Informatics Tools for Clinical Research

Cohort Finding, Accessing Patient Data and Recruitment

Marianne Zachariah, Amanda Do, Ruby Wan
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

UC ReX Data Explorer

Sites	What You Can Search On:
• UCLA • UCSF • UCD • UCI • UCSD	• Demographics • Laboratory Tests • ICD-9 Codes • Medications • Vital Signs • Vital Status

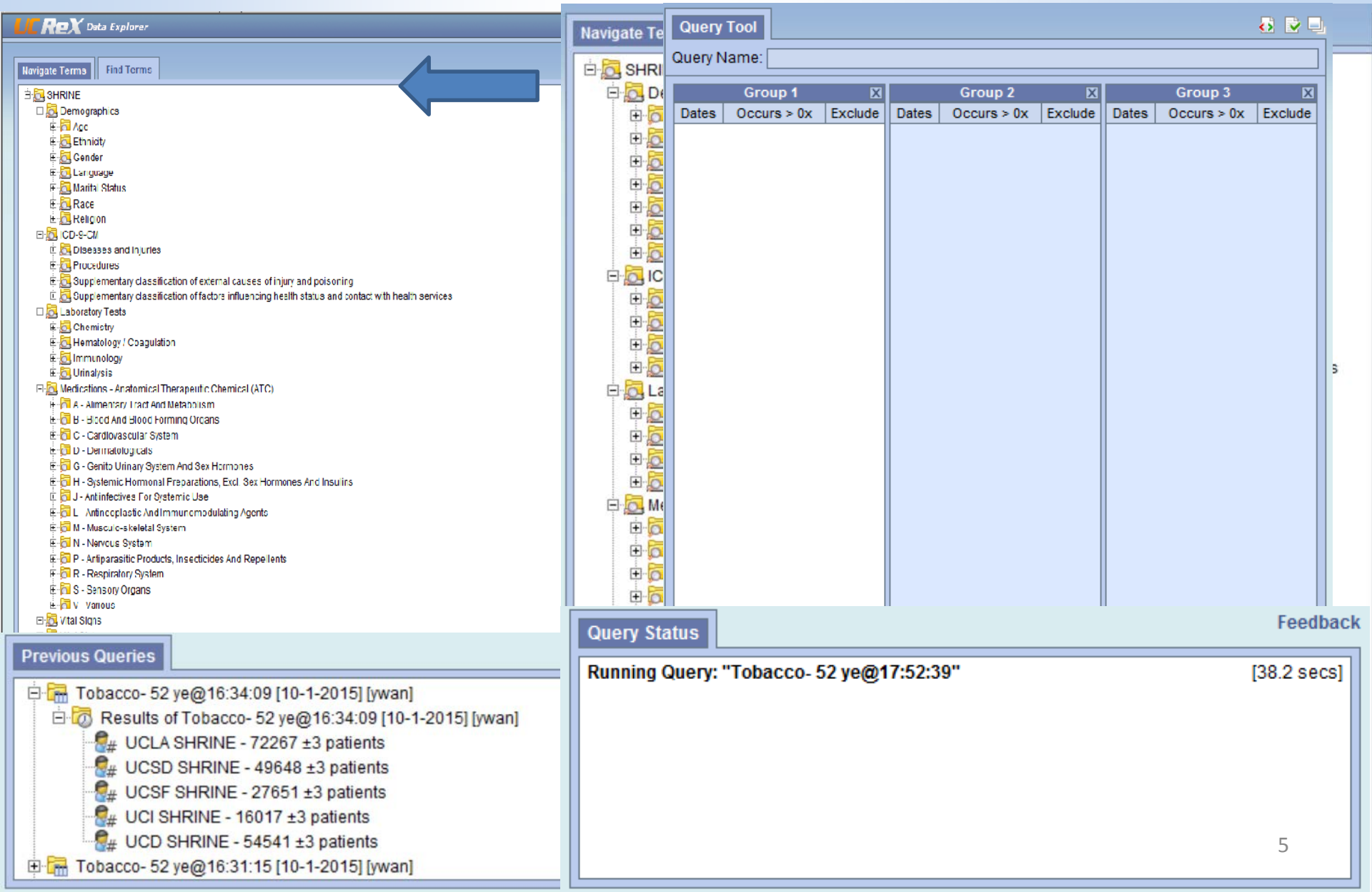
	Distinct Patient Records	Diagnoses	Labs	Medications	Procedures	Vital Signs	**Observations**
UCD	**2,361,467**	46,735,705	117,944,810	27,952,027	1,052,211	46,048,977	**256,343,183**
UCI	**1,585,160**	14,875,209	43,571,225	9,130,634	918,705	7,424,967	**68,510,973**
UCLA	**4,537,355**	37,968,248	128,805,690	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

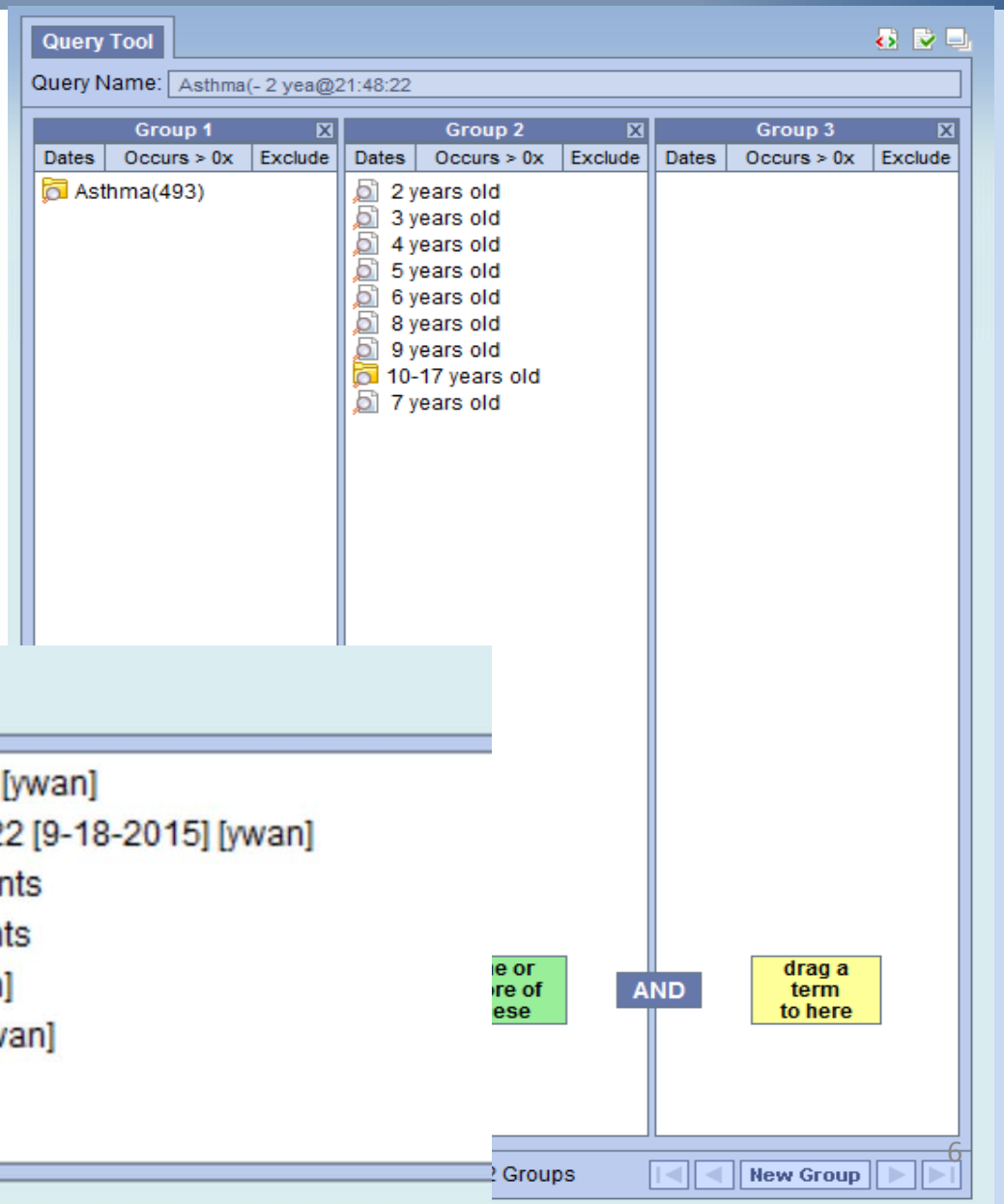
Sites	What You Can Search On:
• UCLA • Cedars Sinai ***Forthcoming by Fall 2015:*** • University of Southern California • Children's Hospital Los Angeles • City of Hope • Community clinics affiliated with Charles R. Drew University	• Demographics • ICD-9 Codes • Medications • Vital Signs • Vital Status

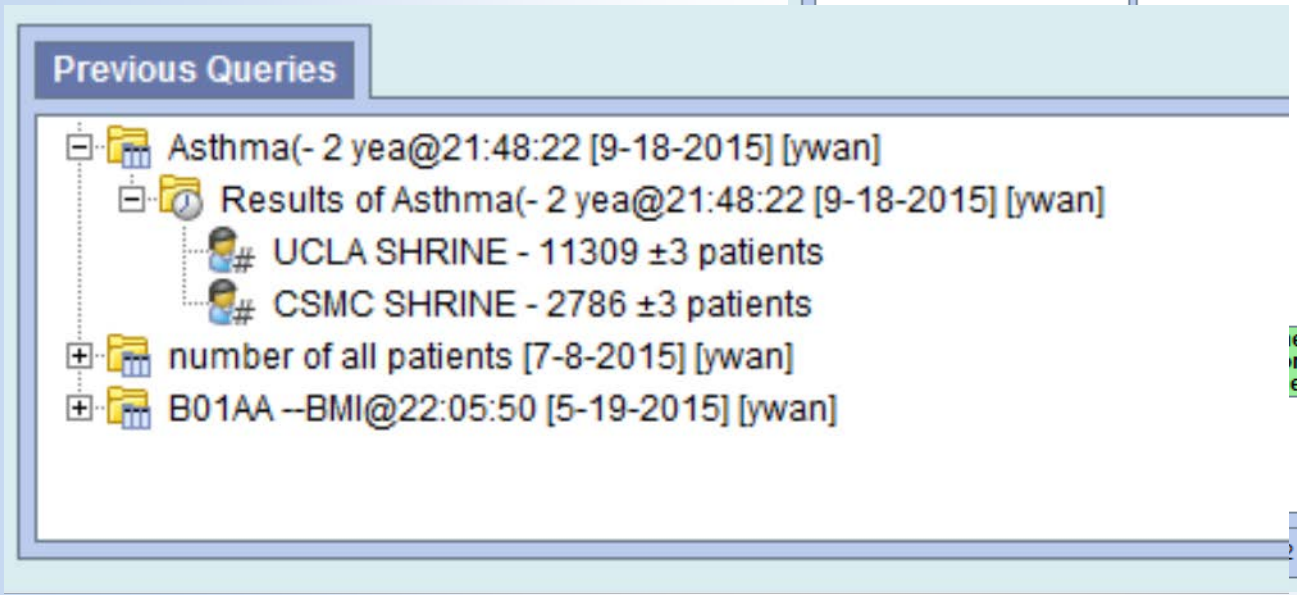
	Distinct Patients	Total Facts
Cedars	2,599,282	79,931,785
UCLA	4,395,293	215,663,166

Obtaining Counts: UC-ReX

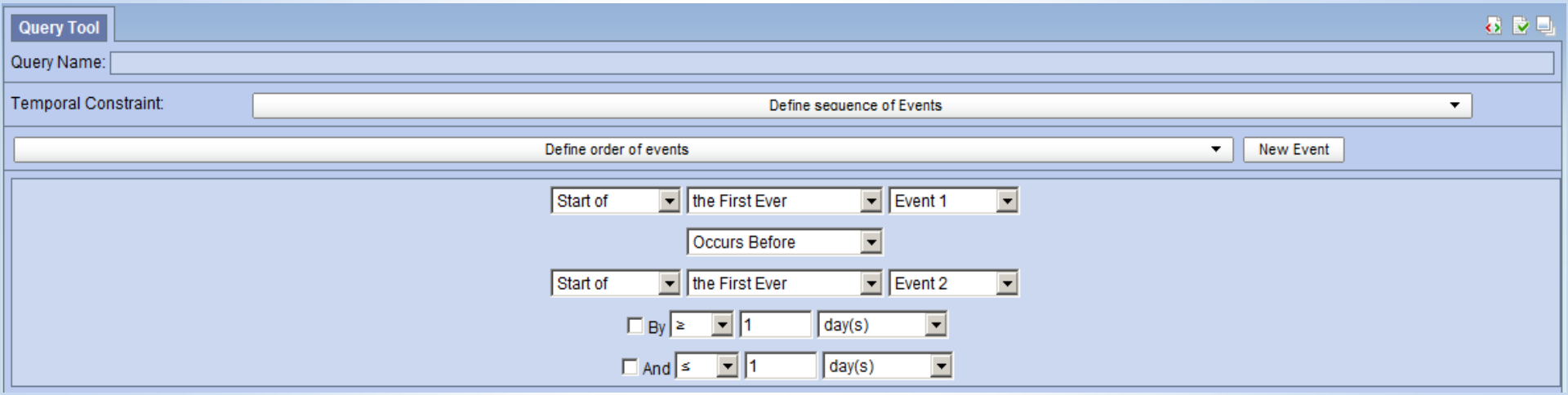


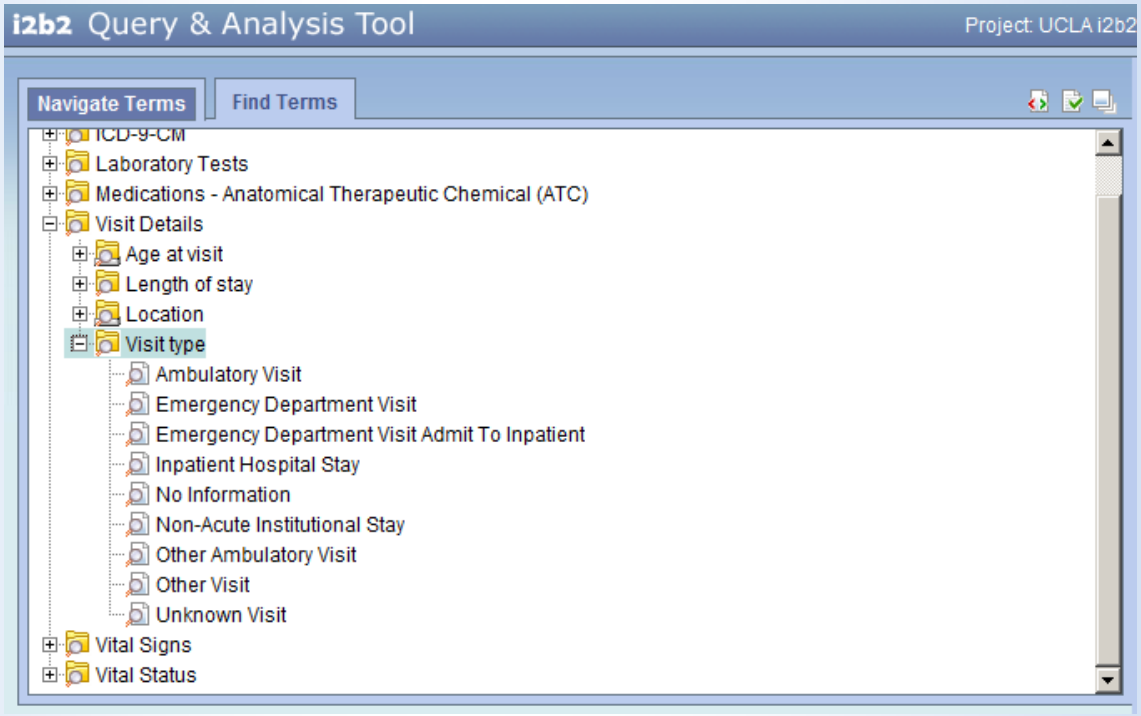
Obtaining Counts: LADR





Obtaining Counts: i2b2





Getting Access to UC-ReX/LADR/i2b2

Requirements:

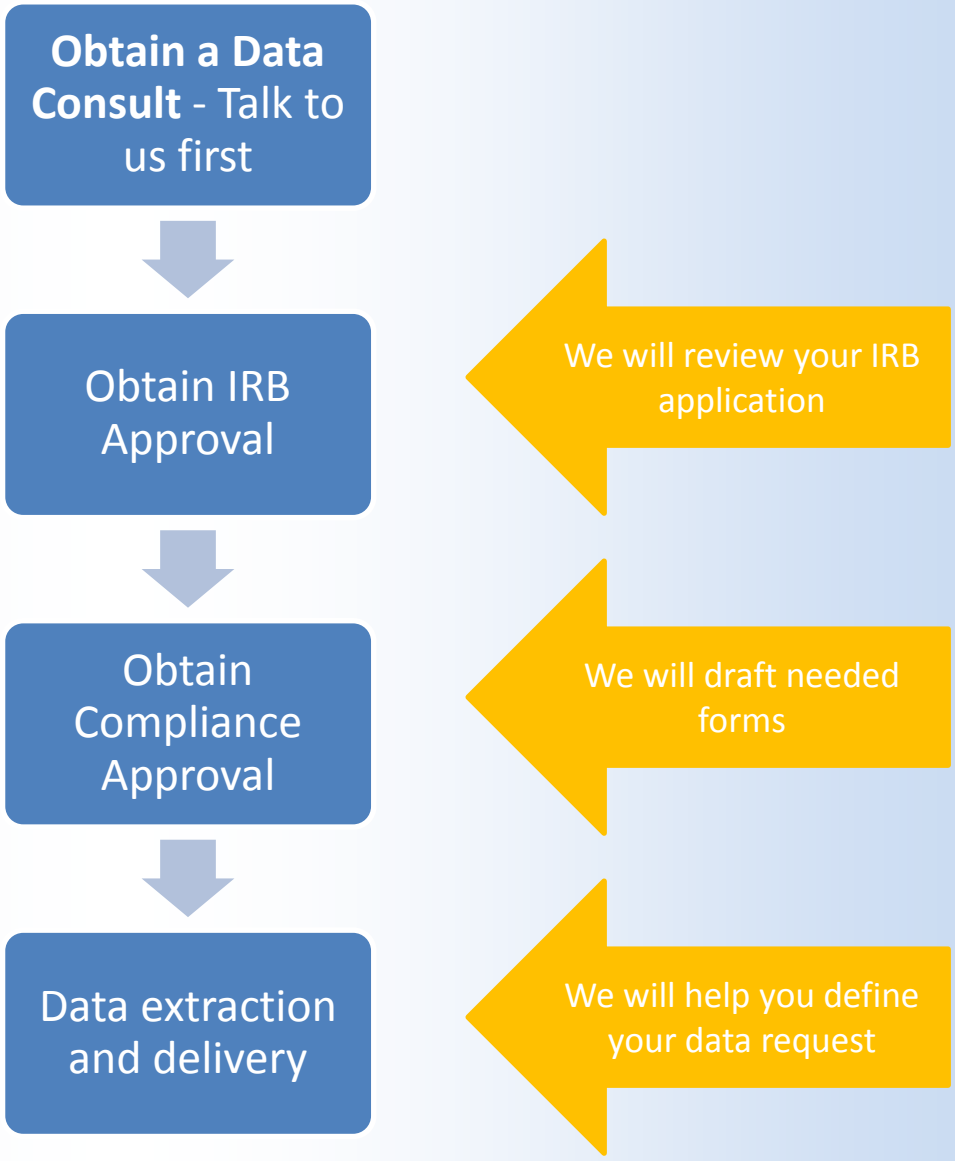
- Affiliation with a participating institution
- Completion of a training
- Submission of signed user agreements for UC-ReX and/or LADR and/or i2b2

Contact Information

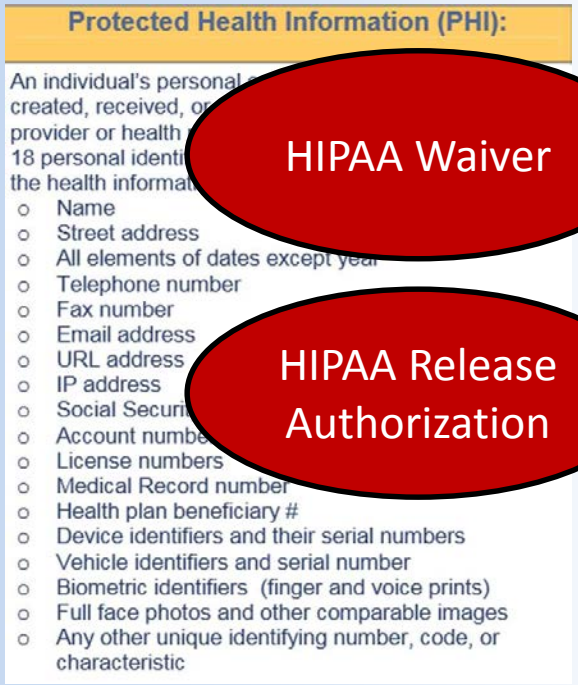
ucrex@ctsi.ucla.edu or ladr@ctsi.ucla.edu

Ruby Wan: ywan@mednet.ucla.edu

Obtaining Medical Record Data to Conduct Your Research



Types of Studies



HIPAA Waiver

HIPAA Release Authorization

- Direct Patient Contact
  - Screening
  - Consented Patients
- No Direct Patient Contact
  - De-identified — Excludes all 18 identifiers
  - Limited — Excludes 16 identifiers
  - Identified
  - Chart Review

Data Elements

Step 1: Generate cohort

Step 2: Extract variables

Imaging Orders and Results

Variable	Include Field	Selection Criteria
Order Procedure Id	☐	
Order Time	☐	
Result Time	☐	
Procedure Code	☐	
Procedure Name	☐	
Accession Number	☐	
Impression	☐	
Narrative	☐	

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.

Microbiology

Order Type	Include Orders	Selection Criteria
Order Procedure Id	☐	
Order Time	☐	
Result Time	☐	
Procedure Code	☐	
Procedure Name	☐	
Specimen Source	☐	
Specimen Type	☐	
Organism Name	☐	
Susceptibility	☐	
Sensitivity	☐	
Antibiotic	☐	

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.

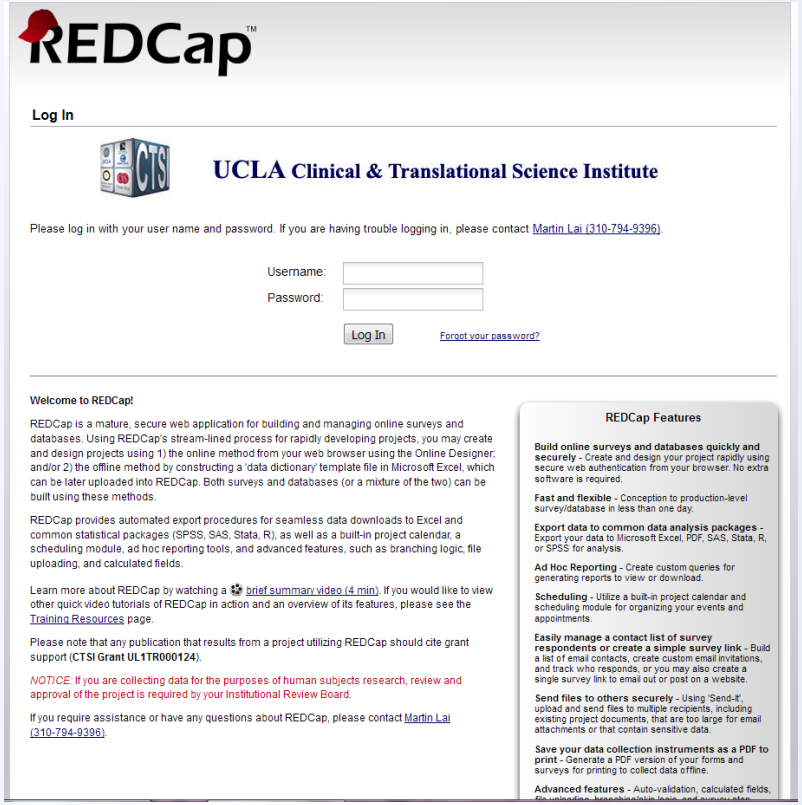
Compliance

- 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

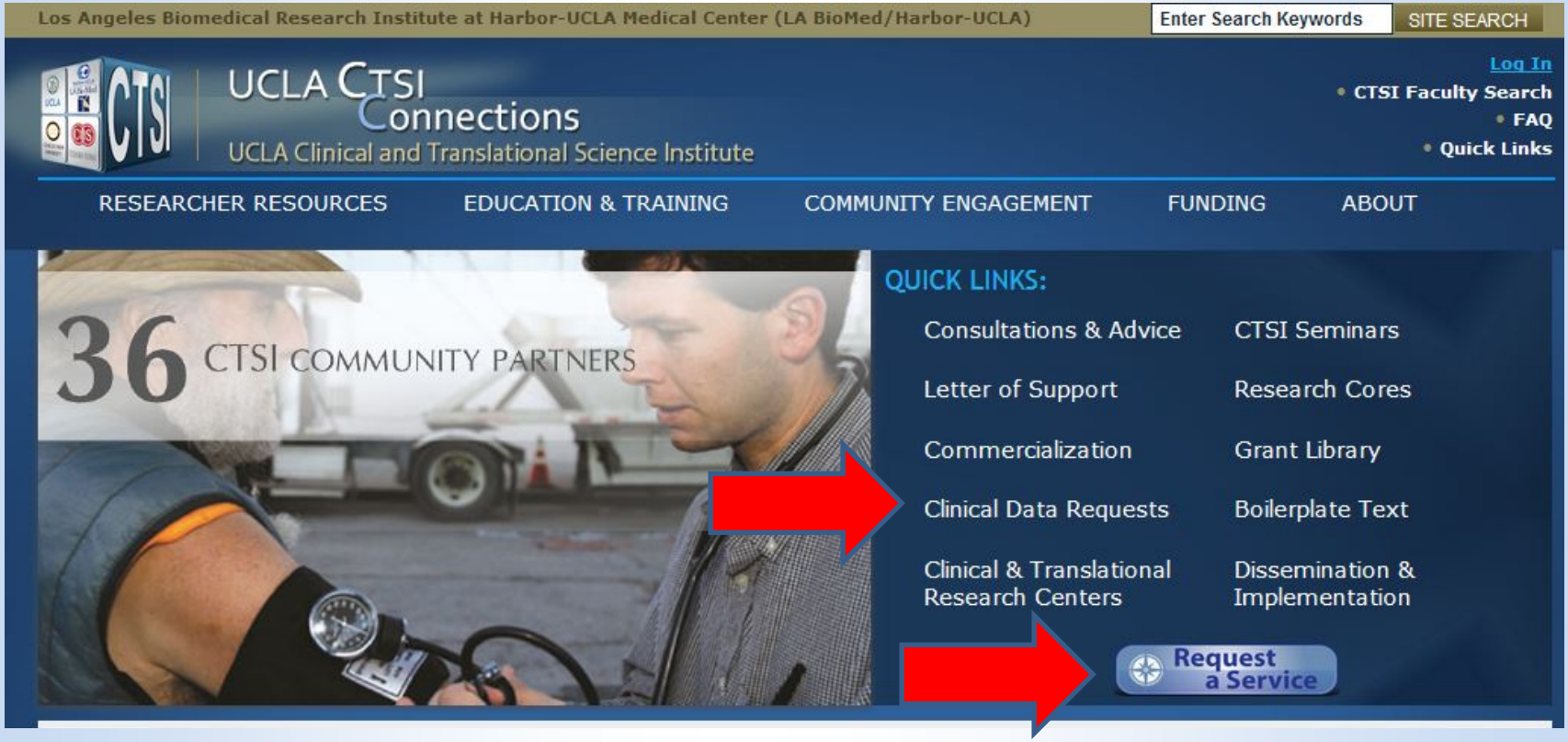
Obtaining Medical Record Data: Data Delivery

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



How to Request Our Services

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



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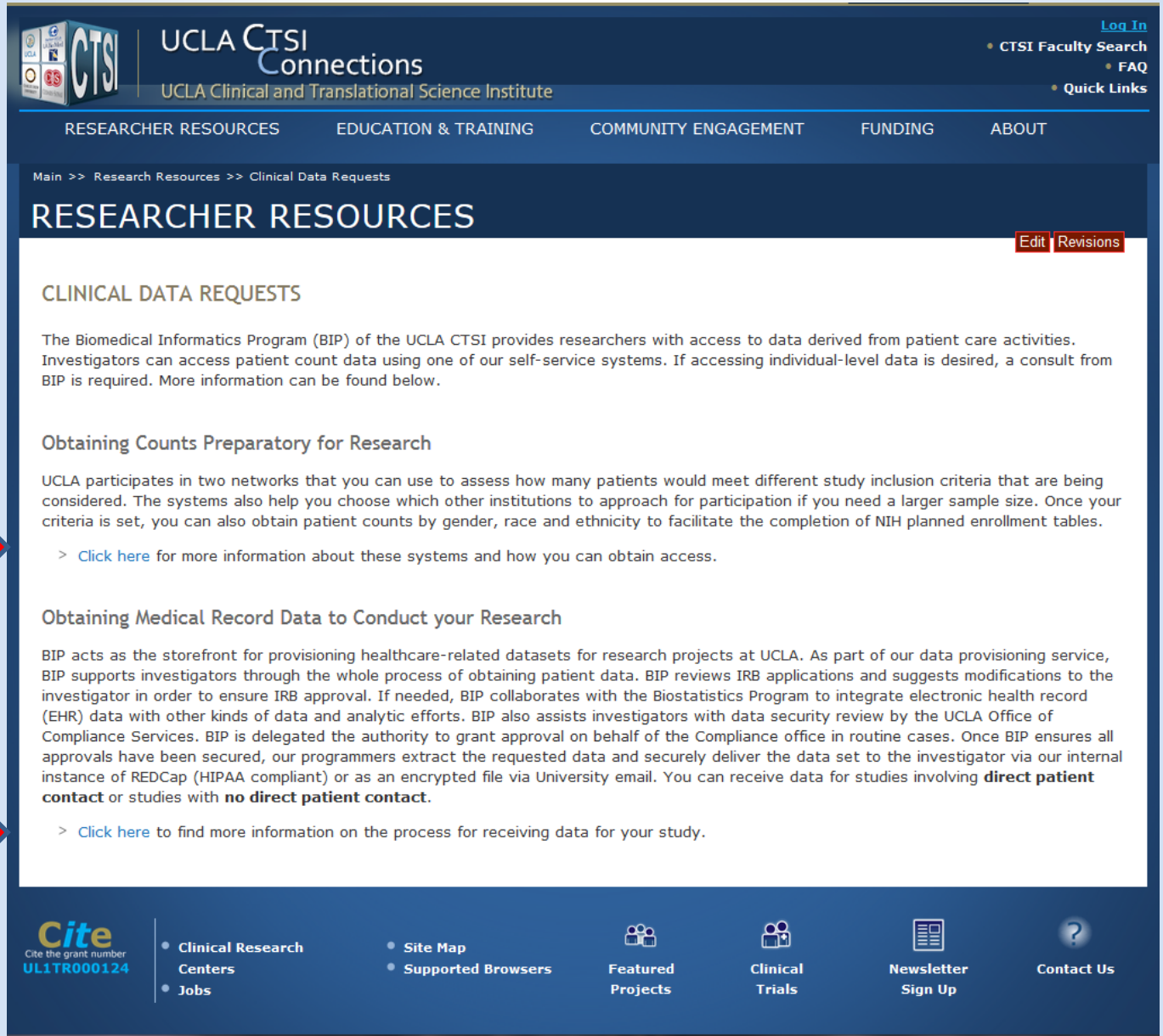

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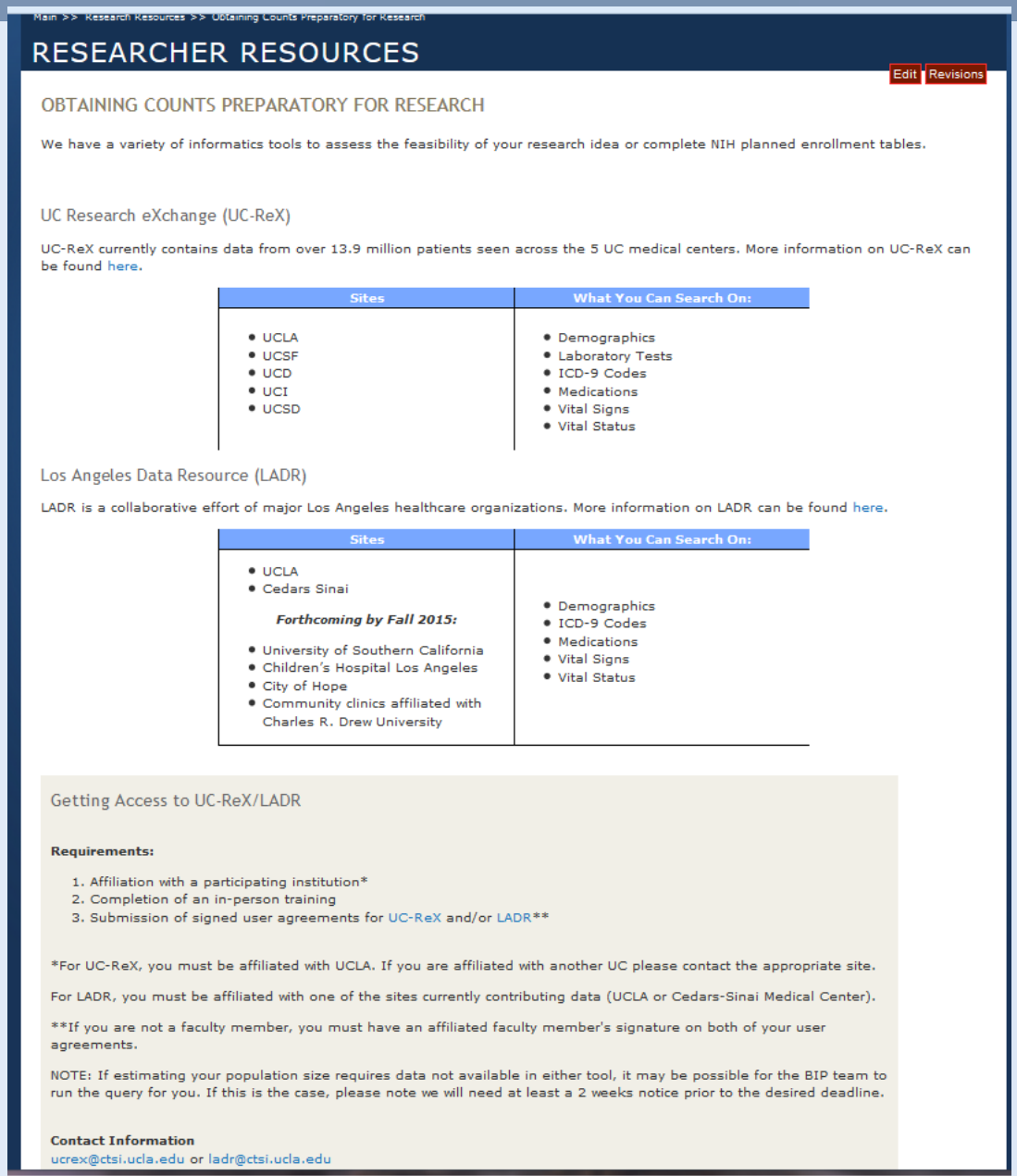

Main >> Research Resources >> Obtaining Counts Preparatory for Research

RESEARCHER RESOURCES

Edit Revisions

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:
• UCLA • UCSF • UCD • UCI • UCSD	• 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:
• UCLA • Cedars Sinai ***Forthcoming by Fall 2015:*** • University of Southern California • Children's Hospital Los Angeles • City of Hope • Community clinics affiliated with Charles R. Drew University	• 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

UCLA CTSI Connections
UCLA Clinical and Translational Science Institute

Log In
• CTSI Faculty Search
• FAQ
• Quick Links

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

RESEARCHER RESOURCES

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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.

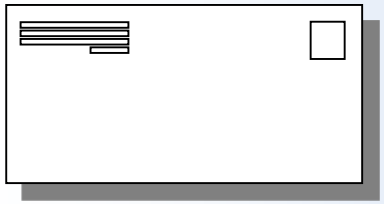
Studies with Direct Patient Contact | Studies with No Direct Patient Contact

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

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- Ruby Wan: ywan@mednet.ucla.edu
- Amanda Do: aldo@mednet.ucla.edu