Agenda

- Welcome and Announcements - Marcia Smith

EFM
  - Closeout packet due date – Yoon Lee
  - PAMS/RAPID update – Yoon Lee & Katie Cadle
  - Effort Reporting – Connie Brown

OHRPP
  - webIRB Updates – Kip Kantelo
  - Reviews by the Nursing Practice Research Council – Pamela Miller, PhD, RN, Nurse Scientist, Department of Nursing Education and Research, UCLA Health
  - Requesting Research Data and Medical Record Access – Marianne Zachariah, Administrator, Biomedical Informatics Program, UCLA Clinical and Translational Science Institute

OCGA
  - OCGA Updates – Patti Manheim
  - Federal Updates – Kathy Kawamura
  - eRA Updates – Cindy Gilbert

Questions and Discussion
Today’s topics

- EFM Staff update – Yoon Lee
- Closeout packet due date – Yoon Lee
- PAMS/RAPID COP update – Yoon Lee/Katie Cadle
- Effort reporting – Connie Brown
Staff Update

New Assistant Director of Fund Management Teams

Jennifer Aguilar

- Effective February 1, 2016
- Lead 3 fund management teams of 30 members
- Oversee invoicing, financial reporting, closeout, overall fiscal compliance and management of sponsored awards
- Has been with ORA since 2001
- Proven track record of success in both technical and managerial areas
- Has experience working in OCGA, ORDM, and EFM
Closeout Packet Due Date:

Due date of the final cost claim in the outgoing sub-agreement on federal awards:

- UCLA currently required subawardees to submit the final cost claim to UCLA within 45 days after the subaward end date.
- FDP member institutions use the standard FDP cost reimbursement subaward agreement.
- FDP standard agreement requires the final cost claim to be submitted to PTE within 60 days after the subaward end date, not 45 days.
- UCLA agreed to honor 60 days in the standard agreement as a FDP member.
- Effective January 5, 2016, the outgoing sub-agreement from UCLA on federal awards will have 60 day requirements instead of 45 days.
Implication of this change to closeout packet due date to EFM

- Currently closeout packets for federal awards are due to EFM within 60 days after the fund end date.

- When the federal award has subawardee(s):
  - Recognizing the due date for the final invoice from the sub is 60 days, 7 additional calendar days will be provided for the department to include subaward expenses in the closeout packet.
  - Closeout packets will be due to EFM no later than 67 days, not 60 days, after the fund end date.

For all sponsored awards except for the federal with subaward

- No change to the due dates of closeout packets
PAMS Go Live

- Scope: what will go live?
  - Worklist
  - Deliverable
  - RAPID COP to upload to PAMS

- Timeline and rollout process

- Training

- Next steps
PAMS Go Live: Scope

WORKLIST PAGE

- Customized worklists for the individual user to prioritize work and monitor progress updated in near real time.
- Ability to track who is responsible for completing a given task at any time.
PAMS Go Live: Scope

DELIVERABLE PAGE

- Easy access to key information about all financial deliverables in one place, including due date, a type of invoice or financial report, frequency, EFM contact, status, etc.
- Ability to retrieve a copy of invoice or financial report submitted to the sponsor

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PAMS Go Live: Scope

FUND BALANCE APPROVAL PAGE

- Ability to upload the RAPID Closeout Packet in PAMS
- PAMS will facilitate the approval process and automatically update the status of the packet → accurate status of all finals in the worklist
- Will enable us to store all key financial documents in PAMS, official system of record for financial management of sponsored awards
PAMS Go Live: Roll out Process

GO LIVE IN PHASES

- Rollout will occur in approximately 3 waves
- Department/Universes that make up each wave are currently being reviewed
- Each wave will take at least 1 month to complete from the beginning of the process until access is granted
- Go live with the first wave is planned to start in the spring 2016
Variety of training will be available to suit the needs of different users

- Online training videos covering individual pages within PAMS
- In-Person Training: Dates to be scheduled around and after go live
- Open Houses

Training will not be mandatory to gain access to PAMS but is highly recommended
PAMS Go Live: Next Steps

- Tasks that will need to be completed by departments prior to gaining access to PAMS:
  - Determine the PAMS Universe assignment
  - Fill out a PAMS Access Form
  - Obtain approval for employees to have PAMS access

- The PAMS Team will reach out to each department when it is time to start obtaining information and provide next steps at that time
  - We are starting early!
  - The PAMS Team will start reaching out to Wave 1 departments within the next few weeks
RAPID COP Update

- PI certification required by Uniform Guidance are added to the certification page in the RAPID closeout packet (2. CFR 200.415)
- The statement will be populated in the closeout packet only for federal and federal pass through fund.
- Updated version of RAPID Smart closeout tool will be uploaded today, 2/11/16, to ORA portal

2. CFR §200.415  Required certifications:

(a) To assure that expenditures are proper and in accordance with the terms and conditions of the Federal award and approved project budgets, the annual and final fiscal reports or vouchers requesting payment under the agreements must include a certification, signed by an official who is authorized to legally bind the non-Federal entity, which reads as follows: “By signing this report, I certify to the best of my knowledge and belief that the report is true, complete, and accurate, and the expenditures, disbursements and cash receipts are for the purposes and objectives set forth in the terms and conditions of the Federal award. I am aware that any false, fictitious, or fraudulent information, or the omission of any material fact, may subject me to criminal, civil or administrative penalties for fraud, false statements, false claims or otherwise. (U.S. Code Title 18, Section 1001 and Title 31, Sections 3729-3730 and 3801-3812).”
Effort Reporting Statistics

• As of 2/11/16

  – UCLA’s Campus Rate (Spring’06 - Summer’15)
    • 99% Certified

  – Spring & Summer 2015 deadline, 2/5/16
    • On-Time Rate – 90%
    • Generated: 11,145
    • Certified: 10,108
    • Open: 1,037

  – Spring & Summer 2015 to date
    • Current Rate – 92%
Historical On-time submission
ERS Announcement

- Fall 2015 & Winter 2016 reports will be released in April 2016

- ERS Training Course
  - Date: Wednesday, May 4th
  - Time: 9:00 a.m. - 3:00 p.m.
  - Place: Wilshire Center, 10th Floor
  - (Sign-up through LMS)

- To Receive ERS Notifications
  - To subscribe: Send an e-mail to: ers-subscribe@lists.ucla.edu. The subject line and body of the e-mail can be blank.
  - To subscribe: Send an e-mail to: ora-news-subscribe@lists.ucla.edu. The subject line and body of the e-mail can be blank.
ERS Reminder and support

• Off-campus access
  – ERS logon: https://ers.it.ucla.edu

• Outreach Support

• Help Desk: ershelp@research.ucla.edu
  – Connie Brown
  – Leticia Calderon
### 100% On-Time

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100% Club
As of February 5, 2016 Deadline

Count 85
“SEE YOU AT …”
Questions

Contact information

Yoon Lee
X40375
yoon.lee@research.ucla.edu
OHRPP Updates

Kip Kantelo, Director
February 11, 2016
Updates

❖ IRB Reliance
  • irbreliance@research.ucla.edu

❖ NPRM

❖ webIRB
  ➢ Internet Explorer
  ➢ Updates
  ➢ Coordination with other units
    ➢ Coverage Analysis
    ➢ Nursing Practice Research Council
    ➢ Biomedical Informatics Program
Thank you!

❖ For questions:
  • North & South General IRBs
    ❁ x57122
    ❁ gcirb@research.ucla.edu
  • Medical IRBs
    ❁ x55344
    ❁ mirb@research.ucla.edu
NURSING PRACTICE RESEARCH COUNCIL (NPRC)

- Council membership includes
  - Doctorally- and master’s-prepared nurses
  - Advanced practice nurses
    - Nurse Practitioners, Clinical Nurse Specialists, Educators, Unit Directors, and Faculty
  - Clinical nurses at the point of care
- Representing UCLA and UCLA Health
  - Ronald Reagan UCLA Medical Center
  - UCLA Medical Center, Santa Monica
  - Resnick Neuropsychiatric Hospital
  - School of Nursing
- Functions under an operational strategic plan that promotes system-wide, inter-disciplinary, research and evidence-based practice
# Nursing Practice Research Council (NPRC)

## Our Philosophy
- We believe that research should guide our clinical nursing practice, and that our clinical nursing practice should generate the questions and direction for research.

## Our Vision
- As a national leader among academic healthcare centers, it is the vision of the NPRC to develop and support innovations that heal humankind through the application of evidence-based knowledge to clinical practice.

## Our Mission
- Our mission is to increase the scientific foundation of practice through research conduct and utilization activities in acute and critical care nursing through five areas of work:
  - Research Development
  - Research Utilization
  - Research Education
  - Research Dissemination
  - Research Infrastructure
The Nursing Practice Research Council (NPRC) supports, encourages, and facilitates nurses' participation in research activities (utilization and conduct) so that optimum patient outcomes are achieved. The NPRC functions under an operational strategic plan that promotes system-wide, multi-disciplinary, research-based practice.

Our Philosophy:
We believe that research should guide our clinical nursing practice, and that our clinical nursing practice should generate the questions and direction for research.

Our Vision:
As a national leader among academic healthcare centers, it is the vision of the NPRC to develop and support innovations that heal humankind through the application of evidence-based knowledge to clinical practice.

Our Mission:
The mission of the Nursing Practice Research Council is to increase the scientific foundation of practice by research conduct and utilization activities in acute and critical care nursing through five areas of work:

Research Development - Provides consultation in the design, implementation, analysis, and publication of nursing research.

NPRC Study Review Information: Application & Consultation.
NPRC Study Review Webpage
http://nursing.uclahealth.org/NPRCReview

Purpose of Review
All research studies involving use of nursing time, effort, and/or resources at UCLA Health System sites require Nursing Practice Research Council (NPRC) approval to assure that the rights and welfare of patients and nurses are protected. The NPRC reviews research proposals for scientific merit and feasibility of implementation at UCLA Health.

Meeting Schedule and Submission Deadline
The NPRC reviews research studies on the first and third Wednesday of each month. Applications must be received at least two weeks prior to the meeting in order to be placed on the agenda. The NPRC and the IRB review may be conducted concurrently. Both NPRC review and IRB approval must be obtained prior to starting the study.

Application Submission
To begin the process, please do the following:
- Complete and submit the Research Study Application (Appendix A) and supporting documents by following the form prompts.
- Please submit a copy of the Institutional Review Board (IRB) approval letter once it has been received.

Study Review
Approval of research proposals will be dependent on the following criteria:
1. The problem is relevant and timely.
2. The research design is appropriate and can be conducted on the desired unit or area.
3. The rights and safety of patients and staff have been adequately safeguarded.
To capture all research studies involving use of nursing time, effort, and/or resources at UCLA Health, including nurses as

- investigators,
- subjects,
- clinical care providers, or
- data or specimen collectors
NPRC RESEARCH STUDY REVIEW: PURPOSE

• To ensure scientific merit and feasibility of implementation at UCLA Health, and to assure that the rights and welfare of patients and nurses are protected
NPRC STUDY REVIEW PROCESS

- NPRC approvals must be obtained prior to study initiation
- NPRC review may be conducted prior to, in parallel with, or following IRB review
- Applications must be received at least two weeks prior to the meeting in order to be placed on the agenda
- NPRC reviews research studies on the first and third Wednesday of each month
- Every attempt is made to ensure that NPRC review does not delay the overall research approval process
NPRC STUDY REVIEW PROCESS

Process:

• Investigator completes “Appendix A” Research Submission Proposal and Checklist and submits attachments (Abstract, Proposal, Informed consent(s), Subject recruitment materials, Copies of all instruments, IRB approval letter, if or when applicable)

• Study reviewed by NPRC, which meets every first or third Wednesday of the month (investigators or designee are invited to participate)

• Outcome of initial review, including any requests to investigators, is communicated in writing within one week following NPRC review

• Following completion of NPRC review, study summary and NPRC recommendation are sent to Health System Chief Nursing Executive (CNE) or Director, Nursing Research and Education (DNRE) for approval

• Following CNE or DNRE review, NPRC informs the investigator in writing of the decision, including Council recommendations and/or stipulations
**NPRC Study Review Process - Timeline**

- **Day 1-14**
  - Investigators submit “Appendix A” and attachments

- **Day 14**
  - NPRC conducts initial review of the study

- **Day 14-21**
  - Review outcome/requests communicated to investigator

- **Day 14-28**
  - Study summary and NPRC recommendation sent to CNE or DNRE
  - NPRC informs the investigator of the proposal status/approval

**Average turnaround time following Initial NPRC Review: 2 Weeks**
Approval of research proposals will be dependent on the following criteria:

- The problem is relevant and timely.
- The research design is appropriate and can be conducted on the desired unit/area.
- *The rights and safety of patients and staff have been adequately safeguarded.*
- *There is potential benefit to patients, staff, or the nursing profession*
- *The study will not interfere with or compromise existing programs of care.*
- *The study is feasible in terms of staff time, space, and/or materials required.*
- There is a plan to share the study results with the nursing staff and appropriate others.
- *Documented approval by the Institutional Review Board of the OHRPP.*
WEBIRB NURSE INVOLVEMENT QUESTION: LOCATION

Location: Section 2.1, between current questions 5.0 ("Is this study cancer related...") and (current) 6.0 ("Federal Regulations require...")
WEBIRB NURSE INVOLVEMENT QUESTION

6.0 Nurse Involvement: Does this study involve any nursing time, effort, and/or resources at UCLA Health System sites, including as subjects, investigators, clinical care providers or data or specimen collectors?  □ Yes  □ No

Note: If you answered "Yes", please submit an application to the Nursing Practice Research Council (NPRC). For contact information or for more information about NPRC and how to apply, click here. IRB approval is not contingent on NPRC approval and you do not need to upload documentation of approval from the NPRC into webIRB.

*****
**WebIRB Nurse Involvement Question (continued)**

**Guidance:** All research studies involving use of any nursing time, effort, and/or resources at UCLA Health System sites require Nursing Practice Research Council (NPRC) approval to assure that the rights and welfare of patients and nursing personnel are protected.

UCLA Health System sites include Ronald Reagan UCLA Medical Center, Santa Monica UCLA Medical Center and Orthopaedic Hospital, Mattel Children’s Hospital, Resnick Neuropsychiatric Hospital, Ambulatory Care clinics, Partial Hospitalization and Intensive Outpatient Program facilities.

You should not answer “yes” in either of the following situations:

- the study only uses nursing resources outside of the UCLA Health System (e.g., a collaborative project with Cedars Sinai)

- the involvement of nurses is limited to nurses whose primary employment is with the research team

**Timing of Review:** NPRC approval may be conducted prior to or in parallel with IRB review. IRB approval is not contingent upon NPRC approval; however, the NPRC and IRB approval are required prior to initiation of the study. The deliberations of this Council are not shared with the IRB unless there are specific subject protection issues raised by the NPRC.
INVESTIGATOR EXPECTATIONS

- Progress Reports:
  - Following approval, studies are monitored through **annual** progress reports ("Appendix D")
    - Meets Magnet® tracking requirement

- Presentations:
  - Investigators may be invited to present their study findings at various NPRC and/or Department of Nursing Research and Education programs and symposiums.
Magnet Recognition Program® recognizes health care organizations nationally and internationally for quality patient care, nursing excellence and innovations in professional nursing practice.

• Magnet® designation is considered the “gold standard” of nursing excellence.

• New Knowledge, Innovation, and Improvements is an essential component of Magnet recognition.
  o New models of care, application of existing evidence, new evidence, and visible contributions to the science of nursing

• Ronald Reagan UCLA Medical Center is a designated National Magnet Hospital.
• UCLA Medical Center, Santa Monica is currently undergoing Magnet® certification review.
**FUTURE DIRECTION**

Challenge:

- Lack of communication between research team and patient care areas creates significant delays in approval and study initiation.

Future Action:

- Investigators will submit a Letter of Support from the Patient Care Area where research will be conducted.
  - To facilitate communication prior to submission of the application and reduce time to study approval.
  - Letter of Support will be available as an online form (link on NPRC website) to be completed by the Patient Care Area Clinic Head, Manager, Unit Director, or Clinical Nurse Specialist.
CONTACT

Pamela Miller, PhD, RN, ACNP, CNS
Nurse Scientist
Research and Evidence-Based Practice Program
Department of Nursing Research and Education
UCLA Health
psmiller@mednet.ucla.edu

We welcome your comments and suggestions as we strive to support you in the successful conduct of your research.
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

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

### Sites

- 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

### What You Can Search On:

- Demographics
- ICD-9 Codes
- Medications
- Vital Signs
- Vital Status

<table>
<thead>
<tr>
<th>Sites</th>
<th>Distinct Patients</th>
<th>Total Facts</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cedars</td>
<td>2,599,282</td>
<td>79,931,785</td>
</tr>
<tr>
<td>UCLA</td>
<td>4,395,293</td>
<td>215,663,166</td>
</tr>
</tbody>
</table>
Obtaining Counts: UC-ReX
Obtaining Counts: LADR
Obtaining Counts: i2b2

**Query Tool**

**Query Name:**

**Temporal Constraint:**

**Define sequence of Events**

**Define order of events**

- Start of the First Ever Event 1
- Occurs Before
- Start of the First Ever Event 2
- By \(\geq 1\) day(s)
- And \(\geq 1\) day(s)

**i2b2 Query & Analysis Tool**

**Navigate Terms**

- 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

Obtain a Data Consult - Talk to us first

Obtain IRB Approval

Obtain Compliance Approval

Data extraction and delivery

We will review your IRB application

We will draft needed forms

We will help you define your data request
Types of Studies

**Direct Patient Contact**
- **Screening**
- **Consented Patients**

**No Direct Patient Contact**
- **De-identified**
- **Limited**
- **Identified**
- **Chart Review**

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

**HIPAA Waiver**
- Excludes all 18 identifiers

**HIPAA Release Authorization**
- Excludes 16 identifiers
### Imaging Orders and Results

<table>
<thead>
<tr>
<th>Variable</th>
<th>Include Field</th>
<th>Selection Criteria</th>
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<tbody>
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<td>Order Procedure Id</td>
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<td></td>
</tr>
<tr>
<td>Order Time</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Result Time</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Procedure Code</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Procedure Name</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Accession Number</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Impression</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Narrative</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

_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

<table>
<thead>
<tr>
<th>Order Type</th>
<th>Include Orders</th>
<th>Selection Criteria</th>
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<tbody>
<tr>
<td>Order Procedure Id</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Order Time</td>
<td></td>
<td></td>
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<tr>
<td>Result Time</td>
<td></td>
<td></td>
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<tr>
<td>Procedure Code</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Procedure Name</td>
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<td></td>
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<tr>
<td>Specimen Source</td>
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<tr>
<td>Specimen Type</td>
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<tr>
<td>Organism Name</td>
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<td>Susceptibility</td>
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<td></td>
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<tr>
<td>Sensitivity</td>
<td></td>
<td></td>
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<tr>
<td>Antibiotic</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

_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.

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**Step 1:** Generate cohort

**Step 2:** Extract variables
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/
How to Request Our Services

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 set 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.
How to Request Our Services

RESEARCHER RESOURCES

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 13.6 million patients seen across the 5 UC medical centers. More information on UC-ReX can be found here.

<table>
<thead>
<tr>
<th>Sites</th>
<th>What You Can Search Out</th>
</tr>
</thead>
<tbody>
<tr>
<td>UCLA</td>
<td>Demographics</td>
</tr>
<tr>
<td>UCSF</td>
<td>Laboratory Tests</td>
</tr>
<tr>
<td>UCD</td>
<td>ICD-9 Codes</td>
</tr>
<tr>
<td>UCI</td>
<td>Medications</td>
</tr>
<tr>
<td>UCSD</td>
<td>Vital Signs</td>
</tr>
<tr>
<td></td>
<td>Vital Status</td>
</tr>
</tbody>
</table>

Los Angeles Data Resource (LADR)

LADR is a collaborative effort of major Los Angeles healthcare organizations. More information on LADR can be found here.

<table>
<thead>
<tr>
<th>Sites</th>
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</tr>
</thead>
<tbody>
<tr>
<td>UCLA</td>
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<tr>
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<td>ICD-9 Codes</td>
</tr>
<tr>
<td>University of Southern California</td>
<td></td>
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<tr>
<td>Children’s Hospital Los Angeles</td>
<td></td>
</tr>
<tr>
<td>City of Hope</td>
<td>Medications</td>
</tr>
<tr>
<td>Community clinics affiliated with Charles R. Drew University</td>
<td></td>
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<tr>
<td>Forthcoming by Fall 2015:</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Vital Signs</td>
</tr>
<tr>
<td></td>
<td>Vital Status</td>
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</tbody>
</table>

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 SID 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 ladri@ctsi.ucla.edu
How to Request Our Services

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.

<table>
<thead>
<tr>
<th>Studies with Direct Patient Contact</th>
<th>Studies with No Direct Patient Contact</th>
</tr>
</thead>
</table>

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.
References

- UCLA CTSI: [http://ctsi.ucla.edu/](http://ctsi.ucla.edu/)
- Clinical Data Requests: [http://ctsi.ucla.edu/researcher-resources/pages/clinicaldata](http://ctsi.ucla.edu/researcher-resources/pages/clinicaldata)

Questions? Contact Us

- Marianne Zachariah: mzachariah@mednet.ucla.edu
- Ruby Wan: ywan@mednet.ucla.edu
- Amanda Do: aldo@mednet.ucla.edu
Federal Updates

Research Administrator's Forum
February 11, 2016
NIH Fiscal Policy – FY16

NOT-OD-16-046

• Non-competing continuations initially issued at 90% of funding will “in general” be fully restored.

• Exceptions will be noted under “Additional Information” on NOA.

For more detailed information, search for your NIH Institute FY16 Funding Levels
NIH

NOT-OD-16-044
Legislative Mandates – limit the use of NIH FY16 funds

FY 2015 Legislative Mandates that remain in effect are as follows:
(1) Salary Limitation (Section 202)
(2) Gun Control (Section 210)
(3) Anti-Lobbying (Section 503)
(4) Acknowledgment of Federal Funding (Section 505)
(5) Restriction on Abortions (Section 506)
(6) Exceptions to Restriction on Abortions (Section 507)
(7) Ban on Funding Human Embryo Research (Section 508)
(8) Limitation on Use of Funds for Promotion of Legalization of Controlled Substances (Section 509)
(9) Dissemination of False or Misleading Information (Section 515(b))
(10) Restriction on Distribution of Sterile Needles (Section 520)
(11) Restriction of Pornography on Computer Networks (Section 521)
K08, K23 (NIH)

NOT-OD-16-054

• Salary Compensation Increased: $100,000

• Reminder: Requirement remains at 75% Effort

Reference:

K08 IC Specific Info
K23 IC Specific Info
APPLICATION - Calculation Example

75% of Institutional Base Salary < $100,000
Compensation = 75% of Institutional Base Salary

Scenario 1:
- Institutional base salary = $125,000
- $125,000 x 75% = $93,750
- NIH contribution = $93,750

75% of Institutional Base Salary > $100,000
Compensation = maximum of $100,000

Scenario 2:
- Institutional base salary = $155,000
- $155,000 x 75% = $116,250
- NIH contribution = $100,000
NRSA FY16 Budgetary Levels

NOT-OD-16-062
Application: for NRSA awards made with FY16 funds (after October 1, 2015)
  • Stipend
  • Training Related Expenses (TRE)

My NOA doesn’t reflect FY16 Levels
  • Awards to be revised matching the current levels
  • Institutional Training Grants – appoints to be amended within Xtrain once NOA is reissued
NRSA FY16 Budgetary Levels

MARC & BUILD programs

Undergrads

<table>
<thead>
<tr>
<th>Career Level</th>
<th>Stipend for FY 2016</th>
<th>Monthly Stipend</th>
</tr>
</thead>
<tbody>
<tr>
<td>Freshmen/Sophomores</td>
<td>$8,808</td>
<td>$734</td>
</tr>
<tr>
<td>Juniors/Seniors</td>
<td>$12,336</td>
<td>$1,028</td>
</tr>
</tbody>
</table>

Predoctoral

Institutional Training & Individual Training

<table>
<thead>
<tr>
<th>Career Level</th>
<th>Years of Experience</th>
<th>Stipend for FY 2016</th>
<th>Monthly Stipend</th>
</tr>
</thead>
<tbody>
<tr>
<td>Predoctoral</td>
<td>All</td>
<td>$23,376</td>
<td>$1,948</td>
</tr>
</tbody>
</table>
NRSA FY16 Budgetary Levels

Postdoctoral
Institutional Training & Individual Training

<table>
<thead>
<tr>
<th>Career Level</th>
<th>Years of Experience</th>
<th>Stipend for FY 2016</th>
<th>Monthly Stipend</th>
</tr>
</thead>
<tbody>
<tr>
<td>Postdoctoral</td>
<td>0</td>
<td>$43,692</td>
<td>$3,641</td>
</tr>
<tr>
<td></td>
<td>1</td>
<td>$45,444</td>
<td>$3,787</td>
</tr>
<tr>
<td></td>
<td>2</td>
<td>$47,268</td>
<td>$3,939</td>
</tr>
<tr>
<td></td>
<td>3</td>
<td>$49,152</td>
<td>$4,096</td>
</tr>
<tr>
<td></td>
<td>4</td>
<td>$51,120</td>
<td>$4,260</td>
</tr>
<tr>
<td></td>
<td>5</td>
<td>$53,160</td>
<td>$4,430</td>
</tr>
<tr>
<td></td>
<td>6</td>
<td>$55,296</td>
<td>$4,608</td>
</tr>
<tr>
<td></td>
<td>7 or More</td>
<td>$57,504</td>
<td>$4,792</td>
</tr>
</tbody>
</table>
NRSA FY16 Budgetary Levels

F33 (Senior Fellows)
Stipend level at current base salary, no more than Postdoc Level 7 or more ($57,504)

Graduate Student Researcher
Stipend at zero level of Postdoc ($43,692)

Training Related Expense (TRE)
Increase in Postdoctoral Trainees & Fellows Allowance: $8,850
NRSA

REMINDER: NRSA proposal content to change for submissions with due dates on or after May 25, 2016

Policy & Guidance Changes - Phase 2
NOT-OD-16-004

….stay tuned more information to come
This session will identify the elements which distinguish a grant from a contract and provide an overview of basic contractual components as it relates to sponsored project activities. Attendees will learn the differences between cost-reimbursable and fixed price agreements and be provided information relating to proposal development (cost proposals, bids, etc.), contractual obligations (FAR clauses, certifications, restrictions, etc.) and monitoring/management of contracts (reporting requirements, restrictions, etc.).
This session will discuss OCGA's process of Outgoing Subawards. Will address definitions, including distinguishing between a subrecipient and a contractor. Included will be a review of the updated outgoing subaward forms. This session is appropriate for anyone with responsibility for issuing outgoing subawards.
MASTER TRAINING
http://www.research.ucla.edu/ocga/training-calendar.html

April
NIH ASSIST

May
Managing Your Valuables

June
Cayuse Basics

Taking you into Summer!
National Science Foundation

FastLane - Automated Compliance Checking

- Performed by FastLane system

Acceptance of Late Proposals

- Proposals submitted via FastLane will not be accepted by the system after published deadline
- Proposals submitted via S2S Grants will be accepted and forwarded to FastLane, but will be rejected by NSF staff based on Grants.gov timestamp
- Proposals with Target Dates:
  - Acceptance at discretion of Program Manager
  - Recommend discussing with Program Manager if planning to submit after target date
Public Access Policy

- Effective Date – January 25, 2016
  - Applies to awards made from proposals received after effective date
  - First set of proposals awarded June/July 2016
  - Public Access Repository launched December 2015
    - Earliest publications requiring deposit will most likely be around Fall 2016
    - PI's may voluntarily deposit publications now

FastLane/Research.gov Working Group

- Under consideration by NSF
- Based on success of, and modelled after, NIH eRA Commons Working Group
- Have suggestions? erahelp@research.ucla.edu
S2S Grants – NIH Warning

• System upgrade performed January 29
• New **Warning** for NIH proposals
• *Authentication of Key Resources Plan*
  ▪ R&R Other Project Information form
  ▪ Other Attachments
  ▪ Exact Filename
S2S Grants – NIH Warning

• Still getting clarification from NIH and S2S Grants vendor

• NIH Resources:
  - FAQs on Authentication of Key Biological and/or Chemical Resources:
    http://grants.nih.gov/reproducibility/faqs.htm#4846
  - NOT-OD-16-011: Implementing Rigor and Transparency in NIH & AHRQ Research Grant Applications
  - SF424 (R&R) Application Guide for NIH and Other PHS Agencies (see pages I-80, I-154, I-161)
S2S Grants – Upcoming Maintenance

• S2S Grants will be unavailable during maintenance:
  Saturday, February 13
  8:00 AM – 8:00 PM
  Infrastructure only – no changes to user experience

• ORA News and S2S Grants News
DATA Act

Digital Accountability and Transparency Act

- Passed in 2014
- Expands USASpending.gov to include agency expenditures
- Requires consistent data standards
- Requires recommendations to reduce recipient burden for contract and grant recipients
- Enables the data to be used by multiple communities
DATA Act

Digital Accountability and Transparency Act

- Opportunity for FDP eRA Committee to address user concerns with inconsistencies at all levels of the project lifecycle.
  - FOA language, agency specific use of SF 424 forms (including FFR), single award template, etc.
  - Proliferation of federal funding agency systems
  - Standardized Roles
Questions