

Informatics Tools for Clinical Research

Cohort Finding, Accessing
Patient Data and Recruitment



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UCLA CTSI Biomedical Informatics Program

Outline

- Obtaining Counts Preparatory for Research

- UC-Research Exchange (UC-ReX)



- Los Angeles Data Resource (LADR)



- Informatics for Integrating Biology & the Bedside (i2b2)

- Obtaining Medical Record Data to Conduct Your Research

- Studies with Direct Patient Contact

- Studies with No Direct Patient Contact

Obtaining Counts: UC-ReX



Sites	What You Can Search On:
<ul style="list-style-type: none"> • UCLA • UCSF • UCD • UCI • UCSD 	<ul style="list-style-type: none"> • Demographics • Laboratory Tests • ICD-9 Codes • Medications • Vital Signs • Vital Status

	Distinct Patient Records	Diagnoses	Labs	Medications	Procedures	Vital Signs	Observations
UCD	2,361,467	46,735,705	117,944,810	27,952,027	1,052,211	46,048,977	256,343,183
UCI	1,585,160	14,875,209	43,571,225	9,130,634	918,705	7,424,967	68,510,973
UCLA	4,537,355	37,968,248	128,805,690	5,373,547	1,460,767	19,227,267	224,643,847
UCSD	2,361,398	18,189,436	85,614,364	29,953,062	119,148	25,104,772	171,003,400
UCSF	3,277,988	8,831,305	94,559,761	9,504,694	433,422	21,536,651	127,468,273
Total	14,123,368	126,599,903	470,495,850	81,913,964	3,984,253	119,342,634	847,969,676

Obtaining Counts: LADR



Sites	What You Can Search On:
<ul style="list-style-type: none">• UCLA• Cedars Sinai <p><i>Forthcoming by Fall 2015:</i></p> <ul style="list-style-type: none">• University of Southern California• Children's Hospital Los Angeles• City of Hope• Community clinics affiliated with Charles R. Drew University	<ul style="list-style-type: none">• Demographics• ICD-9 Codes• Medications• Vital Signs• Vital Status

	Distinct Patients	Total Facts
Cedars	2,599,282	79,931,785
UCLA	4,395,293	215,663,166

Obtaining Counts: UC-ReX

The screenshot displays the UC-ReX Data Explorer interface. On the left, a tree view shows a hierarchy of terms under 'SHRINE', including Demographics, Diseases and Injuries, Laboratory Tests, and Medications - Anatomical Therapeutic Chemical (ATC). A blue arrow points to the 'Navigate Terms' tab. The 'Query Tool' window is open, showing a 'Query Name' field and three empty query groups. The 'Query Status' window at the bottom shows a running query: "Tobacco- 52 ye@17:52:39" with a duration of 38.2 seconds. The 'Previous Queries' window shows a list of past queries, including "Tobacco- 52 ye@16:34:09 [10-1-2015] [ywan]" and its results for various SHRINE sites.

SHRINE

- Demographics
 - Age
 - Ethnicity
 - Gender
 - Language
 - Marital Status
 - Race
 - Religion
- CD-9-CM
- Diseases and Injuries
 - Procedures
 - Supplementary classification of external causes of injury and poisoning
 - Supplementary classification of factors influencing health status and contact with health services
- Laboratory Tests
 - Chemistry
 - Hematology / Coagulation
 - Immunology
 - Urinalysis
- Medications - Anatomical Therapeutic Chemical (ATC)
 - A - Alimentary Tract And Metabolism
 - B - Blood And Blood Forming Organs
 - C - Cardiovascular System
 - D - Dermatologicals
 - G - Genito Urinary System And Sex Hormones
 - H - Systemic Hormonal Preparations, Excl. Sex Hormones And Insulins
 - J - Antinfectives For Systemic Use
 - L - Antineoplastic And Immunomodulating Agents
 - M - Musculo-skeletal System
 - N - Nervous System
 - P - Antiparasitic Products, Insecticides And Repellents
 - R - Respiratory System
 - S - Sensory Organs
 - V - Various
 - Vital Signs

Query Tool

Query Name: _____

Group 1			Group 2			Group 3		
Dates	Occurs > 0x	Exclude	Dates	Occurs > 0x	Exclude	Dates	Occurs > 0x	Exclude

Query Status

Running Query: "Tobacco- 52 ye@17:52:39" [38.2 secs]

Previous Queries

- Tobacco- 52 ye@16:34:09 [10-1-2015] [ywan]
 - Results of Tobacco- 52 ye@16:34:09 [10-1-2015] [ywan]
 - UCLA SHRINE - 72267 ±3 patients
 - UCSD SHRINE - 49648 ±3 patients
 - UCSF SHRINE - 27651 ±3 patients
 - UCI SHRINE - 16017 ±3 patients
 - UCD SHRINE - 54541 ±3 patients
- Tobacco- 52 ye@16:31:15 [10-1-2015] [ywan]

Obtaining Counts: LADR

Query Tool

Query Name: Asthma(- 2 yea@21:48:22

Group 1			Group 2			Group 3		
Dates	Occurs > 0x	Exclude	Dates	Occurs > 0x	Exclude	Dates	Occurs > 0x	Exclude
			2 years old					
			3 years old					
			4 years old					
			5 years old					
			6 years old					
			8 years old					
			9 years old					
			10-17 years old					
			7 years old					

Previous Queries

- Asthma(- 2 yea@21:48:22 [9-18-2015] [ywan]
 - Results of Asthma(- 2 yea@21:48:22 [9-18-2015] [ywan]
 - UCLA SHRINE - 11309 ±3 patients
 - CSMC SHRINE - 2786 ±3 patients
- number of all patients [7-8-2015] [ywan]
- B01AA --BMI@22:05:50 [5-19-2015] [ywan]

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Obtaining Counts: i2b2

Query Tool

Query Name:

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i2b2 Query & Analysis Tool Project: UCLA i2b2

- [-] ICD-9-CM
- [-] Laboratory Tests
- [-] Medications - Anatomical Therapeutic Chemical (ATC)
- [-] Visit Details
 - [-] Age at visit
 - [-] Length of stay
 - [-] Location
 - [-] Visit type
 - [-] Ambulatory Visit
 - [-] Emergency Department Visit
 - [-] Emergency Department Visit Admit To Inpatient
 - [-] Inpatient Hospital Stay
 - [-] No Information
 - [-] Non-Acute Institutional Stay
 - [-] Other Ambulatory Visit
 - [-] Other Visit
 - [-] Unknown Visit
- [-] Vital Signs
- [-] Vital Status

Getting Access to UC-ReX/LADR/i2b2

Requirements:

- Affiliation with a participating institution
- Completion of a training
- Submission of signed user agreements for UC-ReX and/or LADR and/or i2b2

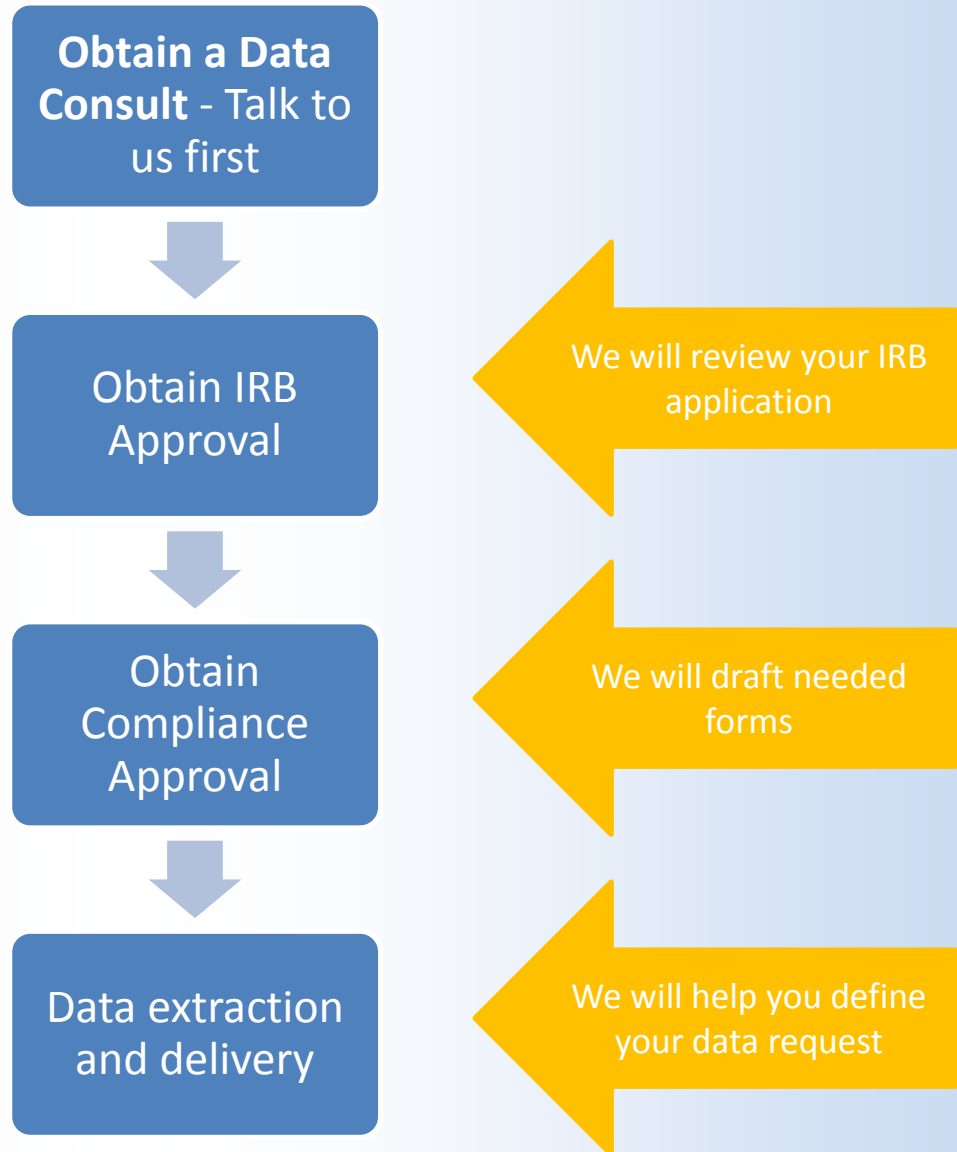
Contact Information

ucrex@ctsi.ucla.edu or ladr@ctsi.ucla.edu

Ruby Wan: ywan@mednet.ucla.edu



Obtaining Medical Record Data to Conduct Your Research



Types of Studies

Protected Health Information (PHI):

An individual's personal information that is created, received, or transmitted by a provider or health plan, and that identifies the individual and the health information.

- o Name
- o Street address
- o All elements of dates except year
- o Telephone number
- o Fax number
- o Email address
- o URL address
- o IP address
- o Social Security number
- o Account number
- o License numbers
- o Medical Record number
- o Health plan beneficiary #
- o Device identifiers and their serial numbers
- o Vehicle identifiers and serial number
- o Biometric identifiers (finger and voice prints)
- o Full face photos and other comparable images
- o Any other unique identifying number, code, or characteristic

HIPAA Waiver

HIPAA Release Authorization

Direct Patient Contact

Screening

Consented Patients

No Direct Patient Contact

De-identified

Limited

Identified

Chart Review

Excludes all 18 identifiers

Excludes 16 identifiers

Data Elements

Step 1:
Generate cohort

Imaging Orders and Results

Variable	Include Field	Selection Criteria
Order Procedure Id	<input type="checkbox"/>	
Order Time	<input type="checkbox"/>	
Result Time	<input type="checkbox"/>	
Procedure Code	<input type="checkbox"/>	
Procedure Name	<input type="checkbox"/>	
Accession Number	<input type="checkbox"/>	
Impression	<input type="checkbox"/>	
Narrative	<input type="checkbox"/>	

Footnotes: Counts of orders by Type can be pulled first for review and to allow for more detailed selection. Result Text can potentially be searched for specific terms or string patterns (regular expressions). Narrative and Impression will each be sent as a separate table with order procedure id, line, and text fields.

Step 2:
Extract variables

Microbiology

Order Type	Include Orders	Selection Criteria
Order Procedure Id	<input type="checkbox"/>	
Order Time	<input type="checkbox"/>	
Result Time	<input type="checkbox"/>	
Procedure Code	<input type="checkbox"/>	
Procedure Name	<input type="checkbox"/>	
Specimen Source	<input type="checkbox"/>	
Specimen Type	<input type="checkbox"/>	
Organism Name	<input type="checkbox"/>	
Susceptibility	<input type="checkbox"/>	
Sensitivity	<input type="checkbox"/>	
Antibiotic	<input type="checkbox"/>	

Footnotes: Counts of orders by Type can be pulled first for review and to allow for more detailed selection. Results prior to 3/1/2013 will have similar layout to the pathology & cytology table above.

Compliance

- We will help draft UCLA Compliance forms
 - Request to Interface or Download Restricted Information (RI) Form*
 - Data Use Agreement (DUA)

* Requires PI and CAO signatures


Obtaining Medical Record Data: Data Delivery

- Password-protected Excel files
- REDCap (Research Electronic Data Capture)



REDCap™

Log In

 **UCLA Clinical & Translational Science Institute**

Please log in with your user name and password. If you are having trouble logging in, please contact [Martin Lai \(310-794-9396\)](mailto:Martin.Lai@ucla.edu).

Username:

Password:

[Forget your password?](#)

Welcome to REDCap

REDCap is a mature, secure web application for building and managing online surveys and databases. Using REDCap's stream-lined process for rapidly developing projects, you may create and design projects using 1) the online method from your web browser using the Online Designer, and/or 2) the offline method by constructing a 'data dictionary' template file in Microsoft Excel, which can be later uploaded into REDCap. Both surveys and databases (or a mixture of the two) can be built using these methods.

REDCap provides automated export procedures for seamless data downloads to Excel and common statistical packages (SPSS, SAS, Stata, R), as well as a built-in project calendar, a scheduling module, ad hoc reporting tools, and advanced features, such as branching logic, file uploading, and calculated fields.

Learn more about REDCap by watching a [brief summary video \(4 min\)](#). If you would like to view other quick video tutorials of REDCap in action and an overview of its features, please see the [Training Resources](#) page.

Please note that any publication that results from a project utilizing REDCap should cite grant support (CTSI Grant UL1TR000124).

NOTICE If you are collecting data for the purposes of human subjects research, review and approval of the project is required by your Institutional Review Board.

If you require assistance or have any questions about REDCap, please contact [Martin Lai \(310-794-9396\)](mailto:Martin.Lai@ucla.edu).

REDCap Features

Build online surveys and databases quickly and securely - Create and design your project rapidly using secure web authentication from your browser. No extra software is required.

Fast and flexible - Conception to production-level survey/database in less than one day.

Export data to common data analysis packages - Export your data to Microsoft Excel, PDF, SAS, Stata, R, or SPSS for analysis.

Ad Hoc Reporting - Create custom queries for generating reports to view or download.

Scheduling - Utilize a built-in project calendar and scheduling module for organizing your events and appointments.

Easily manage a contact list of survey respondents or create a simple survey link - Build a list of email contacts, create custom email invitations, and track who responds, or you may also create a single survey link to email out or post on a website.

Send files to others securely - Using 'Send-It', upload and send files to multiple recipients, including existing project documents, that are too large for email attachments or that contain sensitive data.

Save your data collection instruments as a PDF to print - Generate a PDF version of your forms and surveys for printing to collect data offline.


Advanced features - Auto-validation, calculated fields,

How to Request Our Services

- Submit a service request at <http://intranet.ctsi.ucla.edu/>

Los Angeles Biomedical Research Institute at Harbor-UCLA Medical Center (LA BioMed/Harbor-UCLA)

Enter Search Keywords SITE SEARCH

 **UCLA CTSI**
Connections
UCLA Clinical and Translational Science Institute

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36 CTSI COMMUNITY PARTNERS

QUICK LINKS:

Consultations & Advice	CTSI Seminars
Letter of Support	Research Cores
Commercialization	Grant Library
Clinical Data Requests	Boilerplate Text
Clinical & Translational Research Centers	Dissemination & Implementation

[Request a Service](#)

The screenshot shows a navigation menu with five items: RESEARCHER RESOURCES, EDUCATION & TRAINING, COMMUNITY ENGAGEMENT, FUNDING, and ABOUT. Below the menu is a banner for '36 CTSI COMMUNITY PARTNERS' featuring a photo of a man in a hard hat and a woman in a lab coat. To the right of the banner is a 'QUICK LINKS' section with a grid of links. A red arrow points from the 'Clinical Data Requests' link to the 'Request a Service' button.

How to Request Our Services

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UCLA Clinical and Translational Science Institute

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RESEARCHER RESOURCES EDUCATION & TRAINING COMMUNITY ENGAGEMENT FUNDING ABOUT

Main >> Research Resources >> Clinical Data Requests

RESEARCHER RESOURCES

Edit Revisions

CLINICAL DATA REQUESTS

The Biomedical Informatics Program (BIP) of the UCLA CTSI provides researchers with access to data derived from patient care activities. Investigators can access patient count data using one of our self-service systems. If accessing individual-level data is desired, a consult from BIP is required. More information can be found below.

Obtaining Counts Preparatory for Research

UCLA participates in two networks that you can use to assess how many patients would meet different study inclusion criteria that are being considered. The systems also help you choose which other institutions to approach for participation if you need a larger sample size. Once your criteria is set, you can also obtain patient counts by gender, race and ethnicity to facilitate the completion of NIH planned enrollment tables.

> [Click here](#) for more information about these systems and how you can obtain access.

Obtaining Medical Record Data to Conduct your Research

BIP acts as the storefront for provisioning healthcare-related datasets for research projects at UCLA. As part of our data provisioning service, BIP supports investigators through the whole process of obtaining patient data. BIP reviews IRB applications and suggests modifications to the investigator in order to ensure IRB approval. If needed, BIP collaborates with the Biostatistics Program to integrate electronic health record (EHR) data with other kinds of data and analytic efforts. BIP also assists investigators with data security review by the UCLA Office of Compliance Services. BIP is delegated the authority to grant approval on behalf of the Compliance office in routine cases. Once BIP ensures all approvals have been secured, our programmers extract the requested data and securely deliver the data set to the investigator via our internal instance of REDCap (HIPAA compliant) or as an encrypted file via University email. You can receive data for studies involving **direct patient contact** or studies with **no direct patient contact**.

> [Click here](#) to find more information on the process for receiving data for your study.

Cite
Cite the grant number
UL1TR000124

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How to Request Our Services

Main >> Research Resources >> Obtaining Counts Preparatory for Research

RESEARCHER RESOURCES

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OBTAINING COUNTS PREPARATORY FOR RESEARCH

We have a variety of informatics tools to assess the feasibility of your research idea or complete NIH planned enrollment tables.

UC Research eXchange (UC-ReX)

UC-ReX currently contains data from over 13.9 million patients seen across the 5 UC medical centers. More information on UC-ReX can be found [here](#).

Sites	What You Can Search On:
<ul style="list-style-type: none">• UCLA• UCSF• UCD• UCI• UCSD	<ul style="list-style-type: none">• Demographics• Laboratory Tests• ICD-9 Codes• Medications• Vital Signs• Vital Status

Los Angeles Data Resource (LADR)

LADR is a collaborative effort of major Los Angeles healthcare organizations. More information on LADR can be found [here](#).

Sites	What You Can Search On:
<ul style="list-style-type: none">• UCLA• Cedars Sinai <p>Forthcoming by Fall 2015:</p> <ul style="list-style-type: none">• University of Southern California• Children's Hospital Los Angeles• City of Hope• Community clinics affiliated with Charles R. Drew University	<ul style="list-style-type: none">• Demographics• ICD-9 Codes• Medications• Vital Signs• Vital Status

Getting Access to UC-ReX/LADR

Requirements:

1. Affiliation with a participating institution*
2. Completion of an in-person training
3. Submission of signed user agreements for UC-ReX and/or LADR**

*For UC-ReX, you must be affiliated with UCLA. If you are affiliated with another UC please contact the appropriate site.

For LADR, you must be affiliated with one of the sites currently contributing data (UCLA or Cedars-Sinai Medical Center).

**If you are not a faculty member, you must have an affiliated faculty member's signature on both of your user agreements.

NOTE: If estimating your population size requires data not available in either tool, it may be possible for the BIP team to run the query for you. If this is the case, please note we will need at least a 2 weeks notice prior to the desired deadline.

Contact Information

ucrex@ctsi.ucla.edu or ladr@ctsi.ucla.edu

How to Request Our Services

The screenshot shows the UCLA CTSI Connections website. The header includes the CTSI logo, the text 'UCLA CTSI Connections' and 'UCLA Clinical and Translational Science Institute', and navigation links for 'Log In', 'CTSI Faculty Search', 'FAQ', and 'Quick Links'. A main navigation bar contains 'RESEARCHER RESOURCES', 'EDUCATION & TRAINING', 'COMMUNITY ENGAGEMENT', 'FUNDING', and 'ABOUT'. The breadcrumb trail reads 'Main >> Research Resources >> Obtaining Medical Record Data to Conduct your Research'. The page title is 'RESEARCHER RESOURCES' with 'Edit' and 'Revisions' buttons. The main heading is 'OBTAINING MEDICAL RECORD DATA TO CONDUCT YOUR RESEARCH'. The text explains that IRB and Compliance approval are needed for data requests. It lists four steps: 1. Obtain a Data Consult, 2. Obtain IRB approval, 3. Obtain Compliance approval, and 4. Data extraction and delivery. It also notes that additional requirements depend on whether the study involves direct patient contact. At the bottom, there are two tabs: 'Studies with Direct Patient Contact' and 'Studies with No Direct Patient Contact'. The text under the first tab states: 'There are two major study categories that involve direct patient contact: screening health record data for possibly-eligible patients vs. obtaining health record data for patients already consented and enrolled in a study.'

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Main >> Research Resources >> Obtaining Medical Record Data to Conduct your Research

RESEARCHER RESOURCES

Edit Revisions

OBTAINING MEDICAL RECORD DATA TO CONDUCT YOUR RESEARCH

To receive data derived from patient care at UCLA you will need IRB approval and Compliance approval, unless the data is de-identified. The specific requirements for different types of studies are provided in the tabs below. However, **in general**, we recommend the following steps:

1. **Obtain a Data Consult** - Talk to us first. We help with all aspects of data requests for research purposes. [Click here](#) to request a consult online at intranet.ctsi.ucla.edu.
2. **Obtain IRB approval** - To ensure that IRB-approved procedures are followed, we will need copies of your IRB approval letter, and your complete, currently-approved IRB application.
3. **Obtain Compliance approval** - Unless you are using de-identified data (as defined below), UCLA Compliance will need to approve your data security plans, after the plans are signed by your department's chair or chief administrative officer. We'll draft the Compliance review forms based on your IRB application, which you can then take for signatures.
4. **Data extraction and delivery** - Data can be delivered securely in a variety of ways. Populating a REDCap database is a preferred method, but we can also deliver data in Excel files and by other means.

Additional requirements depend on whether your study involves **direct patient contact**. For studies involving direct patient contact, requirements differ based on whether patients involved have **given consent** for use of their medical record data. For studies that do not involve direct patient contact, an important distinction is whether **chart review** is required. **Find the tab for your study type below** and follow the specific instructions. If your study involves activities in more than one category, please follow the instructions for all applicable categories.

Studies with Direct Patient Contact Studies with No Direct Patient Contact

There are two major study categories that involve direct patient contact: screening health record data for possibly-eligible patients vs. obtaining health record data for patients already consented and enrolled in a study.

Screening UCLA Health Record Data for Purposes of Recruiting Eligible Patients

References

- UCLA CTSI: <http://ctsi.ucla.edu/>
- Clinical Data Requests:
<http://ctsi.ucla.edu/researcher-resources/pages/clinicaldata>

Questions? Contact Us



- Marianne Zachariah:
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- Amanda Do: aldo@mednet.ucla.edu