



UCLA

Office of Research Administration

Research Administration Forum October 12, 2017

Welcome!

Marcia Smith
Associate Vice Chancellor for Research

Agenda

- **Welcome and Announcements - *Marcia Smith***
- **OHRPP – *Kip Kantelo***
 - NIH Single IRB Policy
 - Revised Common Rule
 - NIH Certificate of Confidentiality Policy
 - FDA Expanded Access Policy
- **RPC – *Ann Pham***
 - Export Control – Travel to Iran
- **ORIS – *Jackson Jeng***
 - MFA Roll-out
- **RSAWA Updates – *Jennifer Perkins***
 - AAALAC
 - USDA
 - DURC
- **OCGA – *Patti Manheim***
 - Introduction of New Staff
 - Grant Updates – *Kathy Kawamura*

OHRPP Updates

Kip Kantelo, Director
October 12, 2017

NIH Policy on Single IRBs

- ❖ ~~Policy coming this month~~
released in June '16
- ❖ ~~Effective for Jan May Sept Jan~~
25, 2018
- ❖ Domestic sites of multi-center
- ❖ Proposals to identify cIRB
 - Coordination plans & personnel
 - Certain direct costs allowable

NIH Policy on Single IRBs

❖ IRBrelly SmartIRB framework

- National agreement now in place
- 200+ institutions (including UCLA)
- Some institutions coming up with additional agreements
- Online tool for communication

❖ RAND, UC, CTSI+USC, Commercial IRBs, one-offs

- Commercial IRB scope expanded

NIH Policy on Single IRBs

❖ Challenges

- IRB practices are not uniform
- Institutional Policies
- Ancillary Reviews
- Communications among IRBs, IRB offices and study teams
- Post-Approval Reporting
- Costing

❖ Adapting will require extra work and communication

NIH Policy on Single IRBs

- ❖ UC-wide workgroups wrapping up, more detailed guidance and tools coming
- ❖ For Jan 25 proposals, contact us
 - ❖ irbreliance@research.ucla.edu

Final Rule

- ❖ Released January 19
- ❖ Effective next January (maybe)
- ❖ Uncertainty
 - Congressional review period expiry
 - Administration review
 - No clarifying guidance
 - DOJ hasn't signed on
 - FDA hasn't harmonized
 - Other agencies with layers of policy

Final Rule

- ❖ **On WH docket for 1 year delay**
- ❖ **Proposal to allow flex measures**
 - **Not officially known**
 - **No CR for expedited research**
 - **Some expansion of exemptions**
 - **No grant congruence requirement**

Final Rule

❖ EVC's HRPB Decisions

- **Replacing Continuing Review**
 - ❑ **Annual Administrative Ping**
 - Study active
 - Reminders re amendments, PARs, closure
 - ❑ **Study will be assumed closed if no response**
- **Exemption Determinations**
 - ❑ **Remain with OHRPP**
 - ❑ **webIRB simplifications coming**

Certificates of Confidentiality

- ❖ **What CoCs used to be**
- ❖ **Sudden change**
 - NIH only so far
- ❖ **Coordinating announcement and changes**
 - webIRB
 - Consent templates
 - ePass

Certificates of Confidentiality

❖ NIH-funded projects:

- human subjects OR
- very small risk of re-identification

❖ CoCs automatic

❖ Responsibilities

- Protection from subpoena, etc
- Extra care in releasing info
- Notifying recipients, sub-awardees
- Consent (where applicable)

FDA Expanded Access

- ❖ **Certain categories of expanded access to drugs**
- ❖ **Easier, now along the lines of Emergency Use**
 - **Concurrence of IRB chair rather than IRB review**
- ❖ **Legal analysis in progress, assessing conflict with state law**

Thank you!

❖ For questions:

- **Reliance**
 - ❑ irbreliance@research.ucla.edu
- **North & South General IRBs**
 - ❑ x57122
 - ❑ gcirb@research.ucla.edu
- **Medical IRBs**
 - ❑ x55344
 - ❑ mirb@research.ucla.edu

Travel to Iran

Ann Pham

Export Control Administrator
Research Policy & Compliance

QUICK REVIEW

EXPORT CONTROLS

The **federal laws and regulations** that have been established by the U.S. government to control:

- The export of sensitive equipment, software, and technology
- Trade and financial transactions

These controls are in place to promote national security interests and foreign policy objectives.

REGULATING AGENCIES



THE STORY

AT ANOTHER UC . . .

- A faculty member travelled to Iran **WITHOUT A LICENSE** to accept an award
- Upon his return, he contacted the campus' export control officer to collect the award money
- Campus had to voluntarily disclose the trip and activities to OFAC

WHY DISCLOSE?

IRANIAN TRANSACTIONS and SANCTIONS REGULATIONS (ITSR)

- Almost all direct or indirect commercial, financial, or trade transactions with Iran by U.S. persons or within the United States are prohibited
- These transactions require written authorization (license) from OFAC

THE CAUTIONARY LETTER

THREE VIOLATIONS – 31 C.F.R 560

- Accepting the prize
- Agreeing to attend the award ceremony
- Travelling to Iran for the purpose of attending the ceremony

THE WARNING

- Each violation of the ITSR ≤ **\$289,238**
- OFAC can take future enforcement action and impose civil monetary penalties if additional information warrants renewed attention
- OFAC will “forgive” but will not forget

CONCLUSIONS

- Vice Chancellor for Research sent a memo to all Deans in September 2017
- Contact RPC to discuss proposed travel to or engagements with Iran – conference, award ceremony, teaching, research
- OFAC licenses can take up to six months

CONTACT

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UCLA Multi-Factor Authentication (MFA) and Research Administration Systems

October 12, 2017

UCLA

MFA Is Coming for Employees

Beginning at 9:00 a.m. on October 31, 2017, all UCLA campus employees including staff, faculty, and student employees will be required to use Multi-Factor Authentication (MFA) to access campus systems using their UCLA Logon ID.

To learn more about this important security measure and to enroll, please visit <https://www.it.ucla.edu/mfa-for-employees>.

I have read this notice. Please do not display this notification in the future.

I ACKNOWLEDGE, CONTINUE

What Is MFA?

PASSWORD



+

PROOF



=

ACCESS



Effective Date: **October 31, 2017**

Who Will This Impact?

All faculty and staff

All student employees

Optional for UCLA Health System

- 2200: David Geffen School of Medicine
- 2500: Medical Group (FPG)
- 2600: Vice Chancellor Health Sciences
- 3200: Semel Neuropsychiatric Institute
- 3300: Resnick Neuropsychiatric Hospital
- 4000: Medical Center (RRUCLA, SMH)

What Systems Will Be Impacted?

- All systems protected by UCLA single sign-on (SSO)
- Research Administration systems

A screenshot of the UCLA single sign-on (SSO) login portal. The background is a blue sky with clouds. The word "UCLA" is written in large, white, sans-serif font at the top. Below it, the text "Sign In with your UCLA Logon ID" is displayed in a smaller, blue font. There are two input fields: the first is labeled "Your UCLA Logon ID" and the second is labeled "Your UCLA Logon Password". Below the password field is a blue button with the text "SIGN IN" in white. To the right of the button are two links: "Forgot your UCLA Logon ID or Password?" and "Need a UCLA Logon ID?". The background also shows a grid of various system logos, including "portal", "B", "PA", "EP", and "Research Administration".

UCLA

Sign In with your UCLA Logon ID

SIGN IN

- [Forgot your UCLA Logon ID or Password?](#)
- [Need a UCLA Logon ID?](#)

How Will Things Change?



UCLA

Sign In with your UCLA Logon ID

Your UCLA Logon ID

Your UCLA Logon Password

SIGN IN

- Forgot your UCLA Logon ID or Password?
- Need a UCLA Logon ID?



- S2S Grants**
- UCLA EPASS**
Extramural Proposal Approval And Submission Summary
- PAMS** | Post Award Management System
- ERS** Effort Report System
- UCLA RAPID** PI Portal
Research Administration Process Improvement & Support
- UCLA ORA Portal**
- UCLA ORA webIRB**
- UCLA ORA RATS**
- SafetyNet**
- eDGE**
Electronic Disclosure Gateway

How Will Things Change?



UCLA

Sign In with your UCLA Logon ID

Your UCLA Logon ID

Your UCLA Logon Password

SIGN IN

- Forgot your UCLA Logon ID or Password?
- Need a UCLA Logon ID?



UCLA

Device: Work cell (000-XXX-XXXX)

Choose an authentication method

- Duo Push recommended **Send Me a Push**
- Call Me **Call Me**
- Passcode **Enter a Passcode**

What is this? CF
Add a new device
My Settings & Devices
Need help?



- S2S Grants**
- UCLAPASS**
Extramural Proposal Approval And Submission Summary
- PAMS** | Post Award Management System
- ERS** Effort Report System
- UCLA RAPID** PI Portal
Research Administration Process Improvement & Support
- UCLA ORA Portal**
- UCLA ORA webIRB**
- UCLA ORA RATS**
- SafetyNet**
- eDGE**
Electronic Disclosure Gateway

Final MFA Reminders

- Mandatory MFA Date: **October 31, 2017**
- For More Info: <https://www.it.ucla.edu/security/resources/mfa-at-ucla>

UCLA Information Security Office

GET HELP ⓘ Search this site 🔍

SERVICES ▼ RESOURCES ▼ IT SECURITY POLICIES ALERTS ▼ EVENTS CONTACT

MFA AT UCLA: EMPLOYEE RESOURCES

Multi-factor authentication (MFA) is coming to UCLA Logon ID in October! Enroll now and safeguard your account.

HOW DOES MFA BENEFIT ME?



Due to the dramatic rise in the scope and sophistication of phishing, spear phishing, and malware attacks targeting UCLA faculty and staff, we are deploying MFA for UCLA Logon accounts. Enroll now. [Read more...](#)

HOW DO I ENROLL?



Enrolling in MFA should take about five minutes, and it will make a big difference in securing your accounts. Follow [these steps](#) provided by Bruin OnLine or contact your local IT department for assistance. [Read more...](#)

GET HELP



Your local IT department can assist you in enrolling. The UCLA Information Security Office and Bruin OnLine also offer MFA enrollment support office hours, where you can walk in and get one-on-one assistance. [Read more...](#)

RSAWA UPDATES

Jennifer Perkins, MA, CPIA

Director – Research Safety & Animal Welfare

Institutional Contact for Dual Use Research

AAALAC

- Site visit: August 1-4, 2017
- Lots of positive feedback
- Two mandatory findings, four SFIs
- Council met in September 2017
- Deferred accreditation

USDA

- Annual, unannounced inspections
- Facilities, records
- July 2017 citation → successful appeal
- Reminder: always obtain ARC approval prior to conducting work with live animals

National Biosafety Month

- Every October
- Promoted by NIH OSP
- Strengthen institutional commitment to biosafety
- UCLA IBC participating via weekly educational announcements to IBC Investigator listserv
- Contact ibc@research.ucla.edu to join the listserv

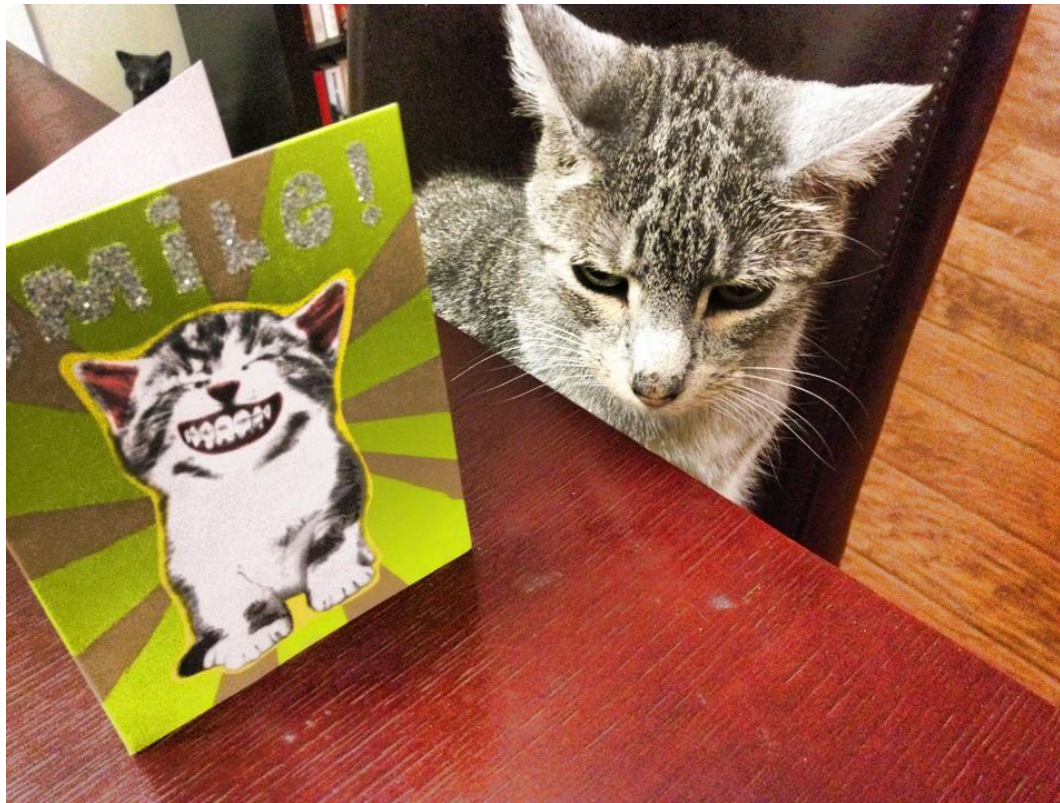
Dual Use Research of Concern

- 2014 USG Policy on DURC
- DUR refers to life sciences research conducted for legitimate purposes that generates knowledge, information, technologies, and/or products that can be utilized for both benevolent and harmful purposes.
- UCLA Dual Use Review Entity reviews research involving 15 agents/toxins defined in the USG Policy
- <http://ora.research.ucla.edu/rsawa/dure>

Radiation Safety Committees

- SafetyNet to replace use of webIRB for MRSC and RDRC submissions
- Testing underway
- Contact rsc@research.ucla.edu to participate in testing

Questions?





Patti Manheim
Director

October 12, 2017

Topics

- OCGA Staff Announcements
- Grants Updates – Kathy Kawamura

OCGA Staff

- Jim Fong - Interim Assistant Director – Contracts Team. 20 plus years experience in research administration in the UC system.
- Eleanor Forbes - Senior Contract and Grant Analyst – Grants/Cooperative Agreements Team. Law clerk for the US District Court, Central District of California, Los Angeles. Contracting expertise in drafting and negotiating research-related contracts for the mathematical, physical, and life sciences, and pre-clinical medical science departments from her tenure at the University of Oxford.
- Samantha McKenzie - Contract and Grant Specialist - Contracts Team. Program Director on a Program Project for the College of Nursing at the University of Cincinnati.
- Megan Ober - Contract and Grant Specialist - Contracts Team. Managed day-to-day operations for the History and Art History Department George Mason University.

OCGA Staff

- Kurt Durlesser – Contract and Grant Analyst – eRA/Records Management Team
- Frank Falcon – Contract and Grant Analyst – Grants/Cooperative Agreements Team
- Deeksha Bhat - Contract and Grant Analyst – Grants/Cooperative Agreements Team

Federal flow through Subgrants Team:

- Joe Gibbs – Sr. Contract and Grant Analyst – Contracts Team
- Yushan Lin - Contract and Grant Analyst – Contracts Team
- Gerald Gamble – Contract and Grant Analyst – Contracts Team

OCGA Staff

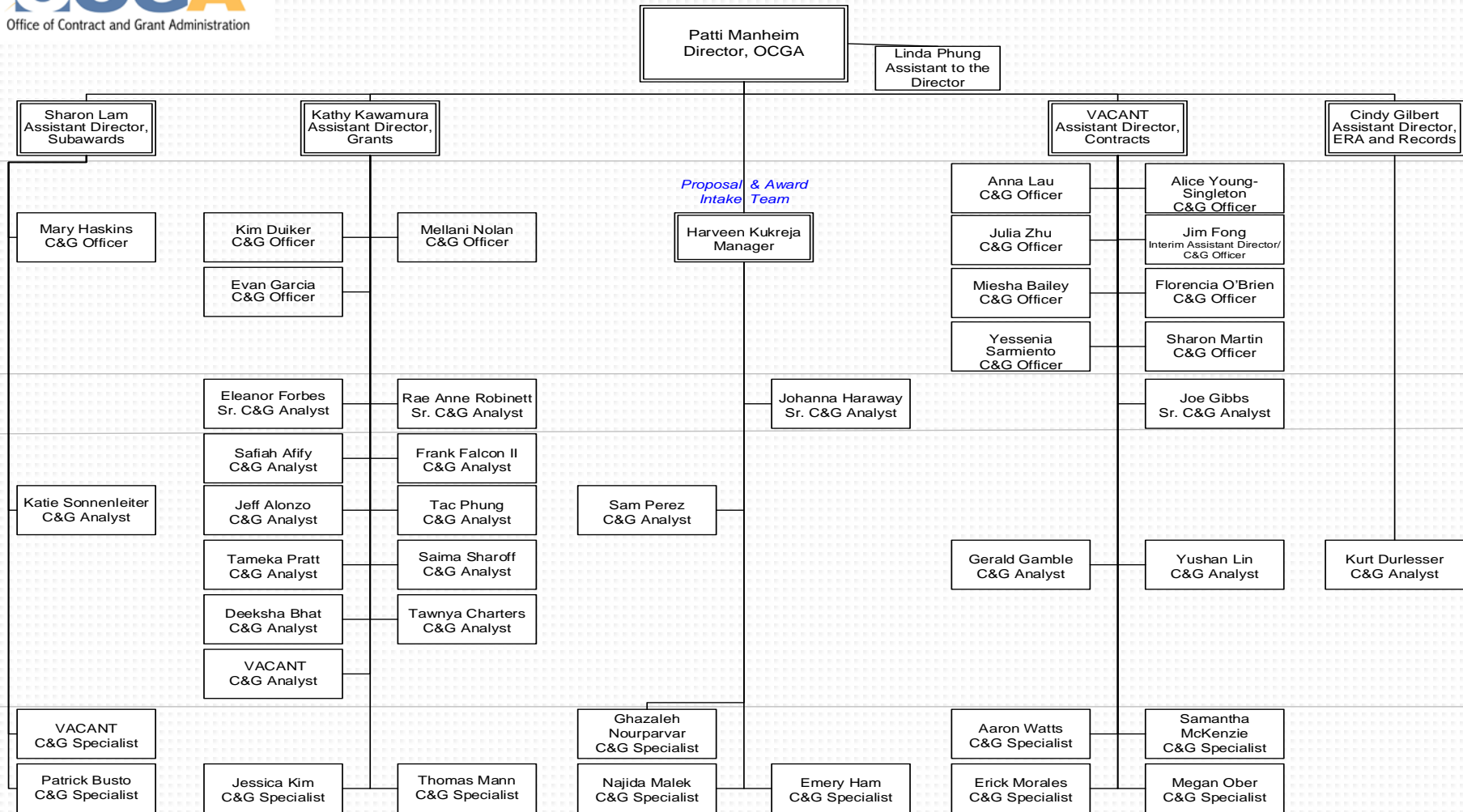
Recruiting for:

- Assistant Director, Contracts Team
- Specialist – Outgoing Subaward team
- Specialist – Award Intake Team
- Contract and Grant Analyst – Grants/Cooperative Agreements Team

OCGA Organizational Chart



Office of Contract and Grant Administration





Grant Updates

Research Administrator's Forum

October 12, 2017

NIH Notice Reminders

NIH Continuing Resolution ([NOT-OD-17-121](#))

Continuing Fiscal Policies for FY17

Non-competing awards issued ~90%

NIH Salary Cap

No Change

NRSA Postdoc Stipend & Tuition/Fee

No Change

NRSA Predoc Stipend & Tuition/Fee

No Change

NIH Salary Cap (FY 2017)

NOT-OD-17-049

NIH Salary Cap: \$187,000

Executive Level II

Effective: January 8, 2017



NIH Notice Reminders

New Review Criteria for the below Applications Types involving Clinical Trials

Career Development Awards ([NOT-OD-17-121](#))

NRSA Individual Fellowships ([NOT-OD-17-122](#))

NRSA Training Grants ([NOT-OD-17-123](#))

- ✓ Applications submitted on or after 1/25/18
- ✓ Additional review criteria (see above notices for details)
- ✓ *“new & more rigorous review criteria for evaluating clinical trials”*
- ✓ *“ensure the highest likelihood of translating research results into knowledge that will improve human health”*

Proposal Feedback

NIH

All Principal Investigators

- Must have the “PI” Role in eCommons Acct
- PI or Contact PI must be affiliated with UCLA

Contact erahelp@research.ucla.edu for assistance with eCommons accounts

Proposal Feedback

NSF

Utilize [Fastlane.nsf.gov](https://fastlane.nsf.gov) for NSF Proposals

WHY?

- NSF developed for NSF proposals
- More automatic compliance checks performed
- Smart Compliance checks based upon submission type.
- Collaborative Proposals must be submitted through Fastlane (link by PIN and generates temp proposal ID)

Appendix included with NSF Fastlane Compliance Checks

NSF Update

Updated Research Terms & Conditions

- Research Terms and Conditions Appendix A
Prior Approval Matrix - October 1, 2017
- Research Terms and Conditions Appendix B
Subaward Requirements - October 1, 2017
- Research Terms and Conditions Appendix C
National Policy Requirements - October 1, 2017

NIH Forms-E

PHS Human Subject & Clinical Trial Information

NOT-OD-17-119

- Effective: Due Dates on/after January 25, 2018
- Appendix - no longer accepted area for CT related documents
- Research Strategy – do not “duplicate” HSR & CT information
- PAs to be published on Oct 25th with usage of Forms-E

NIH Forms-E

PHS Human Subject & Clinical Trial Information

**A Walk-through
of the PHS
Human Subjects
and Clinical Trials
Information Form**

NIH National Institutes of Health
Office of Extramural Research

PHS Human Subjects and Clinical Trials Information

July 2017

[YouTube Video - PHS Human Subject & Clinical Trials Information Form Walk-Through](#)

NIH Forms-E

PHS Human Subject & Clinical Trial Information

PHS 398 Research Plan

Human Subjects Section – **REMOVED**

- Protection of Human Subjects
- Data Safety Monitoring Plan
- Inclusion of Women and Minorities
- Inclusion of Children

NIH Forms-E

PHS Human Subject & Clinical Trial Information

PHS Human Subjects and Clinical Trials Information

Brand New Form

- [Application Guidelines for HS & CT Info](#)
- 6 new pages (new data elements & uploads)
- Detail collected at Study Level
- New data fields designed to align with ClinicalTrials.gov

Composite Benefit Rates

UCLA CBR Assessment

- No change to OCGA practice
- Proposal submitted should continue to use applicable CBR
- Award Expenses will only reflect actual expenses whether CBR or real when expense hits

OCGA PRESENTS:

MEET & GREET

WILSHIRE GLENDON BUILDING
10889 WILSHIRE BLVD.
LOS ANGELES, CA 90095
7TH FLOOR

**TUESDAY
OCT. 31ST**

**DROP IN ANYTIME
BETWEEN 
9 AM TO 12 PM**

**JUDGE OUR HALLOWEEN
DECORATING CONTEST**

**GRAB SOME
TREATS**

MEET YOUR COLLEAGUES FROM OCGA

MASTER TRAINING

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

OCTOBER

Filling out the EPASS: What is it, when is it required and how to complete

Wednesday, October 18, 2017

10889 Wilshire Blvd., Conf Room 820-20

9:30am-11:00 am

This session will address the background and purpose of the EPASS. We will review and discuss each section of the EPASS with specific examples of questions from users. This session is appropriate for anyone with responsibility for completing, reviewing or processing EPASS forms.

MASTER TRAINING

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



NOVEMBER
Contracts 101

DECEMBER
Award Processing