

# Quality Research Administration Meeting

August 29, 2018

## Summer/Fall QRAM 2018

# Agenda

- ERA Update
- Graduate Student Compensation and Cost Share
- C&G Accounting Update
- HRP Update
- Clinical Trials Team Update
- Federal update



# **ERA Update**



# KR Upgrade Debrief

## What is KR and why did we upgrade?

- Kuali is open source software that UCI has downloaded and run locally for Research and Financials
- Kuali products (Research, Financials, Student, Ready) are available to purchase as Software as a Service (SAAS) – ie. "hosted"
- Kuali Coeus (KC) was old technology and no longer supported
- We will be implementing more KR functionality and need to be running current code
- We participate in the Kuali community and product user groups to influence functionality

## Story of the go-live...







# KR Upgrade Debrief

## The Story of the KR Go-Live

- Communicated, COMMUNICATED, and communicated
- Removed majority of code customizations
- Trained approximately 120 people over 12 hands-on sessions
- Planned and practiced the deployment plan
- ...then there was a problem
- AND, we still went live on July 10!





# KR Upgrade Debrief

## Some problems surfaced:

- Increased incident reports
  - Make sure to submit!
- Copy function
  - Reinstated, but is missing from inside the PD doc
  - ERA is working with Kuali
- System time-outs
  - ERA is speculating that errors are occurring due to system time-outs or running KR in many tabs
  - Working with OIT





**Decision Support in ZP** 

PI Dashboard / Portal

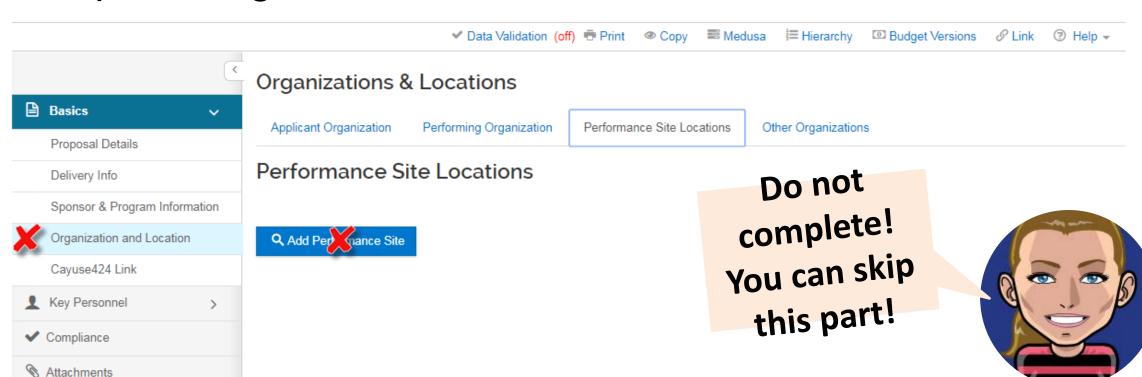




Subscribe to the ERA Listserv for more KR tips and tricks!

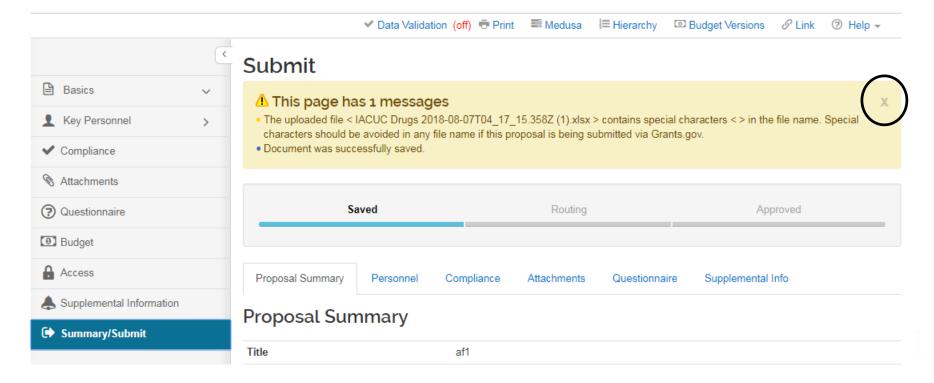


Skip the Organization and Location section!





 Ignore system-to-system validation warning message about special characters in upload filename.

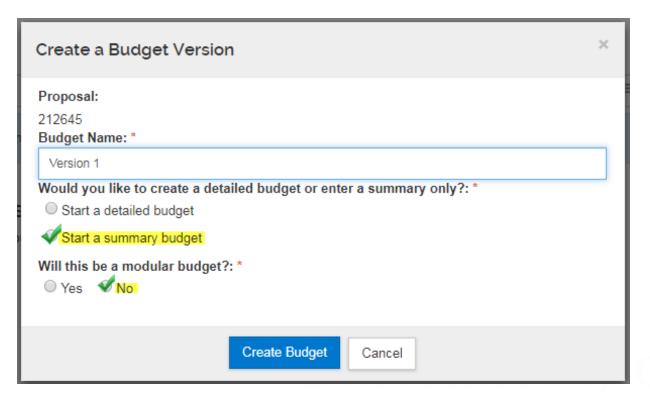


Dismiss this warning banner by clicking on the X.





- Always create a "Summary Budget"
- Always select "No" for Modular Budget (if PHS/NIH sponsor)



DO NOT create a Detailed Budget!





Budget Notes

■ Budget Summary

## Kuali Research - Tips

Budget – enter only Direct and F&A Costs\*



Visit the KR Prop
Dev User Guide
for special
instructions for
Cost Share.

Cost

\*If there is mandatory committed cost share, also complete Cost Sharing line and Institutional Commitments sub-section.

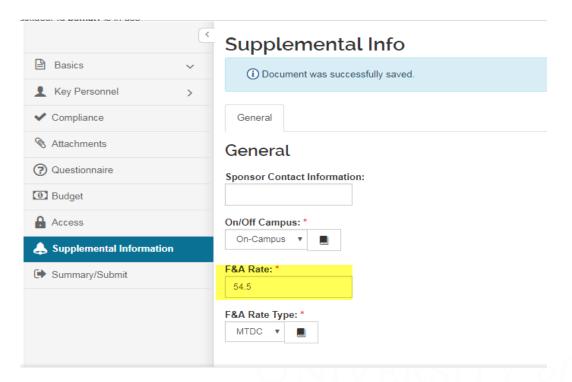


- Proposals with Subawards
  - 1. Sponsor & Program Information Mark the Subawards checkbox.
  - 2. Attachments Attach all Subrecipient package docs to the Internal Attachments page
  - 3. Compliance Add a Compliance Entry by selecting "Outgoing Subaward" (Pending) as the compliance type. Enter Subaward entity name or abbreviation in the Protocol Number field.

Do not enter any subaward info in the Budget!



 On the Supplemental Information section, for the F&A Rate, just enter the number – no need for % sign

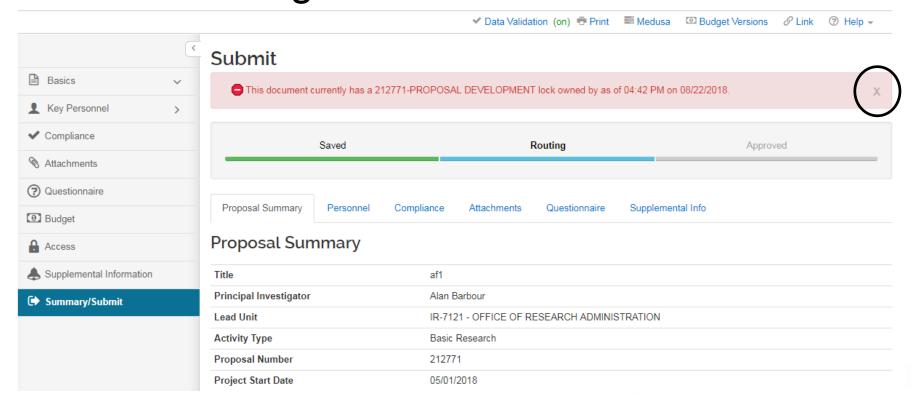


Coming soon:
You'll be able to
enter more than
one F&A Rate in
the very near
future!





Ignore pessimistic lock without lock owner error message.



Dismiss this error banner by clicking on the X.





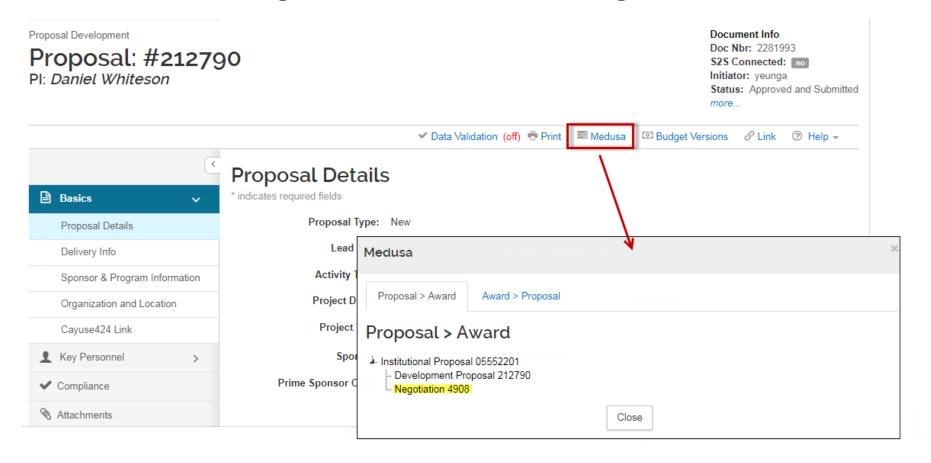
	Proposal Creator (KSAMS)	Admin Contact (KSAMS)	Aggregator (doc level permission only)	Principal Investigator
View Proposal	✓	✓	✓	✓
Edit Proposal	✓	✓	✓	✓
Submit Proposal to Workflow	✓	<b>✓</b>	<b>✓</b>	
Make Revisions	✓	<b>✓</b>	✓	✓
Return Proposal to workflow (after Revisions)	✓	✓	✓	

Contact your
DSA for KSAMS
assignments (or
contact the ERA
Team if you
don't know who
your DSA is.)





Access Negotiation Doc using Medusa



The Institutional Proposal # links everything together.





## Your feedback is valuable to us!





- Check out KR Training materials and ERA FAQ
  - research.uci.edu/sponsored-projects/era/
- Sign up for the ERA Listserv
  - Send a blank email to:

or-era-join@department-lists.uci.edu

- Questions?
  - era@research.uci.edu

Subscribe to the ERA Listserv to stay up to date on all our electronic systems!





# KR Negotiation Module(s)

Demo

## Summer/Fall QRAM 2018

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- Graduate Student Compensation and Cost Share
- C&G Accounting update
- HRP Update
- Clinical Trials Team Update
- Federal update



# Graduate Student Compensation and Cost Share

Beata Najman
Director, Extramural Funds
Nancy Lewis
Executive Director, Sponsored Projects



#### Stipends vs. Salaries

https://www.research.uci.edu/sponsored-projects/contracts-grants-admin/proposal-prep/stipends-salaries-wages.html

<u>Stipends</u>	Salaries and Wages	
-Financial assistance or support paid to university students; no work assigned.	-Compensation for performance of assigned work.	
-No scope of work.	-Scope of work assigned.	
-No required fringe benefits or remissions.	-Applicable UC employee fringe benefits and Fee Remission as appropriate based on eligibility.	
-Student-mentor relationship; no employer-employee relationship.	-Employer-employee relationship, and salary amounts restricted by University salary scales.	
-No grant and contract support unless the purpose of the award is to provide fellowship or scholarship.	-Can be paid from grant and contract funds, and other internal funding sources.	



## **☐** Graduate Student Researcher Appointments

NOTE: UCI Graduate Student Researcher appointments are covered by University academic personnel policies.

- Graduate Student Researcher (GSR)
  Graduate student enrolled full time who performs research related to his or her degree program
- Graduate Student Assistant Researcher (GSAR)
  GSAR performs research which is not related to the student's degree program

GSR and GSAR appointments have enrollment requirements, grade/GPA requirements, and students with these job titles perform research assigned by the PI.



### ☐ Graduate Student Support at UCI

- <u>Fellowship awards</u> may be in the form of payment of fees/tuition and/or nonresident supplemental tuition, and/or a <u>stipend</u>.
- <u>Stipends</u> are intended to financially support a graduate student formally admitted to graduate study in Doctoral or Master's program.
- UCI's Block Allocation Fellowship Support is for fellowships ONLY!

Block fellowship allocations cannot be used to support GSRs and/or GSARs performing research, and they cannot be used as sources of cost sharing for research grants.



#### **NIH Grants Policy Statement**

## **□** Stipend

• A payment made to an individual under a <u>fellowship or training grant</u> in accordance with pre-established levels to provide for the individual's living expenses during the period of training. A stipend is not considered compensation for the services expected of an employee.

### **☐** Stipend Supplementation

• Stipends may be supplemented by an institution from <u>non-Federal funds</u> provided this supplementation is <u>without any additional obligation for the fellow</u>. ....These policies must be consistently applied to all individuals in a similar status regardless of the source of funds. <u>Federal funds may not be used for stipend supplementation unless specifically authorized under the terms of the program from which funds are derived.</u> Under no circumstances may PHS funds be used for supplementation.



#### **NIH Grants Policy Statement**



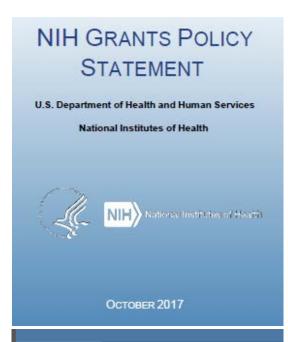
Stipends are not allowable under research grants even if they appear to benefit the research project.

https://grants.nih.gov/grants/policy/nihgps/nihgps.pdf



#### **Graduate Policies and Procedures at UCI**

https://www.grad.uci.edu/forms/academics/Graduate-Policiesand-Procedures.pdf







## Questions?

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# C&G Accounting Update

Beata Najman & Kevin Chung



## **CGA** Update

- CGA Website Update
- CGA Training and Staff Changes
- Notice of Project Expiration
- New C&G Reports



## Notice of Project Expiration

- Automated notification to Principal Investigator, Fiscal Officer, and Account Supervisor
- Automated email from the corresponding C&G Accountant
- Sent 60 days before the Stop Date in the KFS Award Table
- Based on the last closed month's ledger balance
- Easy to print on one page
- Implementation at the end of September



#### NOTICE OF PROJECT EXPIRATION

Principal Investigator: Joe Anteater

Project Title: Ant Rich Diet and its Consequences Sponsor: NATIONAL SCIENCE FOUNDATION

Sponsor Reference Fund Number: CMMI-111111111

UCI Fund Number: 12345

This is a notification that the referenced award has an end date listed as of: **09/30/2018**As of Aug 27, 2018, Fiscal Period JULY 2018, the general ledger activity for the award shows:

Budget: \$900,000.00 Expenses: \$850,000.00 Balance: \$50,000.00

The figures above represent costs posted to the ledger and do not include any pending transactions.

#### In Anticipation of This Project Ending

The Principal Investigator and Departmental Administrators should work on the following steps:

- Ensure that all allocable expenditures are posted to the project in a timely manner
- Review the status of any outstanding liens, Purchase Orders (POs), and Blanket POs
- Review all expenditures to ensure compliance with terms and conditions of the award
- Redirect salaries and rechargeable services planned for the future research work not covered by this award
- If applicable, review any applicable cost sharing contribution, and complete the cost sharing report
- Inform Applied Innovation if inventions or patentable items were generated under this project
- Verify that subaward final expenses have been confirmed and recorded to the ledger
- Notify C&G Accounting about proper disposition of unexpended balance if applicable to the fixed price award
- Complete and submit final technical/performance reports, as required



#### If This Award Is Not Expected to End on 09/30/2018

If this award is expected to be continued, renewed, or extended (with supplemental funds or a no cost time extension), additional steps that may include:

- Progress report submission failure to submit timely reports may delay funding or consideration of any requests for project extension
- Submission to Sponsored Projects or Applied Innovation for the following prior approval requests:
  - Carryforward of funds
  - No cost time extension
  - Supplemental funding

For an up-to-date view of your Awards, take a look at the Award Balance Overview (ABO).

If you have questions, please don't hesitate to contact the appropriate C&G Accountant. <a href="C&G Accounting Contacts by Fund Number">Contacts by Fund Number</a>.

Sincerely, C&G Accounting



www.accounting.uci.edu/cg/



## **C&G** Reports

- Suite of C&G Reports that should help with C&G Financial Management
- Proposed Multiple Views:
  - Current Overdrafts within the Organization
  - Awards Expiring Soon (90 days from today's date)
  - Outstanding Balances for recently expired awards and awards expiring soon
  - General Award Information to download
- Implementation before the end of October



## **C&G** Reports Prototype

Current Overdrafts

DECISION SUPPORT

**UC Fund Number:** 

Awards Expiring Soon

Outstanding Balances

Project Director 2:

Awards Information



### CGR - Current Overdrafts

Showing Fiscal Year 2019 - Period 02 data as of: 08/24/2018, 8pm

Run Date/Time:

Run by:

08/27/2018

5:49:41 PM

Page #:

Kevin B Chung

1 of?

Org or Org Rollup:	(90)30)	Project Director 1:	Calculate Encumbrances	Yes	•	Run

Chart	Sub Fund Type Code	Sub Fund Group Code	UC Fund Number	UC Fund Title	Primary Award Org Code	Primary Award Org Name	Project Director 1	Project Director 2	Award Begin Date	Award End Date	ITD Budget	ITD Actuals	Encumbrance	Variance	ITD Unallocated Budget
IR		100.000	77/00	07786111000000000	-	All the second	THE THINK	-		100000	\$0.00	\$3,937.50	\$0.00	(\$3,937.50)	\$667,252.00
IR					100			-		100000	\$56,545.78	\$64,455.51	\$0.00	(\$7,909.73)	\$764,273.22
IR					100			-		1000011	\$26,000.50	\$26,677.62	\$0.00	(\$677.12)	\$105,255.50
IR			19190		***			-	and the same of	18191918	\$6,272.00	\$11,118.97	\$0.00	(\$4,846.97)	\$136,728.00
IR					***			-		(80) (818)	\$4,129.00	\$8,675.65	\$0.00	(\$4,546.65)	\$15,895.00
IR					-146			-	0.000001	1100910	\$1,215.00	\$6,570.90	\$0.00	(\$5,355.90)	\$335,630.00
IR	100	1960.00	4134	ALTERNATION CONTRACTOR	100	484.00	100000	-	41111111	4504000	\$21 776 33	\$24 861 89	\$0.00	(\$3 085 56)	\$212 076 67



## Questions?

Contact:

Beata Najman, Director, Extramural Funds Accounting

bnajman@uci.edu

(949) 824-0265

OR

Kevin Chung, Financial Management Support Manager

chungkb@uci.edu

(949) 824-4429

## Summer/Fall QRAM 2018

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### **CONGRUENCE REVIEWS**

### Federally-Funded Human Subjects Research

	Pre-2018 Common Rule	2018 Common Rule						
Scope	Non-Exempt Research Involving human subjects that is conducted or supported by HHS							
	An institution with an FWA certifies to HHS that each grant application or proposal has been reviewed and approved by the IRB  Congruence review: ensure the grant application (or proposal) is entirely consistent with any corresponding protocol submitted to the IRB  examples of inconsistencies: target population, treatment arms, experimental dosages, collaborators, performance sites, scope of work, source materials, etc	For research to which the 2018 Requirements apply, the IRB must review and approve such research (e.g., a research protocol) for certification; <a href="https://however.the IRB nolonger">however</a> , the IRB nolonger is required to review and approve the research grant application or proposal  Congruence reviews will be the responsibility of the researcher (beginning July 19, 2018)						
Certification	Certification means the official notification by the institution to the supporting Federal department or agency (in accordance with the requirements of this policy) that a research project or activity involving human subjects has been reviewed and approved by an IRB (in accordance with an approved assurance); research covered by 45 CFR 46.103 may not be initiated prior to receipt by HHS of the certification							
References	45 CFR 46.103(f)  https://www.hhs.gov/ohrp/regulations-and-policy/guidance/irb-review-applications-for-hhs-support/index.html	45 CFR 46.103(d)  https://www.hhs.gov/ohrp/regulations-and-policy/requests-for-comments/draft-guidance-elimination-of-irb-review-of-research-applications-and-proposals/index.html						

<sup>\*</sup>Congruence reviews for federally-funded animal research continues



### **NIH POLICY**

### **Update On "Clinical Trials" Definition**

2015
<a href="#">Revised Clinical Trial</a>
<a href="#">Definition</a>



2017
GCP Training
Requirement



2017

<u>Dissemination of NIH-</u>

<u>Funded Clinical Trial</u>

<u>Information</u>

2018	GUI	DF	N	OTI	CFS
7010	UU.		L		CES

July 20, 2018 NOT-OD-18-212

**Enforcement of NOT-OD-16-149** 

delayed through Sept 24, 2019

August 10, 2018 NOT-OD-18-217

#### **Comments Submission Deadline:**

November 12, 2018

August 27, 2018 NOT-OD-18-167

#### **Comments Submission Deadline:**

October 11, 2018

**SUMMARY** 

Delayed Enforcement and Short-Term Flexibilities for Some Requirements Affecting Prospective Basic Science Studies Involving Human Participants

NIH is <u>delaying enforcement of registration and reporting policies for prospective basic science studies involving human participants</u> (under <u>NOT-OD-16-149</u>) <u>through September 24, 2019</u>. The delayed enforcement of registration and reporting is <u>only applicable for prospective basic science studies that involve human participants</u>.

Request for Information (RFI): Registration and Results Reporting Standards for Prospective Basic Science Studies Involving Human Participants

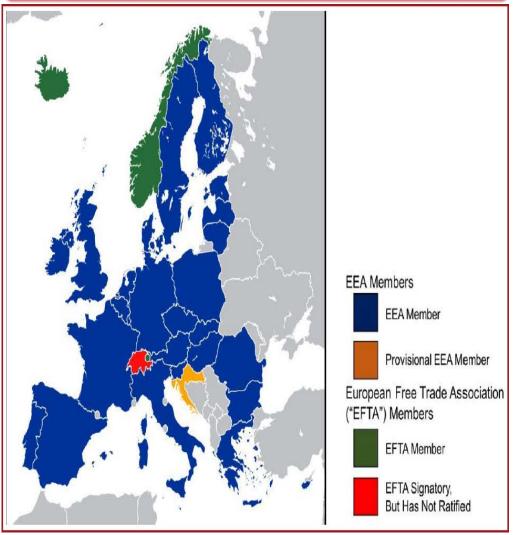
NIH is requesting for input from stakeholders throughout the scientific research community regarding how best to implement the <u>NIH Policy on the Dissemination of NIH-Funded Clinical Trial Information</u> for <u>prospective basic science studies</u> <u>involving human participants</u>. NIH wants to learn more about studies that meet the <u>NIH definition of a clinical trial</u> but are not defined as <u>applicable clinical trials</u>, and also meet the <u>definition of fundamental research</u>.

NIH Request for Public Comment on Draft Protocol Template for Behavioral and Social Sciences Clinical Trials

• NIH is seeking comment on a Draft Behavioral and Social Clinical Trial Template. The template was created to guide investigators through the systematic development of a comprehensive clinical protocol and will be especially helpful to investigators who are less familiar with the information and the level of detail that is required in such a protocol. The template has also been tailored specifically for studies involving a social or behavioral intervention.

### **European Union General Data Protection Regulation**

### **European Economic Area (EEA)**



### **Applicability**

Organization is established in the EEA and acts as a data controller or processor

Organization <u>offers goods or services</u> to individuals in the EEA

Organization monitors the behavior of individuals in the EEA

Transfer of personal data from an EEA country, to the US (outside of the EEA)

Has a contractual relationship with research vendors or other third parties who are subject to the regulation

#### REFERENCES

**EU GDPR** 

**Article 29 Working Party (EU)** 

**UCOP** Guidance (forthcoming)

UCI OIT – EU GDPR - Information Security and Privacy

**UCI OIT – EU GDPR Resource and Guidance** 

UCI HRP (draft) guidance document

US DHHS SACHRP Recommendations

OHRP - Compilation of Guidance based on Country

# **Processing of Personal Data**

Personal Data: Any information relating to an identified or identifiable natural person who is in the EU, regardless of the individual's EU citizenship status

<u>Processing of Data</u> is any operation performed on personal data: collection, recording, storage, use, disclosure, etc

### Impact on <u>Human Subjects Research</u> Activities:

- Requires a legal basis for processing data: 6 allowable basis
- Awards/contracts require additional language
- Consent form requires additional language
  - Transfer of personal data (EEA to US; US to EEA)
  - Data Subject Rights (a list of 7)
- Breach of confidentiality: <u>report within</u>
  72 hrs
- Fines for noncompliance with the GDPR



## Questions?

Contact:

Laverne Estanol

Assistant Director, Human Research Protections

lestanol@uci.edu

(949) 824-4704

### Summer/Fall QRAM 2018

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# Industry Clinical Trials Update

August 29, 2018



## Industry Clinical Trials Team

Tam K. Tran

**Assistant Director** 

tamkt@uci.edu 949-824-7813 Shabana Durrani

Principal Contract Officer

durranis@uci.edu 949-824-7697

 All CDAs, non-master CTAs except for Depts. of Neurology, Dermatology, Pediatrics, IMIND **Heather Kubinec** 

Principal Contract Officer

hkubinec@uci.edu 949-824-9816

 All amendments, all master CTAs, all CTAs for Depts. of Neurology, Dermatology, Pediatrics, IMIND

http://research.uci.edu/sponsored-projects/clinical-trials/index.html



# Agenda

- Increased F&A rate
- DocuSign
- Clinical Trial Determination Tool



## Increased F&A Rate

- Effective July 1<sup>st</sup>, 2018, the Facilities and Administrative rate is 32% of Total Direct Costs (TDC)
- Applied to investigator initiated and sponsor initiated trials funded by industry



## DocuSign

- System for routing documents (e.g., CDAs, contracts, modifications) to secure electronic signatures
- Investigators do not need to have an account
- Final documents will be sent directly to Investigator with a copy to study team
- Improve turnaround time for signature process, decrease study activation time
- Target implementation in September 2018



Products Solutions Pricing Support Resources



FREE TRIAL CONTACT SALES



### Quickly access and sign documents that require your signature



#### STEP 1

#### Click the link in email

With one click, you can access the document and start the document signing process on virtually any internet-enabled device.



#### STEP 2

#### Follow the DocuSign tabs

Tabs and simple instructions guide you through the signing process. Your electronic signatures are secure, legally binding, and widely accepted for most business transactions around the world.



#### STEP 3

#### Finish, and you're done

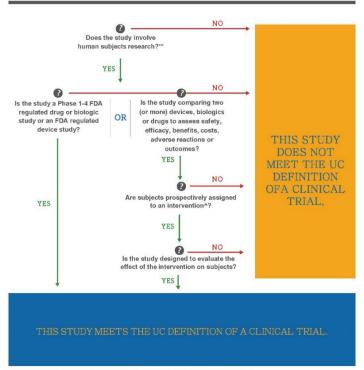
Once you're done signing, click Finish. That's it!



### Clinical Trial Determination Tool



### DECISION TREE FOR UC CLINICAL TRIAL DEFINITION\*



<sup>\*</sup>For the purpose of determining applicability of the UC clinical trial F&A rate and applicable contract terms.

<sup>\*\*</sup>See IRB determination of human subjects research form at: https://tinyurl.com/HSdetermination.

<sup>^</sup>An intervention, in the context of the UC definition of a clinical trial, is the manipulation of a subject via the controlled testing of a drug, device, treatment or diagnostic under an approved protocol. A blood draw, on its own, may not be sufficient to constitute an intervention,

Please contact Tam Tran at tamkt@uci.edu or Angie Karchmer at angie.karchmer@uci.edu if you have any questions.



### Research Administrators United!

- Building relationships and creating partnerships with schools/departments
- Monthly brown bag sessions on C&G topics, morning coffee talks, invite us to your department staff meeting, etc.
- Convene working group to include SPA and department representatives
- We welcome your ideas, feedback, and thoughts!
- Contact us:
  - Tam Tran: <u>tamkt@uci.edu</u> or x47813
  - Shelley Scallan: <u>sscallan@uci.edu</u> or x42644
  - Nadia Wong: <a href="mailto:nadiaw@uci.edu">nadiaw@uci.edu</a> or x40012



Our 1st Hiking Trip!!





## Speaking of feedback...





https://www.research.uci.edu/sponsored-projects/index.html

Email Sandra directly at <u>sandrams@uci.edu</u>

## Summer/Fall QRAM 2018

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# **Federal Update**



The only way to make sense out of change is to plunge into it, move with it, and join the dance.

-Alan Watts

Erika Blossom

**Supervising Principal Contract and Grant Officer** 

Erika.Blossom@uci.edu

(949) 824-2237



### **NSF** Reminder

- NSF Research.gov Proposal Preparation Site Available
  - NSF has launched Research.gov proposal preparation functionality to the research community to collect preliminary feedback and to provide the community an opportunity to acclimate to the new technology.



### NIH

- NOT-OD-18-172 Reminder of NIHs Policy Regarding a <u>Change in Program Directors/Principal</u> Investigators Status
- NOT-OD-18-175 Ruth L. Kirschstein National Research Service Award (NRSA) Stipends, Tuition/Fees and Other Budgetary Levels Effective for Fiscal Year 2018
  - This notices establishes stipend levels for NRSA awards for fiscal year 2018. Training related expenses and the institutional allowance for post-doctoral trainees and fellows have been increased. Training related expenses and institutional allowance for pre-doctoral trainees and fellows remains unchanged. All FY 18 awards will be revised to adjust funding to the FY 18 levels. Appointments to institutional training grants that have already been awarded must be amended in xTrain once the training grant award grant award has been adjusted by NIH. The maximum amount that NIH will award to support the compensation package for a graduate student research assistant remains at the zero level postdoctoral stipend. Please review the notice for additional information.
- NOT-OD-18-202 NIH Synchronizes Institutional Delegations and Now Allows Decimals in Effort Reporting Field in Research Performance Progress Reports (RPPR)
  - The purpose of this notice is to inform grantees of two recent enhancements within eRA Commons to streamline and improve the Research Performance Progress Report (RPPR) process. First, institutional delegations for Interim-RPPRs (I-RPPR) and Final-RPPRs (F-RPPR) have been modified to align with the delegations that institutional users have specified for annual RPPRs. Second, data fields for effort reporting have been modified to enable use of decimals rather than requiring entry of a whole number. Please review the notice for additional information regarding these enhancements in eRA Commons.



### NIH

- NOT-HS-18-006 FY2018- AHRQ to begin allowing Facilities and Administrative (F&A) costs of 8% MTDC for consortia located at foreign institutions
  - The Agency for Healthcare Research and Quality (AHRQ) Funding Opportunity Announcements (FOAs) do not allow foreign institutions to submit grant applications but do allow foreign institutions to participate in projects as members of consortia or as subcontractors only. Beginning October 1, 2017, AHRQ will allow, but not require, applicants to request facilities and administrative (F&A) costs (also known as indirect costs) for consortia located at foreign and international organizations at a fixed rate of 8 percent of modified total direct costs (MTDC), exclusive of tuition and related fees, direct expenditures for equipment, and subawards and/or contracts in excess of \$25,000. Please see the full notice for additional detailed information.



### NIH

- Clarification on the distinction between fixed amount subaward and fixed rate subaward
  - Fixed rate subaward
    - commonly used by Clinical Trial Coordinating Centers to distribute capitation funds
    - Cost per patient in a clinical trial is known, the total amount of the award is unknown (since total award amount will be based on each patient seen)
    - Prior approval <u>not</u> required (unless other conditions apply in <u>NIHGPS Chapter 8.1.1.4</u>)
  - Fixed amount subaward
    - Total value negotiated upfront when the negotiated unit price and the total number of units are known
    - Defined in 45 CFR Part 75.201
    - Prior Approval <u>is</u> required



### NIH

 Contracts and Grants Accounting and Sponsored Projects (SPA) in collaboration with Academic Personnel have updated the DHHS Salary Cap Guidance on the SPA website. The revised webpage can be found here: <a href="https://research.uci.edu/sponsored-projects/contracts-grants-admin/proposal-prep/nih-salary-cap.html">https://research.uci.edu/sponsored-projects/contracts-grants-admin/proposal-prep/nih-salary-cap.html</a>



# Federal Update

**QUESTIONS?** 



## See you next time...

## Winter QRAM

- Date: Wednesday, December 5, 2018
- Time: 1:30-3:30
- Location: UCI Student Center Moss Cove AB