Welcome and Announcements

- Communication from Executive Vice Chancellor and Provost Emily Carter
- Town Hall with NIH Deputy Director Michael Lauer, M.D.
Communication from Executive Vice Chancellor and Provost Emily Carter

Subject: Our Commitment to Ethical Standards in Research

To: Deans, Directors, Department Chairs, Administrative Officers, and Faculty

Please share this message with all researchers in your unit.

Dear Colleagues:

As you are well aware, UCLA is committed to academic freedom and supports international collaborations and scholarly exchanges. At the same time, however, we must comply with U.S. laws and regulations that govern them, including full and transparent reporting to the University and to federal research sponsors of affiliations with and support from foreign governments and other institutions.

The academic community was reminded of this last week when a Harvard professor was arrested because he failed to disclose foreign affiliations and funding sources to federal research sponsors. In August 2019, a researcher at the University of Kansas was indicted for a similar reason. We have read about researchers at other U.S. institutions who have lost their positions because of undisclosed membership in foreign talents programs, because they maintained shadow laboratories in other countries, or because they failed to disclose support for research from foreign governments and other foreign entities.

Former Executive Vice Chancellor and Provost Scott Waugh issued a memo last year emphasizing the importance of complying with U.S. laws and regulations as well as UC and UCLA policies that govern the way international engagements are managed and reported. Recently, the Chancellor, the Vice Chancellor for Research, the Chair of the Academic Senate and I wrote to reaffirm the importance of international collaborations as well as our responsibility to comply with applicable laws and policies.

The UC Statement of Ethical Values and Standards of Ethical Conduct (PDF) apply to all members of the University community. It reminds us that we are all expected to conduct ourselves ethically, honestly, and with integrity. The section on Fair Dealing states that “principles of fairness, good faith and respect consistent with laws, regulations and University policies govern our conduct...” It also states that “no unlawful practice or a practice at odds with these standards can be justified on the basis of customary practice, expediency, or achieving a ‘higher’ purpose.”

I remain exceptionally proud of the innovative and impactful research conducted all across this campus each day. I also appreciate your shared dedication and commitment to compliance with these policies and requirements. Our administration stands ready to assist and provide guidance to ensure all of our activities conform to UC and UCLA policy, funding agency requirements, and U.S. laws.

Questions or concerns about foreign collaborations and any related matters can be brought to Roger Wakimoto, vice chancellor for research, at rwakimoto@conet.ucla.edu.

Sincerely,

Emily A. Carter
Executive Vice Chancellor and Provost
**Town Hall #1**
This event is open to the UCLA community. An RSVP is required as space is limited.

Date: Tuesday, February 18, 2020  
Time: 9:30 am – 10:45 am  
Location: UCLA Neuroscience Research Building Auditorium, 635 Charles E Young Drive South  
Topic: Dr. Lauer will discuss the NIH’s priorities, opportunities and funding landscape, as well as integrity concerns regarding research misconduct, sexual harassment and undue foreign influence.  

**Town Hall #2**
This event is for UCLA early career faculty, postdocs, graduate and master’s students, but is open to the wider UCLA community. An RSVP is required as space is limited.

Date: Tuesday, February 18, 2020  
Time: 1:30 pm – 2:30 pm  
Location: UCLA Neuroscience Research Building Auditorium, 635 Charles E Young Drive South  
Topic: Dr. Lauer will discuss NIH’s perspectives on the biomedical research workforce, including efforts to nurture the next generation of researchers.  

Please direct any questions about the event to: ovcrc@conet.ucla.edu
Welcome & Announcements – Marcia Smith

e-EPASS Demo – Grant Lyon

OCGA Grant Updates – Kathy Kawamura

RSAWA Updates – Jennifer Perkins

OHRPP – Moore Rhys
  ◦ Changes to PAR guidance
  ◦ Learn-at-lunch: IRB Reliance/Single IRB Mandate
  ◦ New staffing for OHRPP QUI

EFM
  ◦ Financial Deliverable Preparation Procedure – Yoon Lee
EPASS System

Research Administrator’s Forum
February 13, 2020
EPASS System - History

- Originally created for and used by the Department of Neurology
- Transferred to ORA/ORIS in order to further develop and roll out to all of campus
- Current iteration of EPASS was deployed on 11/16/2019
- Phased campus rollout to proceed into late 2020
Preliminary User Acceptance Testing

OCGA Proposal and Award Intake

- Harveen Kukreja
- Johanna Haraway
- Sam Perez
- Emery Ham
- Najida Malek
- Cindy Gilbert
User Acceptance Testing

Campus Participants
• Cathy Rujanuruks - DOM
• Chris Laybourn - Pediatrics
• Humphrey Duan - Semel
• Latroy Ganaway – Neurology
• Stacey Tsan – Anesthesiology
• Suzanne Tsang – CNSI
• Tsegaye Teshome - DOM

OCGA Participants
• Addy Moon
• Flora O’Brien
• Frank Falcon
• Gerald Gamble
• Jessica Kim
• Kurt Durlesser
• Megan Ober
• Mellani Nolan
• Sharon Martin
• Travis Dadigian
• Ummi Sayers
• Yessenia Sarmiento
EPASS – Where Are We Today?

- Required fields and validation
- Electronic routing for signatures
- Electronic submission to OCGA
- Data transmission directly from EPASS to PATS
- Elimination of manual proposal acknowledgement and assignment emails
- Comprehensive user guides
EPASS – Where Are We Going?

- Improve navigation within the system
- Improve navigation with the EPASS smartform
- Continue to add/refine training materials
- Add functionality to address additional proposal types
- Integrate with CITI and eDGE training
EPASS Stakeholder Team

**OCGA**
- Patti Manheim
- Cindy Gilbert
- Harveen Kukreja
- Jim Fong
- Johanna Haraway
- Kathy Kawamura
- Kristin Lund

**ORDM**
- Rory Constancio
- Belinda Chen

**ORA**
- Marcia Smith
- Dan Newbower

**ORIS**
- Jackson Jeng
- Grant Lyon
- Michelle Leonard
EPASS - Demonstration
Questions

???

EPASShelp@research.ucla.edu
Thank You

Cindy A. Gilbert  
Assistant Director  
Office of Contract and Grant Administration  
cgilbert@research.ucla.edu  
310-267-4814

Grant Lyon  
Project Manager  
Office of Research Information Systems  
grant.lyon@research.ucla.edu  
310-983-3843
Grant Updates

February 13, 2020
NIH Salary Cap
- **NOT-OD-20-065** NIH Salary Cap based upon Executive Level II
  - Effective 1/5/2020
  - Executive Level II raised to $197,300

NIH Budget
- NIH Budget for FY2020 increased 6.65% to $41.68 billion
  - All of Us, the BRAIN Initiative, Alzheimer’s Research, Childhood Cancer Data Initiative
**NIH- NRSA**

### NRSA Stipend Levels FY2020

<table>
<thead>
<tr>
<th>Career Level</th>
<th>Years of Experience</th>
<th>Stipend for FY 2020</th>
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</thead>
<tbody>
<tr>
<td>Predoctoral</td>
<td>All</td>
<td>25,320</td>
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<tr>
<td>Postdoctoral</td>
<td>0</td>
<td>$52,704</td>
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<tr>
<td></td>
<td>1</td>
<td>$53,076</td>
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<td>$53,460</td>
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<td></td>
<td>3</td>
<td>$55,596</td>
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<td></td>
<td>4</td>
<td>$57,456</td>
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<tr>
<td></td>
<td>5</td>
<td>$59,580</td>
</tr>
<tr>
<td></td>
<td>6</td>
<td>$61,800</td>
</tr>
<tr>
<td></td>
<td>7 or More</td>
<td>$64,008</td>
</tr>
</tbody>
</table>

**Tuition & Fees**
- 60% of actual tuition up to $16,000
- or if dual degree, 60% of actual tuition up to $21,000

**Training Related Expenses (Institutional Training Grants)**
- Predoc: $4,200
- Postdoc: $11,850

**Institutional Allowance (Individual Fellows)**
- Predoc: $4,200
- Postdoc: $11,850

[NOT-OD-20-070](#)

[NRSA FAQs](#)
NIH Forms F

- NOT-OD-20-026
- For use on Applications with due dates on or after May 25, 2020
  - New/Revised Funding Opportunities will in cooperated Forms-F requirement

[Diagram showing high-level form change summary for FORMS-F]
NIH Forms F

**high-level-form-change-summary-FORMS-F**

- Changes mainly affect Human Subject & Clinical Trials Information form pages

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**Study record changes**

- Defaulted Clinical Trial Questionnaire question “1.4.a Does the study involve human participants?” to Yes, since study records are only available when the answer to the “Are Human Subjects Involved?” question on the R&R Other Project Information form is Yes
- Separated “Inclusion of Women, Minorities, and Children” attachment into two attachments – “Inclusion of Individuals Across the Lifespan” and “Inclusion of Women and Minorities”
- Renamed “Enrollment of First Subject” field to “Enrollment of First Participant”
- Added “Inclusion Enrollment Report Title” field to the Inclusion Enrollment Report
- Removed “Brief Summary” attachment
- Renamed “Narrative Study Description” attachment to “Detailed Description”
- Added new question and checkbox – “Is this an applicable clinical trial under FDAAA?”
- Renumbered form fields, as needed
ORCID (Open Researcher and Contributor Identifiers)

- [https://orcid.org/](https://orcid.org/)
  - Fast, Simple Registration
  - Non-Sponsor Specific (many Sponsor utilize / require)

- Per [NOT-OD-19-109](https://orcid.org/)
  - NIH Required
    - Fellowship (F) and Career Development (K)
    - Must be added to NIH eCommons Personal Profile or will result in “error”
    - Error will not be known until AFTER the Proposal is submitted, and passed through NIH eCommons validations
  - *submit early*
Proposal & Award Policies & Procedures Guide (PAPPG; NSF 20-1)

Effective: June 1, 2020

Proposals submitted or due on or after June 1, 2020

- RAPID or EAGER proposals requires email from NSF PO approving submission of proposal
- Biosketches must be in submitted via “NSF-approved format”
  - Language added requiring “all” appointments to be listed
- Current and Pending Support – must be submitted via “NSF-approved format”

NSF-Approved Format

- SciENcv
  - Bio - available now – highly encouraged to use
  - Current/Pending – (March 2020)
- NSF Fillable PDF
  - Bio – pending (March 2020)
  - Current/Pending – pending (Feb 2020)
Science Experts Network Curriculum Vitae

- Part of My NCBI
  - Sign in with NIH eCommons, NSF, Google, or other Institutional Login Accounts

Benefits per SciENcv

- “Eliminates the need to repeatedly enter biosketch information”
- “Reduces the administrative burden associated with federal grant submission and reporting requirements”
- “Provides access to a researcher-claimed data repository with information on expertise, employment, education, and professional accomplishments”
- “Allow researchers to describe their scientific contributions in their own language”
This session will provide a preparer’s perspective on how to utilize NIH’s proprietary proposal submission system (ASSIST) for Multi-Project Applications (MPA). It is suggested that attendees acquaint themselves with the SF424 sections 4, 5 and 9 along with the FOA prior to class. This session will address basic functions of the system along with hints and tips for the department preparers and PIs to employ, ensuring an on-time compliant (error-free) application.
Any Questions?

Contact Information

http://ocga.research.ucla.edu
• New RATS to launch soon
  ◦ Differences
  ◦ Benefits
  ◦ User Population
  ◦ User Interface
  ◦ Smartform
  ◦ User Training
Differences

Top down Narrative Approach

RATS

New RATS

Create Experiments using Procedures and Substances

Create Procedures

UCLA Substances & Procedures Library

Research Team

Protocol Experiment

Procedure

Substance

Substance

Procedure

Substance

Substance

Procedure

Substance

Substance

Substances

Procedures

Substances

Procedures
## Benefits

<table>
<thead>
<tr>
<th>PIs</th>
<th>Reviewers &amp; Committee</th>
<th>Central Administration</th>
</tr>
</thead>
</table>
| • Decreases submission effort  
• Improves overall experience  
• Promotes reusability of substances and procedures | • Updated review process  
• Improves collaboration  
• Reduces manual paper processes | • Centralizes and improves the review process  
• Provides a voice in Huron product direction for future upgrades |
# User Interface

## TEAM00000036

**Jennifer Perkins Team**

**Principal Investigator:** [JENNIFER PERKINS](mailto:jperkins@research.ucla.edu)

**Phone:** 310-924-9645

### Submissions

<table>
<thead>
<tr>
<th>Name</th>
<th>Execute Activity</th>
<th>Date Modified</th>
<th>State</th>
<th>Version</th>
<th>Species</th>
<th>Procedure Type</th>
<th>Scope</th>
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<tr>
<td>TEST</td>
<td>Actions</td>
<td>11/7/2019 9:26 AM</td>
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<td>Rat</td>
<td>Substance Administration</td>
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<tr>
<td>Anesthetic Overdose, AQUI-S 2OE (10% Eucaine)</td>
<td>Actions</td>
<td>9/13/2018 12:28 PM</td>
<td>Active</td>
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<td>Fish</td>
<td>Euthanasia</td>
<td>Standard</td>
</tr>
<tr>
<td>Anesthetic Overdose, Pentobarbital or Pentobarbital Solution</td>
<td>Actions</td>
<td>9/13/2018 12:28 PM</td>
<td>Active</td>
<td>1</td>
<td>Rat</td>
<td>Euthanasia</td>
<td>Standard</td>
</tr>
<tr>
<td>Anesthetic Overdose, Pentobarbital or Pentobarbital Solution</td>
<td>Actions</td>
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<td>Active</td>
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<td>Gerbil</td>
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<td>Mouse</td>
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<td>Standard</td>
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<td>9/13/2018 12:28 PM</td>
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<td>Hamster</td>
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<td>Actions</td>
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<td>Active</td>
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<td>Guinea Pig</td>
<td>Euthanasia</td>
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<td>9/13/2018 12:28 PM</td>
<td>Active</td>
<td>1</td>
<td>Dog</td>
<td>Euthanasia</td>
<td>Standard</td>
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<td>Actions</td>
<td>9/13/2018 12:28 PM</td>
<td>Active</td>
<td>1</td>
<td>Rabbit</td>
<td>Euthanasia</td>
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<tr>
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<td>Actions</td>
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<td>Rhesus Macaque</td>
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<td>Actions</td>
<td>9/13/2018 12:28 PM</td>
<td>Active</td>
<td>1</td>
<td>Pig</td>
<td>Euthanasia</td>
<td>Standard</td>
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### User Interface

#### Filter by
- **Name**

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<th>Name</th>
<th>Date Modified</th>
<th>Type</th>
<th>Scope</th>
</tr>
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<tbody>
<tr>
<td>1,2,4-Trichloro-3-(2,4-dinitrophenyl)benzene (DE-71)</td>
<td>2/11/2020 6:46 PM</td>
<td>Other</td>
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</tr>
<tr>
<td>1-Methyl-4-phenyl-1,2,3,6-tetrahydropyridine (MPTP)</td>
<td>9/20/2018 3:39 PM</td>
<td>Other</td>
<td>Standard</td>
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<tr>
<td>Mercaptoethane Sulfonate Na (Mesna, Uromitexan, Mesnex)</td>
<td>9/20/2018 3:38 PM</td>
<td>Chemical Agent, Other</td>
<td>Standard</td>
</tr>
<tr>
<td>Hydroxy-cyclophosphamide</td>
<td>9/20/2018 3:38 PM</td>
<td>Reproductive Hazard/Teratogen, Chemotherapeutic or Other Hazardous Drug</td>
<td>Standard</td>
</tr>
<tr>
<td>Hydroxy-tamoxifen (tamoxifen, 40HT)</td>
<td>9/20/2018 3:42 PM</td>
<td>Chemical Agent, Reproductive Hazard/Teratogen, Chemotherapeutic or Other Hazardous Drug, Hormonal Regulator</td>
<td>Standard</td>
</tr>
<tr>
<td>Ipomeanol (IPO, 1 pentanone, 4-hydroxypentanone)</td>
<td>9/20/2018 3:42 PM</td>
<td>Toxin of biological origin</td>
<td>Standard</td>
</tr>
<tr>
<td>4-nonylphenol (4-(2,4-dimethylheptan-3-yl)phenol)</td>
<td>9/20/2018 3:41 PM</td>
<td>Chemical Agent</td>
<td>Standard</td>
</tr>
<tr>
<td>5-(5-N-2-aminoethylaminoethylammonium)hexamethylenemammonium</td>
<td>9/20/2018 3:44 PM</td>
<td>Chemical Agent, Antiviral</td>
<td>Standard</td>
</tr>
<tr>
<td>Bromodeoxyuridine (BrdU, 5-bromo-2-deoxyuridine)</td>
<td>9/20/2018 3:41 PM</td>
<td>Chemical Agent, Antiviral, DNA/RNA</td>
<td>Standard</td>
</tr>
<tr>
<td>Fluorouracil (Fluorouracil, Ancobon)</td>
<td>9/20/2018 3:38 PM</td>
<td>Reproductive Hazard/Teratogen, DNA,RNA, Antifungal Agent</td>
<td>Standard</td>
</tr>
<tr>
<td>5-Fluorouracil (Fuorouracil, Adrucil)</td>
<td>9/20/2018 3:40 PM</td>
<td>Chemical Agent, Reproductive Hazard/Teratogen, Chemotherapeutic or Other Hazardous Drug, DNA/RNA</td>
<td>Standard</td>
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<tr>
<td>Lipoygenase inhibitor</td>
<td>9/20/2018 3:43 PM</td>
<td>Reproductive Hazard/Teratogen, Toxin of biological origin, Analgesic</td>
<td>Standard</td>
</tr>
</tbody>
</table>
# User Interface

## TEAM00000036

### Jennifer Perkins Team

**Principal Investigator:** Jennifer Perkins  
Phone: 3107491845  
E-mail: jperkins@research.ucla.edu

<table>
<thead>
<tr>
<th>Name</th>
<th>Date Modified</th>
<th>Type</th>
<th>Scope</th>
</tr>
</thead>
<tbody>
<tr>
<td>Buprenorphine HCl (Buprenex, Simbadol)</td>
<td>10/11/2018 8:52 AM</td>
<td>Reproductive Hazard/Teratogen, Analgesic</td>
<td>Standard</td>
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<tr>
<td>Benzoximate (Oxybuprocaine, Altezocine, Flunox)</td>
<td>9/20/2018 3:38 PM</td>
<td>Anesthetic</td>
<td>Standard</td>
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<tr>
<td>Buprenorphine SR (Zoopharm)</td>
<td>9/20/2018 3:43 PM</td>
<td>Reproductive Hazard/Teratogen, Analgesic</td>
<td>Standard</td>
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<tr>
<td>Ibuprofen (Motrin, Advil)</td>
<td>9/20/2018 3:45 PM</td>
<td>Reproductive Hazard/Teratogen, Analgesic</td>
<td>Standard</td>
</tr>
</tbody>
</table>

4 items  

Page 1 of 1  

[Image of the webpage interface]
Smartform

Protocol #2

Principal investigator: Joe Brain
Faculty Sponsor: 
Submission type: New Protocol Application
Primary contact: IACUC coordinator: 
Consulted vet: PI proxies: 
RATS Legacy #: 

Letter: Protocol type: Experimental Research
Initial Approval Date: 
Admin office: ARC

Codicils: No

Pre-Submission

Pre-Review → IACUC Review → Post-Review → Review Complete

Clarification Requested → Clarification Requested → Modifications Required

History

<table>
<thead>
<tr>
<th>Activity</th>
<th>Author</th>
<th>Activity Date</th>
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</thead>
<tbody>
<tr>
<td>Protocol Created</td>
<td>Joe Brain</td>
<td>2/11/2020 6:17 PM</td>
</tr>
</tbody>
</table>
1. *Experiment name:*  
   Experiment 1

2. *Species:*  
   Mouse

3. Briefly explain the scientific goal of this experiment:
   Experimental Goals

4. Describe the experiment:  
   For any given group/cohort, describe what any given animal will experience from initiation of the study to euthanasia, including order and minimal time between procedures. Detailed procedural descriptions and animal numbers are not needed here, as they will be provided below.
   Description of experiment
5. Select experimental procedures, including euthanasia methods:

6. Table of Animals:
   Note: the calculator will multiply the group size by the number of animals for the experiment.

   a. * Explain how you estimated the appropriate number of animals for the experiment. In addition, please provide an estimation of the number of animals to be used per individual data point etc. in the test box below.

   - Power analysis was conducted using values from effect size based on pilot data or data from similar experiments.
   - Group sizes were selected based on data from 2 citations below.
   - This is a pilot study for which there are no prior studies with which to estimate group size. Data collected from the literature.
   - No statistical comparisons are planned. This is a qualitative or methodology feasibility study using the minimum number of animals from which reliable conclusions can reasonably be expected to be drawn.

   - Other (Please elaborate in the box below)
7. Number of animals by pain category: place all non-USDA regulated species in N: (include each animal only once in the highest pain category).

N: 0
B: 0
C: 0
D: 0
E: 0

a. Justify the need for any animals in pain category E.

8. Identify husbandry exceptions:

9. * Should DLAM need to treat your animals in the event of a reported clinical event or emergency, are there substances (e.g. NSAIDS or other analgesics, antibiotics, etc.) that should not be used?
   - Yes
   - No
   - Clear
# User Training

User training dates

<table>
<thead>
<tr>
<th>Date</th>
<th>Time</th>
<th>Location</th>
<th>Capacity</th>
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<tbody>
<tr>
<td>2/25 Tuesday</td>
<td>2:00 – 3:30 PM</td>
<td>Wilshire-Glendon Building* 10889 Wilshire, room 820-20</td>
<td>16</td>
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<tr>
<td>2/28 Friday</td>
<td>2:30 – 4:00 PM</td>
<td>Biomedical Library 6th Floor, TLC Classroom</td>
<td>30</td>
</tr>
<tr>
<td>3/10 Tuesday</td>
<td>1:30 – 3:00 PM</td>
<td>Biomedical Library 6th Floor, TLC Classroom</td>
<td>30</td>
</tr>
<tr>
<td>3/11 Wednesday</td>
<td>2:30 – 4:00 PM</td>
<td>Biomedical Library 6th Floor, TLC Classroom</td>
<td>30</td>
</tr>
</tbody>
</table>
• ARC Staff: arc@research.ucla.edu or 310-206-6308
• IBC Staff: ibc@research.ucla.edu or 310-794-0262
• RSC Staff: rsc@research.ucla.edu or 310-206-5601
• RSAWA Director: jperkins@research.ucla.edu or 310-794-9645
OHRPP Updates

February 13, 2020
OHRPP Updates

New OHRPP QIU staff

Preview of PAR guidance update

Learn at Lunch

OHRPP Training & HRN
New OHRPP Quality Improvement Unit Staff

Tiffany Rose, Sr. Analyst, QIU
- Previously worked at USC
- Started last week

Anya Rosensteel, Sr. Analyst, QIU
- Internal OHRPP promotion
- Starts next week
PARs – a snapshot of what’s been submitted

There’s a lot of noise

- Average > 3000/yr.
  - That’s more than 58 a week.
  - > 10% IBs
  - Investigator’s brochures are managed differently than all other study documents

- Average 100 SSEs/yr.
  - Many are not urgent

- > 5% external AEs
  - Many of these are follow-ups with no substantive update
Revised PAR Guidance - Goals

Goals:
1. To ensure the IRB receives everything that they need to meet regulatory and compliance oversight functions.
2. To stop submission of materials the IRB does not need to receive in order to reduce the burden on:
   • **The IRB**, especially the Chairs, reviewing and making determinations on unnecessary submissions/duplicate submissions
   • **OHRPP staff** processing unnecessary submissions/duplicate submissions
   • **Researchers and their proxies** submitting/responding to queries on unnecessary submissions
Revised PAR Guidance – purpose of PARs

<table>
<thead>
<tr>
<th>Type of Application</th>
<th>Purpose of the application</th>
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<tbody>
<tr>
<td>Post approval report application</td>
<td>The PI provides information relevant to the ongoing conduct of the research:</td>
</tr>
<tr>
<td></td>
<td>1) After-the fact reporting for deviations necessary to eliminate immediate hazards to participants</td>
</tr>
<tr>
<td></td>
<td>2) Urgent safety information that may suggest an unexpected change to the risks or benefits of the research</td>
</tr>
<tr>
<td></td>
<td>3) Events/information related to non-compliance that could rise to the level of serious or continuing non-compliance</td>
</tr>
<tr>
<td></td>
<td>4) Complaints about the research</td>
</tr>
</tbody>
</table>
PARs – Regulatory requirements

IRBs are required (under 45 CFR 46.108(a)(4) &/or 21 CFR 46.108(b)) to make determinations on events/incidents/new information (when appropriate) related to conduct of the research at the site(s) under that IRB’s jurisdiction and report those to the relevant regulators (OHRP &/or FDA) in a timely fashion:

1. Unanticipated Problems Involving Risks to Subjects or Others
2. Serious non-compliance
3. Continuing non-compliance
4. Suspension of the research by the IRB
5. Termination of the research by the IRB
The guidance is more specific (what we do and don’t want to be submitted via PAR) to help limit submissions to what is necessary for the IRB to review

- Examples for biomedical and social/behavioral research have been added throughout

- For reports/information we will no longer will receive via PAR, instructions are provided on what to do with them.
PAR guidance – what’s changed

GENERAL (cont.):

➢ **Definitions** have been *re-organized* (in order of complexity/severity) and *updated* (for UAP, serious non-compliance and continuing compliance) to conform to UCOP definitions.

➢ These are the definitions we are asking reviewers/IRBs to use when making these determinations

➢ **Remove the term “violation”** throughout the document, as we want to *encourage investigators to report relevant deviations* and it is not a term used in the regulations.
PAR guidance – what’s changed

GENERAL (cont.):

- Clarify that **this guidance is only for IRB reporting** and that **other entities may have other requirements**
- **Add subtypes of categories** under PI reporting responsibilities in sub-headers (indexed)
- Add AAHRPP standards reference, update reference links, and add ICH-GCP references
- Simplify the **IRB responsibilities and procedures section** (to reflect Chair/designee triage)
PAR guidance – what’s changed

ADVERSE EVENTS:

- **Limit initial reports of external AEs** to only ones *where the local PI is certain* it meets all three criteria (serious, related, and unexpected)
  - Necessary as there is a “don’t know” option in webIRB for the question regarding seriousness of event

- **Limit follow-up reports for external AEs** to only those that provide information that the event is now *of greater severity than initially reported*. 
PAR guidance – what’s changed

DSMB REPORTS:

➤ Only reports that indicate the DSMB *has a concern* about the research or that indicate the DSMB has *suspended or terminated the research* should be submitted.

➤ DSMB reports that indicate the study may “continue as planned” should no longer be submitted.
PAR guidance – what’s changed

SAFETY REPORTS:

- PARs are now specifically designated as the mechanism for submitting required progress reports for IDEs, treatment IDEs, and HUDs to comply with these FDA regulations
  - 21 CFR 312.53(c)(1)(vii)
  - 21 CFR 312.66
  - 21 CFR 812.150(a)(1)

- Investigator’s brochures/device brochures will only be submitted via Initial application and Amendment applications moving forward
SAFETY REPORTS (cont.):

- Notification to the IRB of the use of the short form process will now be made in the Amendment application submitted to provide the IRB with the fully translated consent document (to reduce the number of IRB submissions necessary to successfully complete the short form checklist)

- Include a place for investigators to submit “self-assessment” forms – a new component of the forthcoming post-approval monitoring program of the QIU
PAR guidance – what’s changed

SINGLE SUBJECT EXCEPTIONS:

- Single Subject Exceptions are now limited to *only inclusion/exclusion criteria variance* on treatment studies where there is a time constraint that would make submission/processing of an Amendment application not a plausible mechanism.

- Specific *details/justification needed* for the IRB chair/designee to consider a SSE are now described.

- Additional guidance is included for the investigator/clinician to *consider expanded access options* as well.
DEVIATIONS:

- Provide *updated content to be included in the log of deviations* (submitted at CR or kept in study records for no CR studies)

- Clarify that *all* research-related *breaches of confidentiality* meet the threshold for reporting

- Put the *responsibility to notify the IRB of non-compliance trends* on the Principal Investigator
DEVIATIONS (cont.):

➤ Provide guidance on *root causes analyses and CAPA plans* for research deviations that meet the threshold for reporting.

➤ Include directions to *consult with campus and/or health system compliance offices* for specific types of reportable deviations.

➤ Include that *OHRPP QIU may open complaint PARs* for complaints that come directly to the OHRPP office.
PAR guidance – what’s changed

SINGLE IRB/RELIANCE PARS:

Guidance for submission (or not) of PARs under sIRB (reviewing and relying) is now provided.

Throughout the document, “internal” events are defined as happening at sites under the responsibility of a UCLA IRB (to help investigator better understand what actions the IRB may take when other sites rely on the UCLA IRB).
PAR guidance – rollout

Related guidance and other documents will be updated:

• Decision Trees
• IRB Review Type - Amendments to Previously Approved Research
• Complaints, Concerns and Suggestions, and Reports of Undue Influence Regarding the Conduct of Human Participants Research
• Noncompliance and Allegations of Noncompliance Regarding the Conduct of Human Subjects Research
• Research Involving Non-English Speaking Research Participants
• CHECKLIST FOR USING THE “SHORT FORM” METHOD OF CONSENT FOR NON-ENGLISH SPEAKING RESEARCH PARTICIPANTS
• Protocol Violation, Deviation, or Incident Summary Log
PAR guidance – rollout

**Guidance Documents will be made available to stakeholders:**
- On OHRPP website

**Updates announced:**
- Via Human Research News

**Trainings provided to:**
- CRU (hem/onc coordinators)
- All researchers (at least 2 general sessions)
- Specific department trainings *as requested*
- IRB Chairs
- OHRPP staff
webIRB revisions (in development):
- Automated functions will be added to support the guidance
  - Auto-acknowledgement of some AEs
- Change to document management (for IBs)
  ➢ We hope these will roll out a few weeks after the guidance goes live
February 25, 2020, Noon-1pm

“Single IRB mandate and Reliance”

Presenter: Kristin Craun, Director UCLA OHRPP

Location: CHS 17-323
Upcoming presentations:

**March**: Expanded Access, Emergency Use, HUD, and Right To Try

**April**: Post Approval Reporting
OHRPP Quality Improvement Unit will come to your division/department for IRB-related training, customized to your needs.

Please suggest Learn at Lunch series topics

To request a custom training or suggest a Learn at Lunch topic, please contact: OHRPP Assistant Director, Education & Quality Improvement Moore Rhys (310) 794-6339
Reminder - Subscribe to Human Research News

To be the first to know when OHRPP releases guidance and other updates, please subscribe to our listserv

To subscribe, send an email (blank subject and body) to: investigators-l+subscribe@lists.ucla.edu
Any Questions?

Contact Information

Website URL
http://ora.research.ucla.edu/ohrpp

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Moore Rhys, OHRPP Asst. Director, Education & QI
Phone: x46339
Email: moore.rhys@research.ucla.edu
Agenda

• Financial Deliverable Preparation Procedure
  ◦ Background of the changes to the procedures
  ◦ Review of key steps in the procedures prior to the changes
  ◦ Review of changes to the procedures effective January 9, 2020

• RAPID Tool – New Version Released
Financial Deliverable Preparation Procedure

Yoon Lee
Financial Closeout of sponsored Projects

History

- April 2015: EFM announced the procedure for “Federal Fund Closeout”.
- July 2015: The procedure went into effect. It included the following key steps.
  1. Department submits a closeout packet to EFM by the due date.
  2. EFM reviews a closeout packet and work with the department for additional inquires to prepare and submit an accurate financial deliverable to the sponsor.
  3. In the event Department fails to submit a closeout packet by the due date, EFM initiates analysis of final expenditures to prepare and submit a financial deliverable to the sponsor.
- September 2016: EFM announced the procedure for “Financial Closeout of Sponsored Projects”.
  - The procedure for “Federal fund closeout’ was expanded for all sponsored projects.
- January 2017: The procedure went into effect.
- The standard procedure expected of campus to follow is Step #1 and Step #2.
- Step #3 was added as a back up plan in the event when Step #1 and Step #2 are not followed.
  - The purpose of adding the step #3 was to minimize financial and compliance risk for the University.
  - Recovering some costs incurred for the project by submitting financial deliverable on time is better than putting all unbilled/unreported costs at risk for non-reimbursement.
  - Continued or frequent non-compliance with on-time submission will jeopardize future funding.
  - The step #3 was never intended to be the standard procedure for financial closeout of the sponsored projects.
Financial Deliverable Preparation Procedure

What is happening now?

- **1,716** closeout packets were due to EFM.
- **1,182** closeout packets were not submitted to EFM by the due date.
- **534** closeout packets were submitted to EFM by the due date.
  - Not all 534 closeout packets were complete for EFM to conduct a meaningful review.
- **31%** followed the procedure as intended.
- **69%** did not follow the procedure.

1,182 funds were left for EFM to initiate analysis of total expenditure for the project.
Concerns and Plans

- EFM initiating analysis of final expenditure for 69% of sponsored project funds with expenditure over a billion dollars is not sustainable.

- Eliminating the step #3 will place the University back in the position where financial and compliance risk was higher before implementing the new procedures in phases in 2015 and 2017. This is not an option.

- For financial closeout of a high number of the sponsored projects without a closeout packet, the changes to the procedures were necessary.
  - These minimum changes would not address the fundamental concern and the issue of sustainability.

- Strong partnership from campus to submit a complete closeout packet on time is critical to ensure cost recovery and not risk future funding for the University.

- EFM will continue to monitor on-time submission rate of closeout packets and
  - If complete closeout packets are submitted on time 70% or more, these changes can be reversed.
  - If notable improvement is not made, alternative approaches need to be considered to ensure on-time submission of the final financial deliverables to recover costs for sponsored projects.
### Final Financial Report or Invoice

<table>
<thead>
<tr>
<th>When a complete closeout packet is submitted to EFM by the due date:</th>
<th>Prior to January 9, 2020</th>
<th>Effective January 9, 2020</th>
</tr>
</thead>
<tbody>
<tr>
<td>EFM prepares and submits the final to the sponsor. (Additional inquiry may be needed)</td>
<td>No change.</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>When a complete closeout packet is NOT submitted to EFM by the due date:</th>
<th>Prior to January 9, 2020</th>
<th>Effective January 9, 2020</th>
</tr>
</thead>
<tbody>
<tr>
<td>EFM initiates and communicates EFM’s analysis of final expenditures.</td>
<td>No change.</td>
<td></td>
</tr>
<tr>
<td>Department responds to EFM’s analysis within 5 business days.</td>
<td><strong>5 business days → 3 business days</strong></td>
<td></td>
</tr>
<tr>
<td>• EFM accepts all adjustments to EFM’s analysis as long as a complete list of adjusting transactions with appropriate supporting documents are submitted.</td>
<td>No other change.</td>
<td></td>
</tr>
<tr>
<td>• EFM submits the final based on EFM’s analysis when a response is not complete or not received by the due date.</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

“Financial Closeout of Sponsored Projects” procedure document can be downloaded at [https://efm.research.ucla.edu/policies-and-procedures/](https://efm.research.ucla.edu/policies-and-procedures/)
When the sponsor requires an annual financial report to close out each budget period, EFM prepares the annual financial report as follows. (“Final for Budget” in PAMS)

<table>
<thead>
<tr>
<th>Prior to January 9, 2020</th>
<th>Effective January 9, 2020</th>
</tr>
</thead>
<tbody>
<tr>
<td>When a separate fund number is assigned for each budget period:</td>
<td>No change.</td>
</tr>
<tr>
<td>The procedure for “Financial closeout of sponsored project” applies.</td>
<td></td>
</tr>
<tr>
<td>Department responds to EFM’s analysis within 5 business days.</td>
<td>5 business days ➔ 3 business days</td>
</tr>
<tr>
<td>• EFM includes expenses posted to GL after the budget period but incurred during the budget period (based on “doc date” in GL) and excludes unallowable/inapplicable expenses.</td>
<td>• No change</td>
</tr>
<tr>
<td>• EFM accepts all adjustments to EFM’s analysis as long as a complete list of adjusting transactions with appropriate supporting documents are submitted.</td>
<td>• All adjustments ➔ Subward expenses only.</td>
</tr>
<tr>
<td>• EFM submits the final based on EFM’s analysis when a response is not complete or not received by the due date.</td>
<td>• No change</td>
</tr>
</tbody>
</table>
Revision of the Final Financial Deliverables

- Most revision requests are made when the final financial deliverable was submitted based on EFM’s analysis in absence of a closeout packet and response to EFM’s analysis.

<table>
<thead>
<tr>
<th>Revision to reduce expenses</th>
<th>Prior to January 9, 2020</th>
<th>Effective January 9, 2020</th>
</tr>
</thead>
<tbody>
<tr>
<td>The amount to revise</td>
<td>Revise for any amount</td>
<td>No change</td>
</tr>
<tr>
<td>The number of revision</td>
<td>No limit</td>
<td>No change</td>
</tr>
<tr>
<td>The timing of revision</td>
<td>Anytime</td>
<td>No change</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Revision to increase expenses</th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>The amount to revise</td>
<td>Revise for any amount</td>
<td>Was a complete closeout packet submitted to EFM by the due date?</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Yes: $5,000 or over</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• No: $10,000 or over</td>
</tr>
<tr>
<td>The number of revision</td>
<td>No limit</td>
<td>Up to 2 times</td>
</tr>
<tr>
<td>The timing of revision</td>
<td>Anytime</td>
<td>Within 120 days after the submission date of the original final or the original final due date, whichever is later</td>
</tr>
</tbody>
</table>
# Changes to Financial Deliverable Preparation Procedure

## SUMMARY OF CHANGES

<table>
<thead>
<tr>
<th>Areas</th>
<th>Prior to 1/1/20</th>
<th>Effective 1/1/20</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Annual Financial Report</strong> (Closeout by budget period: “Final for Budget” in PAMS)</td>
<td>Accepted all additional expenses for the budget period when supporting documents were provided. Department had 5 business days to respond to EFM’s analysis of expenditures.</td>
<td>Accept adjustments for sub award expenditures only with the supporting documents. 3 business days</td>
</tr>
<tr>
<td><strong>Final financial deliverables, Was a complete closeout packet submitted to EFM by the due date?</strong></td>
<td>Yes EFM submitted the final to the sponsor (additional inquiry may be needed)</td>
<td>No change</td>
</tr>
<tr>
<td></td>
<td>No Department had 5 business days to respond to EFM’s analysis of final expenditures.</td>
<td>3 business days</td>
</tr>
<tr>
<td><strong>Revision of the Final, Is it to reduce the reported expenditure?</strong></td>
<td>Yes Revised for any amount, Unlimited times, Any time</td>
<td>No change</td>
</tr>
<tr>
<td></td>
<td>No Revised for any amount, Unlimited times Any time</td>
<td>Was a complete closeout packet submitted to EFM by the due date?</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Yes: $5,000 or over</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• No: $10,000 or over</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Up to 2 times within 120 days after the submission date of the original final or the original final due date, whichever is later</td>
</tr>
</tbody>
</table>
RAPID Tool – New Version Released

Yoon Lee
• Updated version of the RAPID Tool (version 2/10/20) is available for download from the ORA Portal: http://portal.research.ucla.edu/index.aspx?Section=PostAward

• New version of the tool was needed to support a new QDB connection.
  ◦ QDB was upgraded from SQL Server 2008 to SQL Server 2014 during February 8-9, 2020.
  ◦ Coordination with your local IT helpdesks may be needed to install new drivers (Microsoft® SQL Server® 2012 Native Client – QFE driver). Additional information provided in the downloaded file from the ORA portal.

• Announcements of the updated RAPID Tool version were sent to campus via ORA News and PAMS Listservs on February 11, 2020.

• Subscribe to ORA News: ora-news+subscribe@lists.ucla.edu
Any Questions?

Contact Information

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http://ora.research.ucla.edu/efm/

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