UCLA Research Administration

Research Administration Forum

Marcia Smith

February 13, 2020

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

NIH Deputy Director Town Hall with Michael Lauer, M.D.

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.
RSVP: http://bit.ly/UCLA-Lauer

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.
RSVP: http://bit.ly/UCLA-Lauer-2

Please direct any questions about the event to: ovcr@conet.ucla.edu

Agenda

- **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*

UCLA EPASS
Extramural Proposal Approval And Submission Summary

EPASS System

Research Administrator's Forum

February 13, 2020

EPASS System - History

UCLA EPASS
Extramural Proposal Approval And Submission Summary

- 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

UCLA EPASS
Extramural Proposal Approval And Submission Summary

OCGA Proposal and Award Intake

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

User Acceptance Testing

UCLA EPASS
Extramural Proposal Approval And Submission Summary

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?

UCLA EPASS
Extramural Proposal Approval And Submission Summary

- 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

UCLA EPASS
Extramural Proposal Approval And Submission Summary

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

UCLA ORA
Office of Research Administration

Grant Updates

February 13, 2020

NIH

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

NOT-OD-20-070

NRSA Stipend Levels FY2020

Career Level	Years of Experience	Stipend for FY 2020
Predoctoral	All	25,320
Postdoctoral	0	$52,704
	1	$53,076
	2	$53,460
	3	$55,596
	4	$57,456
	5	$59,580
	6	$61,800
	7 or More	$64,008

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

NRSA FAQs

NIH

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

If your intended due date is…	You must use…
On or before May 24, 2020, including: • Applications submitted for due dates on or before May 24, 2020 • Applications submitted under NIH Late Policy 2-week window of consideration for intended due dates on or before May 24, 2020 • Applications submitted by June 7, 2020 under NIH Continuous Submission Policy for the May 7, 2020 AIDS intended due date	FORMS-E application package
On or after May 25, 2020, including: • Applications submitted for due dates on or after May 25, 2020 • All application types (New, Resubmission, Renewal, Revision) • Applications submitted early for intended due dates on or after May 25, 2020	FORMS-F application package

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

NIH

NIH Forms F

[high-level-form-change-summary-FORMS-F]

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

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

ORCID (Open Researcher and Contributor Identifiers)

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

- Per NOT-OD-19-109
- 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**

NSF

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)

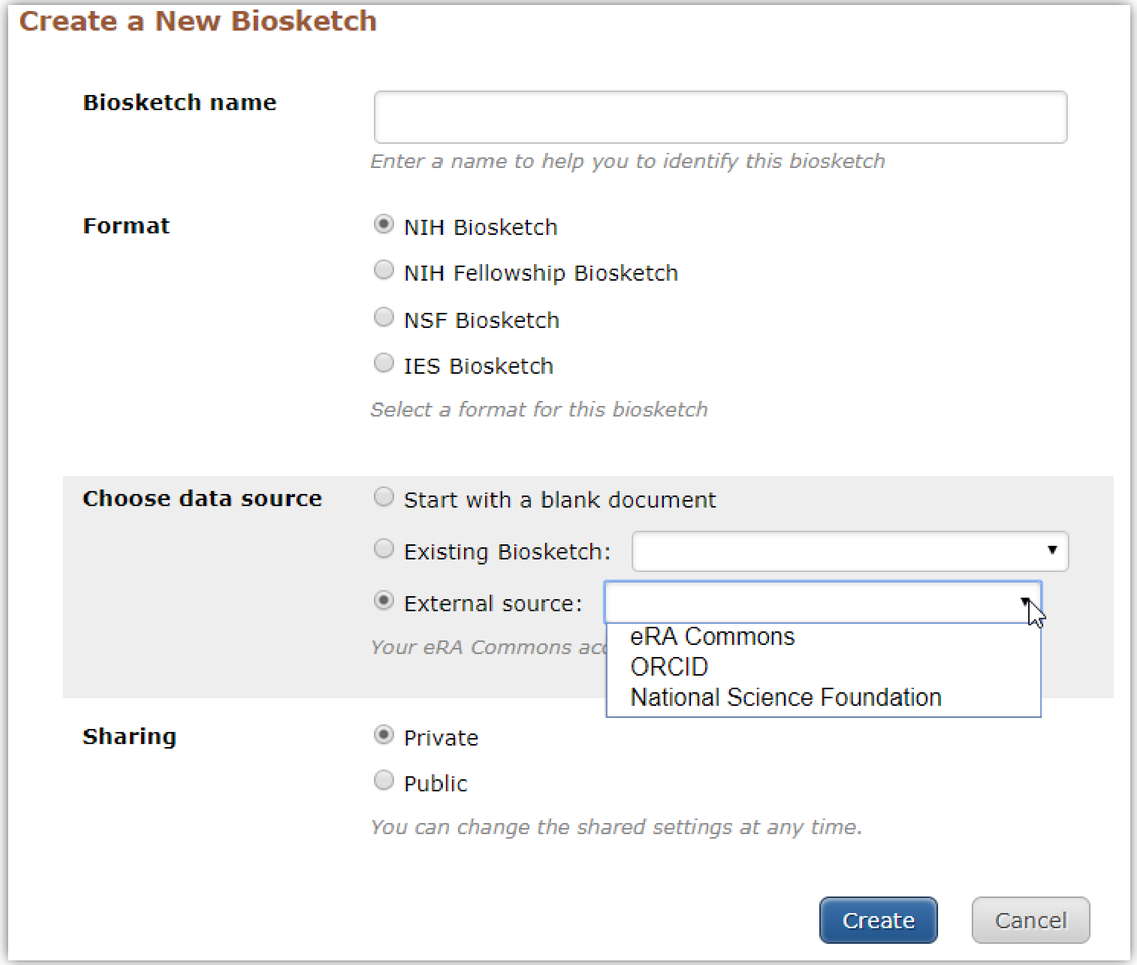
SciENcv

Science Experts Network Curriculum Vitae

- https://www.ncbi.nlm.nih.gov/sciencv/
- Part of My NCBI
  - Sign in with NIH eCommons, NSF, Google, or other Institutional Login Accounts

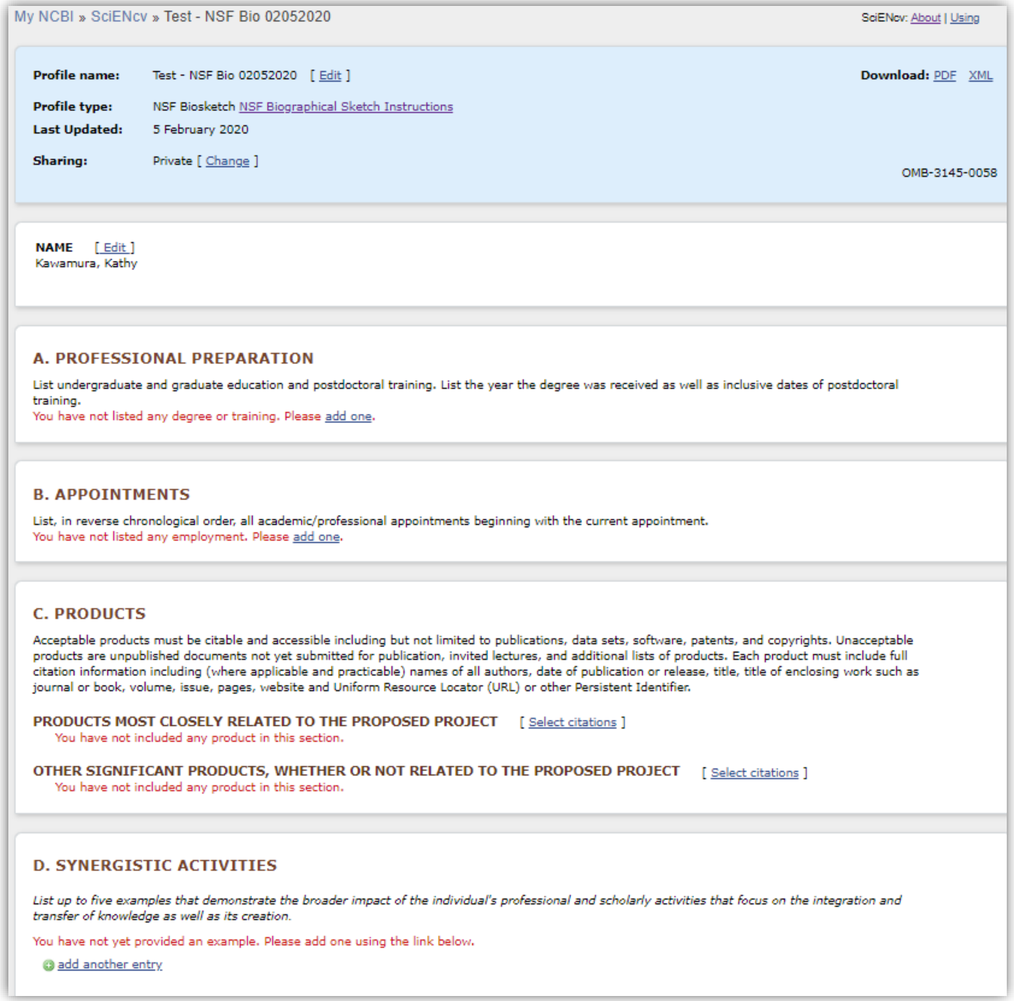
Benefits per SciENcv

- *"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"*



SciENcv

NSF Biosketch



My NCBI » SciENcv » Test - NSF Bio 02052020 — SciENcv: About | Using

Profile name: Test - NSF Bio 02052020 [Edit] — **Download:** PDF XML
Profile type: NSF Biosketch NSF Biographical Sketch Instructions
Last Updated: 5 February 2020
Sharing: Private [Change]
OMB-3145-0058

NAME [Edit]
Kawamura, Kathy

A. PROFESSIONAL PREPARATION

List undergraduate and graduate education and postdoctoral training. List the year the degree was received as well as inclusive dates of postdoctoral training.
You have not listed any degree or training. Please add one.

B. APPOINTMENTS

List, in reverse chronological order, all academic/professional appointments beginning with the current appointment.
You have not listed any employment. Please add one.

C. PRODUCTS

Acceptable products must be citable and accessible including but not limited to publications, data sets, software, patents, and copyrights. Unacceptable products are unpublished documents not yet submitted for publication, invited lectures, and additional lists of products. Each product must include full citation information including (where applicable and practicable) names of all authors, date of publication or release, title, title of enclosing work such as journal or book, volume, issue, pages, website and Uniform Resource Locator (URL) or other Persistent Identifier.

PRODUCTS MOST CLOSELY RELATED TO THE PROPOSED PROJECT [Select citations]
You have not included any product in this section.

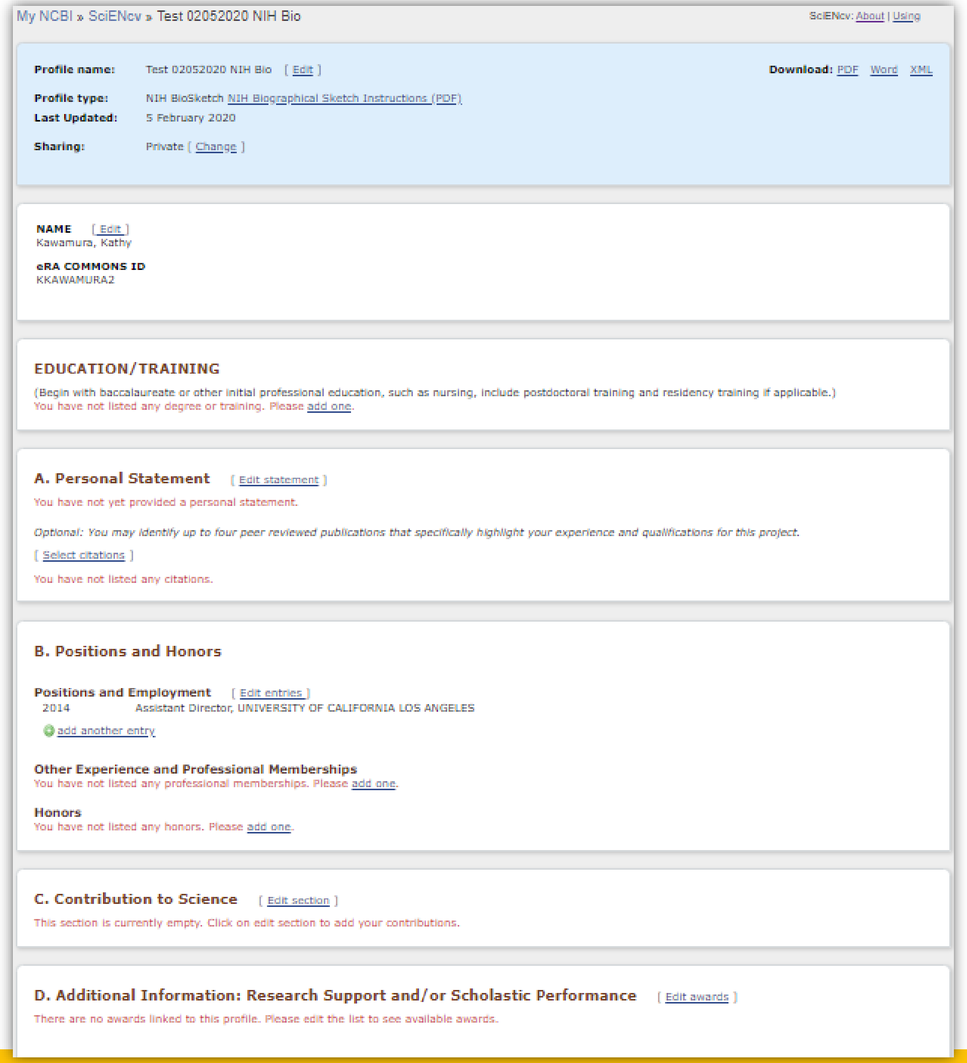
OTHER SIGNIFICANT PRODUCTS, WHETHER OR NOT RELATED TO THE PROPOSED PROJECT [Select citations]
You have not included any product in this section.

D. SYNERGISTIC ACTIVITIES

List up to five examples that demonstrate the broader impact of the individual's professional and scholarly activities that focus on the integration and transfer of knowledge as well as its creation.

You have not yet provided an example. Please add one using the link below.
add another entry

NIH Biosketch



My NCBI » SciENcv » Test 02052020 NIH Bio — SciENcv: About | Using

Profile name: Test 02052020 NIH Bio [Edit] — **Download:** PDF Word XML
Profile type: NIH BioSketch NIH Biographical Sketch Instructions (PDF)
Last Updated: 5 February 2020
Sharing: Private [Change]

NAME [Edit]
Kawamura, Kathy

eRA COMMONS ID
KKAWAMURA2

EDUCATION/TRAINING

(Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable.)
You have not listed any degree or training. Please add one.

A. Personal Statement [Edit statement]

You have not yet provided a personal statement.

Optional: You may identify up to four peer reviewed publications that specifically highlight your experience and qualifications for this project.

[Select citations]

You have not listed any citations.

B. Positions and Honors

Positions and Employment [Edit entries]
2014 Assistant Director, UNIVERSITY OF CALIFORNIA LOS ANGELES
add another entry

Other Experience and Professional Memberships
You have not listed any professional memberships. Please add one.

Honors
You have not listed any honors. Please add one.

C. Contribution to Science [Edit section]

This section is currently empty. Click on edit section to add your contributions.

D. Additional Information: Research Support and/or Scholastic Performance [Edit awards]

There are no awards linked to this profile. Please edit the list to see available awards.

MASTER TRAINING

http://www.research.ucla.edu/ocga/training-calendar.html

FEBRUARY

NIH Assist Basics

from the Preparer's Perspective

Wednesday, February 19, 2020

10889 Wilshire Blvd., Conf Room 820-20

9:30am-11:00 am

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

UCLA Research Administration

RSAWA Updates

Research Safety & Animal Welfare Administration

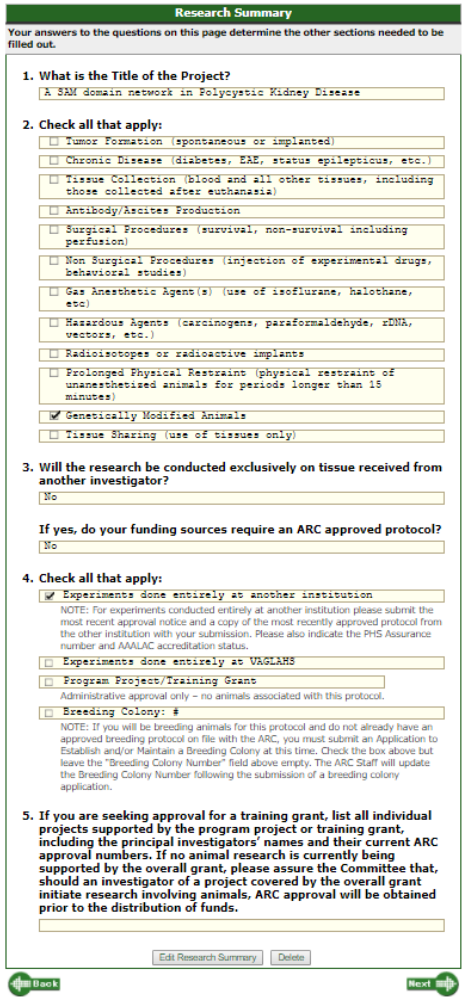
- **New RATS to launch soon**
  - Differences
  - Benefits
  - User Population
  - User Interface
  - Smartform
  - User Training

UCLA Research Administration

Differences

RATS

Top down Narrative Approach



Research Summary

Your answers to the questions on this page determine the other sections needed to be filled out.

1. **What is the Title of the Project?**
   A SAM domain network in Polycystic Kidney Disease

2. **Check all that apply:**
   - ☐ Tumor Formation (spontaneous or implanted)
   - ☐ Chronic Disease (diabetes, EAE, status epilepticus, etc.)
   - ☐ Tissue Collection (blood and all other tissues, including those collected after euthanasia)
   - ☐ Antibody/Ascites Production
   - ☐ Surgical Procedures (survival, non-survival including perfusion)
   - ☐ Non Surgical Procedures (injection of experimental drugs, behavioral studies)
   - ☐ Gas Anesthetic Agent(s) (use of isoflurane, halothane, etc)
   - ☐ Hazardous Agents (carcinogens, paraformaldehyde, rDNA, vectors, etc.)
   - ☐ Radioisotopes or radioactive implants
   - ☐ Prolonged Physical Restraint (physical restraint of unanesthetized animals for periods longer than 15 minutes)
   - ☑ Genetically Modified Animals
   - ☐ Tissue Sharing (use of tissues only)

3. **Will the research be conducted exclusively on tissue received from another investigator?**
   No

   If yes, do your funding sources require an ARC approved protocol?
   No

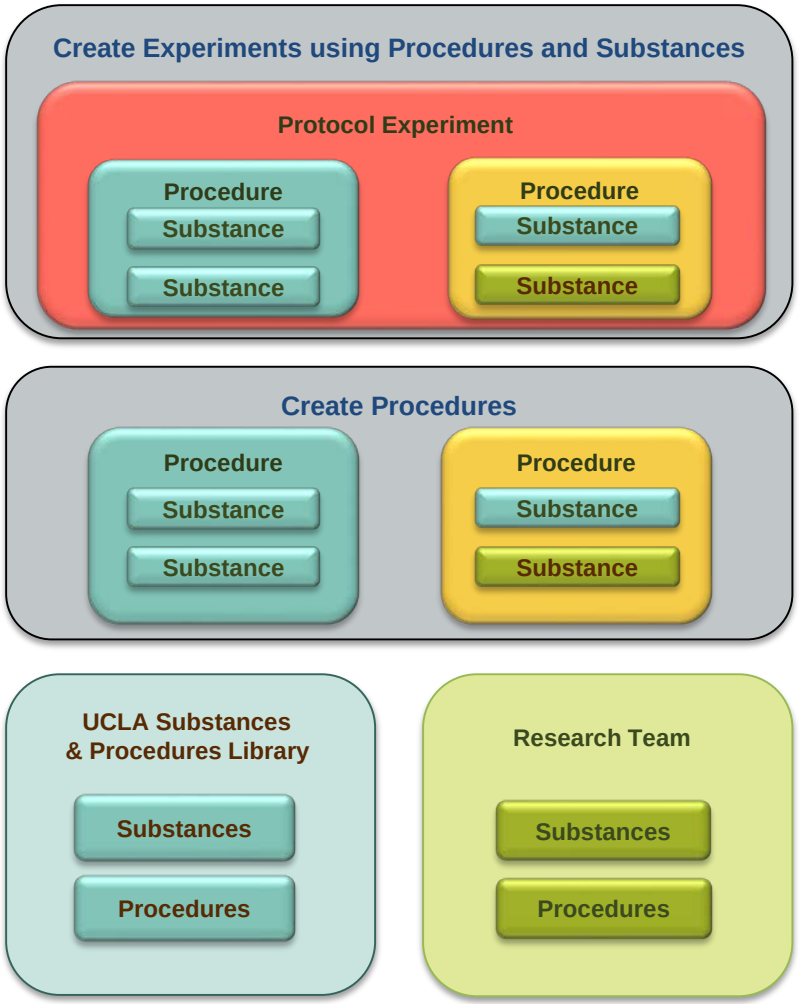
4. **Check all that apply:**
   - ☑ Experiments done entirely at another institution
     NOTE: For experiments conducted entirely at another institution please submit the most recent approval notice and a copy of the most recently approved protocol from the other institution with your submission. Please also indicate the PHS Assurance number and AAALAC accreditation status.
   - ☐ Experiments done entirely at VAGLAHS
   - ☐ Program Project/Training Grant
     Administrative approval only – no animals associated with this protocol.
   - ☐ Breeding Colony: #
     NOTE: If you will be breeding animals for this protocol and do not already have an approved breeding protocol on file with the ARC, you must submit an Application to Establish and/or Maintain a Breeding Colony at this time. Check the box above but leave the "Breeding Colony Number" field above empty. The ARC Staff will update the Breeding Colony Number following the submission of a breeding colony application.

5. **If you are seeking approval for a training grant, list all individual projects supported by the program project or training grant, including the principal investigators' names and their current ARC approval numbers. If no animal research is currently being supported by the overall grant, please assure the Committee that, should an investigator of a project covered by the overall grant initiate research involving animals, ARC approval will be obtained prior to the distribution of funds.**

Edit Research Summary | Delete

Back | Next

New RATS



Bottom up Building Block Approach

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Benefits

PIs	Reviewers & Committee	Central Administration
		
• 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

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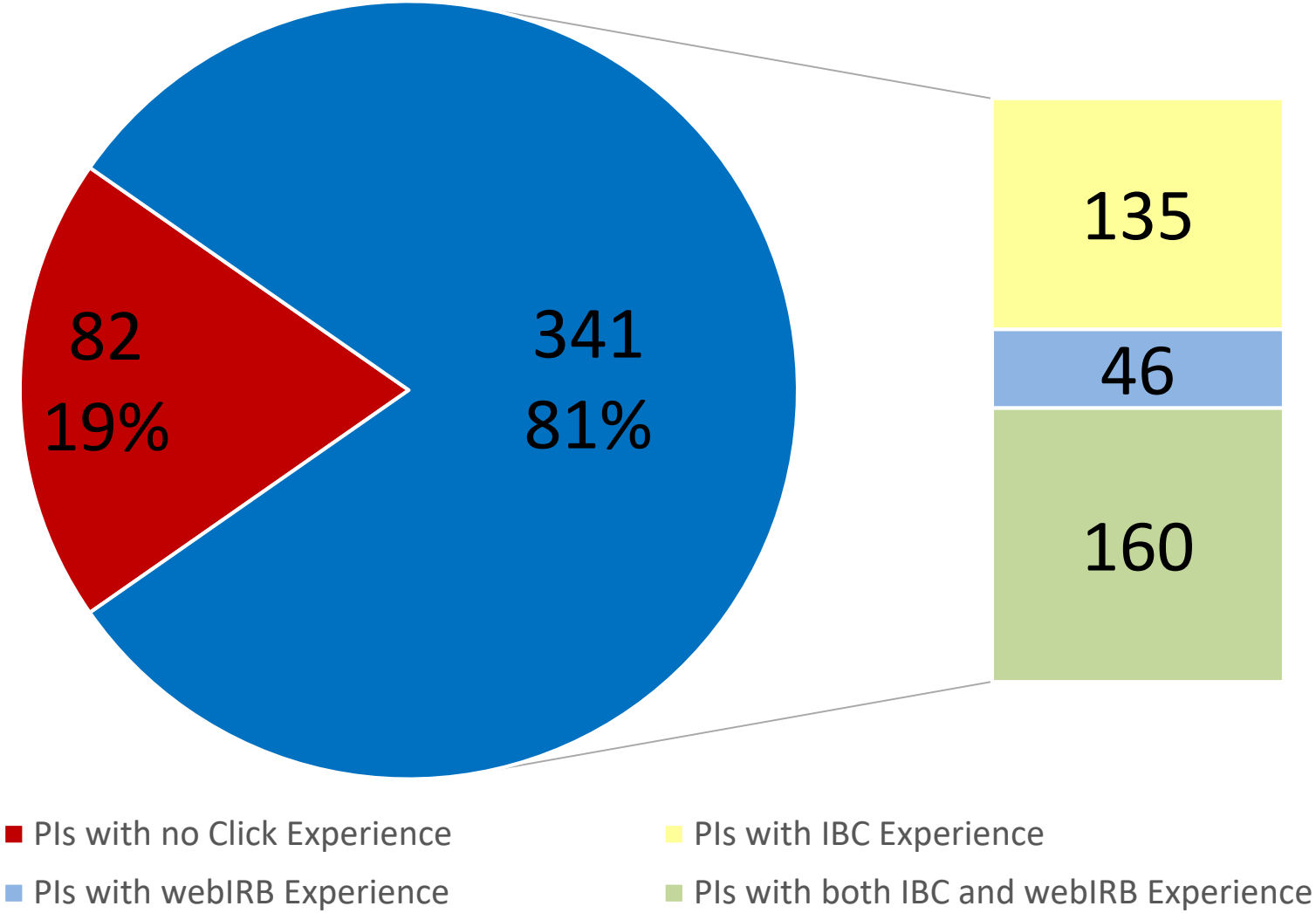
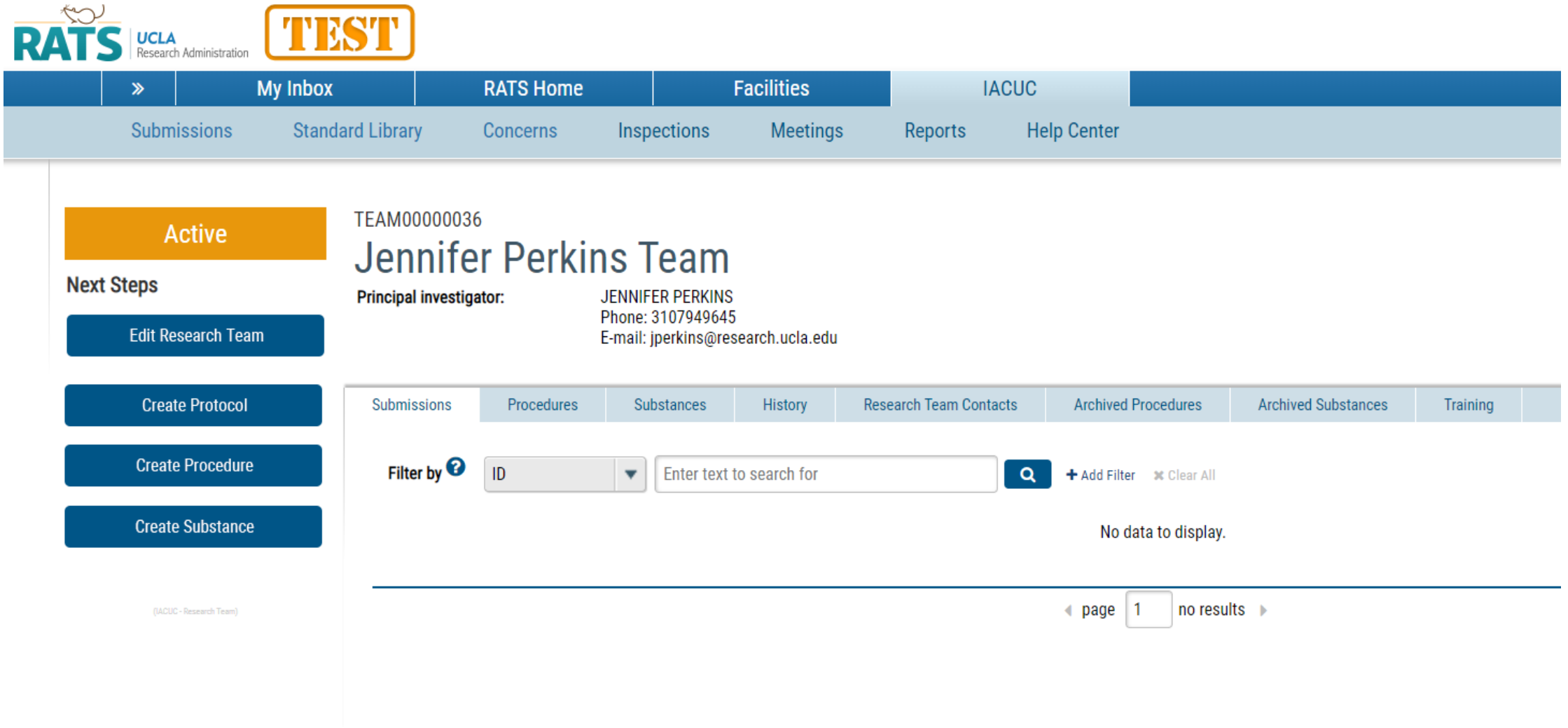
User Population



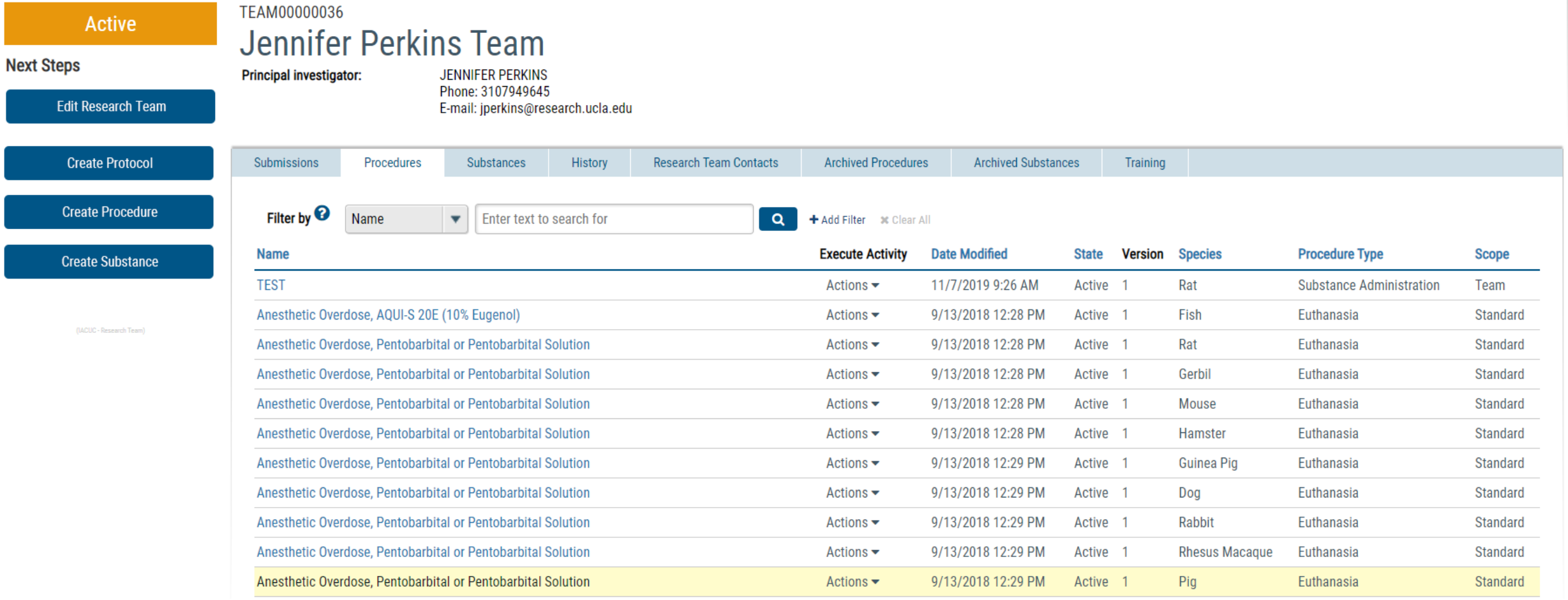
UCLA Research Administration

User Interface



UCLA Research Administration

User Interface



Name	Execute Activity	Date Modified	State	Version	Species	Procedure Type	Scope
TEST	Actions	11/7/2019 9:26 AM	Active	1	Rat	Substance Administration	Team
Anesthetic Overdose, AQUI-S 20E (10% Eugenol)	Actions	9/13/2018 12:28 PM	Active	1	Fish	Euthanasia	Standard
Anesthetic Overdose, Pentobarbital or Pentobarbital Solution	Actions	9/13/2018 12:28 PM	Active	1	Rat	Euthanasia	Standard
Anesthetic Overdose, Pentobarbital or Pentobarbital Solution	Actions	9/13/2018 12:28 PM	Active	1	Gerbil	Euthanasia	Standard
Anesthetic Overdose, Pentobarbital or Pentobarbital Solution	Actions	9/13/2018 12:28 PM	Active	1	Mouse	Euthanasia	Standard
Anesthetic Overdose, Pentobarbital or Pentobarbital Solution	Actions	9/13/2018 12:28 PM	Active	1	Hamster	Euthanasia	Standard
Anesthetic Overdose, Pentobarbital or Pentobarbital Solution	Actions	9/13/2018 12:29 PM	Active	1	Guinea Pig	Euthanasia	Standard
Anesthetic Overdose, Pentobarbital or Pentobarbital Solution	Actions	9/13/2018 12:29 PM	Active	1	Dog	Euthanasia	Standard
Anesthetic Overdose, Pentobarbital or Pentobarbital Solution	Actions	9/13/2018 12:29 PM	Active	1	Rabbit	Euthanasia	Standard
Anesthetic Overdose, Pentobarbital or Pentobarbital Solution	Actions	9/13/2018 12:29 PM	Active	1	Rhesus Macaque	Euthanasia	Standard
Anesthetic Overdose, Pentobarbital or Pentobarbital Solution	Actions	9/13/2018 12:29 PM	Active	1	Pig	Euthanasia	Standard

UCLA Research Administration

User Interface

Active

Next Steps

Edit Research Team

Create Protocol

Create Procedure

Create Substance

TEAM00000036

Jennifer Perkins Team

Principal investigator: JENNIFER PERKINS
Phone: 3107949645
E-mail: jperkins@research.ucla.edu

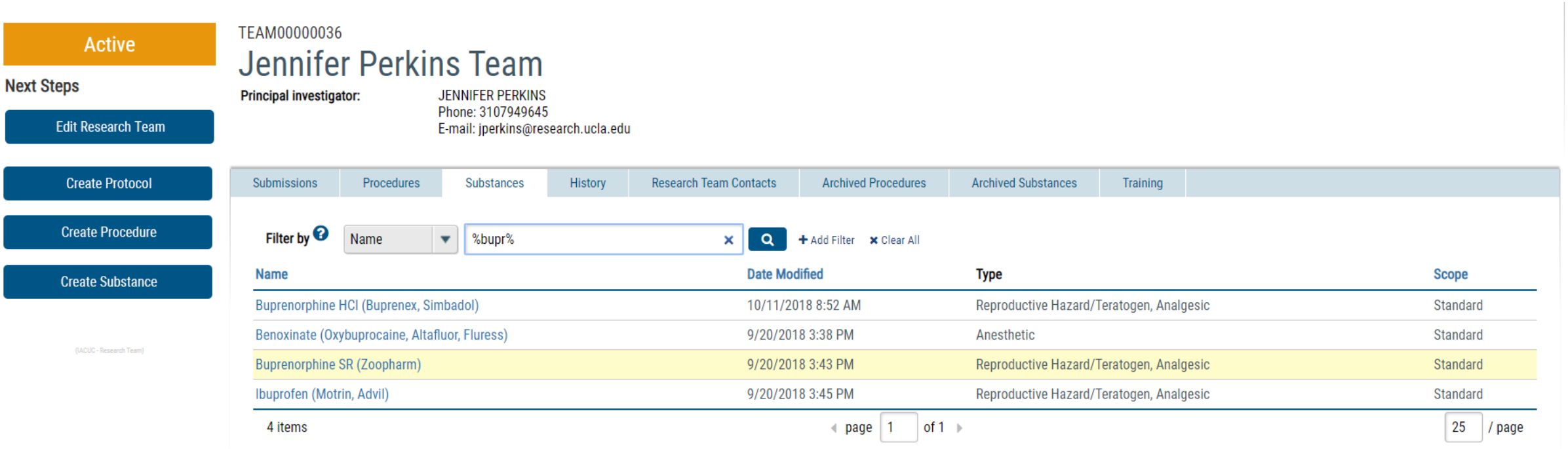
Submissions | Procedures | Substances | History | Research Team Contacts | Archived Procedures | Archived Substances | Training

Filter by | Name | Enter text to search for | + Add Filter | ✖ Clear All

Name	Date Modified	Type	Scope
1,2,4-Tribromo-5-(2,4-dibromophenoxy)benzene (DE-71)	2/11/2020 6:46 PM	Other	Standard
1-Methyl-4-phenyl-1,2,3,6-tetrahydropyridine (MPTP)	9/20/2018 3:39 PM	Other	Standard
2-Mercaptoethane Sulfonate Na (Mesna, Uromitexan, Mesnex)	9/20/2018 3:38 PM	Chemical Agent, Other	Standard
4-Hydroxycyclophosphamide	9/20/2018 3:38 PM	Reproductive Hazard/Teratogen, Chemotherapeutic or Other Hazardous Drug	Standard
4-Hydroxy-tamoxifen (tamoxifen, 4OHT)	9/20/2018 3:42 PM	Chemical Agent, Reproductive Hazard/Teratogen, Chemotherapeutic or Other Hazardous Drug , Hormonal Regulator	Standard
4-Ipomeanol (IPO, 1 pentanone, 4-hydroxypentanone)	9/20/2018 3:42 PM	Toxin of biological origin	Standard
4-nonylphenol (4-(2,4-dimethylheptan-3-yl)phenol)	9/20/2018 3:41 PM	Chemical Agent	Standard
5-(N,N-hexamethylene)amiloride (hexamethyleneamilioride)	9/20/2018 3:44 PM	Chemical Agent, Antiviral	Standard
5-Bromodeoxyuridine (BrdU, 5-bromo-2'deoxyuridine)	9/20/2018 3:41 PM	Chemical Agent, Antiviral, DNA/RNA	Standard
5-Fluorocytosine (Flucytosine, ancobon)	9/20/2018 3:38 PM	Reproductive Hazard/Teratogen, DNA/RNA, Antifungal Agent	Standard
5-Fluorouracil (fluorouracil, Adrucil)	9/20/2018 3:40 PM	Chemical Agent, Reproductive Hazard/Teratogen, Chemotherapeutic or Other Hazardous Drug , DNA/RNA	Standard
5-Lipoxygenase inhibitor	9/20/2018 3:43 PM	Reproductive Hazard/Teratogen, Toxin of biological origin, Analgesic	Standard

UCLA Research Administration

User Interface



UCLA Research Administration

Smartform

Pre-Submission

Next Steps

Edit Protocol

Printer Version

View Differences

- Manage Codicils
- Assign Admin Office
- Assign Coordinator
- Assign PI Proxy
- Manage Ancillary Reviews
- Manage Departures
- Add Comment
- Add Private Comment
- Manage Tags

ARC-2020-007

Protocol #2

Principal investigator:	Joe Bruin	**Letter:**	
Faculty Sponsor:		**Protocol type:**	Experimental Research
Submission type:	New Protocol Application	**Initial Approval Date:**	
Primary contact:		**Admin office:**	ARC
IACUC coordinator:			
Consulted vet:			
PI proxies:			
RATS Legacy #:		**Codicils:**	No

History | Experiments | Documents | Codicils | Reviews | Contacts | Snapshots | Training | Related Concerns | Change Log

Filter by Activity | Enter text to search for | + Add Filter | ✖ Clear All

Activity	Author	Activity Date
Protocol Created	Bruin, Joe	2/11/2020 6:17 PM

UCLA Research Administration

Smartform

1. * **Experiment name:**

Experiment 1

2. * **Species:**

Mouse ...

3. **Briefly explain the scientific goal of this experiment:**

Experimental Goals

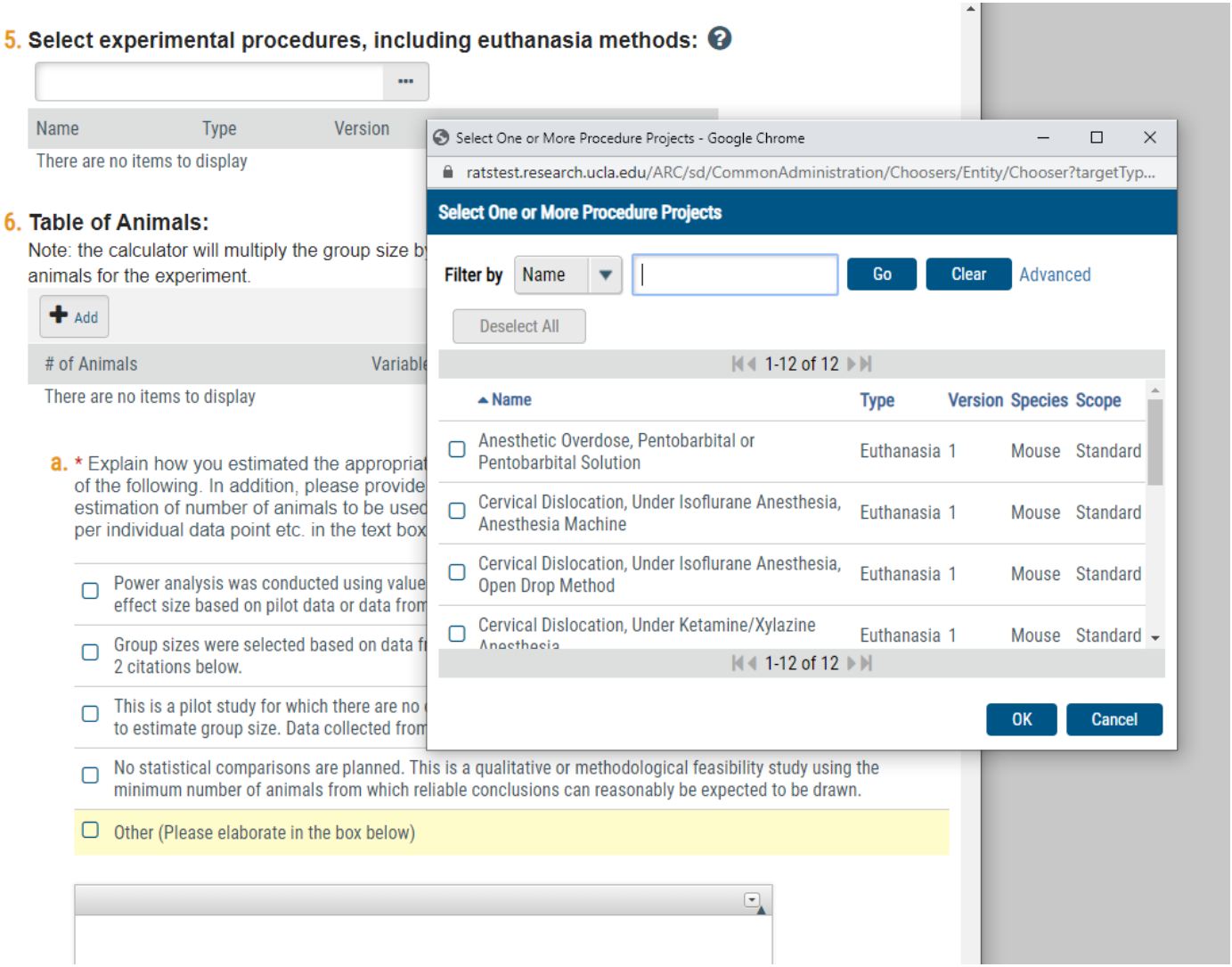
4. **Describe the experiment:**

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 both be provided below.

Description of experiment

UCLA Research Administration

Smartform



UCLA Research Administration

Smartform

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:**

Add

Exception Type	Description and Justification
There are no items to display	

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

UCLA Research Administration

User Training

Research Safety & Animal Welfare Administration

- **User training dates**

Date	Time	Location	Capacity
2/25 Tuesday	2:00 – 3:30 PM	Wilshire-Glendon Building* 10889 Wilshire, room 820-20	16
2/28 Friday	2:30 – 4:00 PM	Biomedical Library 6th Floor, TLC Classroom	30
3/10 Tuesday	1:30 – 3:00 PM	Biomedical Library 6th Floor, TLC Classroom	30
3/11 Wednesday	2:30 – 4:00 PM	Biomedical Library 6th Floor, TLC Classroom	30

UCLA Research Administration

RSAWA Contacts

Research Safety & Animal Welfare Administration

- 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

UCLA Research Administration

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

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

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

PAR guidance – what's changed

GENERAL:

- 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

PAR guidance – what's changed

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.

PAR guidance – what's changed

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

PAR guidance – what's changed

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

PAR guidance – rollout

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

“Learn at Lunch” Series

February 25, 2020, Noon-1pm

“Single IRB mandate and Reliance”

Presenter: ***Kristin Craun***, Director UCLA OHRPP

Location: CHS 17-323

“Learn at Lunch” Series

Upcoming presentations:

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

April: *Post Approval Reporting*

OHRPP Training Opportunities

- ✓ **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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UCLA Research Administration

Extramural Fund Management

February 13, 2020

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?

FY19	Closeout packet			
Fiancial Organization in FS	Due	Submitted by due date	NOT submitted by due date	On-time submission rate
A	2	-	2	0.00%
B	3	-	3	0.00%
C	26	11	15	42.31%
D	1	-	1	0.00%
E	7	-	7	0.00%
F	736	210	526	28.53%
G	26	7	19	26.92%
H	53	15	38	28.30%
I	158	34	124	21.52%
J	3	1	2	33.33%
K	7	1	6	14.29%
L	19	12	7	63.16%
M	381	165	216	43.31%
N	34	14	20	41.18%
O	1	-	1	0.00%
P	3	-	3	0.00%
Q	21	6	15	28.57%
R	20	6	14	30.00%
S	18	9	9	50.00%
T	2	-	2	0.00%
U	110	15	95	13.64%
V	69	26	43	37.68%
W	13	1	12	7.69%
X	3	1	2	33.33%
Total	**1,716**	**534**	**1,182**	**31.12%**

- **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.

Financial Deliverable Preparation Procedure

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 positon 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, alterative 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

	Prior to January 9, 2020	Effective January 9, 2020
When a complete closeout packet is submitted to EFM by the due date:	EFM prepares and submits the final to the sponsor. (Additional inquiry may be needed)	No change.
When a complete closeout packet is NOT submitted to EFM by the due date:	EFM initiates and communicates EFM's analysis of final expenditures.	No change.
	Department responds to EFM's analysis **within 5 business days**. • EFM accepts all adjustments to EFM's analysis as long as a complete list of adjusting transactions with appropriate supporting documents are submitted. • EFM submits the final based on EFM's analysis when a response is not complete or not received by the due date.	5 business days → **3 business days** No other change.

"Financial Closeout of Sponsored Projects" procedure document can be downloaded at https://efm.research.ucla.edu/policies-and-procedures/

Annual Financial Report

- **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)**

	Prior to January 9, 2020	Effective January 9, 2020
When a separate fund number is assigned for each budget period:	The procedure for "Financial closeout of sponsored project" applies.	No change.
When a single fund number is assigned for the entire project period:	Department responds to EFM's analysis **within 5 business days**. • 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. • EFM accepts all adjustments to EFM's analysis as long as a complete list of adjusting transactions with appropriate supporting documents are submitted. • EFM submits the final based on EFM's analysis when a response is not complete or not received by the due date.	5 business days → **3 business days** • No change • All adjustments → **Subward expenses only**. • No change

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.**

	Prior to January 9, 2020	Effective January 9, 2020
Revision to reduce expenses		
The amount to revise	Revise for any amount	No change
The number of revision	No limit	No change
The timing of revision	Anytime	No change
Revision to increase expenses		
The amount to revise	Revise for any amount	Was a complete closeout packet submitted to EFM by the due date? • Yes: $5,000 or over • No: $10,000 or over
The number of revision	No limit	Up to 2 times
The timing of revision	Anytime	Within 120 days after the submission date of the original final or the original final due date, whichever is later

Changes to Financial Deliverable Preparation Procedure

SUMMARY OF CHANGES

Areas		Prior to 1/1/20	Effective 1/1/20
Annual Financial Report (Closeout by budget period: "Final for Budget" in PAMS)		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.	Accept adjustments for sub award expenditures only with the supporting documents. 3 business days
Final financial deliverables, Was a complete closeout packet submitted to EFM by the due date?	Yes	EFM submitted the final to the sponsor (additional inquiry may be needed)	No change
	No	Department had 5 business days to respond to EFM's analysis of final expenditures.	3 business days
Revision of the Final, Is it to reduce the reported expenditure?	Yes	Revised for any amount, Unlimited times, Any time	No change
	No	Revised for any amount, Unlimited times Any time	Was a complete closeout packet submitted to EFM by the due date? • Yes: $5,000 or over • No: $10,000 or over Up to 2 times within 120 days after the submission date of the original final or the original final due date, whichever is later

RAPID Tool – New Version Released

Yoon Lee

RAPID Tool – New Version Released

- **Updated version of the RAPID Tool (version 2/10/20) is available for download from the ORA Portal: https://portal.research.ucla.edu/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

EFM Website

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