospitals does not yet support Office 2007 or Office 2010. To be sure that UH reviewers can open your study documents, attach 2003 versions.

I have a study document I want/need to attach but I wasn’t asked for it when I was putting together my electronic submission packet?

If you have a study document or Department Review Committee approval letter that you would like to include with your submission (but you were not specifically prompted for it) you can attach the document(s) in the last section of the submission packet, “Study Documents”. This section will show you the study documents you have attached thus far (minus consents or assents) and give you the opportunity to attach anything else you need to include with your submission.

While filling out the protocol application, I can't put a figure into the rich text editor where I describe my background information, study procedures, etc.

The inability to insert figures/graphics into the text areas is something that is being worked on and will hopefully be resolved soon. In the mean time, you can copy and paste your figure/schema/table into a separate Word document. That document can then be attached in the "Study Documents" section of your electronic submission packet.

I routed a submission to my PI or the UHCMC IRB but I want to pull it back?

You can access the protocol under your "My Studies" tab. In the Submissions screen, there is a section on the right showing this protocol's "Outstanding Submissions". Here is where there will be a gray "Retract this Submission" button.

You can retract a submission any time during the signoff process. Once you are done revising the application and/or submission packet, you will need to re-route for any necessary signatures.

You can retract a submission after it has been submitted to the IRB as long as the IRB has not picked up the submission from its "iRIS™ Inbox" and sent it down a review path. If the IRB has begun to process the submission and you need to pull it back, you will need to call the IRB office to have the submission withdrawn.

Who do I contact with my questions re: an iRIS™ submission?

You can contact the UHCMC IRB Main Line at 216-844-1529 or Meghan Kulaszewski at 216-844-7388 (meghan.kulas@uhhospitals.org).