Contacts Meeting – September 22, 2016

NIH Updates & Changes

w/ Erika Wilson, Senior Director HS SPPO & HS RSC
Agenda

- Updates & Reminders
  - UC San Diego
  - NIH
  - VCHS
UC San Diego Updates
HS SPPO Updates

• Carina Cortez has been promoted to Grant Analyst.
  • Training to assist with NIH & AHA Fellowships as well as Modular Budget NIH applications.

• Welcome our newest Senior Grant Analysts!
  • Roxanne Knight
  • Jill Mulrooney

OCGA Updates

• The new Associate Director has been selected!
  • Lisa Meredith
Loan Repayment Program (LRP) Contact

• The Health Sciences Institutional Official for the upcoming Loan Repayment Program (LRP) is Rachel Cook.
  • https://www.lrp.nih.gov/

• Changes to this year’s application:
  • The application has been redesigned as well as new FOAS and deadline dates for all involved!
    • The online application period ends the same day as the Colleague and Institutional Documentation Period ends: November 15, 2016. thus, it is crucial to work with your Institutional Official prior to the deadline!
    • Why important? The Institutional Documentation approval process can take two weeks or more and there are times that we don’t receive notification of the application till after it has been submitted or day of. We will be unable to approve if this happens this year.
Procedures for proposals $10,000,000 DC/year

- UC San Diego does not have signing authority for proposals at $10,000,000 or more in DC per year.
- If a proposal is to go out with a budget larger than this, then we will need to obtain approval from UCOP.
  - This procedure takes time!
  - You will need to work with your HS SPPO (or OCGA) Analyst as soon as you learn of this size of a proposal so they can assist you with obtaining the proper approvals and signatures from UCOP, since we cannot do this for you.
Reminder: NEW HS SPPO Submission Timelines

For electronic proposals, the following timelines apply to determine the type of review the application will receive:

• **Full Review**
  - If the proposal is received five (5) business days prior to the deadline **BEFORE 4:30pm**, it will receive a full review.

• **Cursory Review**
  - If the proposal is received five (5) business days prior to the deadline **AFTER 4:30pm**, it will receive a cursory review.

• **AS-IS Review**
  - If the proposal is received three (3) business day prior to the deadline, **AFTER 4:30pm**, it will be submitted as-is without a review.
Reminder: NEW HS SPPO Submission Timelines

For paper proposals (including sub-awards and paper supplements), the following timelines apply to determine the type of review the application will receive:

- **Full Review**
  - If the proposal is received three (3) business days prior to the deadline **BEFORE 4:30pm**, it will receive a full review.

- **Cursory Review**
  - If the proposal is received three (3) business days prior to the deadline **AFTER 4:30pm**, it will receive a cursory review.

- **AS-IS Review**
  - If the proposal is received one (1) business day prior to the deadline, **AFTER 4:30pm**, it will be submitted as-is without a review.
Reminder: New Minimum Requirements

No draft application is required as an uploaded document in ePD if the proposal is:

• an **Administrative Supplement**
• **SNAP Continuation**
  • Note: Subaward Continuations **require** a draft application
• **initiated in ASSIST**
  • **Reminder:** Include the Assist Application Identifier in the ePD Abstract Tab in the Internal Comments
NIH Updates
NOT-HL-16-443: NHLBI Policy Concerning Mentored Career Development (K08 and K23) Awards: % Effort

• For due dates on or after February 12, 2017:
  • NHLBI will allow cardiothoracic, vascular, and trauma surgeons, interventional cardiologists, and electrophysiology cardiologists to request less than the required 75% effort for the specific purpose of maintaining specialty clinical competency skills.
  • Applicants may not request less than 50% effort and must provide a justification clearly stating the reasons for the reduced amount of effort.
  • Salary will be prorated based on the institutional salary not to exceed the NHLBI caps effective at the time of the award.
NOT-OD-16-143: Optional Electronic Method to Request Withdrawal of Applications from Consideration for Funding

- UC San Diego PIs are now able to submit requests to withdraw a processed application using the eRA Commons Prior Approval module. The request can be submitted electronically by an AOR/SO from within the Electronic Research Administration’s (eRA) Commons, navigating from the Prior Approval tab on the landing page.
- Prior Approval Module Guide:
To access the Prior Approval Landing screen:

The PI initiates the request in eRA Commons.

1. Log in to eRA Commons
2. Select the **Prior Approval** tab on the Commons Home screen.
To access the Prior Approval Landing screen:

- PIs will see the option to initiate a request and List My Requests on the Prior Approval landing screens.

![Prior Approval Screen](image)
To access the Prior Approval Landing screen:

- SOs will see the option to initiate a request, plus options for listing existing requests and searching for requests on the Prior Approval landing screen.
NOT-OD-16-130: Changes to the NIH/AHRQ/NIOSH Policy on Post-Submission Materials for Applications Submitted for Due Dates On or After January 25, 2017

Allowable Post-Submission Materials for All Applications

• Revised budget page(s)
• Biographical sketches
• Letters of support or collaboration
• Adjustments resulting from natural disaster
• Adjustments resulting from change of institution
• News of professional promotion or positive tenure decision for any PD/PI or Senior/Key Personnel
• Approval by the NIH Stem Cell Registry of a human embryonic cell line(s) after submission of the application
NOT-OD-16-130: Changes to the NIH/AHRQ/NIOSH Policy on Post-Submission Materials for Applications Submitted for Due Dates On or After January 25, 2017

- Videos that demonstrate devices and experimental data with a temporal element, which refers to the need to show how something functions or occurs over time, or demonstrates movement or change.
- Other post-submission materials specified in the FOA for which the application was submitted or in a special Guide Notice.
- **News of an article accepted for publication since submission of the application**, which must include only:
  - List of authors and institutional affiliations
  - Title of the article
  - Journal or citation (if available)
- Copies of articles, links to articles, or any other materials related to an article accepted for publication will not be accepted as post-submission materials, unless specified in the FOA for which the application was submitted or a special Guide Notice.
Additional Materials for Certain Applications

Institutional Training and Training-related Grants (e.g., T32, T34, T35, T90, TU2, T15, D43, K12, KM1, UR2): in addition to the materials for All Applications above, news - since the training grant application was submitted - of:

• a trainee's or former trainee's graduation, employment, promotion, funding, or publications;
• a faculty member's promotion, funding, or publications; and
• the addition or removal of any faculty member who will be involved in the training program (mentors or senior/key persons).

Individual Fellowship (F-Series) and Individual Career Development Award (K-series) Applications: in addition to the materials for All Applications listed above:

• New information on the Sponsor/Mentor funding, limited to the project title, funding source (e.g., NIH/AHRQ/NIOSH grant number), a brief description of specific aims, and relevance to the fellowship or career development application under review.
• News of change in Mentor(s) or other Senior/Key Persons specified in the original application.
Additional Materials for Certain Applications

Applications submitted to Requests for Applications (RFAs): the same post-submission materials as other applications (see "All Applications" above), for all due dates in the RFA.

Conference Grant Applications (R13, U13): a one-page explanation of all speakers who accepted invitations to participate in the proposed conference after the application was submitted, plus a one-page explanation of all speakers who declined such invitations after the application was submitted. Alternatively the PD/PI may consider submitting a one-page explanation for each plenary slot on the agenda.

Any other types of post-submission materials are not likely to be accepted.
NOT-OD-16-129: New Policy Eliminates Most Appendix Material for NIH/AHRQ/NIOSH Applications Submitted for Due Dates On or After January 25, 2017

The only allowable appendix materials will be:

• For applications proposing clinical trials (unless the FOA provides other instructions for these materials):
  • Clinical trial protocols
  • Investigator's brochure from Investigational New Drug (IND), as appropriate

• For all applications:
  • Blank informed consent/assent forms
  • Blank surveys, questionnaires, data collection instruments
  • FOA-specified items:
    • If appendix materials are *required* in the FOA, review criteria for that FOA will address those materials, and applications submitted without those appendix materials will be considered incomplete and will not be reviewed.
Consequences for submitting disallowed appendix materials

• Applications submitted for due dates on or after January 25, 2017 will be withdrawn and not reviewed if they are submitted with appendix materials that are not specifically listed in this Notice or the FOA as allowed or required.
NOT-HL-16-336: New NHLBI Policy: Investigator-Initiated Single-Site Clinical Trials (Phase II and beyond)

- For due dates on or after January 8, 2017, any application requesting funding for a Phase II and beyond clinical trial using a single site must be submitted to PAR-16-405 Single-Site Investigator-Initiated Clinical Trials (R61/R33).
  - A single site clinical trial is one in which the protocol is implemented by one investigational site that conducts and coordinates the protocol. While a single site clinical trial may enroll participants from multiple locations/clinics within a geographic area, those participants will receive an intervention or undergo outcome assessments under the direction and oversight of one research team at one investigational site.
  - NHLBI will no longer accept applications for single-site clinical trials if submitted through the Research Project Grant (Parent R01) FOA PA-16-160 or its reissue.
NOT-HD-16-019: Notice of Changes to the NICHD Program Project Grant (P01) Program

- NICHD's general P01 FOA (PAR-13-257) has expired (prior to the September 25 deadline) and will not be re-issued.
  - P01 Program Project Grant applications will no longer be accepted for the broad scope of NICHD research interests. Instead, NICHD plans to reserve issuance of FOAs for P01 Program Project Grant applications for specific high-priority research topics that are appropriate for possible support using this multi-component grant mechanism.
NOT-OD-16-134: Revised: Projected FY 2017 Stipend Levels for Postdoctoral Trainees and Fellows on Ruth L. Kirschstein National Research Service Awards (NRSA)

The exact stipend levels and the actual date of implementation are subject to the availability of FY 2017 appropriations and implementation of the new FLSA threshold for professional workers to be eligible for paid overtime.

These projected new stipend levels are planned to be effective December 1st.

<table>
<thead>
<tr>
<th>Career Level</th>
<th>Years of Experience</th>
<th>Actual Stipend for FY 2016</th>
<th>Projected Stipend for FY 2017</th>
<th>Monthly Stipend</th>
</tr>
</thead>
<tbody>
<tr>
<td>Postdoctoral</td>
<td>0</td>
<td>$43,692</td>
<td>$47,484</td>
<td>$3,957</td>
</tr>
<tr>
<td></td>
<td>1</td>
<td>$45,444</td>
<td>$47,844</td>
<td>$3,987</td>
</tr>
<tr>
<td></td>
<td>2</td>
<td>$47,268</td>
<td>$48,216</td>
<td>$4,018</td>
</tr>
<tr>
<td></td>
<td>3</td>
<td>$49,152</td>
<td>$50,316</td>
<td>$4,193</td>
</tr>
<tr>
<td></td>
<td>4</td>
<td>$51,120</td>
<td>$52,140</td>
<td>$4,345</td>
</tr>
<tr>
<td></td>
<td>5</td>
<td>$53,160</td>
<td>$54,228</td>
<td>$4,519</td>
</tr>
<tr>
<td></td>
<td>6</td>
<td>$55,296</td>
<td>$56,400</td>
<td>$4,700</td>
</tr>
<tr>
<td></td>
<td>7 or More</td>
<td>$57,504</td>
<td>$58,560</td>
<td>$4,880</td>
</tr>
</tbody>
</table>

Use these rates for budget projections only!
NOT-OD-16-122: Availability of Resources for Instruction in the Responsible Conduct of Research

• The NIH Research Training website (http://grants.nih.gov/training/extramural.htm) includes additional information on instruction in responsible conduct of research and provides links to the Office of Research Integrity website (http://ori.hhs.gov/), which has resources for the responsible conduct of research.

• The National Academy Press has published the 3rd. edition of the classic, "On Being a Scientist," which is available online at http://books.nap.edu/catalog.php?record_id=12192.
NOT-OD-16-121: Change of Eligibility Period in the NIH Continuous Submission Policy for Reviewers with Recent Substantial Service

- NIH has lengthened the window of time during which peer reviewers (who have served six times in eighteen months) can submit their applications under the NIH Continuous Submission Policy.
  - Eligibility now begins on August 1 following the eighteen month service window and continues through September 30 of the next year.
    - This link is updated monthly by NIH
Reminders!

- **Scientific Environment:**
  - The scientific environment statement is required and should be included in the facilities and other resources document (#10 - Other Project Information section.)

- **Simplification of the Vertebrate Animal Section**
  - NOT-OD-16-006

- **Change in the NIH Definition of Children in Clinical Research**
  - NOT-OD-16-010

- **New Biographical Sketch Format**
  - NOT-OD-15-032 & NOT-OD-16-080
  - A. Personal Statement allows up to 4 publications to be listed
  - C. Contributions to Science has replaced C. Publications. You are allowed a max of 5 contributions, with a max of 4 publications listed for each contribution.
  - Link to additional publications must be a .gov address. You cannot use a .com or .edu address.
Reminders → Rigor & Transparency

**NEW GRANT GUIDELINES**
what you need to know

**WHY UPDATE THE GUIDELINES?**
The updates focus on four areas deemed important for enhancing rigor and transparency:

1. **PREMISE**
The scientific premise forming the basis of the proposed research

2. **DESIGN**
Rigorous experimental design for robust and unbiased results

3. **VARIABLES**
Consideration of relevant biological variables

4. **AUTHENTICATION**
Authentication of key biological and/or chemical resources

Send inquiries to reproducibility@nih.gov
See also NIH Notice NOT-OD-16-011

**WHAT ARE THE UPDATES?**

1. **UPDATES TO RESEARCH STRATEGY GUIDANCE**
The research strategy is where you discuss the significance, innovation, and approach of your research plan. Let’s look at an R01, for example:

   - The new research strategy guidelines require that you:
     - State the strengths and weaknesses of published research or preliminary data crucial to the support of your application
     - Describe how your experimental design and methods will achieve robust and unbiased results
     - Explain how biological variables, such as sex, are factored into research design and provide justification if only one sex is used

2. **NEW ATTACHMENT FOR AUTHENTICATION OF KEY BIOLOGICAL AND/OR CHEMICAL RESOURCES**
From now on, you must briefly describe methods to ensure the identity and validity of key biological and/or chemical resources used in the proposed studies.

   These include, but are not limited to:
   - Cell lines
   - Specialty chemicals
   - Antibodies
   - Other biologics

   Standard laboratory reagents that are not expected to vary do not need to be included in the plan. Examples are buffers and other common biologicals or chemicals.

   - **DO NOT** put experimental methods or preliminary data in this section
   - **DO** focus on authentication and validation of key resources

3. **NEW REVIEWER GUIDELINES**
Here are the additional criteria the reviewers will be asked to use:

   - Is there a **strong scientific premise** for the project?
   - Have the investigators presented adequate plans to address relevant biological variables, such as sex, for studies in vertebrate animals or human subjects?
   - Have the investigators presented strategies to ensure a robust and unbiased approach, as appropriate for the work proposed?

Reviewers will also be asked to comment on that new attachment (see Update 2)!
<table>
<thead>
<tr>
<th>4 AREAS OF FOCUS</th>
<th>WHAT DOES IT MEAN?</th>
<th>WHERE SHOULD IT BE INCLUDED IN THE APPLICATION?</th>
</tr>
</thead>
</table>
| **Scientific Premise** | The **scientific premise** for an application is the research that is used to form the basis for the proposed research question(s). Describe the general strengths and weaknesses of the prior research being cited as crucial to support the application. Consider discussing the rigor of previous experimental designs, as well as the incorporation of relevant biological variables and authentication of key resources. *See related FAQs, blog post** | **Research Strategy**  
➢ **Significance** |
| **Scientific Rigor (Design)** | **Scientific rigor** is the strict application of the scientific method to ensure robust and unbiased experimental design, methodology, analysis, interpretation and reporting of results. Emphasize how the experimental design and methods proposed will achieve robust and unbiased results. *See related FAQs, blog post, examples from pilots** | **Research Strategy**  
➢ **Approach** |
| **Biological Variables** | **Biological variables**, such as sex, age, weight, and underlying health conditions, are often critical factors affecting health or disease. In particular, sex is a biological variable that is frequently ignored in animal study designs and analyses, leading to an incomplete understanding of potential sex-based differences in basic biological function, disease processes and treatment response. Explain how relevant biological variables, such as the ones noted above, are factored into research designs, analyses, and reporting in vertebrate animal and human studies. Strong justification from the scientific literature, preliminary data or other relevant considerations must be provided for applications proposing to study only one sex. *See related FAQs, blog posts, article** | **Research Strategy**  
➢ **Approach** |
| **Authentication** | **Key biological and/or chemical resources** include, but are not limited to, cell lines, specialty chemicals, antibodies and other biologics. Briefly describe methods to ensure the identity and validity of key biological and/or chemical resources used in the proposed studies. These resources may or may not be generated with NIH funds and:  
➢ may differ from laboratory to laboratory or over time;  
➢ may have qualities and/or qualifications that could influence the research data;  
➢ are integral to the proposed research. The authentication plan should state in one page or less how you will authenticate key resources, including the frequency, as needed for your research. Note: Do not include authentication data in your plan. *See related FAQs, blog post** | **Other Research Plan Section**  
➢ Include as an attachment  
➢ Do not include in the Research Strategy. |

**This chart is based on general instructions for research grant and mentored career development applications. It should only be used as a guide. For all applications, please read the applicable Funding Opportunity Announcement (FOA) & Application Guide for specific instructions.**
VCHS UPDATES
CONSOLIDATION AND CLOSEOUT PROCESS

- VCHS will begin the implementation with the fixed price awards

- ALL DBO/AVC HAVE BEEN PROVIDED A CURRENT LISTING OF ALL ACTIVE LSA’S, CLINICAL TRIALS, FIXED PRICE AWARDS

- Verify and/or establish the new residual balance index number per each faculty using fund 60121B
CONSOLIDATION AND CLOSEOUT PROCESS

• ALL Residual balances from each fund type (Fixed Price, LSA, Clinical Trial) will be consolidated to one index fund 60121B program code 404730/434730 and journal rule class (FBRV)

• FIXED PRICE- Misc. fund numbers, VCHS to complete process by October 2016

• LSA- 60153, 60155, complete process by January 2017

• CLINICAL TRIAL- 79600, complete process by April 2017
FIXED PRICE AWARD PROCESS

• Begin with Fixed Price awards
• Determine if award is complete
• Prepare the finalization form and obtain all required signatures
• Indicate the Faculty Discretionary index number
• Submit Discretionary index to OPAFS, they will process a journal to transfer balance
• Inactivate old index and close out
LSA AWARD PROCESS

• Determine award is complete
• Prepare the finalization form and obtain all required signatures
• Indicate the Faculty Discretionary index number
• Department to Prepare and submit journal
• Inactivate old index and close out
CLINICAL TRIAL AWARD PROCESS

• Determine award is complete
• Prepare the finalization form and obtain all required signatures
• Indicate the Faculty Discretionary index number
• Department to Prepare and submit journal
• Inactivate old index and close out
PRESENTATION PLAN AND DISTRIBUTION

• Policies will be forwarded to
  • HSSAL
  • ADBO
  • HS SPPO CONTACTS
  • FINANCE MANAGERS IN DEPARTMENTS
  • RSC