Welcome

Marcia Smith
Associate Vice Chancellor for Research
Agenda

- **Welcome and Announcements**
  - Marcia Smith, Office of Research Administration

- **OHRPP Retention of Research Records**
  - Marcia Malmet, Office of the Human Research Protection Program

- **OCGA Updates**
  - Patti Manheim, Office of Contracts and Grants Administration
    - Operational Management Challenges
    - EPASS Changes
    - Master Training Calendar

- **EFM Updates**
  - Kevin Cook, Interim Director, Extramural Fund Management
    - Organizational Updates
    - Pool to Subaccount
    - Close-out Timeline
    - PAMS

- **Questions and Discussion**
FDA Investigational Drug Studies:

- Clinical investigators must retain study records for a period of two years following the date a marketing application is approved for the drug/indication for which it is being investigated or
- If no application is to be filed or if the application is not approved for such indication, until two years after the investigation is discontinued and FDA is notified.

Review sponsor contract!
Retention of Research Records

- **FDA Investigational Device Studies:**
  - Clinical investigators must retain study records for a period of two years after the latter of the following two dates:
    - The date on which the investigation is terminated or completed, or
    - The date that the records are no longer required for purposes of supporting a premarket approval application or a notice of completion of a product development protocol.

- **NIH Studies** – three years after close of study or six years if PHI involved.
Today’s Topics

• Operational Management Challenges
• OCGA Master Training Calendar
• Revised EPASS
• Introduction of New Staff
Operational Management Challenges

Background - Leadership Bodies – RAPID Results, Updates, Accomplishments, and Initiatives

RAPID Steering Committee

- Convened by EVC Scott Waugh
- Membership includes Vice Chancellors, Deans, Senior Administrators
- AVC Marcia Smith reports to the Steering Committee on ORA operations and the direction of RAPID initiatives
- RAPID Faculty Advisory Committee reports to the Steering Committee and advises on RAPID priorities
Operational Management Challenges

Background

• Presented “Challenges in OCGA Operations Management” to Steering Committee in March
• Stunned/Astounded by ramifications and complexities of OCGA day-to-day operations
• Provost invitation to present to Dean’s Council
Operational Management Challenges

Background

- Dean’s Council
  - Similarly Stunned/Astounded by ramifications and complexities
  - Provost summarizes risks to the institution
  - Deans agree
  - Provost solicits Deans analysis and recommendations
The Issues By the Numbers FY13

Proposals Submitted 4,674
Received 2 days (16 working hours) 1,899 42%
or less in advance of sponsor deadline
Received 4 days (32 working hours) 3,468 74%
or less in advance of sponsor deadline

Larger component of our portfolio is complex
• 20% decrease in federal dollars
• 56% increase in state, foundation, other dollars
Impact of Late Proposals

- OCGA accepts ALL proposals regardless of:
  - How late it is received:
    - 5 minutes prior to deadline?
  - How complete:
    - highly variable quality and completeness
    - highly variable preparer expertise
  - How inflexible the deadline and the electronic system

- Process to accommodate a *reasonable* number of late proposals/real emergencies
Delays in Award Set-Up

- $21M of awards (174) currently on hold waiting for Department or PI response
- FY14 median award processing time:
  - 9 days -- complete proposal record
  - 13 days -- PI/Department information missing
- 46% of all awards in FY13 required additional information from the Department or PI before set-up
- 10% of awards ($88M) in FY13 received for proposals submitted without institutional approval (No department, DRA or OCGA approval)
Increasing Complexity of OCGA Transactions

- Increasing percentage of non-routine – one-of-a-kind or few-of-a-kind transactions
- Complex transactions require coordination with campus experts:
  - Intellectual Property
  - Development
  - Risk Management
  - UCOP
  - General Counsel
  - Humans/Animals
  - Export Control
  - Conflict of Interest
  - PI/Department
Complex, Coordinated Collaboration

- OCGA
- Sponsor
- PI
- CTAO
- Campus Counsel
- OHRPP
- RPC
- VCs
- Other UCs
- Purch.
- Chairs
- Cap Progs
- OARO
- ISR
- Deans
- Risk Mgmt
- UCOP
- EFM
- Tax Svs
- OIP
- Dvlpmnt
- Cap Progs
What are Other UC Campuses Doing?

Berkeley – Hard Line

- Must be complete (including internal forms and all signatures) or returned
  - Draft and placeholder sections are not acceptable
  - Except scope/research plan
- Five days prior to the deadline
  - Including pre-proposals, white papers, LOI’s
  - Incomplete – returned and considered late
- Exceptions require written request for VCR approval – can be denied
What are Other UC Campuses Doing?

Berkeley – Hard Line

- SPO’s office hours: 8:00 am to 5:00 pm (M – F)
- SPO reserves the right to process non-compliant proposals only after on-time proposals for day are submitted
- Unreasonable and unfair to expect on-time proposals to be delayed or receive lesser review due to late proposals
What are Other UC Campuses Doing?

Irvine – Hard Line

• Must be complete (including internal forms and all signatures) or returned
  ▪ Draft and placeholder sections are not acceptable
  ▪ Except scope/research plan
• Standard Proposals:  5 days prior to the deadline
• Non-standard Proposals:  10 days prior to the deadline
  ▪ Sponsor is not Government, UC, or Domestic Higher Ed.
  ▪ Proposal is a contract
  ▪ Proposal includes Award Terms and Conditions
  ▪ Proposal includes SubAwards
  ▪ Limited Submissions
  ▪ Reduced F&A
What are Other UC Campuses Doing?

Irvine – Hard Line

- Applies to **all** extramural proposals – even if NO signature or institutional concurrence
- Final scope/research plan no later than 8 business hours before deadline time
- First-In/First-Out – no preference for late proposals
- Exception to 5/10 days require written request for VCR approval – can be denied
What are Other UC Campuses Doing?

• Will provide data/feedback to Provost and Deans Council
• Currently reviewing standard/mandatory expectations for proposal completeness
• Currently reviewing OCGA proposal review processes and expectations based on when received
• Finalizing proposal receipt process (via Proposal Intake Team)
  ▪ Proposals@research.ucla.edu
Revised EPASS

- Based on campus and ORA feedback
- Updated Form and Instructions available on the OCGA Forms site
Revised EPASS

Section 2: Department or ORU

• Added two ORUs to the pick-list:
  • California Center for Population Research (CCPR)
  • Grand Challenges
Revised EPASS

Section 5: Sponsor Information

• Reorganized fields and provided more information to clarify direct versus prime sponsor
  • Left side: Sponsor Information (Entity which will provide funding directly to UCLA)
  • Right Side: Prime Sponsor Information (Complete this section when UCLA is a subrecipient)
Revised EPASS

Section 6: Proposal Checklist

• Added *Cost Sharing Amount* to cost sharing question(s):

  Is any Cost Sharing/Matching proposed in this application? (Do not include unfunded effort or salary cap differential here.)
  If Yes, required by sponsor?  □ Yes (mandatory committed)  □ No (voluntary committed)

  Cost Share Amount: ___________________________  Source/FAU#: ___________________________

• Human and Animal Subjects; *If yes, indicate “Pending” or IRB #:*

  Human Subjects? If yes, indicate “Pending” or IRB#: ___________________________

  Are study related patient care costs to be billed to the award OR to a third party payor (i.e. medical insurance/Medicare)? If yes, then a Policy 915 Coverage Analysis is required (refer to [www.clinicaltrials.ucla.edu](http://www.clinicaltrials.ucla.edu)).

  Animal Subjects? If yes, indicate “Pending” or ARC#: ___________________________

  Delayed Onset □
Revised EPASS

Section 7: Additional Forms Required

• Added clarifying language to 700-U
  • Required for Research
  • Hover over help for types of Research

| Type of Research: | Applied Org Research, Basic Org Research, Clinical Research, CT Device, CT Drug, CT Gene Therapy, CT Gov./Non-Profit, CT In Kind, CT PI, CT Other, Dev Org Research, Other Org Research, Research Training or Visiting Scientist |

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<td><strong>No</strong></td>
<td>COI (Disclosure Requirements)</td>
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<td></td>
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<td>Sponsor/Prime Sponsor is Federal Public Health Service (PHS) or agency that has adopted the PHS regulations? If yes, provide names of other investigators on page 3 (See UCLA Policy 926).</td>
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<td></td>
<td></td>
<td>Sponsor/Prime Sponsor is Federal (other than PHS), CIRM or special research programs managed by the UC Research Grants Program Office (RGPO)? If yes, attach COI Form 740 &amp; Supplement to Form 740 (if applicable). See UCLA Procedure 925.3.</td>
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<td>Non-Government Sponsor/Prime Sponsor? If yes and project is Research, attach Form 700-U, 700-U Addendum and 700-U Supplement, as applicable, unless sponsor is exempt. See UCLA Procedure 925.2</td>
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OCGA Master Training Calendar

• Beginning September 2014
• First Thursday of each month
• Kinross 210
• 60 – 90 minute sessions on a focused topic
• Presented by subject matter experts
OCGA Master Training Calendar

Click on the topic for details

September 2014
Filling out the EPASS: How and Why

October 2014
Reviewing Program Announcements: What to Look for and When

November 2014
When are COI Disclosures Needed?
OCGA Master Training Calendar

**Topic:** Filling out the EPASS: How and Why

**Date:** Thursday, September 4, 2014
11000 Kinross Ave, Room 210 9:30AM-11:00AM

**Presenter:** Patti Manheim

**Summary:** 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.

**RSVP:** [Click here to RSVP](#)
New OCGA Staff

Sam Perez, Award Intake/Grant Analyst

• Experience
  - Nine years in OCGA as a Contract and Grant Specialist
  - Comprehensive understanding of OCGA processes and procedures, technical expertise with ORA/OCGA systems
New OCGA Staff

Rae Anne Robinett, Senior Grant Analyst

• Previous experience:
• UCLA Office of Intellectual Property and Industry Sponsored Research
  ▪ Eight years of in-depth and comprehensive expertise in reviewing proposals, negotiating complex agreements.
Shauna Huntsman, Senior Grant Analyst

- Effective June 2, 2014
- Experience:
  - Senior Research Administrator at UCSF
  - Grant and contract proposal preparation and award negotiation
  - UC expertise
  - Solid background in federal and non-profit sponsors
OCGA Staff – Open Positions

- Contract and Grant Officer
- Contract and Grant Specialist
- Assistant to the Director
QUESTIONS
Agenda

- Organization Updates
- DHHS Pooled to Subaccounting Transition
- Closeout Timeline
- PAMS Update
Organization Updates
Organization Updates

• Four Open Positions
  ▪ 3 Accountant I’s
  ▪ 1 Accountant II

• Accountant I’s
  ▪ Verbal offers accepted
  ▪ Anticipated to start 5/19

• Accountant II
  ▪ Finalists identified

• Goal is to minimize changes to department contacts as we assimilate the new hires
Pooled to Subaccounting Transition
Pooled to Subaccounting Transition

• **Change in cash draw in PMS**
  - Reimbursements for DHHS expenditures are drawn from the Federal Payment Management System (PMS)
  - EFM currently draws cash from a pooled account
  - EFM must draw cash from subaccounts for new and continuing awards as NIH establishes them in the PMS subaccounts in FY14 and FY15 respectively.

• **How will UCLA address the change?**
  - Goal: To minimize additional burden for departments while being in compliance with the new requirement
  - Proposal: Treat SNAP and Non-SNAP differently to isolate population where change is necessary to accommodate the subaccounting transition
### Pooled Account vs. Subaccounts

#### Pooled Account:
- **Total Draw:** $20 million
- **Total Awards:** 1,000

$20 million draw by UCLA

Draws submitted in aggregate

#### Subaccount:
- **Total Draw:** $20 million
- **Total Awards:** 1,000

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Request made for all award under DHHS/NIH

Draw requested by award
SNAP Example

- **Project Period (Original competitive segment)**
  - January 2010 – December 2015
- **Budget Period End Dates (New smaller competitive segments)**
  - December 2014 and December 2015
- **FFR Due Dates**
  - March 2015 and March 2016
- **New Fund?**
  - No
- **EFM/Department Interaction for FFR Due March 2015?**
  - No – Report off Ledger as of December 2014, this FFR is administrative only
Non-SNAP Example

- **Project Period (Original competitive segment)**
  - January 2010 – December 2015

- **Budget Period End Dates (New smaller competitive segments)**
  - December 2014 and December 2015

- **FFR Due Dates**
  - March 2015 and March 2016

- **New Fund?**
  - Yes – ORA will create the new Funds as RAS Funds in advance of the transition

- **FM/Department Interaction for FFR Due March 2015?**
  - Yes – We will be requesting a Closeout Packet for both Funds
## Summary

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<tr>
<th>Type</th>
<th>SNAP</th>
<th>Non-SNAP</th>
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<tbody>
<tr>
<td>Restricted Carryforward?</td>
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<td>Yes</td>
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<tr>
<td>New Fund?</td>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td>Confirmation w/ Dept of Interim FFR?</td>
<td>No</td>
<td>Yes</td>
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- **NIH Notice for award payment transition to subaccounts:**

- **NIH FAQs for award payment transition to subaccounts:**
Closeout Timeline
Closeout Phases

Phase 1 – Notification and Preparation

90/30/0 Days Before RAPID Closeout Notification to Department/PI

Department/PI Review Fund

Fund Ends

Phase 2 – Reconciliation and Report

45 Days Before Department finalizes review of Fund

30 Days Before Department will provide Fund with Closeout Packet

FFR is Due
Drivers for Closeout Phases

- Final financial reports/invoices are **currently due 90 days** after the Budget End Date for almost all **direct federal** awards

- Final financial reports/invoices are **currently due 60 days** after the Budget End Date for almost all **pass-through federal** awards
Drivers for Closeout Phases (cont’d)

• Effective under the new subaccounting process, no reimbursements will be made on requests for payments more than 90 days after Budget End Date

• **Impact:** All expenditures must post in a timely manner to meet the above referenced deadlines for direct and pass-through federal awards in order to be reimbursed.
Example of FFR Due 90 Days After

5/1 - 6/30
Phase 1
Notification and Preparation

6/30
Budget Period End Date

7/1 - 8/31
Phase 2
Reconciliation and Report

8/30
Closeout Packet Due to EFM

9/1 - 9/30
Expenses At Risk

9/30
FFR Due
Example of Invoice Due 60 Days After

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<th>5/1 - 6/30</th>
<th>7/1 - 7/31</th>
<th>8/1 - 8/31</th>
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<td>Phase 1</td>
<td>Phase 2</td>
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<tr>
<td>Notification and Preparation</td>
<td>Recon/Report</td>
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6/30 Budget Period End Date
7/31 Closeout Packet Due to EFM
8/31 Invoice Due
Avoiding Late Transactions

- Monthly expenditure reconciliation while a Fund is active is the best practice for avoiding out of period transactions
  - This allows the PI and Department to ensure that:
    - Expenses that should have hit are accurately reflected
    - Expenses that hit erroneously are moved in a timely manner
    - F&A expenses have been incurred correctly
- It is the responsibility of the PI and Department to ensure that expenses on a Fund match those reported to EFM and the FFR/invoice
  - Phase 2, representing the 30-60 day period after the Fund ends, is the appropriate time to make sure that any final expenses are applied to a Fund, and any reconciling or correcting entries are executed
Currently Under Consideration

- EFM forming a working group, which will include department representatives, to discuss impact of hard deadlines on closeout process
- If Closeout Packet is not received by the due date, then UCLA is considering reporting off the ledger after EFM does a cursory review of the expenses
- If expenses are deemed questionable by EFM and appropriate and timely justification is not received, then the department will be expected to cover those expenses
- If expenses are posted or received after the contractual deadline for the final report/invoice, then the department or vendor will be expected to cover those expenses
PAMS Updates
System Availability

- Current Availability: 7:30 AM – 6:00 PM, M-F
- System Uptime

![Weekly System Uptime Chart]

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Highlights

- Successfully processed 4 Closeout Packets!

- Bugs and Enhancements
  - Submit to PAMS Help
  - Fixed 75 bugs since go-live
  - Current priority: Assignments and TIF

- PAMS Help
  - PAMSHelp@research.ucla.edu
  - (310) 794-0008

- Quick guides:
  http://ora.research.ucla.edu/EFM/Pages/PAMS/QuickGuide.aspx