Research Administrators Forum

Sponsored by
Office of Research Administration

Jackson Jeng
ORA Office for Research
Information Systems

May 14, 2009
Research Administrator’s Forum
Office of Research Administration
Monthly Meeting for UCLA Research Administrators
May 2009 Meeting Agenda

Welcome
Jackson Jeng, ORA Office for Research Information Systems

Statistics on UCLA Recovery Act Submissions and Awards
Jackson Jeng

Updates from OCGA
Latest News on Recovery Act Funding Opportunities
Connie Whitley, ORA Office of Contracts and Grants Administration

Updates from EFM
Preparations for Recovery Act Fund Management, Update on Cost Transfers
Evelyn Balabis, ORA Extramural Funds Management

Updates from OPRS
Reporting Unanticipated Problems: Incidents, Violations, Deviations and Adverse Events
Sharon Friend, ORA Office for Protection of Research Subjects

Announcement from OCT
Vikki Jenkins, Director, Office of Clinical Trials

Questions and Discussion
Statistics on UCLA Recovery Act Submissions and Awards
ARRA Proposal Processed to Date

- 750 proposals processed to date
- ~$300M proposal dollars

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<td>New</td>
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<td>Revision</td>
<td>8</td>
<td>$2,114,211</td>
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<td>TOTAL</td>
<td>750</td>
<td>$302,807,767</td>
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ARRA Awards Received to Date

- 6 awards received to date
- $3,794,860 awarded dollars

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<td>1</td>
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<td>$1,889,958</td>
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<td>1</td>
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<td>1</td>
<td>$885,543</td>
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Latest News on Recovery Act Funding Opportunities

Connie Whitley
ORA Office of Contract and Grant Administration
NIH Challenge Grant (RC1)

- 292 applications submitted via S2S Grants
- Grants.gov failed at approximately 3:45 p.m. on April 27th
  - Five applications missed the deadline
S2S Activity April 22 – 27*:

- Monday, April 20: 24
- Tuesday, April 21: 47
- Wednesday, April 22: 52
- **Thursday, April 23**: 70
- Friday, April 24: 52
- Saturday, April 25: 19
- Sunday, April 26: 3
- Monday, April 27: 38

*Includes all application types, not just RC1
 NIH Challenge Grant (RC1)

Thank you for all your hard work! It took a lot of people to make it happen!

Great Job!
NIH Reminders/Updates:

- The Commons Help Desk is continuing to clear Competitive Revision applications with ERRORS – please be patient.
- Commons unavailable May 22 – 26
- Too many applications are receiving “Commons Account” errors
- Two day rejection/correction window
  - correct system-identified errors or critical warnings
  - correct PDF compilation issues
  - not for editing content of proposal
NIH RC2 “Grand Opportunity”

- Deadline Changed to Friday, May 29
- OCGA Deadline: no later than 8:00 a.m. on Friday, May 22
- Check with your School/Department/Division for Internal Deadlines
- Checklist available on the OCGA/ARRA website
- Supplemental or updated information after submission … proofread applications prior to submission to OCGA or DRAs
Be sure to use NIH MINIMAL validations!
Complete Proposals Due at OCGA Five Working Days Prior to the Deadline

- Complete proposal package includes:
  - Error-free proposal
  - Signed goldenrod*
  - 740 signed by all senior personnel*
  - Signed PI statement, if NIH*
  - PI exception letter if needed*
  - Complete subaward proposal *

*Transmit to OCGA via the Proposal Summary/Documents section of the S2S Grants system
ARRA Resources
ARRA Indicator Added to Award Synopsis

University of California, Los Angeles
Award Synopsis

UCLA L-Fund No: [Redacted] Inst. No: 2008 Award Status: ACTIVE Action Type: NEW
Principal Investigator: [Redacted] Admin. Unit: [Redacted]

Co-Investigators: [Redacted]

Sponsor: NIH/National Institute
Sponsor Award/Modification No: R01 [Redacted] 5-01:
Prime Sponsor: [Redacted]
Project Title: [Redacted]
Type of Award: GRANT Activity Type: APP ORG RES Program Type: Regular


ARRA: Yes
ARRA Comments Added to Award Synopsis

Referenced Documents:
1. Research Terms and Conditions 7/1/08.
2. Research Terms and Conditions: NIH Agency-Specific Requirements.
3. Division A of the ARRA (Public Law 111-5, Section 1512).

Subagreement:
1. Prior sponsor approval required to subaward a substantive portion of the scope of work.
2. Prior sponsor approval required to add a subaward to a foreign entity if not included in the current approved budget.
3. For sub-award equal to or larger than $25,000, the following information needs to be stated in the quarterly reports:
   - The name of the subawardee
   - The amount of the subaward
   - The transaction type
   - CFDA number
   - Program source
   - An award title
   - The location of subawardee
   - The primary location of performance under the award
   - A unique identifier of the entity receiving the award and of the parent entity of the recipient, should the entity be owned by another entity

Travel Restrictions:
1. Use of US flag air carriers required for foreign travel in accordance with the provisions of the Fly America Act.

Fiscal Report
1. The recipient must submit quarterly reports to HHS, not later than 10 days after the end of each calendar quarter. The reports must contain the following information:
   a. The total amount of ARRA funds.
   b. The amount of ARRA funds received that were obligated and expended to projects or activities.
   c. The amount of unobligated award balances.
   d. A detailed list of all projects or activities for which ARRA funds under this award were obligated and expended including the name of the project or activity, a description of the project or activity, an evaluation of the completion status of the project or activity, an estimate of the number of jobs created and the number of jobs retained by the project or activity and for infrastructure investments made by State and local governments, the purpose, total cost, and rationale of the agency for funding the infrastructure investment with funds made available under this Act, and the name of the person to contact.
   e. Detailed information on any sub-awards made by the grant recipient to include the data elements required to comply with the Federal Funding Accountability and Transparency Act of 2006 (Public Law 109-282).
   f. All sub-awards less than $25,000 or to individuals may be reported in the aggregate, as prescribed by HHS.
   g. Recipients must account for each ARRA awards and sub-award separately.
   h. Recipients must account for each ARRA award separately by referencing the assigned CFDA number for each award.
OCGA ARRA Help Desk

- 10:00 a.m. – 5:00 p.m., Monday – Friday
- 310-794-0548
- OCGAARRAHelpline@research.ucla.edu
General S2S Reminders and Updates

- Some sponsors have opted out of Grants.gov either in whole or in part
- If eligible, S2S Grants should be used
  - Exceptions: NSF (FastLane); NASA (NSPIRES)
- Establish “placeholder” in S2S Grants System ASAP

At minimum, include:
- Proposal name (using proper naming convention)
- PI name
- Deadline date
Deadlines

Please notify OCGA of pending proposals as soon as possible to enable us to marshal appropriate staffing resources
Resources for S2S Grant Users

- Request user access or institutional profile
  S2Sgrantsadmin@research.ucla.edu

- Questions related specifically to S2S
  S2Sgrantshelp@research.ucla.edu

- S2S Grants Login:
  https://s2sgrants.research.ucla.edu

- S2S Grants Resources:
  http://www.research.ucla.edu/ocga/S2SGrantsInfo/index.htm

- S2S Grants Listserv:
  http://lists.ucla.edu/cgi-bin/mailman/listinfo/s2sgrants
Extramural Fund Management Updates

Evelyn Balabis
ORA Office of Extramural Fund Management

May 14, 2009
## Financial Reporting Backlog Initiative

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<tr>
<td>Private</td>
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<td>Completion (%)</td>
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<td>-------------------------</td>
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<tr>
<td>Private</td>
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<tr>
<td>Totals:</td>
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## Effort Certification % Completed

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<th>SP07</th>
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<td>87.8%</td>
<td>87.1%</td>
<td>84.7%</td>
<td>85.0%</td>
<td>82.5%</td>
<td>79.9%</td>
<td>77.9%</td>
<td>75.8%</td>
<td>61.9%</td>
<td>56.0%</td>
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<tr>
<td>04/13/09</td>
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<td>86.3%</td>
<td>85.8%</td>
<td>83.1%</td>
<td>83.1%</td>
<td>80.7%</td>
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<td>75.2%</td>
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<td>01/06/09</td>
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<tr>
<td>04/09/08</td>
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<td>48.1%</td>
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<tr>
<td>01/15/08</td>
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<td>73.6%</td>
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<td>67.6%</td>
<td>38.9%</td>
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ERS – Outstanding Issues

- System is not recognizing corrections made to the payroll system for transactions that have an “Exception / Unrecognized Earnings” status.
- Derived / Weighted percentages are incorrect for employees that are paid on a bi-weekly and monthly basis within a quarter.
- System needs to be more flexible with selection criteria combinations used in order to generate more manageable lists and reports.
- System calculation of percent effort for dual appointment employees is incorrect.
Training – Course 4
Post Award Administration

- 2 Sessions – May 29th & June 2nd
- Major Topics:
  - EFM Overview
  - Award & Proposal Set up
  - Award Management
  - Accounts Receivables
  - Cost Transfers
  - Effort Reporting
  - Closeout Process
  - Audit
Cost Transfer Updates

- DHHS Letter (April 23, 2009)
  - Untimely Cost Transfers – repeat finding
  - Expect diligence in working to correct deficiency
  - Crucial to provide assurance that the funds are adequately safeguarded and managed
  - Failure in addressing finding could result in:
    - Repayment of Federal Funds Received
    - Receiving Reduced Federal funds
    - Jeopardizing the receipt of future Federal funds

- Payroll Cost Transfer Hard Edit
  - Implementation Target - September 2009
Cost Transfer Updates

- Avoid Unnecessary Cost Transfers
  - Charge appropriate fund initially
- Review financial ledgers monthly to facilitate timely discovery of errors
- Provide appropriate justifications
  - How did the error occur?
  - Tie cost benefit to award being charged
  - Why >120 days? What measures are being taken to insure no reoccurrence?
- Frequency of cost transfers may be an indication of poor award management
Cost Transfer Updates

- Enhancements to current NPEAR process
  - Answer 4 questions
    - Why is the transfer being made?
    - Why it was originally charged to the fund being credited?
    - How was it determined that this expense belongs to the acct/cc/fund now being charged?
    - Reasons for the delayed action if adjustment is made after 120 days
  - Ability to save and forward rejected journals (WIP#) so departments do not have to re-enter the transaction if resubmitting
Recovery Fund Updates

- **Awards**
  - 6 Awards received – totaling $3,794,860
    - 1 NPI
    - 1 Dentistry
    - 2 Microbiology, Immunology & Molecular Genetics
    - 1 Pediatrics
    - 1 Neurology

- **ARRA flag**
  - Indicator on Synopsis
  - Moving to R-net QDB

- **ARRA Post Award Team**
  - Brian Atienza – team lead
    - batienza@research.ucla.edu X 43145
OPRS Human Research Protection Program: Revised Post IRB Approval Reporting Requirements

Sharon Friend
Director of OPRS Operations
May 14, 2009
Overview

- Why the Change?
- What’s Required
- What and When to Report
- Case Studies
Why the Change?

- Revised Federal Guidance
  - OHRP
  - FDA Guidance

- Association for the Accreditation of Human Research Protection Programs (AAHRPP) Guidance
What’s Required

Federal regulations require the “prompt reporting to the IRB, appropriate institutional officials, and the department or agency head of any unanticipated problems involving risk to subjects or others”

45 CFR 46.103(b)(5)
21 CFR 56.108(b)
What’s an Unanticipated Problem?

Any event, experience or outcome that meets *all* of the following criteria:

- Unexpected
- Related or possibly related to participation in the research
- Suggests that the research places subjects or others at greater risk of harm than was previously known or recognized
What happens beyond reporting of unanticipated problems?

An unanticipated problem usually requires consideration of modifications to:

- the research protocol,
- informed consent documents, or
- other corrective action to protect the safety, welfare, or rights of subjects
What is different now?

- **Focus** in on the unexpected events

- **IRB Guidelines** now require both
  - Fewer adverse event and violation reports and
  - Additional updated safety reports

- **New Forms** for reporting
  - Adverse Events (Internal and External)
  - Protocol Violations, Deviations and Incidents
  - Other Safety Reports
What is the goal of reporting?

- Protect the safety, rights and welfare of human research subjects
- Ongoing evaluation of the risks and benefits of the research
- Ensure that adequate safeguards are in place
- Inform subjects of any significant new information that may alter their decision to participate in the research
What to Report

- The following events meet the definition of unanticipated problems:
  - Protocol Violations or Deviations—intended or accidental
  - Protocol Incidents, including subject complaints
  - Adverse events

- Updated Safety Reports (DSMB Reports, Audit Reports, Revised Investigator Brochure, Notification of Sponsor Suspension…)

Unanticipated Problems (UPs)

- Violations
- Deviations
- Incidents

Unanticipated Problems

- Adverse Events
- Updated Study Safety Information
When to Report

- **10-day** Reporting Requirements
  - Adverse Events that are UPs
  - Protocol Violations or Incidents that are UPs
  - Updated Safety Information

- **5-day** Reporting Requirement
  - Protocol change to eliminate immediate hazard to subjects
When to Report (continued)

- **2-day** Reporting Requirements
  - Internal on site death PI determines to be unexpected and related or possibly related

- **Continuing Review**
  - Violations, deviations or incidents that are not unanticipated problems
  - Brief narrative summary of adverse events

- See *Summary Sheet* on website
Case #1: Should this be reported to the IRB?

A subject is enrolled in a trial evaluating an investigational device versus standard of care for carotid artery stenosis and recent transient strokes. After the device placement the subject suffers a stroke. The consent form lists a 5-10% chance of stroke as a risk. The DSMB attributes the event to the study device. To date 2 out of 20 subjects have suffered a stroke.
Case #2: Should this be reported to the IRB?

The PI is notified by the study sponsor that the dose used in one of the study arms is found to cause increased toxicity to subjects. The sponsor instructs the PI to immediately transfer subjects to another study arm and to perform additional safety tests.
Case #3: Should this be reported to the IRB?

An investigator conducting social-behavioral research on college students collects personal identifiable sensitive information. The data is stored on a laptop. The computer is stolen.
Case #4: Should this be reported?

A researcher is conducting a study that involves surveys of sexually risky student behavior. On the evening of the survey, one of the students who participated in the study experiences an asthma attack requiring a visit to the ER.
Questions? More Information?

- Call Bette Okeya at 310-206-2040
- E-mail bokeya@oprs.ucla.edu
- E-mail gcirb@oprs.ucla.edu
Announcement from the Office of Clinical Trials

Vikki Jenkins
Director
May 14, 2009
Questions and Discussion