Research Administrators Forum

Sponsored by
Office of Research Administration

Marcia Smith
Associate Vice Chancellor
Research Administration

October 8, 2009
Agenda

Welcome
Marcia Smith, Office of Research Administration

Update and Progress on ARRA Reporting
Evelyn Balabis, EFM

Update from Office of Animal Research Oversight (OARO)
Kathy Wadsworth, OARO

Update from Office of the Human Research Protection Program (OHRPP)
Sharon Friend, OHRPP

Research Policy and Compliance: COI, Clinical Trial Registration, NSF RCR
Ann Pollack, OVCR, Research Policy and Compliance

RAPID Project Update – Financial Reporting Team
Evelyn Balabis, EFM
Keith Steele, Pediatrics
Maurice Taylor, EFM
Rory Constancio, Graduate School of Education and Information Studies
Neda Navab, School of Medicine

Questions and Discussion

Adjourn
ORA Update

Upcoming FEP Deadlines

- SOM and Fiscal Year Appointees:
  - Due today to OCGA for Fall Quarter payroll deadline of October 12th

- Academic Year Appointees:
  - Due November 9th to OCGA for Winter Quarter payroll deadline of November 13th

ORA offices closed for service on November 25th
ARRA REPORTING UPDATE

Evelyn Balabis
Extramural Fund Management
ARRA REPORTING UPDATE

- 249 ARRA Reports have been submitted
- 13 ARRA Reports submitted to Prime Institution (UCLA as a sub)
- 3 remaining with issues

Due to the high volume, we are not sending individual confirmations of report submission. The information will be available on the recovery.gov website at the beginning of November.
ARRA REPORTING UPDATE

- Lessons we are Learning
  - Report submission is based on issue date.
  - Watch your logic on the submissions – status of “not started” should not have jobs or expense.
  - Careful when you cut and paste the award and project descriptions – sometimes this is creating symbols.
  - Make sure you complete the process by clicking the “submit to EFM” button we got a few that had updated status but not submitted.
THANK YOU!

- Great response from the campus – on 9/30/2009 we had over 90% submission!
- For the ones that came in and were set up after 9/30 campus units responded and submitted the reports quickly.
Animal Research Administration Updates

Kathy Wadsworth
Director,
Office of Animal Research Oversight (OARO)
Update #1:

- OPRS-ARC is now the **Office of Animal Research Oversight**

- Reflects the mission of our office:
  - Support the ARC
  - Compliance, inspection, education & outreach
Sample RATS Protocol

ARC Applications

- ARC Submission Deadlines
- Online Protocol Submission (RATS)
- Eligibility as Principal Investigator
- Veterinary Consultation
- Pre-Committee Review
- ARC Certification
- Supplemental Forms:
  - Medical History Questionnaire Form
  - Medical History Questionnaire Waiver Form for Visitors
  - Registration of Transgenic Rodents
- VA/UCLA Memoranda of Understanding (MOU)
- Resources for Investigators:
  - Estimating the Number of Animals
  - Search for Alternatives
  - How to Write an Application Involving Research Animals
  - Sample RATS Protocol

ARC Submission Deadline

Applications must be submitted to the ARC no later than the submission deadline. The ARC usually convenes twice per month, and the deadline for submission is generally 17 calendar days prior to a meeting. (Meeting dates and deadlines are subject to change and will be promptly posted when changes are necessary.)
New Lab Member Checklist

1. ARC Training/Certification Program
2. CITI Online Training
3. Other Campus Training Programs
   - Division of Laboratory Animal Medicine (DLAM)
   - Office of Environmental, Health, and Safety (EH&S)
4. Frequently Asked Questions
5. Resources
6. New Lab Member Checklist

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New Lab Member Checklist

Please complete the following. You MUST be signed off by your supervisor before you may touch an animal. Be aware, you will need a Brain ID number to email some of these classes.

- **DLAM Training:** [http://dlam.ucla.edu/training/courses.html](http://dlam.ucla.edu/training/courses.html)
  - Mouse Users Wet Lab (to work with mice)
  - Rat Users Wet Lab (to work with rats)
  - Species Specific Users Wet Lab (to work with other species)
  - General Barrier Training (to work in the barrier facility)
  - Anaplastic Surgical Techniques (for surgical procedures)
- **ARC Certification:** [http://www.cprc.ucla.edu/services/certifications.html](http://www.cprc.ucla.edu/services/certifications.html)
  - General Certification (CITI Program Training)
- **UCLA Health surveillance program (not a class):**
  - Fill out a Medical History Questionnaire (MHQ) online: [https://portal.uclahealth.org](https://portal.uclahealth.org)
- **Review of the animal use protocol:**
  - All research personnel should read each animal use protocol in which they will be listed and fully understand all procedures in which they will be involved.
  - Once you have completed all parts of the required classes, please take this checklist to your supervisor and ask further to add you to the protocol. Your supervisor will sign this checklist once the ARC approves you to work with animals.

In addition to the above, you may be required to take the following from the Office of Environmental, Health, and Safety:

- **Online Safety Training:** [http://oesonline.ucla.edu/login](http://oesonline.ucla.edu/login)
  - Biological Safety Cabinet, Biosafety Level 2, and Medical Waste Management (required for use of any biological materials)
  - Bloodborne Pathogen Standard Training (if handling human materials such as human cell lines)
  - Hazardous Chemical Waste (for handling hazardous chemicals)

Other classes may be necessary depending upon your work within the lab (for example, Radiation Safety, Barrier Training, etc.). Please make sure you have completed all necessary training before beginning work.

**Supervisor’s Signature:**

Date: ____________________

I hereby confirm that I have checked (T) to ensure that the ARC has approved this person to work with animals in this protocol.
Director Kathy Wadsworth
Assistant Director Andy Perkins
ARC Administrator Jennifer Perkins
ARC Compliance Coordinator Rosa Harmon
ARC Coordinator Karen Womack
ARC Specialist Annie Ryan

x66308
arc@oprs.ucla.edu
http://www.oprs.ucla.edu/animal
Human Research Protection Program Updates

Sharon Friend
Director
Office of the Human Research Protection Program
October 8, 2009
OHRPP Commitments

- To promote and facilitate the protection of the safeguards and rights of human subjects in research
- To support and facilitate the conduct of human research
- To develop and improve OHRPP program transparency, efficiency, and consistency
The OHRPP Is > the IRBs

OHRPP Director

IRBs: 2 General Campus And 3 Medical

Education and Quality Improvement
OHRP Circle of Protection and Continuous Quality Improvement

- IRB Review
- Education and Training
- Post Approval and Quality Improvement Activities
Activities of the Quality Improvement Unit

- Reviews and processes post approval event reports
- Conducts routine and for-cause site visits
- Provides on-site targeted education and training
- Investigates allegations and reports of noncompliance and works with investigators to prepare reports for review by the IRB
- Audits activities of IRB
Activities of the Education and Training Unit

❖ On-Line and Printed Materials:
  ▪ webIRB Project
  ▪ CITI On-Line Training
  ▪ HRPP Website
  ▪ Human Research News

❖ In-Person Training
  ▪ Weekly On-Campus Consults (3x/week ⇒ 5)
  ▪ Monthly Brown Bags at Kinross: How to Prepare an IRB Application
  ▪ Monthly Campus Presentations on General Topics (in development)
  ▪ Presentations upon Request
Results of Revised Applications and Revised Process for Expediting Expedited Studies

- **Increased**
  - number of questions asked up front to PIs

- **Decreased**
  - length of correspondence back to PI
  - number of deferrals
  - turnaround times to approval
OPRS Metrics

New Protocols, Expedited: Volume and Turnaround Times

- New Protocols - Expedited Volume Approved
- New Protocols - Expedited Turnaround Time (Complete Submission to Final Approval)
- New Protocols - Expedited Turnaround Time (Complete Submission to First Action)
Director: Sharon Friend
Assistant Directors:
- Alison Orkin, GC IRBs
- Alisa Irwin, MIRBs
- Quality Improvement, Bette Okeya
- webIRB and Education, Carrie Fisher

http://www.oprs.ucla.edu/human
Questions and Discussion
Research Policy & Compliance

Ann Pollack
Assistant Vice Chancellor – Research
October 8, 2009
Topics

- UCLA Procedure 925.3
- ClinicalTrials.gov adverse event reporting requirement
- NSF America COMPETES Act Implementation
UCLA Procedure 925.3

- “Disclosing Financial Interests Relevant to Federally Sponsored Contracts and Grants for Research”
- **NSF**: Disclosure required for all sponsored projects
- **Other federal agencies**: Disclosure required for sponsored research only
ClinicalTrials.gov Adverse Event Reporting

- Effective September 27, 2009
- “Responsible Party” must report adverse events when reporting or updating the results of a clinical trial
ClinicalTrials.gov Adverse Event Reporting

- “Responsible Party”
  - For PI-initiated clinical trial
    - Principal Investigator
  - For sponsor-initiated clinical trial
    - Sponsor or Sponsor’s designated Principal Investigator
NSF America COMPETES Act Implementation

Requires training in the *Responsible Conduct of Research* for all undergraduates, graduate students, and postdoctoral scholars who will be supported by NSF to conduct research.
NSF America COMPETES Act Implementation

- UCLA must have training plan in place by January 4, 2010
- Vice Chancellor for Research, Dean of Students, Graduate Division working on plan
Project Prioritization

Most sponsors require UCLA to report how money was spent during an award. Sponsor deadlines for these reports are frequently 90 days after an award end date. For some sponsors, payment to UCLA is dependent on financial report submission.

- **August 2009 Metrics**
  - 157 financial reports completed
  - 527 financial reporting in backlog (~3 months)
  - 26% submitted to sponsor by deadline over past 12 months
  - 24.6% submitted to EFM by sponsor deadline (n=459)
Project Prioritization

- Increasing volume
- Impact from ARRA (Recovery Act) awards
- Large number of late financial reports
- Large number of revised financial reports
- Backlog of 3 months
- Late reports threaten “expanded authorities” – flexible award terms -- and ultimately future funding
- Increasing complexity of reporting requirements
- Significant opportunities identified
  - Increase in efficiency for EFM and department staff
  - Improved technology
  - Improved compliance
Project Team Approach

RAPID project structure brings together central campus offices (EFM, OCGA, etc.) and campus representatives (school level, departments, fund managers, etc.) to work together in creating a solution.

- **Project Team Membership Defined**
- **Phase 1** – Evaluate Current Process
  - Further detailed analysis with project team and documentation of current process
  - Discussion and documentation of challenges related to the current process
  - Discussion and documentation of current performance metrics
- **Phase 2** – Process Design
  - Brainstorm on new and existing ideas to improve the process
  - Discussion and development of new process incorporating improvement ideas
- **Phase 3** – Action Plan
  - Discussion of steps necessary for successful change of the process
  - Development of action workplan
- **Phase 4** – Execute Action Plan
Project Organization

Functional Requirements -> Technical Requirements <-> Vetting/Communication

Testing <-> Training <-> Pilot/Rollout

Leadership Involvement/Policy Enforcement <-> Other Considerations

Project Team <-> Steering Committee
RAPID Outreach and Communication

- RAPID Faculty Advisory Committee
- RAPID Workgroups
- Monthly RA Forum Meetings
- RAPID Update Meetings
- ORA News
- RACC Meetings
- CAO Meetings
- OOC Meetings
- Department Faculty Meetings
- RAPID Web Site (in development)
- Email: RAPIDfeedback@research.ucla.edu
- ORA Portal
Core Workgroups and Team Leads

- **Functional Requirements** (Maurice Taylor, Rory Constancio)
- **Technical Team** (Terry Wingo, Edwin Riluao, Neda Navab)
- **Communication/Vetting** (Keith Steele, Evelyn Balabis)
- Testing (Terry Novorr, Brian Atienza)
- Training (Raellen Man, Maurice Taylor)
- Pilot and Rollout (Jennifer Aguilar, Raellen Man)
- Leadership Involvement/Policy Enforcement (Marcia Smith, Rory Constancio)
- Other Considerations (TBD)

**Bold** workgroups are currently active
Workgroup Membership

**ORA**
- Marcia Smith

**EFM**
- Evelyn Balabas
- Maurice Taylor
- Brian Atienza
- Christian Diaz
- Jennifer Aguilar
- Jevon Echave
- Edwin Riluao
- Willian Paja
- Winny Migletz

**Campus Representation**
- Raellen Man
- Terry Novorr
- Keith Steele
- Duy Dang
- Neda Navab
- Rory Constancio
- Michelle Phillips
- Ned Avejic
- Tonya Bester
- Nancy Blumstein
- Fleur Schultz
- Lana Song

**ORIS**
- Jackson Jeng
- Terry Wingo

**AIS**
- Jacqueline Ronen

**Huron**
- Nate Haines
- Sarah Horner
Goals and Expected Results

- Better integration of technology - SINGLE SYSTEM!!
  - Integrated data retention and historical information
  - Increased efficiency, reduced handoffs
- Standardization of the process across EFM and campus
  - Ability to track internal turnaround times for financial reports
  - Ease of training through standardization
- Efficient and accurate financial reporting
- Improved compliance and management information
- On time submission of financial reports
- Reduction of revised financial report submissions
- Improved accountability and visibility into roles and responsibilities
- Improved collaboration between EFM and campus
- Increased faculty involvement and awareness
- Culture change!
Early Initiatives

- Define EFM closeout requirements
- Standardize closeout packet/tools for schools and departments
- Eventually this closeout package will be web-based and will be a “smart form”
- Migrate 30 day reminder communications to new system
- Provide users ability to run FS reports (made available through the ORA portal) for expenses
  - After fund end date
  - On unallowable/warning object costs
  - From subcontracts/subgrants
  - From intercampus agreements
- Improve FSR due reports in conjunction with MFNOA
Next Steps

- Continue execution of action plan; involves 12 subteams; 5 are currently in action: Steering Committee, Core Project Team, Functional Team, Technical Team, Vetting/Communication
- Complete Early Initiatives (all are in process)
- Communication and Vetting
How Can I Be Involved?

- There will be a need for testing/piloting products-please volunteer!!
- Again, we need as much help, from as many people to make this project be successful
- Contact us at RAPIDfeedback@research.ucla.edu