Research Administrators Forum

Sponsored by the Office of Research Administration

Marcia Smith
Associate Vice Chancellor

April 14, 2011
Agenda

- Welcome and Announcements
  - Marcia Smith

- OARO Update
  - Kathy Wadsworth (OARO)

- OHRPP Update
  - Sharon Friend (OHRPP)

- OCGA Update
  - Patti Manheim (OCGA)

- Proposal Submission – Unallowable Costs
  - Cindy Gilbert (OCGA)

- RAPID Effort Reporting Compliance Initiative
  - Marcia Smith (ORA)
  - Shannon McGarry (IRLE)
  - Greg Swindell (EFM)

- Give ‘em the Pickle
  - Jackson Jeng (ORIS)
ORA/RAPID Updates

PI Tools Deployed
- RAPID Faculty Advisory Committee
- PI Fund Expiration 90-Day Notice
- PI Portal Roll-Out with Projections

Federal budget debate and threat of government shutdown

RA Forum Evaluation Form
Animal Research Administration Update

AAALAC is Coming !!!

Kathy Wadsworth
Director
Office of Animal Research Oversight (OARO)
AAALAC Accreditation site visit coming up July 2011

- Association for Assessment and Accreditation of Laboratory Animal Care, International
- Private, non-profit, NOT subject to FOIA
- Peer-Review every 3 years
- Required by UCOP
The Accreditation Visit ...

- 3-4 site visitors.
- *Carte blanche* to inspect all animal facilities, including study areas and surgery locations.
- Review at all records, i.e., ARC minutes, protocols, surgery records, monitoring records.
Decision to Accredit …

- Findings brought before the AAALAC Council.
- Outcomes:
  - Full Accreditation
  - Conditional Accreditation
  - Probation
  - Revoke Accreditation
What can you do to help your lab prepare ...

- Let your lab know that AAALAC is coming in July.
- Encourage your lab to attend the AAALAC town hall meetings (May/June).
- Schedule an OARO/DLAM Lab meeting prior to AAALAC.
The Reward …

The Council is pleased to inform you that the program complies with AAALAC, International standards as set forth by the Guide for the Care and Use of Laboratory Animals. Therefore, continued FULL ACCREDITATION shall be awarded.”
ARC: Who to Contact at OARO?

- Kathy Wadsworth: (310) 825-5227
- OARO General line: (310) 206-6308
- OARO email: arc@oaro.research.ucla.edu
- OARO Website: http://www.oaro.research.ucla.edu
OHRPP Update

Sharon Friend, Director
April 2011
Revised Biomedical Consent Forms

- Biomedical Consent Form Template
  - General Biomedical
  - National Cancer Institute
  - Specimen Collection Planned

- Consent Form Standards and Sample Language
Purpose of Revisions

- Increased readability and ease of use for both subjects and researchers
  - Language level at \( \sim 8^{\text{th}} \) grade
  - Formatting is easier to read
- Non-Required Sections and UCLA-isms removed
- Meets national standards and best practices

*With significant input and feedback from various users.*
Biomedical Consent Form Template

- Used for > minimal risk medical studies only.*
- Provides updated look and formatting.
- Distinguishes between required and optional sections.
- Provides required and suggested language.
- Uses question and answer format.
- Is written at ~ 8th grade reading level.
- Is accompanied by the UCLA Consent Form Standards document.
- Sections link directly to standards and suggested language.

*Use Behavioral Consent Form templates for questionnaires and quality of life studies.
UNIVERSITY OF CALIFORNIA LOS ANGELES
CONSENT TO PARTICIPATE IN RESEARCH

[Insert title of the study]

[Insert a lay or working title of the study – for study participants]

INTRODUCTION

[insert name and degrees of the Principal Investigator], and associates from the [insert department affiliation] at the University of California, Los Angeles are conducting a research study.

The researchers will explain this study to you. Research studies are voluntary and include only people who choose to take part. Please take your time about deciding whether to participate in this study. Before deciding:
- You can discuss this study with friends and family.
- You can also discuss it with your health care doctor or request a second opinion.
- If you have any questions, you can ask the researchers for more information before deciding to participate.

The research team is asking you to be in this study because...

WHY IS THIS STUDY BEING DONE?

The purpose of this research study is...

The following definitions may help you understand how this research study is designed:

This study is being funded by...

HOW MANY PEOPLE WILL TAKE PART IN THIS STUDY? (optional section)

XX people will take part in this study at UCLA. About XX people will participate in this study nationwide.

WHAT WILL HAPPEN IF I TAKE PART IN THIS STUDY?

Before you begin the study:
Before you begin the study, you will need to...

During the study:
If you take part in this study, the researcher(s) will ask you to...

HOW LONG WILL I BE IN THIS STUDY?

This study will last...

WHAT KINDS OF RISKS OR DISCOMFORTS COULD I EXPECT?

Known risks and discomforts:
The possible risks and/or discomforts associated with the procedures described in this consent form include:

Unknown risks and discomforts:
The experimental treatments may have side effects that no one knows about yet. The researchers will let you know if they learn anything that might make you change your mind about participating in the study.

ARE THERE ANY BENEFITS IF I PARTICIPATE?

Possible benefits to me:
The possible benefits you may experience from being in this study include...

Possible benefits to others or society:
There will be no direct benefit to you from participating in this study. However, this study will help the researchers learn more about [procedure/drug/ intervention/ device]. Hopefully, this information will help in the treatment of future patients with [disease/condition] like yours. [Note: Do not use this statement if participants will be billed for research-related procedures.]

WHAT OTHER CHOICES DO I HAVE IF I DON'T WANT TO PARTICIPATE?

If you decide not to take part in this study, or if you withdraw from this study before it is completed, the following alternative procedures or courses of treatment are available:

CAN THE RESEARCHERS REMOVE ME FROM THIS STUDY? (optional section)

The researchers may end your participation in this study for a number of reasons, such as if your safety and welfare are at risk, if you do not follow instructions or if you miss scheduled visits. The researchers or the study sponsor might also decide to stop the study at any time.

If you decide to stop being in the study, or are removed from the study, or the study is stopped the researcher will ask you to...

HOW WILL INFORMATION ABOUT ME AND MY PARTICIPATION BE KEPT CONFIDENTIAL?

The researchers will do their best to make sure that your private information is kept confidential. Information about you will be handled as confidentially as possible, but participating in research may involve a loss of privacy and the potential for a breach in
Consent Form Standards

- Linkable from consent form template
- General formatting instructions—required and recommended
- Section-by-Section Instructions and guidance
- Sample and suggested language, for example
  - Risks associated with withdrawing from current medication
  - HIV testing risks
- Required language, for example
  - Treatment and compensation for injury
  - Use of specimens in research
- Guidance for signature lines
- Separate section for genomic research studies
OCGA Updates

Patti Manheim
Office of Contract and Grant Administration

April 14, 2011
Updates

- Outreach Opportunities
  - Contact me for staff meetings, faculty meetings, other?
    - patti.manheim@research.ucla.edu
    - jgibbs@research.ucla.edu

- ORA Address Change
  - Suite 211
  - Update Face Pages, Sponsor Forms, etc.

- Administrative Costs on Proposal Budgets
PROPOSAL BUDGETS

Major Projects and Administrative Costs

Cindy A. Gilbert
Senior Grant Analyst/eRA Coordinator
Office of Contract and Grant Administration

April 14, 2011
Direct Costs

- Personnel – salaries, wages and benefits
- Travel
- Equipment
- Supplies
- Other
  - GSR Fee Remission and NRTW
  - Patient Care
  - Animal Care
  - Services
  - Subawards
  - Consultants
F&A Costs

- Buildings and Maintenance
- Utilities
- Libraries
- General Use Supplies/Equipment
  - Computer, photocopy, paper, pencils
- Postage
- Administrative/Clerical Salaries
Direct versus F&A Costs

**DIRECT COSTS**
- Salaries
- Fringe Benefits
- Equipment
- Travel
- Subawards
- Services (Recharge Units)
- GSR Tuition Remission
- Consumable Supplies
- Patient Care Costs
- Other Direct Costs

**F&A Costs**
- Project Asst Salary
- Telephone
- Office Machines
- Business and Finance
- Utilities
- Copying Postage
- ORA
- Library
- Building Maintenance
Exceptions

- Major Projects
- Administrative/General Costs Above and Beyond Normal Support Provided by the Department
Administrative Salaries

- Examples of “major project” from Exhibit C:
  - Large, complex programs such as General Clinical Research Centers, Primate Centers, Program Projects, environmental research centers, engineering research centers, and other grants and contracts that entail assembling and managing teams of investigators from a number of institutions.
TBN, Project Assistant, 3 cal mos/year: The project assistant will make travel arrangements, set-up meetings, and prepare and distribute documents.

TBN, Project Assistant, 3 cal mos/year: This project involves investigators from four academic departments at UCLA as well as five other U.S. universities. The project assistant arrange one project meeting per year at UCLA and monthly webinars for 15 – 20 key personnel. S/he will make travel arrangements; schedule webinars; and prepare and distribute meeting materials to/from all participants. S/he will also maintain a website for efficient access to project-related manuscripts and resources by all project personnel including postdocs, technicians, and student researchers.
Examples of “major project” from Exhibit C:
Projects which involve extensive data accumulation, analysis and entry, surveying, tabulation, cataloging, searching literature, and reporting (such as epidemiological studies, clinical trials, and retrospective clinical records studies).
Miles Quare, Data Analyst, 3 calendar months/year (years 1 and 2): Mr. Quare will assist the PI and postdoc with data collection and entry.

Miles Quare, Data Analyst, 3 calendar months/year: During years 1 and 2 of the project, 375 – 400 ten-page surveys will be filled out by study volunteers. Mr. Quare will distribute surveys to participants identified by the PI and postdoc, collect completed surveys, and transfer data to the database for analysis by the postdoc. Mr. Quare received his B.S. in Statistics in 2010 and volunteered on various statistical projects in the Psychology and Physiology departments during his Junior and Senior years.
Administrative Salaries

- Examples of “major project” from Exhibit C:
  Projects that require making travel and meeting arrangements for large numbers of participants, such as conferences and seminars.
Administrative Salaries

TBN, Project Assistant, 1.2 calendar months: The project assistant will make travel arrangements; prepare vendor payments, and monitor budgets.

TBN, Project Assistant, 1.2 calendar months: The conference will take place over four days San Antonio, TX and 290 – 325 attendees from North America. The project assistant will prepare and distribute registration materials; arrange and prepare reimbursements for travel for the program committee and keynote speakers; work with venue staff to plan meeting rooms, AV needs, block rates, and catering; and monitor budgets and spending.
Examples of “major project” from Exhibit C:
Projects whose principal focus is the preparation and production of manuals and large reports, books and monographs (excluding routine progress and technical reports).
Administrative Salaries

**TBN, Project Analyst, 1 calendar month/year:** We are requesting a modest 1 calendar month per year for a project analyst to perform project-specific work such as preparing, editing and submitting project reports and deliverables and monitoring budgets and expenditures.

**TBN, Project Analyst, 1 calendar month/year:** The project analyst will assist the PI with design, layout and content of bi-monthly nutrition newsletters for hard-copy and electronic distribution to 50 low-cost women’s clinics in Los Angeles county. S/he will also maintain mailing and distribution lists, and monitor the expenditures and budget related to newsletter publication and distribution.
Administrative Salaries

- Examples of “major project” from Exhibit C:

  Projects that are geographically inaccessible to normal departmental administrative services, such as research vessels, radio astronomy projects, and other research fields sites that are remote from campus.
TBN, Administrative Specialist, 6 calendar months (years 1 and 2): The specialist will coordinate payroll, purchasing and travel functions; prepare and distribute correspondence and manuscripts; schedule meetings and monitor budgets.

TBN, Administrative Specialist, 6 calendar months/year: This project involves the full time effort of six researchers at the Toolik Field Station in Alaska in years 1 and 2. An administrative specialist is requested to coordinate administrative functions for these researchers including coordination of payroll, purchasing and travel functions; preparation and distribution of correspondence and manuscripts; scheduling, and monitoring of budgets. S/he will attend bi-weekly departmental staff meetings with administrators at the UCLA campus via webinar and with the PI as necessary.
Administrative Salaries

- Examples of “major project” from Exhibit C:
  Individual projects requiring project-specific database management; individualized graphics or manuscript preparation; human or animal protocols; and multiple project-related investigator coordination and communications.
Administrative Salaries

TBN, Administrative Specialist, 1.5 calendar months/year: The administrative specialist will assist with preparation and coordination of IRB approvals.

TBN Administrative Specialist: The proposed clinical study will recruit patients from 60 hospitals in Southern California. The administrative specialist will assist the study coordinator in collecting IRB approvals for all sites and informing the UCLA PI, study coordinator, and site PI when update or renewal of protocol(s) are required so that no lapses in IRB approval occur. S/he will also assist the coordinator with entry of applications/updates in the UCLA Web IRB system.
Administrative Salaries

- When preparing budget justifications that include administrative salaries
  - be specific and detailed as to how the project meets the criteria for major projects;
  - provide sufficient detail and/or explanation to hold up under scrutiny of a sponsor or auditor, or both;
  - provide programmatic justification for the position.
- Consult with OCGA or EFM.
Questions?
Effort Reporting System

- Greg Swindell
  Assistant Director, Compliance and Cash Flow
  Extramural Fund Management

- Shannon McGarry
  Chief Administrative Officer
  Institute for Research on Labor and Employment
Effort Reporting Metrics

As of 4/13/11

 Completion Rates at UCLA
 - 72% certification rate for Summer 2010
 - 92% certification rate on Campus

 Open Reports
 - Currently 9,321 open reports out of 120,313
 - 953 reports are in Certified/Adjustment Required status
 - 145 reports are Partially Certified
Effort Reporting System will be offline from 6PM Thursday, April 14 through Sunday, April 24 for report generation and testing.

Effort Reporting Issue Dates and Deadlines for Certification

- The Fall 2010 and Winter 2011 Quarters will be released simultaneously.

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<tr>
<th>Quarter</th>
<th>Scheduled Release Date</th>
<th>Projected Due Date</th>
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<td>Fall 2010</td>
<td>April 25, 2011</td>
<td>July 22, 2011</td>
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ERS Workgroup Update

- Workgroup focus on certifying reports Winter 2009 – Current
- NEW Open House – May 5, 2011 10AM - 12:00PM
  Please bring your questions related to effort reporting. We will have our Effort Reporting Working Group team members on hand, with special expertise including, but not limited to, the following topics:
  - Certified/Adjust Reqd Reports
  - 9/12 Summer Salary and Effort
  - Multi-Line Certification
  - Negative Effort Reports
  - Exception Reports
  - Howard Hughes Medical Investigator

Questions in the meantime? Contact ershelp@research.ucla.edu