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FAQs About Accessing Identified EHR Data for Research at UCSF

Have questions about getting identified patient data for projects at UCSF Health or in the San Francisco Health Network (SFHN, which includes Zuckerberg San Francisco Hospital and broader clinics)? These FAQs will help!

Table of Contents

All about IRB approval for your study

Does my study require IRB approval?

Researchers at UCSF or UCSF-affiliated institutions, conducting human subjects research require IRB approval before initiating their studies. The following webpages on the UCSF IRB website have helpful information in determining whether your study requires IRB approval and, if so, what type of review will be required. Note that research using de-identified data only is not considered human subjects research and does not require IRB review.

- New Study – This page includes information on what to consider before submitting to the IRB; what, when, and how to submit to the UCSF IRB, and minimum submission standards and study preparation tips. It also includes an Initial Submission Checklist.
- Does My Research Require IRB Review? – This page includes information on what types of projects are considered human subjects research, who on the project needs IRB approval, principal investigator eligibility, and other frequently asked questions.
- Quality Improvement (QI) and Quality Assurance (QA) – This page includes information on which types of quality improvement and quality assurance projects require IRB review and which do not. Note that in order to obtain Limited or Identified EHR data through Academic Research Systems (ARS), IRB approval is required. If a quality improvement project does not require IRB review, EHR data would be obtained through quality improvement analysts within the health system.
- Public Health Surveillance vs. Research – This page includes information on distinguishing public health surveillance activities from research activities, as well as how to proceed when one project includes components of both.

How do I submit my IRB application?

Studies are submitted to the UCSF IRB via iRIS. In order to access iRIS, a principal investigator must have a MyAccess account. The UCSF IRB website has additional information about accessing and using iRIS for IRB submission.

- iRIS Accounts and Access – This page has information on how to access iRIS, including for individuals with and without a UCSF ID. It also includes instructions on how to list non-UCSF personnel in an IRB application.
- iRIS Online Application System: Info and FAQs – This page has answers to a collection of frequently asked questions related to iRIS, including accessing iRIS, entering and submitting study information, tracking an application's status, and managing other study documents.

How do I submit my study application to the UCSF IRB if I do not have a UCSF ID?

The UCSF IRB serves as the IRB of record for UCSF as well as various affiliated institutions, including the San Francisco Department of Public Health (SFDPH) and the San Francisco Veterans Affairs Medical Center (SFVAMC). The UCSF IRB website has information about how to navigate the IRB submission process if you are a member of one of these affiliated institutions and do not have a UCSF ID.

- UCSF Affiliated Institutions – This page has information about the affiliated institutions for which UCSF serves as the IRB of record. It also includes a list of SFDPH investigators who are authorized to submit UCSF IRB applications as Principal Investigators, as well as instructions for how to be added to this list.
- Getting an iRIS Account: Individuals without a UCSF ID – This page has information about how researchers at affiliated institutions can access iRIS and submit a UCSF IRB application.

What human subjects protection training is required?

Prior to IRB submission, all key study personnel must complete CITI Human Subjects Protection Training. The UCSF IRB website has information about this required training.

- CITI Human Subjects Protection Training – This page includes information about who must complete CITI Human Subjects Training, how to register and complete the training, refresher training, and whether CITI training from other institutions is valid at UCSF.

What additional forms and approvals are needed for research involving SFHN EHR data?

The San Francisco Health Network (SFHN) is the healthcare delivery arm of the San Francisco Department of Public Health (SFDPH), and SFHN includes both Zuckerberg San Francisco General Hospital (ZSFG) as well as community-based clinics and other facilities within SFDPH. Research involving ZSFG/SFHN patients, patient data, personnel, resources, and facilities, as well as research based at non-ZSFG SFDPH sites, requires completion of the UCSF Research at ZSFG Protocol Application, including the Research Statement of Work, which must be completed and submitted to the UCSF at ZSFG Vice Dean's Office after IRB approval but before study activities begin. Projects using de-identified data from ZSFG/SFHN patients also need to complete and submit the Research Statement of Work.

Be sure to allow ample time for the appropriate signatures to be obtained. The UCSF IRB and UCSF at ZSFG websites have additional information about these forms, including the operational leaders who will need to review and approve the study, depending on the location in which the study will take place.

- UCSF Affiliated Institutions – This page includes information about additional IRB requirements for SFDPH researchers and people conducting research involving SFHN, including the SFDPH Research Proposal Approval form, SFDPH HIPAA Compliance policy, and a list of SFDPH investigators who are authorized to submit IRB applications as principal investigators.
- Research Protocol Applications at ZSFG – This page includes information about the additional forms required for conducting research involving ZSFG, including the UCSF Research at ZSFG Protocol Application. When you are extracting EHR data for your research, this form will require you to enter information about who will extract the data, where the data will be delivered and/or stored, and whether it will be identifiable data with HIPAA-protected information.

Who can I contact with questions about the study approval processes?

Key contacts for questions about the IRB submission process are:

- UCSF IRB

Additional information about forms and approvals as well as key contacts for ZSFG/SFDPH research can be found here:

- UCSF Research Protocol Approvals at ZSFG | SFDPH

Secure Data Storage via the Research Analysis Environment (RAE)

Where can I securely store EHR data for research?

The Research Analysis Environment (RAE), formerly known as MyResearch, is a secure data hosting service supported by UCSF Academic Research Systems (ARS) that allows UCSF researchers and their internal or external collaborators to access and work with data containing PHI. RAE also supports data analysis and other programs. Using RAE is required in order to access EHR data from UCSF Health and/or SFHN delivered by Academic Research Systems (ARS).

- Research Analysis Environment (RAE) – This page on the UCSF Information Technology website includes information on how to access RAE by making an account, who to contact for support, information on the three tiers of services offered, and the tools and applications available within the platform.

- Meet "RAE" – The New MyResearch – This fall 2020 Research Data Series talk gives an overview of RAE. Slides and video are accessible to UCSF faculty and staff.
- RAE Knowledge Bank Wiki – This Wiki site includes How-To articles, answers to frequently asked questions, and other helpful information about RAE.

How much does secure data storage in RAE cost?

A RAE account is free for up to 10GB/month per study, but a UCSF accounting chartstring is still required in order to create the account. Storage use over the initial 10GB costs $0.24/GB/month. Note that one principal investigator can have multiple RAE sites, one for each study. Students without a principal investigator or chartstring can access a 5GB storage drive.

How do I access secure data storage in RAE if I am a researcher from a UCSF-affiliated institution (like SFDPH)?

Only UCSF principal investigators can "own" a RAE site. In addition, only UCSF faculty and staff can request the creation of a new RAE site or the addition of new collaborators to an existing RAE site. However, UCSF faculty and staff can request that non-UCSF collaborators be given access to an existing RAE site using the RAE Request Form and selecting "Add New Users to an existing RAE site."

Can I create a RAE site for secure data storage if I do not have a UCSF funding number?

Students can create a 5GB RAE site without a UCSF funding number. All other users are required to enter a UCSF funding number when filling out the RAE Request Form in case their storage needs exceed 10GB/month per study.

Requesting EHR Data

How do I determine what type of EHR data I should request?

There are various types of EHR data that can be used for research – counts of specific patients for cohort identification, de-identified data for cohort studies, de-identified data with real dates and zip codes, or fully identified data. In addition, it can be helpful to review UCSF and ZSFG Clarity Pick Lists to help define your cohort or identify the data you wish to extract.

- Overview: Data Resources for Research – This page can help researchers identify the type of data that they need – from fully de-identified to fully identified. It also has links to many different data resources and tools.
- Data Extraction Consultation – This page has links to example data specification forms (example data requests) as well as UCSF and ZSFG Pick Lists, which can be helpful to review in specifying what data you wish to extract.
- HIPAA and The Minimum Necessary Rule – These pages have information about HIPAA and the minimum necessary standard requiring that only the minimum data needed for immediate use should be made available. This applies to EHR data requests for research.
- DeID Clinical Data Knowledge Base – This Wiki, accessible to UCSF faculty and staff, includes information on how to get started with requesting de-identified UCSF clinical data, helpful data dictionaries and other documentation, links to code repositories on a UCSF secure Enterprise GitHub, and information on joining a user group. Note that there is not yet a de-identified clinical data warehouse for SFHN clinical data.

How do I request identified electronic health record data for my research study?

All requests for identified EHR data for research must be made through the UCSF Clinical and Translational Science Institute (CTSI) Data Extraction Consultation form and fulfilled by Academic Research Systems (ARS). Even if a researcher has IRB approval for their study, researchers are not allowed to extract data directly from the electronic health record for research. Before submitting a request for a data extraction consultation, be sure the study already has IRB approval and, if identified data are requested, that a RAE site for the study has been created. The UCSF Data Resources and CTSI websites have helpful information on how to access the right data for your study.

- Data Extraction Consultation – This page has information for setting up an initial data extraction consultation to help researchers refine and coordinate their data request. This is the first step in requesting clinical data for research from UCSF Health and SFHN/ZSFG.
- How to Get Identified Data for Research or Recruitment – This page includes information on how to get fully identified EHR data for research. At the bottom, it includes a link to the APeX (UCSF) and ZSFG Clarity Pick Lists to help identify the specific variables to include in a data request.

You may be prompted to provide more information or steps if you want to share data with any third parties, such as completion of a Material Transfer or Data Agreement.

What happens after I submit my data extraction consultation form?

After submitting the initial data extraction consultation form, a CTSI intake specialist will follow up with the researcher as needed with a more detailed questionnaire and/or set up a time for an

initial consultation to develop clear specifications for the request. Researchers will also need to fill out a data specification form (example data specification forms and blank forms can be found here) as part of their correspondence with the CTSI intake specialist.

Once clear specifications are determined, the CTSI intake specialist will submit the request to an ARS programmer who will provide the researcher with a cost and time estimate. Once the researcher approves the estimate, the request will enter the queue for fulfillment.

Be sure to allow ample time for this process; data extraction requests can take 1-3 months to fulfill.

How has the 2019 transition to Epic within SFHN affected the EHR data I can request for research use?

As SFDPH continues to focus on stabilization in its Epic implementation, prioritizing the analytics needs for its core regulatory and value-based care metrics, there will be some limitations to the legacy SFHN EHR data accessible to researchers through ARS and to the amount of data validation ARS is able to conduct. Researchers should refrain from contacting the SFDPH IT teams themselves in an attempt to understand or fix problematic data. We ask for your patience in focusing on the minimum data required to fill your research aim and what is available through ARS services at the time of your request.

How much does EHR data extraction cost?

The first hour of consultation for UCSF researchers any project based at UCSF and affiliated CTSI institutions is free. This page has information about the hourly rate for subsequent consultations and work done by consultants after the initial hour.

How do I request EHR data if I am a researcher without a UCSF affiliation?

Researchers who do not have UCSF MyAccess credentials can select “non-UCSF” when requesting a data management and extraction consultation on this page.

Can I request EHR data for research if I do not have a UCSF funding number?

Researchers without a UCSF funding number can request a Data Extraction Consultation, an initial conversation to help researchers refine and coordinate their data request. However, the fulfillment of data extractions requests (actually extracting and delivering the data) requires a UCSF funding number.

What are my options if I don't have funding?

A CTSI Scholarship Fund for up to 8 hours of data extraction services is available to eligible applicants who have qualified & unfunded research projects. Eligibility requirements include:

- The data extraction estimate provided by CTSI/ARS analysts during the 1-hour free consultation must be no more than 15-20 hours.
- The applicant must attest that they have no dedicated funding for this project, and have limited access to discretionary funds that could be used for this purpose
- Scholarships are limited to one per PI per fiscal year.
- Complete a data extraction consult request for more details on this scholarship.

OR .... you can use UCSF's de-identified clinical data! The de-identified data are meant to be self-serve datasets to enable research, where you don't need an IRB approval to access the data and you don't need to wait for a data broker. Find out more: DeID Clinical Data Knowledge Base

Who can I contact with questions about requesting EHR data for research?

Key information about requesting electronic health record data for research include:

- UCSF Data Resources Website
- UCSF Research Consultation Website (part of CTSI)