Research Administrators Forum
Sponsored by
The Office of Research Administration
March 19, 2009
Marcia Smith
Associate Vice Chancellor
for Research

Agenda
- Welcome
- Updates from ORA Leadership
- Updates from RPC Leadership
- Updates from OCT Leadership
- Questions and Discussion
- Adjourn

Extramural Fund Management
Evelyn Balabis, Director
Fund Management

- Backlog Project Update
  - Financial Report Submission
  - Invoice Submission

Financial Reporting Statistics

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Invoicing Statistics

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Fund Management

- Invoicing
  - Add to ORA Web Portal
    - Adding payment information
    - Potential receivable concerns

Cost Transfers

- A-133 Audit finding
- Monitor Research Awards Monthly
- NPEAR
  - On-line Process 120 day transactions
  - Explanations should include why error occurred, why discovered late and future actions to prevent reoccurrence
- Payroll
  - Fatal Warning is coming to prevent payroll transfers after 120 days. Clean up now!

Effort Reporting

- Recently Upgraded to ERS version 9.3
- Consequence Letter Status
  - Waiting for Academic Senate Approval
- Website Development
  - Improve communication channels
  - Newsletter
  - Listserv Announcements
  - List of FAQ’s
  - Certification Cycle Schedules
Effort Reporting
- Compliance Management Reports
  - Developing management reports to include certification completion percentage with drill down capability.
- Developing more Robust Training
  - What is Effort Reporting?
  - Understanding and using the system tool - ERS

OPRS Quality Improvement Program
Judith L. Brookshire, Director

Human Research Protection Program
- Quality Improvement Program (QIP)
  - On-site review of human research studies
  - Research participant’s experience report
  - Review and assessment of HRPP operations and procedures
  - Evaluation of IRB member and IRB staff performance
HRPP QIP Coordination

- Coordinates Activities with other Quality Assurance/Improvement Units on Campus
  - UCLA School of Medicine Quality Assurance Program
  - UCLA Office of Compliance and Privacy
  - Jonsson Comprehensive Cancer Center Internal Quality Assurance Program
  - Department of Medicine Clinical Trials Compliance Office
  - GCRC Office of Research Participant Advocacy

On-Site Review of Human Research Studies

- QI On-Site Routine (not for cause) Review
  - PI’s understanding and compliance with regulations and policies
  - Effectiveness of resources
  - Identification of current trends in practice
  - HRPP educational program

- QI On-Site Directed (for cause) Review
  - Determinations necessary to protect subjects
  - HRPP educational program

- QI Reports to the IRB
  - Determinations to correct deficiencies
  - HRPP educational programs

Post-Approval Reporting (PAR)

- New Guidance and Procedures
  - Consolidates previous policies addressing biomedical adverse event reporting, violations and incidents
  - More definitive submission criteria for reporting adverse events, violations and incidents
  - New reporting requirement of updated study safety information
HRPP Collaborative Institutional Training Initiative (CITI)

- Nationally recognized
- Online web based training program
- Education modules and quizzes relevant to research and discipline
- Replaces current online training and certification requirements
- April 1, 2009 implementation
- September 1, 2009 all key research personnel must complete
- HRPP/OPRS training and education

Animal Research Oversight Quality Improvement Program (QIP)

- ARC/DLAM Educational Meetings
  - Review ARC policies and DLAM procedures
  - Increased communication
  - Decrease in number of serious noncompliance
- ARC QIP Site Visits
  - Post approval onsite (not for cause) review of animal research protocols and facilities
  - Assure that experiments conducted in the lab match those described in the approved protocol
  - Identify/Correct “protocol drift”
  - Reports may go to the ARC if deficiencies are found
  - QIP Site Visits do not replace semiannual facility inspections

ARC Collaborative Institutional Training Initiative (CITI)

- Online web based ARC General Certification course and quiz
- Replaces current didactic ARC General Certification requirement
- April 1, 2009 implementation
  - By September 1, 2009, all personnel listed on protocols must be recertified if more than 3 years, and
  - September 1, 2009 all previously exempted personnel must be certified
- ARC/OPRS training and education
OPRS Office Hours at Outreach Campus Locations

- MIRB: Mondays, noon to 4PM: Center for Health Sciences (CHS) Building, Room 14-214K. (contact Michele Carter, mcarter@oprs.ucla.edu)
- ARC: Fridays, 10:00am to noon: Center for Health Sciences (CHS) Conference Room B3-143. (contact Kathy Wadsworth, kwads@oprs.ucla.edu)
- GIRB: To be announced (contact Alison Orkin, aorkin@oprs.ucla.edu)

OPRS Human Research Protection Program: Improvements Plan Rollout

Sharon K. Friend, MS, CIP
OPRS Operations Director

Why Now and How?

- As a result of faculty input
- In preparation for WebIRB
- As part of accreditation requirements
- Roll out in three phases
- Over next four to six weeks
- Feedback welcome
Phase I

- Improved OPRS Human Research website
- Updated policies and guidance posted
- Revised Exempt Certification Forms
- Revised social/behavioral consent templates
- PI Self Certification Form for Non-Human Subject Research Determination
- Revised post approval reporting forms and decision trees: adverse events, violations and incidents, other updated safety information

Phase II

- Elimination of the requirement for IRB “administrative” approvals for
  - grants with indefinite plans for the use of human subjects at the time of grant award (e.g., training grants) and
  - for grants with multiple protocols that each have their own IRB approval (e.g., program projects or center grants)

Phase II (continued)

- Revised Continuing Review form
- New Application for Studies Involving No Subject Contact
- Dedicated IRB staff for expedited processing of studies that qualify for expedited review
- Surveys posted for Researchers and Research Participants to elicit feedback
Phase III

- Revised HS-1, divided into two versions
  - Social Behavioral/Health Services
  - Biomedical
- Application Supplements
- 34 more translations of Bill of Rights
- Posting of IRB approval packets on the Office of Research portal

ORA Online Resource Center Update

March 2009 RAF
Jackson Jeng, ORIS

Background and Purpose

- Official launch communicated via July 30th memo from VC for Research, Dr. Roberto Peccei
- Web-based portal for UCLA’s research community, accessible on and off-campus via any web browser at http://portal.research.ucla.edu
- Single sign-on enabled, which means a separate user name and password are not required. However, some reports/tools are secured and require users to log in.
- Provide faculty, administrators and staff with a single point of access to both existing and new research-related information and resources
- Create a simple, seamless user experience for all research administration online tools
- Enhance overall communication between campus and central administration
Portal Usage Statistics – Visitors/Month

From June 2008 – February 2009
✓ Average: 1,026 visitors per month

Portal Usage Statistics – Top Content

The following Portal reports/tools are most frequently viewed:
✓ Award Statistics Reports
✓ Fund Expiration Report
✓ IRB Protocol Review Status
✓ Overdue Financial Status Reports

In the Pipeline

Several new reports are currently under development and coming soon:
✓ Award Statistics by Sponsor (ORA) – View and search for award statistics by sponsor type and name
✓ EFS Certification Rates Report (EFM) – Monitor certification completion rates, report counts and statuses by organizational hierarchy
✓ Invoice Due Report (EFM) – View Overdue, Completed and Upcoming Invoices due and their statuses; similar to existing FSR Due report
✓ Online Award Documents (OCGA) – Sponsor award documents will be scanned and viewable online via the Award Status & Synopsis Report
✓ Online IRB Approval Documents (OPRS) – IRB approval notices will be scanned and viewable online via the IRB Protocol Review Status Report
Contact Us

- Email portal@research.ucla.edu with:
  - Access requests (*except for the FSR Due report)
  - Support issues
  - Questions
  - Bug/error reports
  - Suggestions for enhancements
- We welcome your feedback and suggestions for improving the Portal.

Recent Enhancements

Look for the icon

Recent Enhancements

New info banner highlighting enhancements
Recent Enhancements

Click to compare against prior year.

Prior year’s data appears in highlighted columns.

Click to compare against prior year.
Recent Enhancements

Recent Enhancements

Other Updates

- Research Policy and Compliance
  - Ann Pollack, Assistant Vice Chancellor

- Office of Clinical Trials
  - Vikki Jenkins, Director
Research Policy & Compliance

Ann Pollack
Assistant Vice Chancellor – Research
March 19, 2009

Revisions being made...

- UCLA Policy 993 (Research Misconduct)
- UCLA Procedure 925.3 (Conflict of Interest)
- UCLA Policy 920 (RAS)
- UCLA Policy 913 (Disposition of Unobligated Balances)
- SBIR/STTR Guidance
UCLA Office of Clinical Trials:
Organization Chart

UCLA Office of Clinical Trials:
Key Responsibilities

- Contracting (limited to industry-funded clinical trials, no federal grants)
- Budgeting (and Device trial matters)
- Facilitation-oriented services:
  - Protocol feasibility
  - Pre-award process navigation help
- Training
  - Formal classes & ad hoc
  - Study coordinator mentoring
- Support services
  - Study coordinator pool
  - Regulatory submissions assistance
- Outside IRB pilot program (WIRB)
- Quality Review Program (Friendly, educational reviews focused on GCPs)

UCLA Clinical Trials Office:
OCT Website

- www.clinicaltrials.ucla.edu
  - For Faculty/Staff
    - One-stop for industry-funded clinical trial pre-award process information
    - Restricted to internal to UCLA – special log-in credentials required to access
  - For Patients
    - Post Your Trials for Recruitment purposes
    - The site averages over 6,000 hits per month
UCLA Clinical Trials Office:
Key Contacts

- Introducing New OCT Staff
  - Regulatory/IRB submission services – Augustine Fernandes
  - SOM Dean’s Office Clinical Trials Quality Review Program Administrator – Denise Rock

- Know Your OCT Contacts:
  - Contracting contacts
  - Facilitation/Budget review contacts
  - IRB Submissions services (nominal fee)

1) Ophthalmology/Jules Stein, Urology-except Clinical Trials for Dr. Leonard Marks- see Vicki Christodoulou
2) Dentistry, Obstetrics/Gynecology
3) Clinical Nutrition, Digestive Disease/CURE Clinic, General Internal Medicine
   1) Ann Ciminera
   2) Carli Rogers
   3) Helene Orescan

1) Geriatrics, Pulmonary
2) Rheumatology, Care Center, Dermatology
3) Infectious Diseases
   1) Ann Ciminera
   2) Carli Rogers
   3) Helene Orescan

1) Anesthesiology, Family and Preventative Medicine, Nursing, Pathology, Physiology, Public Health, Nephrology, NPI, Psychiatry, Urology-Clinical Trials for Dr. Leonard Marks only
2) Neurology
3) Immunology and Allergy
   1) Ann Ciminera
   2) Carli Rogers
   3) Helene Orescan

1) Hematology-Oncology, Pediatrics
2) Cardiology, Pharmacology, Radiation Oncology, Radiological Sciences, Emergency Medicine
3) Orthopedic Surgery, Surgery
4) All Device Trials
   1) Helene Orescan
   2) Carli Rogers
   3) Ann Ciminera

4) Depends on Dept/Div.

Vicki Christodoulou, B.S., M.S.
vchristodoulou@mednet.ucla.edu
310 794-8953

SOM Dean’s Clinical Trials Quality Review Program

- Designed as a friendly, educational oriented review program, rather than a monitoring, compliance audit, or for-cause audit program
- Limited to clinical research not covered by another QA or QI program (i.e., will not duplicate cancer center, & GCRC QA program efforts)
- Spans all categories of sponsorship (e.g. NIH, industry, non-profit, internally funded)
- Focuses on “higher risk” studies
- Covers key areas of study conduct, primarily:
  - High-level ICF process
  - Protocol compliance
  - Regulatory documentation
  - Other areas of concern

- Report findings and recommendations are approved by the School of Medicine Clinical Research QA Committee and sent to PI and Dept. Chair and now also to the IRB
- When significant findings arise that require reporting to the IRB or an actual audit or for-cause investigation, these will be referred to the IRB, the Compliance office, or others appropriate to determine next action as required

Subject to change – check OCT website often: www.clinicaltrials.ucla.edu

Virginia Anders, Acting Director, OCGA
Evelyn Balabis, Director, EFM

Recovery Act Basic Funding

- NIH: $10.4 Billion
- NSF: $3.0 Billion
- DOE, Office of Science: $1.6 Billion
- ARPA-E: $400 Million
- NASA: $550 Million
- DOD, Energy-Related R&D: $200 Million
- NIST: $180 Million
- PLUS – Additional funds for the IGs and GAO

ORA is Preparing by:

- Adding temporary staff
- Preparing computer workstations
- Helpline
- Posting these slides
- Setting up a FAQ, as well as important ARRA links on OCGA’s web site.
Timeline

- Federal agencies must launch ARRA website by March 20, 2009.
- First big deadline is the NIH Challenge grant—due April 27, 2009.
- Federal agencies must post their spending plan by May 1, 2009.
- Federal agencies must have disbursed their funds by September 30, 2010.

UCLA expects a surge in research activity as well as...

- Construction grants
- Equipment grants
- Community policing grants
- Many areas on campus will be involved
- All Federal agencies involved
- May have flow down funds through State and local governments and other non-profit entities.

Deadlines

- We suggest that you establish internal deadlines in your department.
- Please notify OCGA of pending proposals as soon as possible to enable us to marshal appropriate staffing resources.
Concerns with Grants.gov
- OMB memo of March 9 regarding Grants.gov and other critical systems
- Federal funding agencies advised to examine alternatives
- Department of Energy has suspended use of Grants.gov for submissions (eff. 3/12/09)
- FastLane available for NSF
- NSPIRES available for NASA

Strongly encourage submission of proposals through S2S-Cayuse if it supports the agency to whom you are applying
- Real-time error checking
- Ability to generate hard copy or electronic copy (PDF) for alternate transmission to sponsor
- Give faster submission and receipt of proposal

Establish “placeholder” in S2S Grants
At minimum, include:
- Proposal name (using proper convention)
- PI name and Deadline date

Naming Convention:
FML: initials of grant analyst or DRA
Bruin, J = PI last name, first initial
RFA-OD-09-003 = funding opportunity number (FOA)
Sample for RAF = descriptive information for preparer/PI
S2S-Cayuse

- Additional hands-on training
  - Wednesday, April 1, 2009
  - 8:30 a.m. – 12:30 a.m.
  - CLICC classroom
  - Seating limited
- Drop-in open house sessions
- Watch ORA List-serv for announcements

First Big Deadline is for NIH Challenge Grants
Deadline: Monday, April 27th

May submit as early as March 30th

Friday March 27 is UCLA’s Observance of Caesar Chavez Day
(State observance is March 30th)

NIH Challenge Grants

- Complete proposal packages must be in OCGA no later than 8:00 am on Tuesday April 21st (5 working days before the deadline to ensure submission)
NIH Challenge Grants

- Complete proposal package includes:
  - signed goldenrod
  - ready-to-submit proposal
  - 740 if required
  - PI exception letter if needed
  - a signed PI statement
  - complete subaward proposal

NIH Challenge Grants

- Budget Preparation
  - Requires a detailed budget
  - F & A waivers not generally considered
  - Foreign Subawards – not more than 10% or up to $25,000 in aggregate may be budgeted

NIH Challenge Grants

- Outgoing subawards may not provide “quick-start activities”
- RC1 awards count as substantial funding for New Investigator/ESI eligibility
- Additional support staff may be justified due to complexity of reporting and administrative requirements
Resources for S2S Grant Users

- S2S Grants Login: https://s2sgrants.research.ucla.edu
- S2S Grants Resources: http://www.research.ucla.edu/oega/S2SGrantsInfo/index.htm

Links to important government websites related to ARRA

- Recovery.gov - Searchable database of how and where tax dollars are spent as a result of the ARRA
- Agency Recovery site links
- American Association for the Advancement of Science report regarding ARRA
- National Institutes of Health
- NIH statement regarding the ARRA
- National Institute of General Medical Science
- National Center for Research Resources
- National Science Foundation
- Department of Defense
- Department of Energy
- NASA
- National Institute of Standard and Technology

Looking Forward...

- All contracts will be awarded as fixed price
- More deadlines throughout the year
- Some other agencies have deadlines posted - many will by March 20th
- Currently Dept of Energy has an 4-27 deadline as does EPA
- Some NASA programs are starting to post
More Information

- Check the OCGA website for more information - we will share as it as it becomes known.

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Post Award

- EFM is Preparing by:
  - Setting up Recovery Act Indicator
  - Template development which includes ARRA specific Terms and Conditions
  - Cross training iPAS staff on eRAS processing
    - eRAS processing requires a backup fund number
  - Delays caused by:
    - Lack of Account or Cost Center (CC)
    - Account not linked to the Cost Center

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Award Processing

- Recovery Act Awards will have priority status in processing – still requires overnight to obtain fund number
- Very Important to provide complete information on the Goldenrod – this will help avoid delays
Post Award Requirements

- Reporting details and mechanism are still being developed by government agencies
- Due dates: Not later than 10 days after the end of each calendar quarter – starts with the quarter ending 6/30/09 and reporting by 7/10/09.
- Quarterly financial reports will have to be ledger based to meet the 10 day reporting deadline

Requirements, continued

- Monthly monitoring and review of expenditures and progress is critical to successful compliance
- Departmental / PI Responsibility Reporting Requirements
  - Description of the project or activity
  - Evaluation of the completion status of the project or activity
  - Estimate of the number of jobs created and the number of jobs retained

Requirements, continued

- 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)
- Specific Instructions for reporting, including required formats, and mechanisms will be provided in subsequent guidance
Other Terms and Conditions

- Buy American
- Wage Rate Requirements – Prevailing rates based on Secretary of Labor
- Preference for Quick Start Activities (ARRA) – recipients shall give preference to activities that can be started and completed expeditiously, including a goal of using at least 50% of the funds for activities that can be initiated not later than 120 days after the date of the enactment of ARRA. Maximize job creation and economic benefit.

Questions?