Welcome

Marcia Smith
Associate Vice Chancellor for Research
Agenda

• Welcome and Announcements – Marcia Smith

• RAPID Update – PAMS – Jessica Carney, Allison Philabaum
  ▪ Post Award Management System Project Update and Demonstration

• OCGA Update – Patti Manheim
  ▪ Award Set Up and Impacts of New PHS Disclosure Processing

• Research Policy and Compliance – Ann Pollack
  ▪ Update on Implementation of Revised PHS COI Regulations

• OHRPP Update – Sharon Friend
  ▪ CTSI and UC IRBs Memorandum of Understanding

• Office of Compliance Services – Shanley Curran, Polina Eshkol
  ▪ Clinical Research Billing Compliance Program

• Questions and Discussion
Project Update & Sneak Peek
Jessica Carney, PAMS Project Manager
Allison Philabaum, PAMS Business Analyst
Agenda

- PAMS Update
  - Phase 1 Scope
  - Project Status
- Another Sneak Peek
  - Payroll & TIF
- Q&A
Reminder: Phase 1 Scope

- Focus on *Compliance* and *Time Savings* via:
  1. Real-time customized worklist
  2. Compliance dashboard
  3. Pull non-payroll & payroll financial data
  4. Push non-payroll financial transactions
  5. Approval workflow
  6. Financial reporting, invoicing, fund closeout
Reminder: Phase 1 Scope

1. **Real-time tracking customized worklist** for individuals in departments & central office

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**Workload**

**5 Interim Reports and Invoices**

- 3 Upcoming 30 days
- 2 Past Due

**13 Closeout Packets Due to EFM**

- 8 Upcoming 30 days
- 2 Upcoming 30 days
  - Missing Managing PI
- 3 Past Due

**4 Pending Response**

- 2 NCTE/Amendment
- 2 Carry Forward Approval

**22 Pending Y/N Action - Under Dev**

- 10 EFM
- 12 Dept
Reminder: Phase 1 Scope

2. Compliance dashboard

Closeout Packet Overview

Expenditure Review

- Prior Years
- Expenses Outside Period - Non Payroll
- Expenses Outside Period - Payroll
- Unallowable/Warning Codes
- Administrative Salaries
- Subawards
- Encumbrances & Memo-Liens
- Salary Over the Cap
- Additional Cost Transfers
- Cost Share
- F&A Reconciliation
- Fund Balance and Approvals

Status Legend: ✓ Department Complete  ■ Department Review
Reminder: Phase 1 Scope

3. Pull non-payroll & payroll financial data from campus central systems

Summary by Sub

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<th>Description</th>
<th>Appropriation</th>
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<th>Encum And Memo Liens</th>
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Direct Balance: $3,535.02
Indirect Balance: $232.60
Total: $3,817.82
Reminder: Phase 1 Scope

4. Push non-payroll financial transactions to campus central systems (Payroll transfers future phase)
### Reminder: Phase 1 Scope

5. Standard approval workflow

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<td>EFM Preparer (Craig, Kayle):</td>
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Reminder: Phase 1 Scope

6. Financial reporting, invoicing & fund closeout for contracts & grants (Training grants future phase)

Review PAMS Deliverable

[Image of invoice]

Pennsylvania State University
Attn: Susan Lavan
College of Earth and Mineral Sciences
248B Deike Building
University Park, PA 16808

Pay to the order of
The Regents of the University of California
UCLA Administrative Main Cashier Office
Box 951432, 1125 Murphy Hall
405 Hilgard Avenue
Los Angeles, California 90095-9000

Contract/Agreement/P.O. No.
3902-UCLA-NASA-A76A:11
Prime Award No. NNA09DA76A

Invoice No. 57994 - 38
10/16/2012

11/08/2012 Nov RAF PAMS Update & Sneak Peek
PAMS Project Status

- **Functional Updates**
  - Accommodate policy/procedure changes to ensure compliance (Single Fund Number, Dept/EFM Thresholds etc.)

- **Integration with other systems**
  - UC Path, Financial System, NPEAR, PATS
  - Accommodate for systems changes to ensure compatibility

- **Development**
  - Screens
  - Business logic
  - Connect Screens with business logic
PAMS Test Status

- Formed Test Team

- Unit Test (elements on page)
  - 80% screens passed

- System Test (data accuracy)
  - Prepping system test data
  - Scripting system test scripts

- Integration Test (workflow)
  - Planning
  - Department Volunteers
PAMS Sneak Peek: Payroll & TIF

4 Scenarios:

1. Transfer salary, transfer TIF
2. Justify salary, transfer or justify TIF
3. Transfer all TIF
4. Justify all TIF
Thank You!

Technical & Business Analyst Teams

GABY  JESSICA  ALLISON  MILA  STEPHANIE  LOUIS
SALINI  TERRY  JOVAN  DAN  KATIE
Today’s Topics

- Award Processing Update
Award Processing - Background

Award Intake Team

- Turnaround time for Expedited Awards *improved by 65% - 80%*
Awards Processing – Current and Future

What are the factors that affect award processing?

• Volume
  - ~1,700 actions processed July – September 2012
    • 1,178 awards with funds
    • 500 other award transactions (administrative changes, terms and conditions, NCEs, etc.)

• Missing Internal Documents
  - Awards processed 6 days faster when all internal documents are present at time of submissions
  - $5 - $12M outstanding awards

• New Process for PHS FCOI
  - Before UCLA can accept an, all investigators need to have disclosed in eDGE, even if they have previously completed a 740.
  - Different disclosure requirements and more complex review/analysis by RPC.
# Awards Processing – PHS FCOI Regulations

## Awards Issued *Prior to August 24, 2012*
- Investigators file 740 with proposal.
- If positive, 740 routed to RPC for review.
- CIRC and sponsor review concurrent
- When award made, RPC notifies PHS that FCOI review is complete.
- RPC notifies OCGA.
- OCGA can process award after FCOI review and notification process is complete.

## Awards Issued *On or After August 24, 2012*
- eDGE disclosure required even if 740 was filed with proposal submission prior to August 24.
- eDGE disclosure thresholds and definitions changed.
- RPC analysis more complex.
- RPC conducts relatedness review to determine if CIRC review is needed.
- CIRC review is conducted (if necessary).
- RPC reports FCOIs to PHS.
- OCGA can process award after FCOI review and notification process is complete.
Awards Processing – PHS FCOI Regulations

- If a non-competing/continuation award is received—*make sure all Investigators have disclosed in eDGE, forward p. 3 of EPASS to OCGA as soon as possible.*
- If a JIT request is received/pending – *make sure OCGA receives it, make sure all Investigators have disclosed in eDGE, forward p. 3 of EPASS to OCGA as soon as possible.*
- New award coming in – *make sure all Investigators have disclosed in eDGE, forward p. 3 of EPASS to OCGA as soon as possible.*
Awards Processing – PHS FCOI Regulations

• Review Triggers
  ▪ a Just-in-Time Request is received,
  ▪ a new award is received,
  ▪ a continuation award is received,
  ▪ a pending progress report is due.
Sponsors That Require Compliance with PHS Regulations - Federal

- Agency for Healthcare Research and Quality (AHRQ)
- Agency for Toxic Substances and Disease Registry
- Centers for Disease Control (CDC)
- Food and Drug Administration (FDA)
- Health Resources and Services Administration (HRSA)
- Indian Health Services (IHS)
- National Institutes of Health (NIH)
- Office of Global Affairs
- Office of the Assistant Secretary for Health, including
  - Office of Minority Health Resources Center (OMH)
- Office of Population Affairs (OPA)
- Office of Research Integrity (ORI)
- Office of Research on Women’s Health (OWH)
- Office of the Assistant Secretary for Preparedness and Response, including
  - Biomedical Advanced Research and Development Authority (BARDA)
  - Substance Abuse and Mental Health Services Administration (SAMHSA)
Sponsors That Require Compliance with PHS Regulations - Other

- Alliance for Lupus Research
- American Cancer Society
- American Heart Association
- Arthritis Foundation
- CurePSP Foundation for PSP | CBD and Related Brain Diseases
- Juvenile Diabetes Research Foundation
- Susan G. Komen for the Cure

If unsure; contact rpchelp@research.ucla.edu.
Make sure all Investigators have disclosed in eDGE.

Forward p. 3 of EPASS to OCGA
eDGE Improvements

- Login button was made (slightly) larger
- The "Manage My Disclosures" button was changed to read "Create/Edit Disclosures"
- Submission instructions made clearer at the bottom of the Disclosure Details page
New Create/Edit Disclosures Button

Welcome to your Home Page.
This page has links to all of the items applicable to your role as a discloser.
The Inbox displays your disclosures that have a task requiring completion.
Other tabs provide links to your disclosures and personal profile.
Submission Instruction Clarification

Disclosure Update for COITEST PI 23: Disclosure Details

Please provide information on each company/external organization with which you have a Significant Financial Interest. If the relationship has not previously been disclosed, click on the "New Disclosure" button. If the relationship has been previously disclosed, click on the "Edit" link next to the disclosure to update.

Once you are finished updating your disclosures, please submit your disclosure. To do this, click the checkbox at the bottom of the page and click "Finish".

If you would like to submit your disclosure at a later time, please click "exit" or close your browser window.

If you would like to submit your disclosures now and you confirm that your disclosure is up-to-date, please check this box and click "Finish": ☑️
eDGE Statistics

- As of October 22, 2012, approximately 1200 individuals completed eDGE disclosures
- Since RPC received 1\textsuperscript{st} request for review with all eDGE disclosures submitted (mid-September), approximately 120 relatedness reviews have been completed by RPC
Relatedness Reviews

- Investigators provide broad disclosures of SFIs related to their institutional responsibilities.
- RPC must compare disclosures made in eDGE by the PI/PD and all other Investigators on a project-by-project, transaction-by-transaction basis (relatedness reviews).
- These reviews determine whether a disclosed Significant Financial Interest (SFI) is related to a particular proposal or award and require further review by the Conflict of Interest Review Committee (CIRC) to determine whether it’s a financial conflict of interest (FCOI).
- Review begins when RPC receives notification about a Just-in-Time Request, receipt of an award, or pending progress report due.
Relatedness Reviews

- Relatedness review may determine that none of the Investigators have SFIs related to the project. *End of review.*
- Relatedness review may determine that one or more investigators on a project have one or more SFIs that are related to the PHS-supported research. *Requires further review.*
How to help us ensure timely reviews

• Investigators should disclose in eDGE as soon as possible rather than waiting until a proposal is ready for submission or an award received.

• Information about fundable priority scores, requests for submission of Just-in-Time information or other signals that an award is likely should be shared.
  - Please alert OCGA and ISR to JIT requests
  - Please send other information about the possibility of funding to rpchelp@ucla.edu
UCLA Reliance on Other UC IRBs, UCLA CTSI IRBs and Beyond

Sharon Friend, OHRPP Director
Research Administration Forum
November 8, 2012
What Is an IRB Reliance Agreement?

- By mutual or collective written agreement, one or several IRBs agree to rely on the IRB review of one or several other IRBs.
- The agreement is typically called an “MOU” (Memorandum of Understanding).
How a Reliance Agreement Works*

Reviewing IRB

- assumes full responsibility as IRB of record
- reviews entire study
- assures local issues are identified and addressed
- coordinates communication with all PIs

Relying IRB

- accepts determinations made by Reviewing IRB in their entirety
- has responsibility for ensuring that
  - Ancillary approvals (MRSC, COI, IBC) are in place
  - Sufficient resources are available

*NOTE: This is model commonly used by commercial IRBs
>Two CTSI’s Involved in IRB Reliance Agreements for UCLA Investigators

**UCLA**
- Cedars-Sinai Medical Center
- Charles Drew University of Medicine and Science
- LA Biomedical Institute at Harbor UCLA Medical Center
- UCLA

**UC Medical Centers**
- UC Davis
- UC Irvine
- UCLA
- UC San Diego
- UC San Francisco
How to Use the MOUs

- General process is similar for both UC MOU and UCLA CTSI MOU but because UC process is web-based procedures are slightly different.

- Review information on UCLA CTSI site for “CTSI IRB Reliance Review Process” at http://ctsivhome.ctrl.ucla.edu/research/pages/irb

- Review information on “UC IRB Reliance Registry for Studies under the UC MOU” on UC Berkeley site at http://cphs.berkeley.edu/irbreliance.html
### Instructions to the Principal Investigator/Lead Investigator at the Reviewing IRB
1. Read the discussion tree for an overview of the process and points to consider when determining which IRB should provide review.
2. Complete this Notice and ensure that information cited from the research of the other UC site is included.
3. Obtain the signatures of the Reviewing IRB for this Notice.
4. Submit the completed Notice with your (or your observers') signed form(s) to the Reviewing IRB.
5. Once approved, you can begin the study. The Reviewing IRB must wait for the Acknowledgment Letter before they can begin.

### A. Reviewing Campus Principal Investigator/Lead Investigator:

#### 1. Reviewing Campus Study Title:

| [ ] Note | [ ] Full Committee | [ ] Expedited Review |

#### 2. Application Type

| [ ] Full | [ ] Modified | [ ] Exempt |

#### 3. Review Type

| [ ] Continuing Review | [ ] Expedited Review |

#### 4. UC Location Which Will Provide IRB Review

- UCB Berkeley
- UC Davis
- UC Davis Medical Center
- UC Irvine
- UC Merced
- UC Riverside
- UC San Diego
- UC Santa Barbara

#### 5. Funding Information

| [ ] Contract/Grant | [ ] Federal Government |
| [ ] Endowment | [ ] Other Gov. (e.g., State, local) |
| [ ] Gifts, device donation | [ ] Industry |
| [ ] Grant | [ ] Other Private |

#### 6. Who is the Primary Sponsor? (Institution)

- [ ] Yes
- [ ] No

#### 7. Who is the PI on this award?

- [ ] Yes
- [ ] No

#### 8. PIRU on the IRB Application:

- [ ] Yes
- [ ] No

#### Contact Person

- [ ] Yes
- [ ] No

#### Additional Contact Person(s) if any:

- [ ] Yes
- [ ] No

#### Notice of Intent to Rely

- [ ] Yes
- [ ] No

Page 1 of 4
February 2009
Overview of How UC and UCLA CTSI MOUs Work

After Investigators confer with each other and their IRBs to determine which IRB reviews study,

1. **Relying PI registers** by completing (on-line) form which outlines his/her institution’s role in study

2. **Lead PI** (at reviewing institution) **submits usual IRB application** and uploads PDFs of completed registrations from Relying PIs

3. **Reviewing IRB reviews** entire study including Relying PI PDFs
4. **Reviewing IRB sends IRB Approval Letter** to Reviewing PI and Relying IRBs

5. **Relying IRBs review local PI registration** and if other approvals are in place, resources are sufficient, and local concerns addressed, accepts reliance on Reviewing IRB

6. **Relying IRB sends Acknowledgement Letters** to Reviewing Campus, Relying PIs and Relying IRBs—automatically generated
Which IRB Reviews Multi Site Study?

Considerations:
- Recipient of prime award
- Primary Study Site
- IRB expertise

Easiest Choice: If prime grantee and location where all or most of study recruitment and procedures occur is same site, IRB review will be at that site.
Examples of UCLA IRB Reviewing for UCSF

- Study to assess the effects of nutrition training on primary outcomes for men living with AIDS in improving body composition and immune status as assessed at several follow up points; and …

- Project to develop educational programs to train nurses, physicians, and physical therapists about the 5P Fall Prevention Method, implement the 5P Method at Santa Monica UCLA Medical Center and UCSF’s Moffitt-Long Hospital Complex, assess its effectiveness and examine the cost implications for the hospitals and …. 
Study to examine how different tertiary cancer centers provide post-treatment survivorship care, and how well the existing models of care at each site facilitate adherence to guideline recommendations for surveillance, adherence to adjuvant endocrine therapy, and management of common post-treatment symptoms.
Important PI Caveats

- **Lead PI** serves function similar to Coordinating Center and assumes additional responsibilities related to coordination of activities.

- **Relying PI** cannot begin study activities until:
  - Reviewing IRB has approved study,
  - All local ancillary approvals (MRSC, IBC, COI) are in place, and
  - Relying IRB has acknowledged approval in writing.
Important Caveats when Relying on Another IRB

Relying PI must

- *modify informed consent form* to include local contact information (see handout) unless one ICF with local information is submitted for initial review.
- *coordinate renewals or amendments* with Lead PI.
- *monitor and report unanticipated problems* to Reviewing IRB. Coordinate with Lead PI.
- notify Reviewing PI when *closing study at local site or withdrawing* from MOU.
Other External IRBs Available to UCLA Researchers

See OHRPP website for details:

- The National Cancer Institute Central IRB (NCI CIRB) for some oncology groups studies (submit through webIRB)
- Western IRB
- Rand
- Rarely, others may approved on a case-by-case basis
Where to Go for Help

- OHRPP Website: External IRBs
  [http://ohrpp.research.ucla.edu/pages/external-irbs#ucla-rand](http://ohrpp.research.ucla.edu/pages/external-irbs#ucla-rand)

- OHRPP Senior Staff, including:
  - Augustine Fernandes: 983-3155; augustine.fernandes@research.ucla.edu
  - Alison Orkin: 206-3969; aorkin@research.ucla.edu
  - Sharon Friend: 825-5855; sfriend@research.ucla.edu
Clinical Research Billing Compliance Program

Shanley Curran, RN, CCRP, CHC, Esq.
Manager, Clinical Research Billing Compliance

and

Polina Eshkol, BA, CCRP, CPMA, CHRC
Clinical Research Billing Compliance Auditor & Trainer

November 8, 2012
1. **OVERSIGHT**

   a. Legacy CRB process/practice discovery

   b. CareConnect Research Application Build

   c. Review of and Assistance with Operational Clinical Study Billing-related Policies, Processes, Tools, and Training

   d. Creation of Policy/Procedure for Clinical Study Billing Compliance Program component of the Office of Compliance Services

   e. Participation in Compliance Committees
2. EDUCATION AND TRAINING

   a. Monthly CRB E-Tips

   b. OCS Webpage with FAQs and CRB links

   c. CRB Guide in New Provider Training Materials

   d. Responsive Ad Hoc Guidance/Training

   e. Participation in internal and external programs
3. COMMUNICATION-REPORTING

a. To UCOP

b. Internal
   a. Enterprise Executive Oversight Board
   b. Health System and DGSOM Compliance Committees
   c. Department Leadership
   d. Study Teams

c. External
   a. Insurance Carriers
   b. Regulatory - CMS, OIG, DHHS/NIH
4. **ENFORCEMENT AND SCREENING**
   a. CMS
   b. OIG

5. **AUDITING AND MONITORING**
   a. Quarterly routine audits
   b. Focused audits as approved/directed by Chief Compliance Officer
   c. Liaison for UCOP Audit & Compliance Services
   d. Audits required under annual EOB-approved Work Plan

6. **RESPONSE AND PREVENTION**
   a. Direct Reports
   b. Compliance Hotline
Required Clinical Study Submission and Study Team Training for Go-Live

**STUDY RECORD** – Clinical study information must be ready in CareConnect for Go-Live March 2013. To allow time for questions, each clinical study team should submit as soon as possible using the Research Study Submission Form available here: [http://careconnect.uclahealth.org/secure.cfm?id=122](http://careconnect.uclahealth.org/secure.cfm?id=122)

**TRAINING** - Please enroll in the following classes if you will conduct or coordinate clinical studies within the UCLA Health System inpatient and/or outpatient setting.

- AMB 130 Research I - Clinical
- AMB 140 Research II - Charge Review and Billing

[http://careconnect.uclahealth.org/Workfiles/secure/Training/Catalog_082112.pdf](http://careconnect.uclahealth.org/Workfiles/secure/Training/Catalog_082112.pdf)
Shanley Curran, RN, CCRP, CHC, Esq.
Manager, Clinical Research Billing Compliance
Office of Compliance Services for UCLA Health System & DGSOM
924 Westwood Blvd. Suite 810
Los Angeles, CA 90024-2929
scurran@mednet.ucla.edu
o: 310.794.8269  m: 310.666.3849

Polina Eshkol, BA, CCRP, CPMA, CHRC
Clinical Research Billing Compliance Auditor and Trainer
Office of Compliance Services for UCLA Health System & DGSOM
924 Westwood Blvd. Suite 810
Los Angeles, CA 90024-2929
peshkol@mednet.ucla.edu
Tel: (310) 794-8266

CRBC webpage: http://compliance.uclahealth.org/body.cfm?id=73
CRBC FAQs: http://compliance.uclahealth.org/body.cfm?id=189
Tips From The OCS: http://compliance.uclahealth.org/body.cfm?id=166