Knowing what is OK: Recruiting Participants for Clinical Research at UCI
Part 1: Recruiting through UCIMC

Associated Resource Sheet/FAQs

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Resources

Many of these resources require UCI Health System (HS) access. If you do not yet have a UCI Health System account, please sign the Confidentiality Agreement of UCI Health and send it to Kevin Zhang (kezhang@uci.edu) to obtain an HS account.

1) Anonymized UCI Clinical Data Warehouse (CDW)

The anonymized UCI CDW contains most structured electronic health records (EHR) data captured at the UCI Health since 2009, covering clinical encounters, vital signs, laboratory test results, diagnoses, clinical procedures, and medication prescriptions of more than 750,000 unique patients. The database is refreshed monthly. No IRB is required for research use.

Link to Anonymized UCI CDW Virtual Workshop.

2) UC COvid Research Data Set (UC CORDS)

UC CORDS is a continuously updated dataset containing SARS-CoV-2 testing results and inpatient COVID-19 treatment information from all UC medical campuses. It is a HIPAA Limited Data Set, of which direct identifiers are removed but original dates of services are retained. The dataset is refreshed monthly. No IRB is required for research use.

Link to UC CORDS Virtual Workshop.

How to request access to #1 and #2: Sign the UCI CDW Data Use Agreement and/or UC CORDS Data Use Agreement and return to Kevin Zhang (kezhang@uci.edu). If you do not yet have a UCI Health System account, please also sign the Confidentiality Agreement of UCI Health and email to Kevin Zhang.

3) Anonymized UC Health Data Warehouse (UCHDW)

UCI researchers who have data queries developed using the anonymized UCI CDW can apply for special permission to execute their queries on an anonymized version of the UC Health Data Warehouse (UCHDW), which is similar to the UCI CDW but contains structured EHR data from all UC medical campuses (UC Davis, UCSF, UCLA, UCI, and UCSF). The database is refreshed monthly. No IRB is required for research use. URL: http://analytics.uchealth.edu. To access the URL you need to be on either the Health Systems network or using UCI Health VPN. Email Kai Zheng (kai.zheng@uci.edu) on how to apply for an account.

4) National Covid Cohort Collaborative (N3C) Data

N3C (https://ncats.nih.gov/n3c/about/) is one of the largest clinical data resources for accelerating research on COVID-19. As of today, the N3C dataset contains 2.1M+ patients, of which 300k+ tested positive for COVID-19, contributed by 72 institutions nationwide including UC, Mayo Clinic, Johns Hopkins University, and Children's Hospital of Philadelphia. All UCI researchers can access the N3C data for free; IRB approval may be required depending on the nature of the data requested.

Link to N3C Virtual Workshop.

5) All of Us Research Data

The NIH All of Us Research Program (https://www.researchallofus.org/) is one of the largest biomedical data resources with health data and biospecimens collected from a diverse cohort of participants nationwide. Currently, the program has enrolled over 300k participants. Data include participant responses to survey questionnaires (basic demographics, overall health, lifestyle, family history, medical history, and healthcare access), physical measurements, electronic health records, and genomic data. All UCI researchers can access the data for free. IRB is not required for research use.

Link to All of Us Virtual Workshop.

6) Cohort Discovery Tool

The Cohort Discovery Tool allows researchers to perform cohort identification and study feasibility analyses for their research with de-identified patient data from the UCI Health Enterprise Data Warehouse. This is a free self-service tool. To access the Cohort Discovery Tool, you need to be on either the Health Systems network or using UCI Health VPN. See further information under the FAQs below.

Link to tutorials and tips.

FAQs

Do patients sign a document when they become a UCI patient that allows researchers to contact them?

A patient signs two documents when they register to receive care at UCI facilities. The documents inform the patient that UCI is an academic research organization and may use their health-related information to 1) contact them to recruit them for research projects, and 2) use health information for research without needing to contact them. One document is the "Terms and Conditions of Service" and the other is the "Notice of Privacy Practice" (required by HIPPA).

Before a researcher can contact a patient for research participation, the researcher must obtain Institutional Review Board (IRB) approval for the proposed project. The IRB will ensure patient health information (PHI) and patient safety are protected. The IRB also addresses requirements for informed consent or waiver of informed consent as well as HIPPA privacy requirements for HIPPA authorization or waiver of HIPPA authorization.

Why should a researcher include the provider in the recruitment process?

The IRB approves the recruitment methods for a research study and evaluates the recruitment methods on various factors to ensure protection of the patients' safety and welfare. When a researcher seeks to recruit patients at UCIMC, one important factor is the partnership between researcher and health care provider. This partnership ensures there is appropriate expertise to oversee the study recruitment. Moreover, the IRB can issue specific HIPPA waivers for a study, which may allow discussion between the researcher and the provider to determine eligibility of a patient before contacting a patient.

What are some best practices for creating a successful partnership between a researcher and a provider?

Before you start recruitment from a provider's site, it is important to develop a strong partnership with the provider. Here are some recommended strategies:

- Be persistent when establishing the relationship. Providers can be busy and may need reminders of what the research project is trying to accomplish and why you need their support. An in-person visit can help you establish this relationship.
- Provide a succinct summary of the research protocol to the provider and discuss whether these procedures will affect the clinic's workflow.
- Secure an agreement from the provider that will allow you to recruit from their clinic and keep the provider in the loop about when you will be in their clinic to recruit participants.
- Inform and involve the provider's support staff to ensure you have their permission to approach the patients.

Epic

What is Epic?

Epic is the software utilized by UCI Health to store Electronic Medical Records (EMR) for patients at UCI Medical Center.

How does a researcher get access to Epic?

A researcher can submit a ticket to the UCI Health IT Service Desk to request access to Epic. IRB approval and appropriate HIPPA waivers are required when requesting access. After the ticket is submitted

and approved the researcher will be contacted by UCI Health IT who will provide the appropriate training based on the level of access required into Epic and the necessary paperwork.

Now that I have IRB approval to use Epic for recruitment and access to Epic, can I screen patients through a clinician's schedule? What type of permission is needed between researcher and provider?

A clinician's schedule can be used to perform initial screening for participants if you have IRB approval to use Epic in this way. It is also important for there to be a working relationship between researcher and provider, so the provider knows and agrees to the researcher recruiting their patients.

What does a "Break the Glass" prompt mean when searching Epic?

The "Break the Glass" prompt indicates there are special protections on the record since these patients may be employees, relative of employees, or VIP patients. This feature is used to monitor for employee snooping and inappropriate access. Researchers who wish to recruit these patients will need to provide the IRB Human Subjects number, indicate it is for research, and have the appropriate IRB HIPPA approval waiver, so that appropriate access can be verified.

Honest-Broker System

What is the Honest-Broker service?

The Honest-Broker service is provided by a team of data analysts who will help researchers go into the back end of the Clinical Data Warehouse (contains structured Electronic Health Records collected from UCI Health) to build a query based on inclusion/exclusion criteria and data elements desired and then will retrieve the information about the data. The data provided to the researcher is dependent on what was approved in the IRB. The provided list can then be used to do further participant screening depending on the approval received from the IRB.

How do you get started with the Honest-Broker service?

The Cohort Discovery Tool is a free self-service tool that researchers can use to perform cohort identification and study feasibility analyses for their research with de-identified patient data from the UCI Health Enterprise Data Warehouse. To access the Cohort Discovery Tool you need to be on the Health Systems network or using UCI Health VPN. If additional information is required, researchers can submit a ticket to the UCI Health IT Service Desk for the Honest-Broker service. Click on "Service Catalog", scroll down, and select "Data Request". Provide as many requirements and details as you can, including the IRB protocol for the study. Then click the "Order Now" button. To request a consultation to understand the Honest-Broker service, please email cbmisupport@uci.edu.

Can a researcher go into Epic to screen the patients further after the list is received from the Honest-Broker query?

This depends on the IRB approval for the study. If this is the process approved by the IRB, then yes. It is important to spell out the screening and recruitment process in the IRB application so that the IRB will review and approve the procedures.

Patient Communication for Recruitment

I now have a list of potentially eligible patients for the study (from Honest-broker service or screening through EPIC), what is appropriate when contacting patients for a research study?

All communications should protect the PHI of the potential participant. If you are approved to recruit participants at the provider's clinic, then work with the provider and support staff to determine the appropriate place and method to approach their patients that does not interfere with the clinic workflow or prevent the patient from receiving medical care.

If you have received IRB approval to recruit using a form of electronic communication, it is especially important to protect the PHI of the potential participant. Recruitment methods using phone calls, emails, and text messages need to use secure and UCI Health IT approved platforms. If you have concerns about what information can be communicated with a patient during recruitment contact UCI Health Privacy & Compliance Office.

What are UCI Health IT approved platforms for recruiting patients for a research study?

There is currently no list providing this information. To determine what is approved or to obtain approval for a new platform, please contact UCI Health IT.

What is the process for getting a non-approved application or service approved, so it can be used to recruit and communicate with patients?

The application or service will need to be approved by UCI Health IT. UCI Health IT will vet the application or service to make sure it meets the standards for security and privacy. Contact UCI Health IT through their Service Desk.

Data

Can researchers merge data collected from patients during the study with the information contained in their EHR?

Yes. A protected research environment can be created where the datasets can be uploaded to and within this environment the datasets can be manipulated and analyzed. The data cannot be downloaded from the protected research environment. Additional uploads to the protected environment will be reviewed by the administrator of the protected environment. To create a protected research environment contact UCI Health IT.