Research Administrators Forum

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Office of Research Administration

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April 16, 2009
OPRS Human Research Protection Program: AAHRPP Site Visit and HRPP Improvement Plan Update

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Association for the Accreditation of Human Research Protection Programs

- The Association for the Accreditation of Human Research Protection Programs, Inc. (AAHRPP) promotes and recognizes high quality Human Research Protection Programs—worldwide.

- To earn accreditation, organizations must provide tangible evidence — through policies, procedures, and practices — of their commitment at all levels of the organization
  - not only to protect rights and welfare of research participants
  - but also to promote and advance human research more efficiently and effectively
Benefits of AAHRPP Accreditation

- Development of more effective and efficient review processes through the self-assessment and continuous quality improvement process
- Enhancement of UCLA’s HRPP reputation and the quality of our human research
- Reduction of review inconsistencies as a result of written policies, guidance and procedures
- Ability to more easily develop reciprocal IRB review agreements with other AAHRPP-accredited institutions
- Expanded educational outreach

Other Accredited Institutions

In CA:
- UC San Francisco
- UC Irvine
- UC Riverside
- USC
- Cedars-Sinai
- Stanford
- VA Greater LA
- VA San Diego
- VA San Francisco

Outside CA:
- Johns Hopkins
- Harvard
- Duke
- Vanderbilt
- U of Washington
- U of Michigan
- U of Minnesota
- Washington U
- Pfizer
Where is UCLA in the process?

- Conducted a detailed self-assessment of HRPP:
  - Reviewed processes to assure we achieve desired outcomes of accreditation standards
  - Revised and updated policies, guidelines, procedures, forms and processes as needed

- Preparing for second on-site evaluation visit (April 29 – May 1): Two Site Visitors will
  - Review program SOPs, protocols and minutes
  - Interview various IRB members, staff, PIs and research staff as well as key organization officials (for a total of 63 people)

HRPP Improvement Plan Rollout Update

- Improved OPRS Human Research website
- Updated guidance and policies posted
- 34 more translations of Bill of Rights posted
- Elimination of the requirement for IRB “administrative” approvals
- ARRA IRB Pre-Assignment Request Form
Updated and Revised Application and Reporting Forms Posted

- PI Self Certification Form for Non-Human Subject Research Determination + Decision Tree
- Exempt Certification Forms (2 types)
- No Subject Contact Application (for studies accessing or studying data and/or human biological specimens with identifiers)
- Application for the Involvement of Human Participants in Research—formerly HS-1:
  - Social Behavioral, Education and Health Services
  - Biomedical
  - Place to indicate “expedited review category”

Application Supplements

These supplements are to be used with primary application:

- Investigator
  - Disclosure of Financial Interests
- Populations
  - Inclusion of Children and Minors
  - Inclusion of Prisoners
  - Inclusion of Pregnant Women, Fetuses, Fetal Tissue
  - Inclusion of Neonates
Supplements Continued

- **Consent**
  - Waiver of Informed Consent
  - Surrogate Consent
  - Emergency Medical Research Waiver of Informed Consent

- **Methods and Procedures**
  - Genetic Analysis
  - Investigational Device
  - Investigational Drug
  - Multi-Institutional Research
  - Data and/or Specimens Repositories

Improvements Rollout continued

- **Revised post approval reporting forms and decision trees**: adverse events, violations and incidents, other updated safety information

- **Surveys** posted for Researchers and Research Participants to elicit feedback

- **Collaborative Institutional Training Initiative (CITI)** on-line human research training initiated

- **Town Hall Meeting** to go over improvements
  - Thursday, April 23, 2009
  - 9:00 to 10:30; here
May Preview

- Dedicated IRB staff for expedited processing of studies that qualify for expedited review
- Posting of IRB approval packets on the Office of Research Portal

Other Updates

- Research Policy and Compliance
  - Ann Pollack, Assistant Vice Chancellor
Updates on American Recovery and Reinvestment Act (ARRA) Funding

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

OCGA ARRA Help Desk

- 10:00 a.m. – 5:00 p.m., Monday – Friday
- 310-794-0548
- ARRAHelpline@research.ucla.edu
OCGA ARRA FAQ

Resources for S2S Grant Users

- **S2Sgrantsadmin@research.ucla.edu** to request user access or institutional profile
- **S2Sgrantshelp@research.ucla.edu** for questions related specifically to S2S
- Grants system S2S Grants Login: [https://s2sgrants.research.ucla.edu](https://s2sgrants.research.ucla.edu)
Use S2S-Grants if the funding agency to which you are applying is supported

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

S2S-Grants Naming Convention

Naming Convention:
FML: Bruin, J; RFA-OD-09-003; Sample for RAF

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
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

DEADLINES!
Deadlines

- Please notify OCGA of pending proposals as soon as possible to enable us to marshal appropriate staffing resources
  - Establish place holder if an S2S submission

NIH Challenge Grants (RC1)

- COMPLETE applications due at OCGA no later than 8:00 a.m. Tuesday, April 21, 2009
- BE SURE TO USE NIH-MINIMAL VALIDATION TYPE
- Currently 272 applications in the system – ONLY 14 SUBMITTED!

We’ve a long way to go!!!
**RC1 Reviewers Checklist**

**RC2 Deadline is May 27, 2009**

- RC2 Reviewers Checklist will be out soon (be sure to use NIH MINIMAL validations!)

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**Other Deadlines for complete applications to OCGA:**

- **NIH Competitive Revisions**
  - Should have been in OCGA 8:00 a.m., Wednesday, April 15, 2009

- **NIH Grand Opportunities (GO/RC2)**
  - No later than 8:00 a.m., Thursday, May 21, 2009

- **Supplements**
  - Deadlines vary
  - Not S2S eligible
Recovery Proposal Hints and Tips

- Will be posted on RA Forum website as an addendum to this presentation

VERY IMPORTANT!

- GRANTS.GOV WILL BE UNAVAILABLE THE WEEKEND OF APRIL 18 AND 19
- WILL NOT BE ABLE TO SUBMIT PROPOSALS
- WILL NOT BE ABLE TO RETRIEVE FUNDING OPPORTUNITY ANNOUNCEMENTS (FOA)
  - If application is S2S eligible, make sure FOA is in the system
  - If application is not S2S eligible, download the FOA to your computer before this weekend
Administrative Costs

- OMB Circular A-21 governs University use of Federal funds
- Administrative costs not generally allowed as a direct cost – included in indirect cost rate calculation
- Exception allowed for “major project” defined as project requiring non-routine level of administrative support

Administrative Costs (cont.)

- UCOP, COGR, other institutions have suggested that ARRA grant terms make ARRA awards “major projects” by definition, i.e. non-routine level of administrative support required to meet ARRA reporting requirements
  - Only department-based costs that can be directly associated to a project would be recoverable
  - Central costs cannot be directly associated to a specific project and would not be recoverable
Administrative Costs (cont.)

“Pros and Cons” of proposing administrative costs in ARRA proposals:

- Administrative costs may be disallowed by sponsor before award, and award reduced accordingly
- If not included in proposal, department must support reporting requirements with other funding sources, or through rebudgeting

“Pros and Cons” continued:

- If charged after the fact through rebudgeting, cost could be disallowed in audit and would be refundable to the government
- Costs may be approved thereby providing help to department in meeting extraordinary reporting requirements
Administrative Costs (cont.)

- If requested in budget, include appropriate justification. See sample language from COGR:
  - Due to the extraordinary administrative oversight and reporting activities associated with awards made under the American Recovery and Reinvestment Act, this proposal includes (insert appropriate percentage of effort) salary support for the additional administrative services required by the Act should an award be issued. Regulatory support for this request is located at OMB Circular A-21 F.6. a. (2.), which states: “Direct charging of salaries of administrative and clerical staff costs may be appropriate where administrative or clerical services required by the project are significantly greater than the routine level of such services provided by academic departments.”

Administrative Costs (cont.)

- If rebudgeted after award, justification must be sent to EFM and retained in department file to support any audit inquiry.
ARRA Post Award Updates

NSF – National Science Foundation

- Expend funds in a timely manner on allowable award costs
- NSF will monitor expenditures. If after 12 months no allowable expenditures have taken place, NSF may consider reducing or terminating the award and reallocating the funds.

ARRA Post Award Updates

- Reporting Requirements
  - Increased administrative burden on department administrators to insure progress reports are submitted on time and to track new and retained jobs funded by ARRA – all due 10 calendar days after quarter ends.
  - Reported costs must be Ledger based – reports due 10 calendar days after quarter ends (for subawards – due 5 calendar days after the quarter ends)
  - Monitor awards monthly
  - Will include commitments and encumbrances on ledger as obligated funds
ARRA Post Award Updates

- Assign separate Fund numbers for ARRA funds
  - Separate fund numbers for new awards
  - Separate fund numbers for supplements
  - Sponsor requirements:
    - No commingling of ARRA funds and non-recovery funds
    - No carry-forward of ARRA funds to non-recovery funds
    - No carry-forward of non-recovery funds to ARRA funds

ARRA Sponsor Requirements

- Separate draw-downs for ARRA funds
- Separate CFDA #’s for ARRA funds
  - 93.701: non-construction ARRA funds
  - 93.702: NCRR construction ARRA funds
- Separate Financial Reports / Closeout of ARRA funds
  - ARRA Supplements
    - Separate reporting from parent fund
    - No rebudgeting between parent fund and recovery supplements
    - ARRA supplements are eligible for a one-time no-cost extension
UC / UCLA Specific Updates

- ARRA flag in InfoEd at the budget level
- New Fund Group Codes – Financial System & QDB
  - 100210 - Federal Grants, Plant Funds – ARRA
  - 406110 – Federal Appropriations – ARRA
  - 406230 – Federal Grants – ARRA
  - 406340 – Federal Contracts - ARRA
UC / UCLA Specific Updates

- New flow-through Codes
  - ‘6’ – Contract, grant or other agreement funded partially by federal ARRA funds, and partially by a State or Private Source
  - ‘7’ – Contract, grant or other agreement funded 100% by federal ARRA funds, although allocated by a State or Private source.

UC / UCLA Specific Updates

- ARRA MANAGEMENT REPORTS THROUGH THE WEB PORTAL
  - Interdisciplinary work group, with broad campus representation will be convened to assess management reporting needs for ARRA funds