

# Quarterly Research Administration Meeting

February 17, 2021



### Welcome and Housekeeping

- This is virtual!
- We will be "spotlighting" our speakers
- All participants are on mute
- Please enter any questions and feedback into the chat
  - Or, send directly to Jonathan Lew in the chat
  - We will be facilitating questions at relevant times during presentations and in between topics



## Agenda

- General Updates
- Cannabis Research, Committee and Role
- NIH Loan Repayment Program
- Federal Updates
- C&G Accounting Updates
- Applied Innovation Topics
- Human Research Protections Updates
- ERA Project Updates



#### Who is here?

#### Jniversity of California - Irvine



### General Updates – Staff Updates

Sponsored Projects Administration (SPA):

- Garrett Larsen
- Alison Dang
- Luis Cendejas
- Wanda Kao
- Jasmin Ramirez



### General Updates – Staff Updates

#### Human Research Protections (HRP):

- Jessica Sheldon
- Boram (Bo) Choung
- Audrey Covarrubias-Aguilera
- Muzhgan Afzal
- Muriel Marroquin



### **General Updates**

- Office of Research in the process of vacating 141
   Innovation in Research Park
  - Campus-wide cost reduction efforts
  - Upcoming lease expiration
  - Continued remote work
  - Vacating incrementally
  - Address remains unchanged
    - Until further notice!



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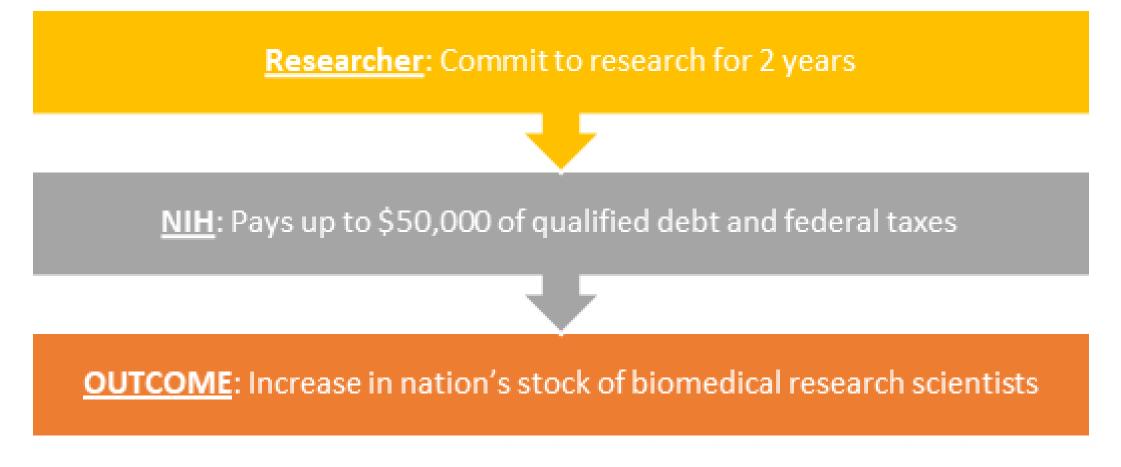
### **NIH Loan Repayment Plan** February 17, 2021

Diana Stephens Institute of Clinical and Translational Science Education Director



## About LRP

NIH Loan Repayment Programs (LRPs) are a vital component in our nation's effort to keep health professionals in research careers





### Five Categories of LRPS

<b>U</b> Clinical Research	<ul> <li>Patient-oriented research w/ human subjects or materials of human origin on causes &amp; consequences of disease in humans</li> <li>Accepted and reviewed by all participating NIH ICs</li> </ul>
Pediatric Research	<ul> <li>Research related to diseases or disorders in children</li> <li>Basic research allowed</li> <li>Accepted and reviewed by all participating NIH ICs</li> </ul>
Health Disparities Research	<ul> <li>Research focusing on minority &amp; and other health disp. pop.</li> <li>Basic, clinical, social and behavioral research allowed</li> <li>Accepted and reviewed by all participating NIH ICs</li> </ul>
Contraception & Infertility Research	<ul> <li>Research focusing on conditions impacting ability to conceive/ bear children &amp; provide methods of preventing pregnancy</li> <li>Applications reviewed solely by NICHD</li> </ul>
Clinical Research DB	<ul> <li>Same as Clinical Research LRP</li> <li>Available for researchers from disadvantaged backgrounds</li> <li>Applications reviewed solely by NIMHD</li> </ul>



### Application Cycle Timeline

September 1 – November 15	Application Cycle Open
November 15	Application, IBO & Colleague Deadline
Jan – May	Application Review
May	IC Initial Selections
May – July	Financial Vetting and Verifications
Mid-July – August	Final Funding Decisions/ Notification
November	First Lender Payments



### Basic LRP Criteria



Doctoral Degree

M.D., Ph.D., or equivalent

\*Exception: Contraception & Infertility Research LRP Research Funding

Research Funding Domestic nonprofit, university, or government org

\*NIH grant support NOT required Educational Loan Debt

At least 20 percent of applicant's annual income Research Time

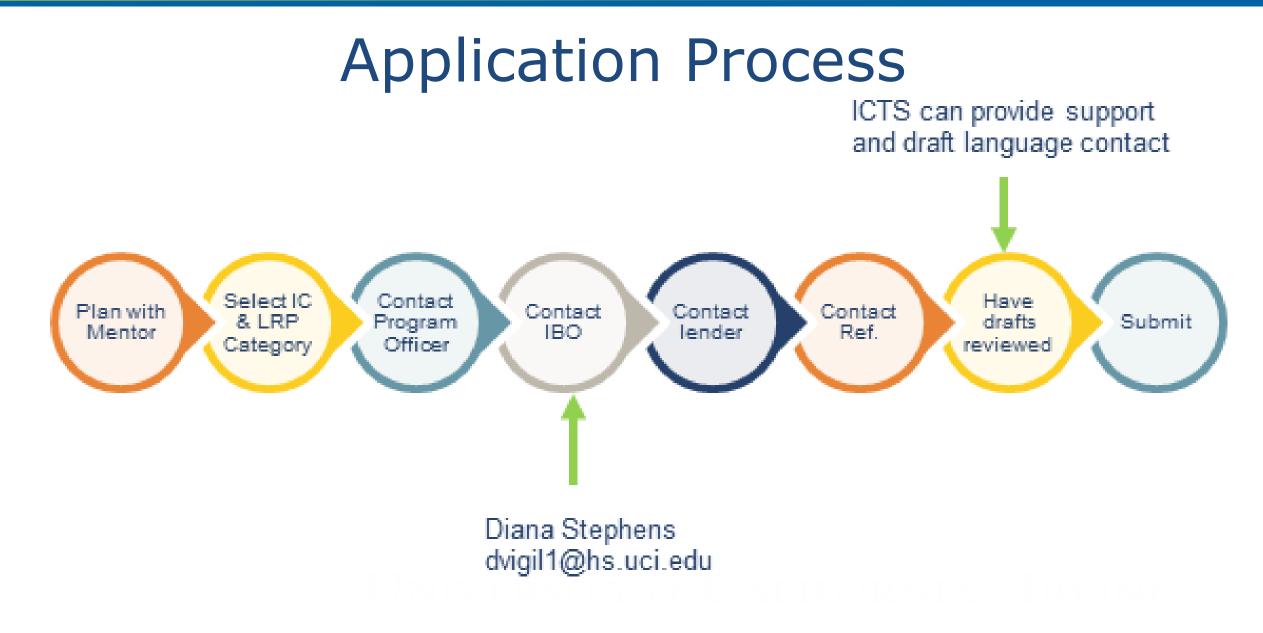
At least 20 hours/week



Citizenship

U.S. Citizen or permanent resident







#### **UCI Resources**

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Grant Library

ICTS has a library of successful LRP grants



Affiliated Scholars Advancement Program ICTS program to develop career development support



Statistical Support Center of Statistical Consultation offers 1hour free consultation



Grant Writing Support ICTS offers a K grant writing program. UCI SOM offers an R01 boot camp.



### Questions?

## Contact ICTS for Support

Diana Stephens, MBA Institutional Business Officer Education Director Institute of Clinical and Translational Science dvigil1@hs.uci.edu

#### University of California - Irvine







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### National Defense Authorization Act (NDAA) Section 889

Applies to Federal Grants and Contracts

- Prohibits using federal funds to <u>purchase</u> telecommunications and video surveillance services or equipment from Huawei, ZTE, Hytera, Hangzhou, and Dahua (2 CFR 200.216)
- Prohibits federal agencies from contracting with an entity that simply uses "covered telecommunications equipment or services" as a substantial or essential component of any system (FAR 52.204-24, 51.204-25)
- Effective on all expenditures charged to Federal awards as of August 13, 2020



### Cybersecurity Clauses in Federal Contracts

- FAR 52.204-21 Basic Safeguarding for Federal Contract Information
  - 17 Controls
  - Applies to Federal Contract Information (FCI)
- DFARS 252.204-7012 Safeguarding Covered Defense Information
  - NIST 800-171 Standard
  - Applies to Covered Defense Information (CDI)
- DFARS 252.204-7019, 7020



## NIH Update



Prohibition on Expending NIH Grant Funds

for Covered Telecommunications Equipment or

<u>Services</u>

- OMB revised 2 CFR Part 200 to align with Section 889 of the John S. McCain National Defense Authorization Act for Fiscal Year 2019 (Public Law 115-232) and the revision was effective for all agencies on August 13, 2020.
  - Recipients and subrecipients are prohibited from expending grant funds to:

Procure or obtain; extend or renew a contract to procure or obtain; or enter into a contract (or extend or renew a contract) to procure or obtain equipment, services, or systems that use covered telecommunications equipment or services as a substantial or essential component of any system, or as critical technology as part of any system.

Learn more: <u>NOT-OD-21-041 and FAQs</u>



### <u>Requirement for Trainee Diversity</u> <u>Report to be Submitted Electronically</u>

- Beginning October 30, 2020, recipients are required to submit Trainee Diversity Reports electronically
- Applies to awards that require appointments through the xTrain system, including the following:
- T15, T32, T34, T35, T37, T42, T90, TL1, TU2, TL4, TU2, K12/KL2, R25, R38, R90, RL5, RL9
- RPPRs lacking an electronically generated report will not be accepted.
- For the K12/KL2, R25, KM1 and R90, eRA will check whether an appointment has been made. If an appointment was made, NIH will require an electronically generated report. If no appointment was made the system will not be able to generate a report and a manual upload will be required.
- Learn more: NOT-OD-20-178



### DHHS Salary Cap Increase 2021

- Salary limitation on direct salary for individuals under NIH grants, contracts and cooperative agreement awards has increased to the current Executive Level II salary of \$199,300 effective January 3, 2021. This change is also applicable to the agencies under the Department of Health and Human Services (DHHS), including, Agency for Healthcare Research and Quality (AHRQ) and the Substance Abuse and Mental Health Service s Administration (SAMHSA).
- For all federals awards subject to this increase, PIs may rebudget to accommodate the current Executive Level II salary level if adequate funds are available. Please note that no additional funds will be awarded by the federal government to cover this increase.
- For UCI, this increase becomes effective for pay periods beginning February 1, 2021. Please note that UCOP has submitted a request to the UC Path team to update the DHHS salary cap in UC Path.
- Learn More: NOT-OD-21-057



### Notice of Legislative Mandates in Effect for FY 2021

- Provides current requirements outlined in statutory provisions that limits or conditions the use of funds on NIH grant, cooperative agreement, and contract awards for FY 2021.
- Review the notice for additional information regarding this policy update.
- Learn More: NOT-OD-21-056



### Notice of Fiscal Policies in Effect for FY 2021

- Provides guidance about the NIH Fiscal Operations for Fiscal Year 2021 and implements the Consolidated Appropriations Act, 2021 (Public Law 116-260), signed into law on December 27, 2020.
- The following NIH fiscal policies are instituted in FY 2021:
  - FY 2021 Funding Levels: Non-competing continuation awards made in FY 2021 will generally be issued at the commitment level indicated on the Notice of Award. The NIH awarding Institutes/Centers (ICs) will develop and post their fiscal policies consistent with overall NIH goals and available FY 2021 funds.
  - Next Generation Researchers Initiative Policy: NIH will prioritize meritorious R01equivalent applications from <u>Early Stage Investor (ESI)</u> PD/PIs. By providing funding priority for ESIs, NIH intends to encourage funding applications that involve researchers earlier in their career in accordance with the policy established in FY 2017 and described in NIH Guide Notice <u>NOT-OD-17-101</u>.



#### Ruth L. Kirschstein National Research Service Award (NRSA) Stipends, Tuition/Fees and Other Budgetary Levels Effective for Fiscal Year 2021

- This Notice supersedes NOT-OD-20-070 and establishes stipend levels for fiscal year (FY) 2021 Kirschstein-NRSA awards for undergraduate, predoctoral, and postdoctoral trainees and fellows.
- The Training Related Expenses and Institutional Allowances for predoctoral and postdoctoral trainees and fellows and the Tuition and Fees for all educational levels remain unchanged from the prior budget year.
- The budgetary categories described in this Notice apply only to Kirschstein-NRSA awards made with FY 2021 funds.
- All FY 2021 awards previously issued using <u>NOT-OD-20-070</u> will be revised to adjust funding to the FY 2021 levels.
- Appointments to institutional training grants that have already been awarded in FY 2021 must be amended to reflect the FY 2021 stipend levels once the training grant award has been adjusted by the awarding agency.
- Learn More: NOT-OD-21-049



<u>Updated Guidelines for Enhancing Diversity and Creating</u> <u>Safe Environments in Conferences Supported</u> <u>by NIH Grants and Cooperative Agreements</u>

- This Notice provides updated guidance on enhancing the diversity of conferences supported by the National Institutes of Health (NIH) (under the R13 and U13 activity codes) and replaces previous guidance in <u>NOT-OD-03-066 Guidelines</u> For Inclusion Of Women, Minorities, And Persons With <u>Disabilities In NIH-Supported Conference Grants</u>.
- It also reiterates the expectation that organizers of NIHsupported conferences maintain inclusive, safe, and respectful environments for all attendees and provides examples of strategies to accomplish this expectation.

<u>Updated Guidelines for Enhancing Diversity and Creating</u> <u>Safe Environments in Conferences Supported</u> <u>by NIH Grants and Cooperative Agreements</u> (cont.)

- Conference grant applicants (R13/U13) must include plans to enhance diversity during the selection of organizing committees, speakers, other invited participants, such as session chairs and panel discussants, and attendees.
- Plans to enhance diversity will be assessed during the scientific and technical merit review of the application. Plans will be considered in the overall impact score.
- Awardees will be required to report on the effectiveness of plans to enhance diversity of underrepresented groups in annual Research Performance Progress Reports (RPPR) and the Final-RPPR.
- Learn more: NOT-OD-21-053



#### Notice of Changes in the Review Criteria for Applications Submitted for NIH Support for Scientific Conferences (R13 and U13)

- Changes to the review criteria for applications submitted to NIH for support of Scientific Conferences (R13 and U13) related to the implementation of guidelines announced in <u>NOT-OD-21-053</u> Updated Guidelines for Enhancing Diversity and Creating Safe Environments in Conferences Supported by NIH Grants and Cooperative Agreements.
- All changes take effect for R13/U13 applications submitted for the April 12, 2021 application due date.
- Applications submitted to NIH for support of Scientific Conferences (R13 and U13) are required to include a Diversity Plan. Reviewers will consider the Diversity Plan in determining the scientific and technical merit of the application, and in providing an overall impact score. The Diversity Plan will be evaluated as an additional review criterion and not receive a separate criterion score.

#### Notice of Changes in the Review Criteria for Applications Submitted for NIH Support for Scientific Conferences (R13 and U13) (cont.)

- R13/U13 applicants should describe in the Personal Statement of the Biographical Sketch senior/key persons' past experiences with enhancing diversity by increasing the participation of individuals from diverse backgrounds, including those from underrepresented groups, in biomedical sciences.
- Reviewers will be asked to evaluate:
  - Is(are) the PD(s)/PI(s) well suited for organizing and fulfilling the goals of this conference, including efforts to enhance diversity?
  - Are the qualifications and past performance of the PD(s)/PI(s) appropriate, and are they well suited for their described roles in the conference?
  - Are the key personnel and selected speakers appropriate and well suited for their described roles in the conference?
- Learn More: NOT-OD-21-055



## Questions?

Nancy Lewis, Executive Director, Sponsored Projects Administration <u>nrlewis@uci.edu</u>

Grace Park, Assistant Director, Sponsored Projects Administration parkgj@uci.edu







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### **Contracts & Grants Accounting**

- General Updates
- UK No Longer Part of Open Skies
- Direct Retros
- New Fixed Price Award Closeout Process
- New Contracts and Grants Aging Report

#### University of California - Irvine



### UK No Longer Part of Open Skies

"As of January 1, 2021, The United Kingdom (U.K.) is no longer a member of the EU. Consequently, the Open Skies Agreement with the EU does not pertain to the U.K. Travelers must use a U.S. Flag Carrier to travel from the U.S. to the U.K. and not a U.K. airline (e.g., British Airways), unless they use a different Fly America Act exception. Travelers may continue to use an EU agreement for travel from the U.S. to the U.K. as long as the flight stops in the EU prior to arrival in the U.S. or the U.K."

https://www.gsa.gov/policy-regulations/policy/travel-managementpolicy/fly-america-act

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## **Direct Retros**



- Explain how the error occurred and why the transfer is being requested. If partial transfer, explain the basis for proration and/or split
- Who approved the transfer of funds? (e.g. Name of PI, Department CAO)
- The transfer benefits the award as the PI was budgeted for 10% effort and has been working continuously on this project.
- Explain the untimeliness if transfer is: > 120 days after original transaction date, and/or > 90 days after the fund end date.





## Fixed Price Award Closeout Process

#### NEW Procedure

Within 90 to 120 days after the expiration of a fixed-price award, the department/unit administering the award completes the Fixed-Price Award Closeout Form and emails it to the appropriate accountant in the Contracts and Grants Accounting (CGA) Office.

#### • NO CHANGE to the Form

IF THERE IS A LARGE UNEXPENDED BALANCE (GREATER THAN \$10,000 OR GREATER THAN 25% OF THE TOTAL AMOUNT RECEIVED FROM THE SPONSOR), PLEASE EXPLAIN IN THE SPACE BELOW THE CIRCUMSTANCE(S) THAT LED TO IT AND/OR THE REASON(S) FOR IT.

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## New Contracts & Grants Aging Report

- We will be publishing the new report in ZotPortal
- Shows data as of the last business day
- Data will be shown by Fund
- Can search or filter by:
  - Org or rollup Org for the Award
  - UC Fund Number
  - Primary Project Director's UCINetID

#### University of California - Irvine



#### **Report Summary**

												E	xport to PDF Ex	port to Excel Data
	SUPPORT		С	ontracts & Grants A	ging Ro	eport			Run D Page # Run b		02/12/20 1 of?	021 11:43:32 AJ	М	
Award Or	rg or Org Rollup Code:		Primary Project Director UCINetID:	Run										
UC Fund	Number:													
Sub Fund Group Type	Agency Name	Fund Number	Project Title	Project Director	Project Director UCINetID	Award Begin Date	Award End Date	Inception to Date Expenses	0-30 Days	31-60 Days	61-90 Days	91-120 Days	Over 120 Days	Open Amount
FC	ANTEATERS UNIVERSITY	2XXXX	Anteaters are awesome!	Principal Investigator Anteater	ants	Oct 1, 2018	Aug 31, 2025	<u>2,053,914.28</u>	<u>\$0.00</u>	<u>\$0.00</u>	<u>\$0.00</u>	<u>\$339,009.19</u>	<u>\$0.00</u>	<u>\$339,009.19</u>
FC	US DEPARTMENT OF ANTEATERS	2xxxx	Finding the best Anthills for Anteaters	Principal Investigator Anteater	ants	Jul 21, 2020	Jun 30, 2025	<u>5,216.47</u>	<u>\$0.00</u>	<u>\$0.00</u>	<u>\$0.00</u>	<u>\$0.00</u>	<u>\$0.00</u>	<u>\$0.00</u>



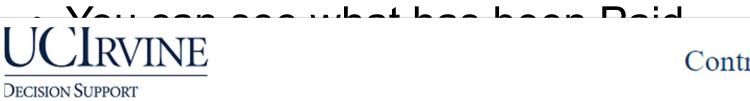
## Drill down to see history and details

#### • You can see what is Open UCIRVINE

Contracts & Grants Billing Aging Details

#### DECISION SUPPORT

CGB Details - OC Fund Number CG	3B Details - Customer Number	CGB Details - Age Bucket	Document Number	CGB Details - Aged Days	CGB Details - AR Amount	CGB Details - Paid Amount	CGB Details - Open Amount
-01101		91-120		101	339,009.19	0	339,009.19
Overall - Summary	339,009.19	0	339,009.19				



#### Contracts & Grants Billing Aging Details

CGB Details - UC Fund Number	CGB Details - Customer Number	CGB Details - Age Bucket	Document Number	CGB Details - Aged Days	CGB Details - AR Amount	CGB Details - Paid Amount	CGB Details - Open Amount
		31-60		51	7,776.87	7,776.87	0
Overall - Summary					7,776.87	7,776.87	0



INVOICE DETAILS

## Drill down to Contracts & Grants Invoice

* COST CATEGORY NAME	TOTAL BUDGET	INVOICE AMOUNT	CUMULATIVE EXPENDITURES	BUDGET REMAINING	TOTAL PREVIOUSLY BILLED	TOTAL AMOUNT BILLED TO DATE	AMOUNT REMAINING TO BILL
Salaries and Wages							
Fringe Benefits		101100-001		0000071100	1000120001000	100010771100	(1994) (777) (10)
Supplies and Materials							
Equipment				10.080		(110)	
Travel							
Other Direct Costs			100,700,000	101-001-001		10,786,88	110,700,000
Subawards							
Indirect Costs	1411 (1414)	(Frailitheast)	strategic by one			1041(1010)(111)	(10.000.00)
Unallocated Budget							
Total Direct Cost			100000.000000000				1000100001000
Total Indirect Cost	1071000-171		10100-00101-000		100000000000000000000000000000000000000	1001-0010-001	100110-000
Total Cost				29, 040, 001		1.1000.000.000	
Milestone or Predetermined Bill Previously Billed		0.00			0.00		
Total Invoice		339,009.19					



## **Questions?**

#### Beata Najman, Director, Extramural Funds Accounting <u>bnajman@uci.edu</u>

Kevin Chung, Financial Management Support Manager chungkb@uci.edu



# Quarterly Research Administration Meeting, continued!

February 24, 2021







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February 2021

#### Industry Sponsored Research (ISR)

**UCI** Beall Applied Innovation

#### Meet the Team

**UCI** Beall Applied Innovation UC

Final thoughts on Messaging

**ISR Team** 

Natalie Tedford	James Wang	Anne DeMarie
<u>natalie.tedford@uci.</u> edu	jamesw9@uci.edu	ademarie@uci.edu
Engineering ICS	Physiology & Biophysics Surgery	Dept. of Medicine Cancer Center
		Kelly Carlson
		<u>kelly.carlson@uci.edu</u>
		Material Transfer Agreements (MTA's)
	natalie.tedford@uci. edu Engineering	natalie.tedford@uci. edujamesw9@uci.eduEngineeringPhysiology & Biophysics Surgery

Industry Sponsored Research handles agreements involving research funded by or through for-profit industry sponsors. Our Industry Contract Officers support researchers in negotiating agreements with companies, including:

- Confidentiality / Non-Disclosure Agreements
- Collaboration agreements
- Federally funded subcontracts received through industry
- Industry funded subcontracts received through a university/non-profit
- Research contracts funded by major corporations

Note: ISR handles proposals and agreements with a for-profit component, <u>excluding</u> clinical trials and outgoing subcontracts (i.e. UCI to a company).

ISR receives frequent requests for sponsored research agreements (contracts) prior to submission of a proposal. Many of these requests become after-the-fact and the proposal process and any associated regulatory committee approvals can delay ISR's final signature on a sponsored research agreement.

Have you submitted a proposal in Kuali?

Has the proposal been reviewed, approved, and "submitted"? Do you need regulatory committee review and approval (IRB, IACUC, COI, etc.)? **UCI** Beall Applied Innovation

#### **Questions?**

Industry Sponsored Research David Gibbons, Director



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## Human Research Protections

Beverley Alberola Director



#### Effective February 1: IRB Documentation Sharing Update:

- IRB Documentation Sharing Update:
- Beginning this month, HRP will provide IRB **Application and supporting documentation to Chao** Family Comprehensive Cancer Center (CFCCC) to help facilitate their Protocol Review and Monitoring **Committee (PRMC) process.** An update to the IRB Application text to reflect this practice is anticipated March 2021. Any questions, contact the PRM unit at CancerCenter Committees@hs.uci.edu.



## Effective February 1: Surrogate Consent Update:

 The Investigator Certification of Surrogate Decision Makers for Potential Subject's Participation in University of California Research Form has been updated to remove signature lines.

#### University of California - Irvine



#### Effective February 1: Translated Short Form Updates:

- Removal of errant Investigator signature line for all translated languages
- New Urdu translated Short Form available
- Certificate of Translations available

#### UNIVERSITY of CALIFORNIA - IRVINE



#### **Effective February 1: Appendices Updates:**

Appendices O, P:

- Instructional text is clarified and better organized
- Removed the requirement to justify minimal risk
- Open text fields replaced by appropriate response options

Appendix U:

 Prompts for additional necessary documentation related to adding a reliance



#### Effective February 15: Consent Updates:

• Combining the UC HIPAA Research Form with the IRB Approved Consent Form as a single PDF, at the time of IRB approval. Upon UCI IRB approval, only a Word (editable) version of the UCI IRB Approved Consent Form will post to the <u>UCI IRB Document Depot</u>. A Word version of the UCI HIPAA Research Form will not post.



#### **Effective February 15:** *More* Consent Updates:

- New Certificate of Confidentiality language added to address possible access to Epic for UCI Health treatment purposes
- Template text added to prompt researchers to include, as applicable, suggested methods of birth control
- Template text added to prompt researchers to address subject reimbursement
- Template text updated to further define routine care medical costs during a clinical research study vs. standard of care medical costs that occur outside (absent) of a clinical research study
- Template text added to include more specificity when imaging is done for research purposes.



\*All referenced forms are available on the HRP <u>Apps</u>
 <u>& Forms page</u>!\*





## **Questions?**

## Beverley Alberola, Director, Human Research Protections <u>beverley.alberola@uci.edu</u>



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#### The (Dynamite) ERA Team:

Barbara Martin Alison Kim Jonathan Kavi Maureen





## **ERA Tips and Reminders**

- Denial Letters
- Login.gov
- Users will be required to use two-factor authentication (2FA) through Login.gov to access eRA Commons, ASSIST, Internet Assisted Review (IAR), and Commons Mobile by September 15, 2021.
- Users can register for a Login.gov account and start using 2FA now. This is recommended so you'll be familiar with the process by the time it's required in September
- <u>https://nexus.od.nih.gov/all/2020/12/15/era-will-require-the-use-of-login-gov-to-access-era-commons-assist-iar-and-commons-mobile-in-2021/</u>



## **ERA Project Updates**

- KR Protocols
  - Phase 1 April 2021: Non-Human Subjects Research
     Determination
  - Phase 2 August 2021: EVERYTHING ELSE! IRB and hSCRO: Full Committee, Minimal Risk, sIRB, Expanded Access...and more

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hSCRO	
HPS	
IRB App	KR Protocols
IRB Mod	
IRB CPA/Closing	
IRB UP Report	
IRB eAgenda	
IRB Doc Depot	
Auto Email Reminders/Confirmations	
CITI Tutorial Verification	Cognos
Protocol Search	



## **ERA Project Updates**

- KR Conflict of Interest (COI)
  - Preliminary work
  - Spring/Summer 2021: Implementation activities



### Transition to KR S2S

#### Cayuse 424 (Proposals)



Kuali Research System-to-System (S2S) Including Budget

#### University of California - Irvine



## **Report Updates**

- COMING SOON!
  - Personnel Awards Credit by Role
    - Date range for "active" awards, proposal data, redesign
  - Awards by Campus Area
  - Date range instead FY
  - Proposals by Campus Area NEW!
  - ATS Updates
  - Proposal Development number and link
- Did you know?
  - DW Query Protocols



## Research Administration Data Tools Training

- Increased number of questions related to RA data
- ERA will host training sessions and post materials

- Or, if you have a group, let us know and we'll schedule a session.
  - Email: <u>era@research.uci.ed</u>u to schedule time

#### University of California - Irvine



#### Winter QRAM 2021

## **Questions?**



Winter QRAM 2021

## "See" you next time...

Spring Virtual QRAM May 19, 2021 10:00-11:30 AM

Send us topics you want to hear about!