



**UCLA**

Office of Research Administration

# Research Administrators Forum February 11th, 2016

# Welcome!

**Marcia Smith**  
Associate Vice Chancellor for Research

# 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**



**UCLA**

Extramural Fund Management

# EFM Updates

Research Administrator's Forum  
February 11, 2016

# 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

## 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.

# Closeout Packet Due Date



## 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

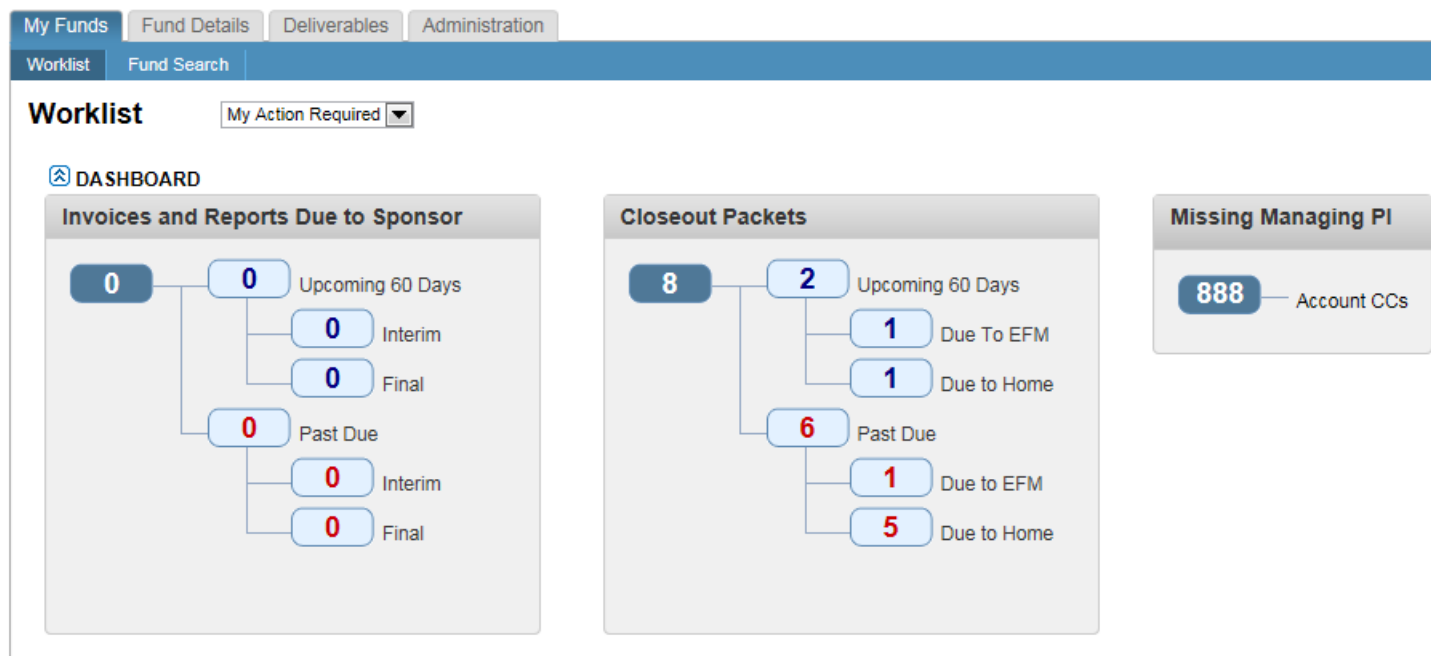
- Scope: what will go live?
  - Worklist
  - Deliverable
  - RAPID COP to upload to PAMS
- Timeline and rollout process
- Training
- Next steps

# 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

Due Date	Category	Type	Frequency	Owner	Status	Submitted Date	Approved Deliverable
02/28/2016	Invoice	Final	Once	EAR, SHEH JEN	COP Not Started		
12/31/2015	Invoice Milestone	Interim	Monthly	EAR, SHEH JEN	Deliverable Not Started		
10/31/2015	Invoice Milestone	Interim	Monthly	EAR, SHEH JEN	Deliverable Not Started		
07/31/2015	Invoice Milestone	Interim	Monthly	EAR, SHEH JEN	Deliverable In Process		
06/30/2015	Invoice Milestone	Interim	Monthly	EAR, SHEH JEN	Reviewed Not Submitted	06/19/2015	
05/31/2015	Invoice Milestone	Interim	Monthly	EAR, SHEH JEN	Submitted-Revised	05/20/2015	
05/30/2015	Invoice Milestone	Interim	Once	EAR, SHEH JEN	Deliverable Submitted	05/20/2015	
04/30/2015	Invoice Milestone	Interim	Monthly	EAR, SHEH JEN	Deliverable Submitted	05/13/2015	
03/31/2015	Invoice Milestone	Interim	Monthly	EAR, SHEH JEN	Reviewed Not Submitted	03/10/2015	
02/28/2015	Invoice Milestone	Interim	Monthly	EAR, SHEH JEN	Reviewed Not Submitted	03/10/2015	
01/31/2015	Invoice Milestone	Interim	Monthly	EAR, SHEH JEN	Deliverable Submitted	01/30/2015	

# 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




[Fund Details](#) > [Overview](#) > Fund Balance and Approvals

My Funds | Fund Details | Deliverables | Administration

Overview | Financial Summary ▶ | Expenditure Review ▶ | Review ▶

<< Overview Fund No: \_\_\_\_\_ PI: \_\_\_\_\_

### Fund Balance and Approvals

**Approvals History**    Approval Comments: 

Dept Preparer ( _____ ):	Approved by ( _____ )	on 02/06/2015
Dept Approver ( _____ ):	<input type="button" value="Approve"/> <input type="button" value="Reject"/>	
PI ( _____ ):	<input type="button" value="Upload RAPID COP"/>	
EFM Preparer ( _____ ):		
EFM Approver ( _____ ):		

# 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

# PAMS Go Live: Training



- 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

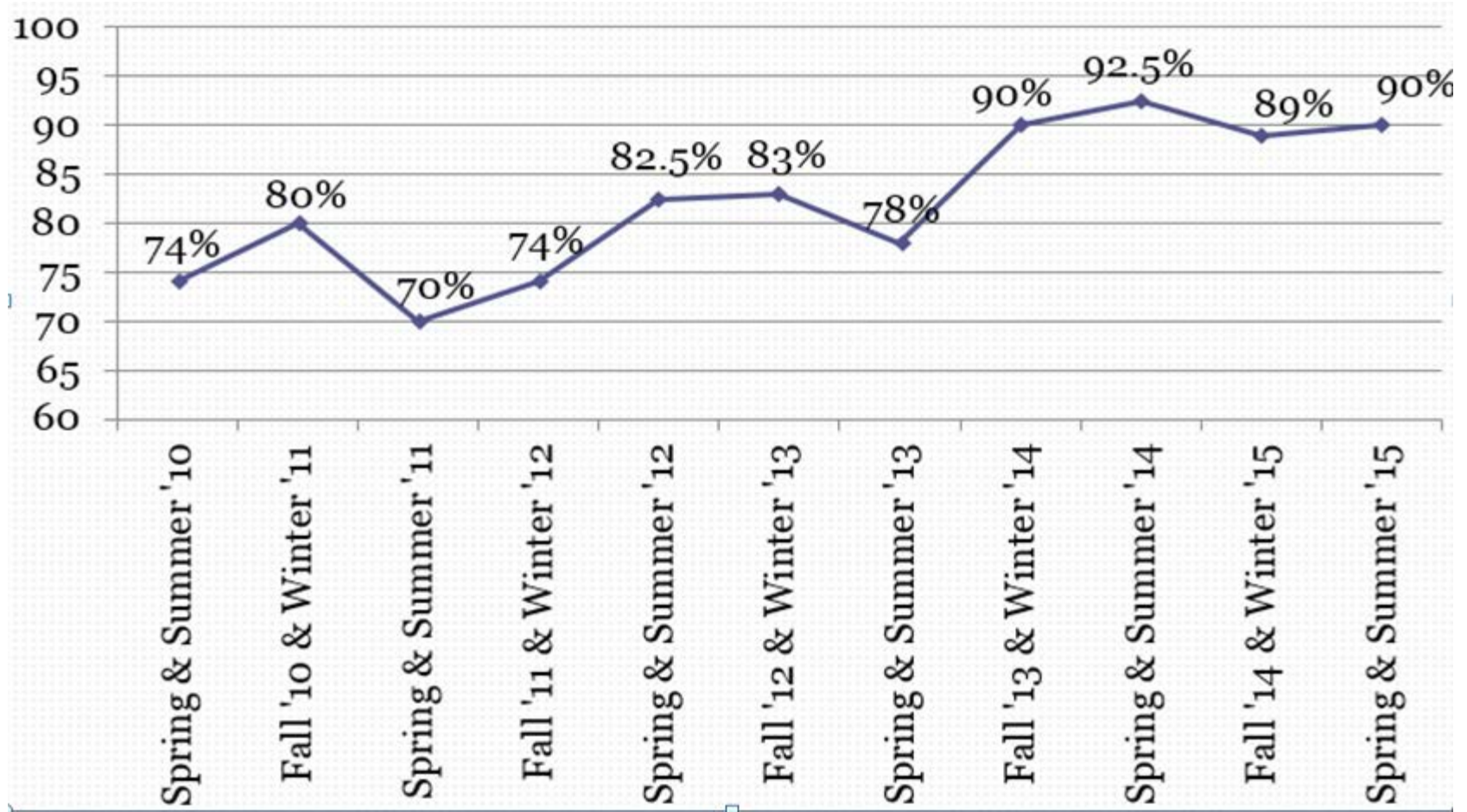
## **2. CFR §200.415 Required certifications:**

(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 4<sup>th</sup>
  - Time: 9:00 a.m. - 3:00 p.m.
  - Place: Wilshire Center, 10<sup>th</sup> Floor
  - (Sign-up through LMS)
  
- ❑ To Receive ERS Notifications
  - **To subscribe:** Send an e-mail to: [ers-subscribe@lists.ucla.edu](mailto: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](mailto: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
  - Virtual Private Networking (VPN):  
<https://www.bol.ucla.edu/services/vpn/pptp>
  - ERS logon: <https://ers.it.ucla.edu>
- Outreach Support
- Help Desk: [ershelp@research.ucla.edu](mailto:ershelp@research.ucla.edu)
  - Connie Brown
  - Leticia Calderon

# 100% On-Time

As of February 5, 2016 Deadline

DEPT CODE	DEPARTMENT	DEPT CODE	DEPARTMENT	DEPT CODE	DEPARTMENT
0070	EDUCATION	1245	INTERREGIONAL PROGRAMS	1720	SURGERY-LIVER AND PANC. TRANSP
0125	BIOENGINEERING DEPARTMENT	1250	CNTR FOR LATIN AMERICAN STUDIE	1916	CANCER PREVENTION & CNTRL RESE
0130	CHEMICAL ENGINEERING	1265	NR EASTERN STDS-VON GRUNEBaum	1918	CNTR FOR HEALTH POLICY RESEARC
0135	CIVIL & ENVIRONMENTAL ENGINEER	1269	CTR FOR SOUTHEAST ASIAN STUDIE	1920	COMMUNITY HEALTH SCIENCES
0142	CENTER OF FUNCTION ACCEL NANOM	1295	SOCIAL SCIENCES GRANT SUPPORT	1930	ENVIRONMENTAL HEALTH SCIENCES
0145	COMPUTER SCIENCE	1370	DENTAL RESEARCH INSTITUTE	1935	EPIDEMIOLOGY
0157	THE WESTERN INSTI FOR NANOelec	1400	DEANS OFFICE-SCHOOL OF MEDICIN	2040	CRUMP INSTITUTE FOR MOLECULAR
0160	ELECTRICAL ENGINEERING	1430	NEUROBIOLOGY	2060	ASIAN AMERICAN STUDIES CENTER
0285	INFORMATION STUDIES	1445	BIOLOGICAL CHEMISTRY	2075	CHICANO STUDIES RESEARCH CENTE
0350	SOCIAL WELFARE	1460	BIOMATHEMATICS	2090	INST OF GEOPHYSICS & PLANETARY
0464	FILM, TELEVISION & DIGITAL MED	1505	PHYSIOLOGY	2095	JOINT INSTI REG EARTH SYST SCI
0505	INSTITUTE OF PLASMA SCI & TECH	1554	MEDICINE-DERMATOLOGY	2112	JONSSON CANCER CENTER
0513	EDUCATIONAL INITIATIVES	1555	MEDICINE-ENDOCRINOLOGY	2135	MOLECULAR BIOLOGY INSTITUTE
0518	CALIF NANOSYSTEMS INSTITUTE	1558	MEDICINE-GERIATRICS	2155	INST OF ENVIRONMENT AND SUSTAI
0519	UNDERGRADUATE RESEARCH CENTERS	1559	MEDICINE-HEMATOLOGY-ONCOLOGY	2200	RESEARCH AND EDUCATION TECHNOL
0521	CTR FOR ENVTL IMPACTS OF NANOT	1560	MEDICINE-INFECTIOUS DISEASE	2890	OFFICE OF EMERGENCY PREPAREDNE
0523	ACADEMIC ADVANCEMENT PROGRAM	1568	MEDICINE-CARE CENTER	2933	SMH: RAPE TREATMENT CENTER
0725	SLAVIC LANGUAGES AND LITERATUR	1570	MEDICINE-CENTER FOR HUMAN NUTR	3020	LUSKIN CENTER FOR INNOVATION
0755	DEPARTMENT OF COMMUNICATION ST	1574	MEDICINE-NANO MEDICINE	3835	UCLA INTERNATIONAL INSTITUTE
0757	INST FOR PURE & APPLIED MATHEM	1581	NEUROLOGY-LONI	4550	OFFICE OF VP INFORMATION TECHN
0845	INTEGRATIVE BIOLOGY & PHYSIOLO	1644	PEDIATRICS-CRITICAL CARE	4806	EAO PROGRAMS/URBAN COLLAB
0875	PSYCHOLOGY	1645	PEDIATRICS-ENDOCRINOLOGY	4807	BRUIN CORPS
0910	DUCHENNE MUSCULAR DYSTROPHY RE	1655	PSYCHIATRY/BIOBEHAVIORAL SCI	5300	GRADUATE DIVISION
0920	BOTANICAL GARDENS	1670	RADIATION ONCOLOGY	5415	BIOMEDICAL LIBRARY
0995	EARTH, PLANETARY, AND SPACE SC	1685	RADIOLOGICAL SCIENCES	5625	UNEX-EDUCATION
1010	MATHEMATICS	1705	ORTHOPEDIC SURGERY	8022	RES GRANTS PRGM OFFICE
1085	ANTHROPOLOGY	1711	SURGERY-GENERAL	8052	DIVERSITY AND ENGAGEMENT
1182	PUBLIC POLICY	1713	NEUROSURGERY	8088	CALIFORNIA DIGITAL LIBRARY
1205	SOCIOLOGY	1714	SURGERY-ONCOLOGY	8642	BUDGET OFFICE
1210	SOCIAL SCI COMPUTING	1716	SURGERY-PEDIATRIC	8644	CA WATER RESRC RES INSTITUTE
1215	CALIFORNIA CNTR FOR POPULATION	1717	SURGERY-PLASTIC	8650	ACCOUNTING & FINANCIAL RPTNG
1230	CENTER FOR WORLD LANGUAGES	1718	SURGERY-CARDIOTHORACIC	<b>Count</b>	<b>95</b>

# 100% Club

As of February 5, 2016 Deadline

DEPT CODE	DEPARTMENT	DEPT CODE	DEPARTMENT	DEPT CODE	DEPARTMENT
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1205	SOCIOLOGY	1718	SURGERY-CARDIOTHORACIC	<b>Count</b>	<b>85</b>

“SEE YOU AT ...”



# Questions

## Contact information

Yoon Lee

X40375

[yoan.lee@research.ucla.edu](mailto:yoan.lee@research.ucla.edu)



# **OHRPP Updates**

**Kip Kantelo, Director**  
**February 11, 2016**

# Updates

## ❖ IRB Reliance

- [irbreliance@research.ucla.edu](mailto: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](mailto:gcirb@research.ucla.edu)
- **Medical IRBs**
  - ❑ x55344
  - ❑ [mirb@research.ucla.edu](mailto:mirb@research.ucla.edu)



**NURSING PRACTICE RESEARCH COUNCIL - WebIRB  
OHRPP RESEARCH ADMINISTRATORS' FORUM**

**FEBRUARY 11, 2016**

# 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

# NPRC Homepage

<http://nursing.uclahealth.org/NPRC>

UCLA Campus | UCLA Health | School of Medicine Translate: Select Language | ▾

**UCLA Health** | it begins with U SEARCH BY KEYWORD(S) 🔍

About Us | Patient Care Initiatives | Professional Practice Model | Professional Development | **Research & EBP** | Magnet Journey at UCLA Health

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## UCLA Department of Nursing

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**Research & EBP**

Home > Research & EBP > Nursing Practice Research Council (NPRC)


### Nursing Practice Research Council (NPRC)



**Nursing Practice Research Council (NPRC)**

NPRC Study Review

- Annual Research and Evidence-Based Practice Conference
- Clinical Practice Council (CPC)
- Staff Nurse Evidence-Based Practice Fellowship
- Research Institute
- Advanced Leadership Institute (ALI)
- Contacts & Consultations




Ronald Reagan UCLA Medical Center designated National Magnet Hospital

**Council Meetings:**

Date: 1st Wednesday  
Time & Location: Varies;  
contact [Karyn Greenstone](#)

Chair: [Kandace Whiting](#)  
Co-Chair: [Pattie Jakei](#)

[NPRC Study Review information, Application & Consultation](#)



**Dedicated to Bridging Research and Practice**

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 Webpage

## <http://nursing.uclahealth.org/NPRCReview>

UCLA Campus | UCLA Health | School of Medicine Translate: Select Language | ▼

**UCLA Health** | it begins with U SEARCH BY KEYWORD(S) 🔍

About Us | Patient Care Initiatives | Professional Practice Model | Professional Development | **Research & EBP** | Magnet Journey at UCLA Health

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**Research & EBP**

- Home
- Research & EBP Home

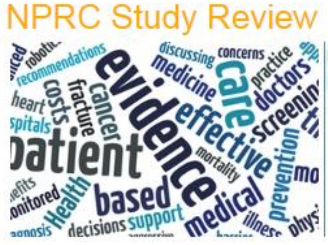
**Nursing Practice Research Council (NPRC)**

- [NPRC Study Review](#)
- Annual Research and Evidence-Based Practice Conference
- Clinical Practice Council (CPC)
- Staff Nurse Evidence-Based Practice Fellowship
- Research Institute
- Advanced Leadership Institute (ALI)
- Contacts & Consultations



Ronald Reagan UCLA Medical Center designated National Magnet Hospital

## NPRC Study Review



### NPRC Review Information and Application

**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, and
- 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/area.
3. The rights and safety of patients and staff have been adequately safeguarded.

# NPRC RESEARCH STUDY REVIEW

- 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

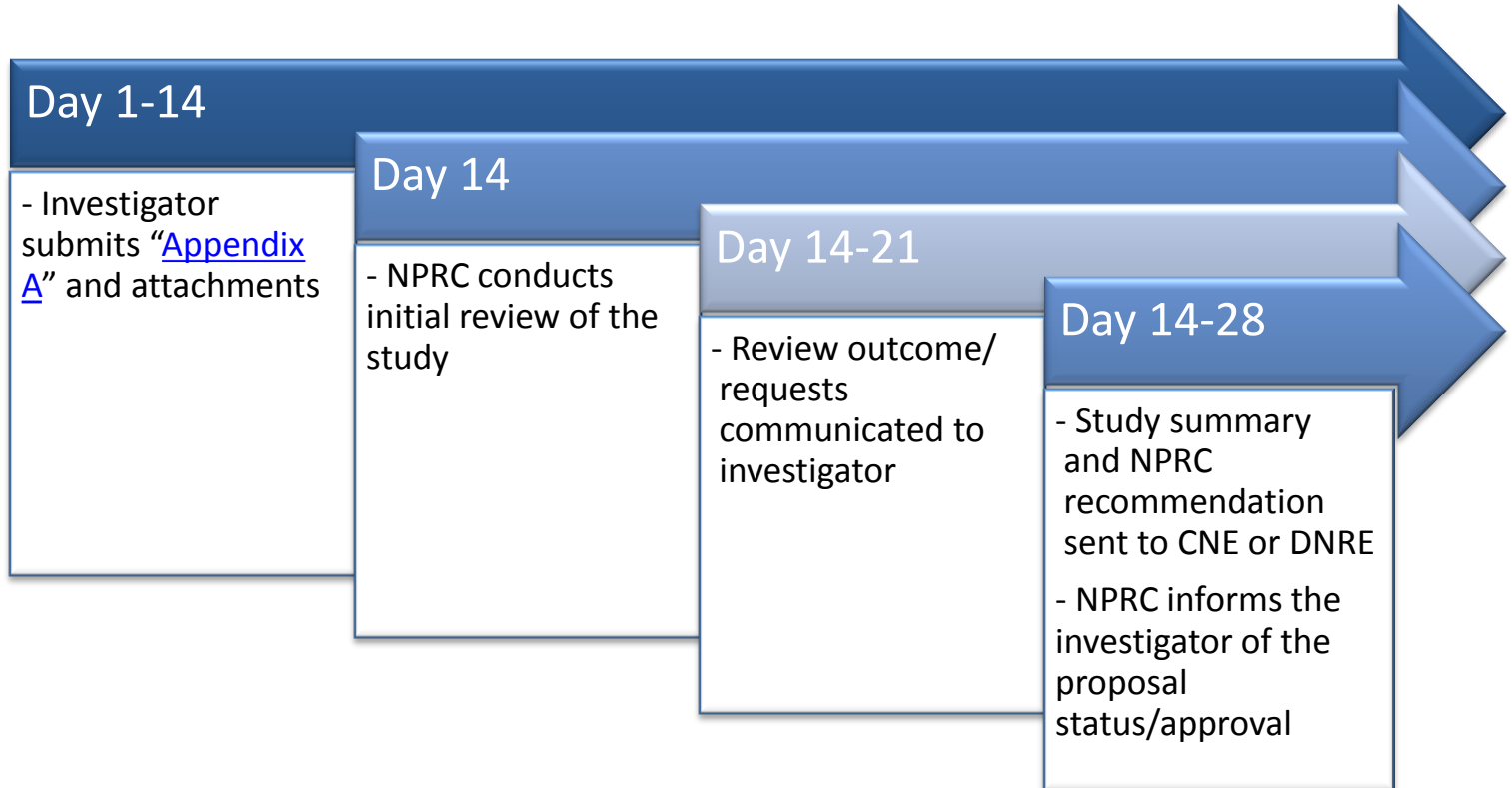
- NPRC approvals must be obtained prior to study initiation
- NPRC review may be conducted prior to, in parallel with, or following IRB review
- Applications must be received at least two weeks prior to the meeting in order to be placed on the agenda
- NPRC reviews research studies on the first and third 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



**Average turnaround time following Initial NPRC Review: 2 Weeks**

# NPRC STUDY REVIEW

**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...”)

Section 2.1:  
Project Identification Information

Project Identification Information

1.0 \*Type of Submission (Select one)

Research Study  
 Application for Approval of "Research Participant Pool" or recruitment database only  
Clear

2.0

5.0 \*Is this study cancer related, including the recruitment of individuals with cancer, collection of cancer human biological samples, specimens or data, or the recruitment of individuals because they are cancer survivors or at risk of developing cancer and/or involves gene therapy?  
 Yes  No Clear  
**Note:** If you answered "Yes", you must submit an application to the Jonsson Comprehensive Cancer Center (JCCC) Internal Scientific Peer Review Committee (ISPRC). Click [here](#) for instructions for submitting to the ISPRC. The ISPRC approval notice or letter of exemption should be attached in Section 2.1/Item 6.2 of the webIRB application.

6.0 \*Federal regulations (45 CFR 46.111) require scientific review before an IRB approves a study. For the majority of studies being reviewed and approved by the UCLA IRB, the IRB performs this review. See [http://ora.research.ucla.edu/OHRPP/Documents/Policy/4/Scientific\\_Review.pdf](http://ora.research.ucla.edu/OHRPP/Documents/Policy/4/Scientific_Review.pdf) for additional details.  
Do you want the IRB to consider external scientific or scholarly review?  
 Yes  No Clear

6.1 If yes, indicate the source of scientific or scholarly review for the study. Check all that apply.  
 National Institutes of Health (NIH)  
 The funding agency (other than NIH)

**Note:** A "Research Participant Pool" is a list of potential research subjects that may be contacted by investigators.

5.0

6.0

(current)

# 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<sup>®</sup> 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

- 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.
  - 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](mailto: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



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

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

# Obtaining Counts: LADR



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

	Distinct Patients	Total Facts
<b>Cedars</b>	2,599,282	79,931,785
<b>UCLA</b>	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 on the right shows a 'Query Name' field and three empty query groups. The 'Query Status' window at the bottom shows a running query for 'Tobacco- 52 ye@17:52:39' with a duration of 38.2 seconds. The 'Previous Queries' window shows a list of past queries with patient counts for each site.

**SHRINE Hierarchy:**

- 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 - Antiinfectives 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 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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AND

drag a  
term  
to here

# Obtaining Counts: i2b2

**Query Tool**

Query Name: \_\_\_\_\_

Temporal Constraint: \_\_\_\_\_ Define sequence of Events

\_\_\_\_\_ Define order of events New Event

Start of [ ] the First Ever [ ] Event 1 [ ]

Occurs Before [ ]

Start of [ ] the First Ever [ ] Event 2 [ ]

By  $\geq$  [ ] 1 [ ] day(s) [ ]

And  $\leq$  [ ] 1 [ ] day(s) [ ]

**i2b2 Query & Analysis Tool** Project: UCLA i2b2

**Navigate Terms** **Find 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

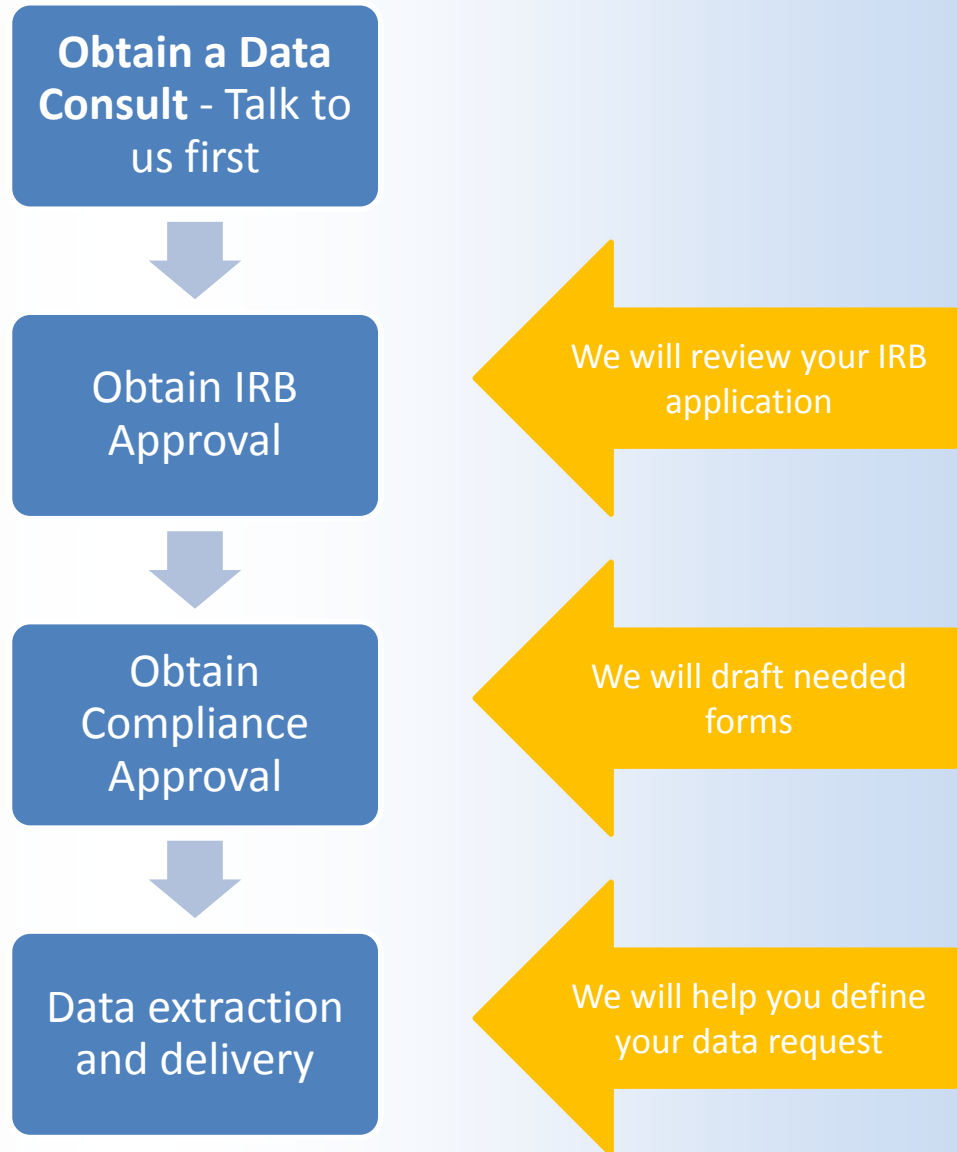
## Contact Information

[ucrex@ctsi.ucla.edu](mailto:ucrex@ctsi.ucla.edu) or [ladr@ctsi.ucla.edu](mailto:ladr@ctsi.ucla.edu)

**Ruby Wan:** [ywan@mednet.ucla.edu](mailto: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)  [SITE SEARCH](#)

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

[Log In](#)  
• [CTSI Faculty Search](#)  
• [FAQ](#)  
• [Quick Links](#)

[RESEARCHER RESOURCES](#)   [EDUCATION & TRAINING](#)   [COMMUNITY ENGAGEMENT](#)   [FUNDING](#)   [ABOUT](#)

**36** CTSI COMMUNITY PARTNERS

**QUICK LINKS:**

<a href="#">Consultations &amp; Advice</a>	<a href="#">CTSI Seminars</a>
<a href="#">Letter of Support</a>	<a href="#">Research Cores</a>
<a href="#">Commercialization</a>	<a href="#">Grant Library</a>
<a href="#">Clinical Data Requests</a>	<a href="#">Boilerplate Text</a>
<a href="#">Clinical &amp; Translational Research Centers</a>	<a href="#">Dissemination &amp; Implementation</a>

[Request a Service](#)

The screenshot shows a navigation menu with two red arrows pointing to the 'Request a Service' button. One arrow points from the 'Clinical Data Requests' link to the button, and another points from the 'Clinical & Translational Research Centers' link to the button.

# How to Request Our Services

The screenshot shows the UCLA CTSI Connections website. The header includes the UCLA CTSI logo, the text 'UCLA CTSI Connections' and 'UCLA Clinical and Translational Science Institute', and navigation links for 'Log In', 'CTS Faculty Search', 'FAQ', and 'Quick Links'. A secondary navigation bar lists 'RESEARCHER RESOURCES', 'EDUCATION & TRAINING', 'COMMUNITY ENGAGEMENT', 'FUNDING', and 'ABOUT'. The main content area is titled 'RESEARCHER RESOURCES' and contains a sub-section for 'CLINICAL DATA REQUESTS'. Two red arrows on the left side of the page point to the following sections:

- Obtaining Counts Preparatory for Research**: This section explains that the Biomedical Informatics Program (BIP) provides access to patient count data. It notes that investigators can use self-service systems for general data, but a consult is needed for individual-level data. A link is provided for more information.
- Obtaining Medical Record Data to Conduct your Research**: This section describes BIP's role as a storefront for healthcare-related datasets. It details the process of obtaining patient data, including IRB review, data security, and delivery via REDCap or encrypted email. It distinguishes between studies involving 'direct patient contact' and those with 'no direct patient contact'. A link is provided for more information.

The footer contains the 'Cite' logo with the grant number 'UL1TR000124', a list of links (Clinical Research Centers, Jobs, Site Map, Supported Browsers, Featured Projects, Clinical Trials, Newsletter Sign Up, Contact Us), and a search icon.

# How to Request Our Services

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:
<ul style="list-style-type: none"><li>• UCLA</li><li>• UCSF</li><li>• UCD</li><li>• UCI</li><li>• UCSD</li></ul>	<ul style="list-style-type: none"><li>• Demographics</li><li>• Laboratory Tests</li><li>• ICD-9 Codes</li><li>• Medications</li><li>• Vital Signs</li><li>• Vital Status</li></ul>

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

#### 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](mailto:ucrex@ctsi.ucla.edu) or [ladr@ctsi.ucla.edu](mailto:ladr@ctsi.ucla.edu)

# How to Request Our Services

The screenshot shows the UCLA CTSI Connections website. The header includes the CTSI logo and navigation links for 'Log In', 'CTSI Faculty Search', 'FAQ', and 'Quick Links'. The main navigation bar lists '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.'

UCLA CTSI Connections  
UCLA Clinical and Translational Science Institute

Log In  
CTSI Faculty Search  
FAQ  
Quick Links

RESEARCHER RESOURCES EDUCATION & TRAINING COMMUNITY ENGAGEMENT FUNDING ABOUT

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](http://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

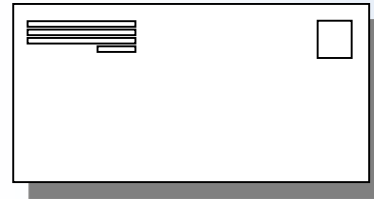
There are two major study categories that involve direct patient contact: screening health record data for possibly-eligible patients vs. obtaining health record data for patients already consented and enrolled in a study.

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:  
mzachariah@mednet.ucla.edu
- Ruby Wan: [ywan@mednet.ucla.edu](mailto:ywan@mednet.ucla.edu)
- Amanda Do: [aldo@mednet.ucla.edu](mailto: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

The Google logo is displayed in its standard multi-colored font.

NCI 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
- $\$125,000 \times 75\% = \$93,750$
- NIH contribution = \$93,750

75% of Institutional Base Salary >\$100,000

Compensation = maximum of \$100,000

## *Scenario 2:*

- Institutional base salary = \$155,000
- $\$155,000 \times 75\% = \$116,250$
- 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

Career Level	Stipend for FY 2016	Monthly Stipend
Freshmen/Sophomores	\$8,808	\$734
Juniors/Seniors	\$12,336	\$1,028

## Predoctoral

### Institutional Training & Individual Training

Career Level	Years of Experience	Stipend for FY 2016	Monthly Stipend
Predoctoral	All	\$23,376	\$1,948

# NRSA FY16 Budgetary Levels

## Postdoctoral

### Institutional Training & Individual Training

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

# 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

# MASTER TRAINING

<http://www.research.ucla.edu/ocga/training-calendar.html>

## **FEBRUARY**

### **Contracts 101**

Wednesday, February 24, 2016

Kinross, Suite 210

9:30-11:00 am

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.).

# MASTER TRAINING

<http://www.research.ucla.edu/ocga/training-calendar.html>

## MARCH

### OCGA Outgoing Subaward Basics

Wednesday, March 23, 2016

Kinross, Suite 210

9:30-11:00 am

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>

*Taking you into  
Summer!*

**April**

**NIH ASSIST**

**May**

**Managing Your Valuables**

**June**

**Cayuse Basics**



**UCLA**

Office of Contract and Grant Administration

# **Electronic Research Administration Updates**

**Cindy Gilbert**

**Assistant Director**

**[cgilbert@research.ucla.edu](mailto:cgilbert@research.ucla.edu)**

**February 11, 2016**

# National Science Foundation

## FastLane - Automated Compliance Checking

- Performed by FastLane system
- List of automated compliance checks available at:  
[http://www.nsf.gov/bfa/dias/policy/autocheck/compliancechecks\\_july15.pdf](http://www.nsf.gov/bfa/dias/policy/autocheck/compliancechecks_july15.pdf)

## 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

# National Science Foundation

## 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](mailto: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  
<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-16-011.html>
  - SF424 (R&R) Application Guide for NIH and Other PHS Agencies (see pages I-80, I-154, I-161)  
[http://grants.nih.gov/grants/funding/424/SF424\\_RR\\_Guide\\_General\\_VerC.pdf](http://grants.nih.gov/grants/funding/424/SF424_RR_Guide_General_VerC.pdf)

# 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