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What is iRIS?

iRIS (formerly known as iMedRIS) is the online application system you will use to submit your

new study and all subsequent IRB submissions. The Human Gamete, Embryo, and Stem Cell Research Committee (GESCR) [3] also utilizes iRIS.

iRIS enables online tracking, review, post-approval compliance activities and data management. The system also functions as a document repository, providing you with easy access to study records and documents. You can use iRIS anywhere you have internet access, connecting research partners around the world. Training [4] is available.

Interactive Tutorials [5] **(NEW - October 2018)** ?In October 2018 we created a suite of interactive online tutorials for working in iRIS. Go to the iRIS Help website [2] (MyAccess login required) to take these tutorials.

Accessing iRIS

How do I get access to iRIS?

See the iRIS Account [6] page for detailed information on obtaining an account.

iRIS is accessible via MyAccess [7]. Click the "IRB - iRIS" link. The use of is VPN no longer required or recommended for off-campus access.

If you need access to particular studies within iRIS, review the next FAQ, "How can I be added to a study?"

How can I be added to a study?

If you are Key Study Personnel, a current member of the study team must submit a modification [8] to request that you be added to the study.

If you are research support staff or a study contact who is not Key Study Personnel, you are not required to submit a modification to be added to the study. Follow these instructions [9] instead.

Can I get access to information on all studies that are being done in my department?

The IRB may grant special departmental access [6] to department MSOs, department Research Finance Administrators or other individuals who can justify needing this type of access.

Follow the instructions here [6]. After you receive this access, you will have read-only access to all studies that are being done in your department(s). You will be able to access copies of approval letters via Submission History, view the IRB Application to see which funding sources and personnel are on the study, or print or save copies of the IRB Application, consent forms, etc.

Which internet browser should I use?

The current version of iRIS is compatible with **all browsers**. Turn off the web browser?s pop-up blocker for the iRIS site.

- If you are working in Internet Explorer (IE) 9, turn off Compatibility View.
- If you receive the pop-up error message 'blockUI requires jQuery v.1.2.3 or later! You are using 1.11.1,' clear the cache in your browser.
- Consult with your Desktop Support analyst [10] regarding which version of IE you should use based on the applications you access. Some campus web-based applications are not compatible with certain versions of IE.

Do Sponsors have access to iRIS?
No, Sponsors are not granted access to iRIS and should request documents through the study team.

System Info

How often should I save my work?

Both MyAccess and iRIS will automatically log you out if you are inactive in the system. As such, we recommend that you save your work regularly.

Where can I get help on using iRIS (interactive tutorials, quick guides, etc.)?

Interactive Tutorials [11] **(NEW - October 2018)** ?In October 2018 we created a suite of interactive online tutorials for working in iRIS. Go to the iRIS Help website [2] (MyAccess login required) to take these tutorials.

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  Introduction to the IRB Process[12]

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  iRIS 101: Homepage Orientation & Finding your IRB Forms & Documents [13]

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  Submitting a New IRB Study [14]

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Making Changes to Approved IRB Studies [15]

- **Responding to Linked Stipulations from the IRB** [16]

Quick Guides [17] ? These PDF quick guides that contain step-by-step instructions and screenshots. They are available on the iRIS Help website [17] or within iRIS by clicking on the Help button in the right-hand corner.

Submission Instructions ? The Submissions [18] section of our website has instructions and guidance on entering new studies [19] and other submissions in iRIS.

Application Help Links ? If you get stuck answering a question in iRIS, hover over the help bubble next to the question and then click on the link that appears for Instructions and/or Guidance.

iRIS Application Outlines ? The outlines include all potential sections you may need to complete and can be used as guides. They are available in the Help section in iRIS.

Training Classes [20] ?The IRB offers several in-person training sessions [4]. Registration is required.

Contact Us ? You can contact our office [21] at 415-476-1814 or IRB@ucsf.edu [22].

What are the benefits of using the iRIS system?

Here are just a few of the benefits that the iRIS system offers to investigators and their support staff:

Faster review process and communication of status ? Electronic submission will reduce processing time and speed up the time to approval. PIs and study contacts will receive approval letters by email immediately after they are prepared.

Study information at your fingertips ? Where you have Internet access, you have access to your protocol information.

Improved document management ? The system identifies which documents are currently approved, helping you use the correct versions.

Intuitive application ? The IRB Application will branch out based on how you answer key questions, so you won't have to figure out which supplements to submit.

Documentation of submission for sponsors ? You will have a record of each document that you submit.

Easier access to IRB approval records ? Study approval records will be accessible to PIs, study staff, and key departmental administrators.

Environmentally friendly ? Prior to the implementation of iRIS, the IRB received about 5 million pieces of paper each year. The electronic system has helped us eliminate this waste and supports UCSF's efforts to incorporate environmentally-friendly practices across campus.

Is iRIS compliant with 21 CFR Part 11?

iRIS has been implemented as a Closed System at UCSF, consistent with 21 CFR Part 11. Every user of the system must be individually authenticated and specifically authorized to gain access to the system. Additional levels of control and authorization are required before users can carry our specific functions within the system (e.g., to submit, review and/or approve research).

Users must log into the system through a secure portal which the University monitors, and users are required to use both a unique ID and a password to gain access the system. Users are required to protect and keep confidential their IDs and passwords and follow all University information security policies. Users are responsible for the actions, certifications and determinations they make while logged into the system. Actions within the system are recorded and time-stamped. Study and system records are available for review in both printed and electronic format.

Entering and Submitting Study Submissions

Do all submissions go through the iRIS system?

Yes. Only the following types of submissions should be submitted via paper, not in iRIS: Emergency Use Requests [23] and Administrative Reviews for Human Research Studies Not Being Conducted by a UCSF PI But Accessing UCSF Facilities, Patients or Personnel [24].

What is the process for entering studies?

Information on entering new studies is provided in the New Study [25] page. The online IRB Application form uses branching technology, and certain sections of the form will automatically appear after you answer key questions. You do not need to navigate through sections of the IRB Application that do not apply to your type of study.

How long will it take to enter a new study in iRIS?

It may take as little as 30 minutes for a chart review study to several hours or even several days for a complex study. Before you enter your study, review our guidance on submitting new studies [19]. Also, review the factors that may affect the time it takes to enter a study to learn how you can prepare to submit your study:

How complex is your study? ? The iRIS applications build and branch based on how you answer key questions, so the applications for complex studies usually have more sections.

Are you prepared to answer all of the questions in the IRB and/or GESCR Applications? ? Look over the iRIS application outlines to see which questions you may be asked to answer. Contact members of your research team or the study sponsor for help. If your study is being funded through UCSF, be sure to ask your Research Services Analyst (RSA) for information about the funding source, including the RAS proposal or award number.

Do you have access to all of the supporting documents you need to attach? ? Go over the Initial Submission Checklist [26] to determine what attachments you need to submit.

Is the PI available to sign off on the study? ? The PI must electronically sign off on the initial review, so factor in the PI?s availability if you are not the PI of the study.

Do you have any application templates?

Yes, use the iRIS application outlines as guides to see which questions you may need to answer in the electronic application(s). The outlines are available in the Help section in iRIS. Some sections of the applications are only required if your research has certain characteristics.

Why can?t I edit my Application?

Once your application is submitted to the IRB, it is locked and becomes part of the official study record. You will need to add a revision in order to edit it.

You also may be unable to edit and/or save changes if you are looking at the application in ?Entire View.? Switch to ?Section View? in order to edit.

It looks like I lost all of my answers in the IRB Application! Can you help?

Most likely, you have not lost your work. Instead, you have either: a) changed an answer that affects the way the form branches or b) finished the application and entered the Initial Review Submission Packet.

Branching Change: Changing some answers will affect the way the IRB Application branches. Sometimes section links will disappear from the left-hand menu of the form. You have not lost any work ? data you previously entered is still there, but new sections may have been added to the form. You must click the "Save and Continue to the Next Section" button through each page to rebuild the form before you can submit it. Also be sure to answer any new questions.

Entering the Initial Review Submission Packet: The last section in the IRB Application is labeled ?End of Study Application.? Unless you need to complete the GESCR Application, you will automatically enter the Initial Review Submission Packet after you click ?Save and Continue to the Next Section? on this page.

The Initial Review Submission Packet is a separate form in which you will add a lay study summary, list special processing instructions, and attach consent forms or other study documents. The application you just completed also will be automatically attached here. The Initial Review Submission Packet bundles all of the components of the submission together, kind of like stapling a paper packet.

If you need to get back into the IRB Application to edit or check your work, you can get there by one of two ways:

Option #1: Section 2.0 of the Initial Review Submission Packet

- The IRB Application is attached in section 2.0 of the Initial Review Submission Packet, so you can get to by following these steps:
- Answer the questions in section 1.0 of the Initial Review Submission Packet.
- Click ?Save and Continue? in section 1.0.
- Click the Edit/View icon next to the application. This will take them back into the application form.

Option #2: Study Mgmt Link in Navigation

- Click on the ?study mgmt.? link in the Navigation list (beneath your account name and department).
- You will then see the study dashboard. The link to the application is on the left-hand side of this page. Click on the link and then click the "Edit/View" button next to the correct version.

If neither of these two scenarios match your situation, contact the IRB office at 415-476-1814.

What does the Copy button do?

When you click on the My Studies button from your home page, you will see a list of your studies. Next to each study, you will see a Copy button. This button will copy the Application for that study. It will not copy the attachments.

You can copy a study that is incomplete and in draft status or a study that has been submitted. Some users have created a IRB Application template that they never submit, and they instead copy that template each time they begin to submit a new, similar study.

Note: If you copy a study, the copy will not be assigned a study number until you submit it. Please remember to update the study title in section 1 of the Application.

Who can signoff and submit studies?

Anyone can fill out the study application, but the PI must sign off on and submit a new study. The PI must also sign off on and submit the Continuing Review Form. All other study submissions can be submitted by investigators, research support staff or study contacts who are listed in section 3 of the IRB Application.

Important Note: Only individuals listed in section 3 of the IRB Application will have access to the study (via My Studies) after it is submitted. If you are not Key Study Personnel but need access to the study, be sure to add yourself as a study contact.

What is a study contact?

Study contacts are copied on all important email notifications that the PI receives, including requests for submission corrections, approval letters and continuing review reminders. You can add as many study contacts as you?d like in section 3 of the IRB Application.

Study Status and Tracking

How can I track my submission?

Submission tracking is incredibly easy in the iRIS system.

- Go to the My Studies section and open the study.
- Click on the "Submission History" link
- Locate the submission you want to track, and click the Track Location icon.

You will be able to see which IRB panel received the submission and which IRB analyst has been assigned to process the submission. If the submission has been assigned for review, you also will be able to see that information. You can contact the assigned analyst [21] for more information.

In the workflow tracking, you should see a note that says, "IRB Committee XX Panel received the submission." If you do not see this note, the IRB may not have received the study. Contact us at 415-476-1814.

What does the study status mean and when is it updated?

The overall study has a status in iRIS. Here are what these statuses mean and some important notes about the statuses. You can also check the Submission History if you need more detail about where the study is at in the review process.

Important Notes About Study Statuses

- The study status automatically updates from "Draft" to "Pending ? Submitted for Initial Review" once you submit the study to the IRB. The status will also automatically change to "Expired" once the expiration date is reached the the study has not been renewed. **The CHR manually updates all other statuses according to the type of study and where it is in the review process.**
- Only studies with a "Draft" status can be deleted by the study team. If you need to delete a study that has already been submitted, contact the assigned IRB analyst [21] and request for the study to be withdrawn.
- If the study status is green, the study is Active and can be conducted as described in the application. The only exception is for pending modifications ? the IRB must approve the modification before the change can implemented. Pending modifications do not change the overall study status.

Study Statuses:

Draft	The study has not been submitted and is still in draft mode. Follow the final step in the "Creating a New Protocol" quick guide if you thought you submitted the study, but the study is still in Draft status. This quick guide is accessible by clicking on the Help icon in iRIS.
Pending - Submitted for Initial Review	The study has been submitted. Check the Submission History for more information on the study status/workflow tracking.
Incomplete	The study is has been returned by the IRB as Incomplete because it did not meet the minimum submission standards [19].
Active	The study is active and approved by the IRB. (Note that this status is being phased out and will be replaced by one of the following Active statuses at the time of your next submission to the IRB.)
Exempt	The exempt [27] study is active and approved by the IRB.
Active - Expedited	The expedited [27] study is active and approved by the IRB.
Active - Full Board	The full board [27] study is active and approved by the IRB.
UC MOU - Relying	The study is active. The study is relying on another UC IRB [28] for review.

Active - Closed to Accrual	The study is active and approved by the IRB. The study is closed to accrual of new subjects.
Active - Data Analysis Only	The study is active and approved by the IRB. The approval is limited to data analysis activities.
UC BRAID - Reviewing	The study is active and approved by the IRB. This study is part of a multicenter clinical trial that is conducted at multiple UC sites. This application serves as a primary point of review for other UC sites participating in this clinical trial. For more information visit http://www.ucbraid.org/. [29]
UC BRAID - Relying on Other UC	The study is active. This study is a multicenter clinical trial and is relying on the review of another UC site participating in the clinical trial. For more information visit http://www.ucbraid.org/. [29]
CIRB Reviewed	The study is active. The study is relying on the NCI CIRB [28] for review.
Returned for Pre-review Changes	The IRB has returned the study for correction during the pre-review screening process. Look for the Submission Correction [30] task on your home screen.
Returned by Committee	The IRB has returned the study for revisions or clarifications after formal review. Look for the Submission Correction [30] task on your home screen.
Expired	The study has expired.
Closed	The study has been closed [31].
Withdrawn	The study has been withdrawn by the IRB.

Suspended	The study has been suspended. You will receive more information from the IRB about the suspension.
Active: Hold on Accrual	The IRB has put a hold on accrual. You will receive more information from the CHR about the hold.
Not Human Subjects Research?	The IRB will not review the study because the study does not qualify as human subjects research [32].

What is my study number?

The iRIS system automatically assigns a 7-digit number to your study. The first two digits represent the year in which you first add your study in iRIS. The study retains this 7-digit number for its life.

What is the submission reference number?

After you submit an initial review or post-approval form (e.g. the Continuing Review Form), that submission is assigned a unique reference number. If the IRB sends the submission back to you for corrections, the response you submit back to the IRB via the Review Response Submission Form will be assigned the same reference number as the original submission. This number will help you figure out which submissions (original or responses) are linked.

You can find the reference number in the Submission History. You also can open the study via My Studies, click on the name of the form you submitted (e.g. Initial Review Submission Packet or Modification Form) and see the reference number there.

Funding Questions

How do I search for find my sponsor?

The searchable sponsor list in iRIS is a copy of the master list of UC sponsors. This list is refreshed each night. Some sponsor names have been abbreviated, so search for keywords in the sponsor's name. If you are unable to find your sponsor, follow the instructions in the IRB Application.

What information do you need about my funding source?

You will be asked to provide the following information about each of the study?s funding source(s). If you do not know how to answer some of these questions, contact the

administrator who handles this study's funding.

Sponsor Role: Clarify what role the sponsor has in the study, including funding, protocol control, data coordination, monitoring, auditing or passthrough (e.g. UCSF has received the funding, but no human subjects research will take place at our site).

Awardee Institution: Clarify if the funding is coming through UCSF or an affiliate institution. Note: If UCSF has a subcontract with another institution, select UCSF here.

Is the Institution the Prime Grant Holder? Clarify if the main grant is held by an investigator at our site or by an investigator at another institution.

Contract Type: Clarify if the funding type is a cooperative agreement, contract, drug/device donation, fellowship, grant, subcontract or unfunded research collaboration.

UCSF RAS System Proposal Number and/or UCSF RAS System Award Number: These numbers are generated by the UCSF Research Administration System (RAS) for every contract or grant administered by the Office of Sponsored Research (OSR) or Industry Contracts. Proposal numbers begin with a "P" followed by 7 digits. Award numbers begin with an "A" followed by 6 digits.

If UCSF is not the awardee institution, you will not have one of these numbers and will not have to complete these sections.

Important Notes: If funding has already been awarded or the contract is being processed by the UCSF OSR or Industry Contracts unit, your sponsor is in the system and the project has a UCSF RAS System Proposal or Award number. Check with your department's Research Service Analyst (RSA) to ask how the sponsor is listed in the UC sponsor list and what the Proposal or Award number is. If you need additional assistance, contact the Contracts and Grants Award Team at CGAwardTeam@ucsf.edu [33].

Grant-specific Information:

Grant Title: List the grant title if it is different from IRB Application title.

PI Name: List the PI of the grant if this individual is not the PI of the IRB study.

Explain Any Significant Discrepancies From the IRB Application: Clarify if the research described in the grant does not match the research described in the IRB Application and why the two descriptions differ.

Consent Documents, Other Study Documents and Approval Letters

My approved consent forms have been stamped. Should I consent subjects using these consent forms?

Whenever possible, the IRB recommends consenting study subjects using the stamped version of the consent document. Doing so will help confirm that you are using the currently approved consent form.

How big is the consent form approval stamp?

Please leave a 1.25? margin at the top of each page of the consent form to accommodate the approval stamp.

Should I track my changes in the consent form?

No, turn off tracked changes before uploading your consent form.

iRIS includes an internal document comparison tool. You and the IRB can use this tool to see what changes were made in different versions of the consent form if you submitted MS Word documents.

To use this tool, open your study via My Studies. Click on the ?Informed Consent? link from the study management dashboard. Click on the folder icon to see all of the versions of a particular consent document. Check the boxes next to the two versions you want to compare, and then click ?Compare Consent Versions? button.

The comparison tool can also be used to compare different versions of the IRB Application, submission forms (such as the Modification Form) and Word versions of Other Study Documents.

Should I upload a Word document or a PDF version of the consent form?

The comparison feature does not work with PDFs, so upload a Word document whenever possible.

How should I submit my information sheet or verbal consent script?

These items are considered to be consent documents, so please attach them in the ?Consent Documents? section of the Initial Review Submission Packet. Exception: For exempt studies, upload these documents in the "Other Study Documents" section.

How do I submit a translated version of the consent form?

After the study is approved, get the approved consent form translated [34]and submit it via a Modification Form.

What version number and date should I use?

iRIS version numbers include two digits, such as version 1.0. You can modify the first number, but the number following the decimal point is hard coded and cannot be changed.

Each time you add a revision to the document or form, the second part of the number will change: e.g. version 1.0 becomes version 1.1. You can update the first part of this number, if you wish.

You also are able to assign a version date to consent forms and study documents. You can use any version date that you would like. However, we recommend that you update the version date when you revise the document.

How do I find my approval letter?

Please watch the "Finding Your IRB Approval Letter" video on the iRIS Help website [17]. This video shows you how to access and save your past and current IRB approval letters, and discusses the important regulatory information that is included in the letters.

Will approval letters be signed by an IRB member and are they compliant with regulatory requirements?

The UCSF approval letters issued via iRIS are not signed by a member of the IRB. However, these letters and other available information comply with all regulatory requirements. In addition, iRIS is compliant with FDA 21 CFR Part 11 (Electronic Records; Electronic Signatures).

Additional information on general conditions of approval and notes on approval documentation are available on the IRB Review Process [35] of our website. We will not issue separate letters to comply with additional requests from sponsors.

The GESCR Committee [3] provides a separate approval letter listing all sponsor-required information, such a research type and funding.

Managing Your iRIS Submission

How do I respond to a request for revisions?

Click on the Help icon within iRIS or visit the iRIS Help website [17] and read the quick guide "Responding to Requests for Submission Correction." Also review the Responding to Stipulations in iRIS [30] section of our website.

How do I submit a modification, continuing review (renewal), adverse event report, protocol violation or other post-approval report?

1. Go to My Studies and open your active study.

2. In the Submission Forms section of the study submissions dashboard, click on the name of the form that you want to submit.

3. Click on the Add New Form button to start the form.

For information on how to complete the individual forms, review the guidance in the appropriate section of the Submissions [36] section of our website.

Can I delete a form I no longer want to submit?

Yes, you can delete a form if the IRB has not started processing it yet.

1. Go to My Studies and open your study.

2. If necessary, retract the submission you want to delete by clicking on the "Retract Submission" button and then click OK.

3. In the Submission Form column, click on the name of the form you want to delete (i.e. Modification Form).

4. You will see a list of forms you have submitted. Check the box next to the form you want to delete and click the "Delete Selected Form" button.

Can I save a PDF copy of the IRB Application and other submission forms?

Yes. Open the form and click on the "Printer Friendly" button. You can then choose to print the form as an HTML form or a PDF form. Select "PDF Form" to save the form as a PDF.

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Source URL: https://irb.ucsf.edu/iris-online-application-system-info-and-faqs

Links
[1] https://iris.ucsf.edu
[2] http://iris-help.ucsf.edu/irb-iris
[3] https://irb.ucsf.edu/stem-cell
[4] https://irb.ucsf.edu/education-opportunities
[5] https://iris-help.ucsf.edu/
[6] https://irb.ucsf.edu/iris-accounts-and-access
[7] http://myaccess.ucsf.edu
[8] http://hrpp.ucsf.edu/modification#personnel
[9] http://hrpp.ucsf.edu/node/201#personnel
[10] http://it.ucsf.edu/
[11] https://iris-help.ucsf.edu
[12] https://courses.learning.ucsf.edu/?eCourse=347456
[13] https://courses.learning.ucsf.edu/?eCourse=347463
[14] https://courses.learning.ucsf.edu/?eCourse=347469
[15] https://courses.learning.ucsf.edu/?eCourse=347472
[16] https://courses.learning.ucsf.edu/?eCourse=347477
[17] https://iris-help.ucsf.edu/irb-iris
[18] https://irb.ucsf.edu/submissions
[19] https://irb.ucsf.edu/new-study
[20] http://hrpp.ucsf.edu/education-opportunities

[21] https://irb.ucsf.edu/contact-us
[22] mailto:IRB@ucsf.edu
[23] https://irb.ucsf.edu/emergency-use-and-compassionate-use-experimental-drugs-and-devices
[24] http://hrpp.ucsf.edu/node/307#who
[25] http://hrpp.ucsf.edu/new-study
[26] http://hrpp.ucsf.edu/sites/hrpp.ucsf.edu/files/initial-submission-checklist.pdf
[27] https://irb.ucsf.edu/levels-review
[28] https://irb.ucsf.edu/relying-other-irbs
[29] http://www.ucbraid.org/
[30] https://irb.ucsf.edu/responding-stipulations-iris
[31] https://irb.ucsf.edu/study-closeout-report
[32] https://irb.ucsf.edu/not-human-subjects-research
[33] mailto:CGAwardTeam@ucsf.edu
[34] https://irb.ucsf.edu/consenting-non-english-speakers
[35] https://irb.ucsf.edu/irb-review-process
[36] http://hrpp.ucsf.edu/submissions