Quarterly Research Administration Meeting

June 19, 2019
### Table Topics

<table>
<thead>
<tr>
<th>Sponsored Projects Administration</th>
<th>Research Protections</th>
<th>Electronic Research Administration</th>
<th>Contracts &amp; Grants Accounting</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Federal and Non-Federal Contracts and Grants</td>
<td>• Human Research Protections</td>
<td>• Kuali Research</td>
<td>• Post Award Administration</td>
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<tr>
<td>• Clinical Trial Contracting</td>
<td>• Animal Care and Use</td>
<td>• Research Management System</td>
<td>• Account Balance Overview (ABO) Tool</td>
</tr>
<tr>
<td>• Conflict of Interest</td>
<td>• Human Stem Cell Research</td>
<td>• Cayuse 424</td>
<td>• Payroll Certification</td>
</tr>
<tr>
<td>• Export Control</td>
<td>• Single IRB / Reliances</td>
<td>• Award Data and Reports</td>
<td>• Policies and Regulations</td>
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<tr>
<td>• Subcontracting</td>
<td>• Education &amp; Quality Assurance Program</td>
<td>• ...and more!</td>
<td>• ...and more!</td>
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<td>• ...and more!</td>
<td>• ...and more</td>
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</tbody>
</table>
Agenda

- Table Topics
- IRB Fees
- IACUC Overview
- UCI Center for Statistical Consulting
- ORCID
- Federal Update
- Training Grant Website
- Contracts & Grants Accounting Update
- ERA Update
- DocuSign
- Table Topics (3:00-3:30)
Agenda

- *Table Topics*
- **IRB Fees**
- IACUC Overview
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- *Table Topics (3:00-3:30)*
IRB REVIEW FEES

Beverley Alberola, CIP
Interim Director, IRB Operations
The Human Research Protections unit in the Office of Research charges Institutional Review Board (IRB) fees for reviewing new and continuing clinical research submissions that are partially or fully supported by industry sponsors.

IRB Review Fees apply to all clinical research involving human subjects that are funded in whole (including chart review studies) or in part by industry sponsors.

DEFINITION OF CLINICAL RESEARCH: Designed to assess the safety, efficacy, benefits, adverse reactions, and/or other outcomes of drugs, devices, diagnostics, treatments, procedures, medical evaluations, monitoring or preventive measures.
IRB REVIEW FEES

Are **NOT** charged for:

- Exempt research;
- Modifications/ amendments to approved studies;
- Unanticipated Problems
IRB REVIEW FEES

Human Subjects Research Budgets

- Researchers need to account for applicable IRB Review Fees in their proposed budgets for industry-sponsored projects, as well as budgets for all subcontracts they expect to receive from such industry sponsors.
IRB REVIEW FEES

IRB Review Fee Collections Process

- IRB fees are assessed once the research is approved by the IRB.
- Fees will be recharged to the study account.
- For recharges, e-mail notification is provided to the investigator and the department business office regarding the amount and date of each charge.
# IRB REVIEW FEES

**UCI IRB Fee Structure**

IRB Applications received on or after July 1, 2019 will be charged these fees. Because IRB Fees may be increased or decreased by future rate adjustments, please escalate these rates by 3% per year for budgeting purposes.

<table>
<thead>
<tr>
<th>Review Type</th>
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<tr>
<td>Initial Review - Full Committee:</td>
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<tr>
<td>Initial Review – Central IRB is IRB of Record:</td>
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<tr>
<td>Initial Review - Expedited:</td>
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<td>Continuing Review - Full Committee:</td>
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<td>Continuing Review - Expedited:</td>
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<tr>
<td>Continuing Review - 7 Year De Novo - Full Committee:</td>
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IRB REVIEW FEES

IRB Applications received between April 1, 2012 – June 30, 2019 will be charged these fees for the life of the study.

<table>
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IRB REVIEW FEES

IRB Applications received prior to April 1, 2012 will be charged these fees for the life of the study.

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Questions?

Beverley Alberola

beverley.alberola@uci.edu
Agenda

- *Table Topics*
- IRB Fees
- **IACUC Overview**
  - UCI Center for Statistical Consulting
  - ORCID
- Federal Update
- Training Grant Website
- Contracts & Grants Accounting Update
- ERA Update
- DocuSign
- *Table Topics (3:00-3:30)*
IACUC Overview

Melanie Fabian
IACUC Overview

• Who we are

• What we do

• What you need to know
Who we are

- Chair, Dr. Nancy Burley
- Attending Veterinarian Dr. Claire Lindsell
  - Associate Veterinarian Dr. Roger Geertsema
  - Senior Veterinarian Dr. Stacey Kang
- Institutional Animal Care and Use Committee
  - UCI Faculty, mostly animal users themselves
  - Non-scientific member
  - Community members (unaffiliated with UC)
What We Do

• Review and approve activities involving live animals at UCI (protocol review)
• Review the entire animal program and inspect all facilities every 6 months
• Review concerns involving animal use
• Investigate possible issues of non-compliance
• Report to regulatory agencies
• Maintain AAALAC accreditation
Protocol Review

- Rationale for the use of animals
- Justification for the species and number of animals needed
- Assurance that the experiments are not unnecessarily duplicative
- Detailed description of experiments and procedures
- Appropriate anesthesia, analgesia, sedation, monitoring, humane endpoints
- Adequate training of personnel
Animals at UCI

• More than 95% rodents
  – Transgenic mice
  – Rats
• Other species
  – Pigs – gastrointestinal and urological research and training
  – Sheep – heart valves
  – Frogs – cellular research
  – Zebrafish – genetics research
  – And yes, alligators!
Our Campus Partners

• University Laboratory Animal Resources (ULAR)
  – Coordinate animal procurement, billing, husbandry services
  – Assign space for animal-using faculty
  – Take daily care of animals

• Environmental Health and Safety (EH&S)
  – Review all animal-use protocols for human hazards
  – Conduct safety meetings and educate research staff
The IACUC Website

- [https://research.uci.edu/compliance/animalcare-use/index.html](https://research.uci.edu/compliance/animalcare-use/index.html)
- Website includes:
  - Complete instructions for how to submit protocols
  - A detailed user guide for the Research Management System (RMS), our online protocol system
  - Links to ULAR and EH&S
  - Links to the Protocol Search Tool and Meeting Results
  - All sorts of other useful stuff
What you need to know

• The IACUC administrative staff is here to help you and your faculty

• We’re also here to ensure that all live animals used in research, testing or teaching at UCI are treated humanely and ethically

• Questions? Contact us!
  – IACUC@uci.edu

• And remember…
Animal Research Matters!

Medical & Scientific Advances
- 1796-Smallpox Vaccine (cows)
- 1920s-Discovery of Insulin (dogs)
- 1930s-Development of Anesthesia (rats, rabbits)
- 1940s-Penicillin (mice)
- 1950s-Polio Vaccine (mice and primates)
- 20th century and beyond!
  - Disease diagnosis, prevention and treatment
  - Reproductive Technology
  - Premature newborn care
Questions?
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Statistical Resources for UCI Researchers

Joni Ricks-Oddie, PhD MPH

Director, UCI Center for Statistical Consulting | Department of Statistics
Director, Biostatistics, Epidemiology & Research Design Unit | ICTS
Why are we here?

• To help!

• Our goals with the UCI community:
  – Promote High Quality Research and competitive proposal development
  – Provide High Quality Statistical Support
  – Partner with researchers and research groups
Our services provide a holistic approach

- Provide assistance at all stages of project development from study design through final publication.
- Grant proposal preparation
- Study design
- Planning and conducting statistical analysis,
- Power and sample size calculations
- Interpretation of results
- Manuscript/poster/abstract review and preparation
- Response to reviewers
- IRB applications,
- Training in the use of statistical software
- Research database design
FREE

- 1st hour of consultation on any new project
- Drop-In Consulting Sessions
- Grant Submission Support
  - CSC and/or ICTS/BERD staff including in grant as budget or sub-award (% FTE)
  - Study Design
  - Power Analysis/Sample Size
  - Statistical Methods Planning and write-up

FEE

- Consultation beyond the first hour on any project outside of Grant Submission Support
  - Study design to reviewer response
- Grant preparation if we are not included in the grant
How we work?

- Consultation Request
- Assigned to Statistician
- Initial Meeting
- Scope of Work Drafted
- Collaboration Begins
FAQ

• Do you have a set of Standard Operating Procedures?
• We have groups interested in getting trained to use statistical software is that something you could help with?
• A research group need to learn how to do a specific type of analysis. Could you teach researchers to do that?
• We need a statistician(s) to be part of a grant? Do you have someone who could help?
The UCI established the **ICTS BERD Unit** and the **CSC** to assist UCI investigators (faculty, staff, postdoc, student) to conduct and communicate rigorous, reproducible, high quality research.

**Primary activities of BERD/CSC**
- Statistical support for grant submissions
- Statistical and design issues for new studies
- Statistical analysis planning, implementation, and interpretation
- Study Design
- Development of research protocols
- Manuscript writing and revisions assistance

**Services**
- Weekly drop-in consultation (BERD Only)
  - Tuesdays 12-2pm, by appointment
  - Brief statistical consultation FREE of charge
- Extended study design / data analysis (BERD/CSC)
  - Hourly fee ($80/hr)
- Long-term collaboration
- %FTE statistical support for project (BERD/CSC)

**Contact BERD Unit**
- Website: icts.uci.edu/services/berd1.php
- Joni Ricks-Oddie, Director (BERD & CSC) jricksod@uci.edu 949-824-0513
- Erika Whitton, Administrative Coordinator ewhitton@uci.edu 949-824-3350

**Contact CSC**
- Website: http://statconsulting.uci.edu/
- Joni Ricks-Oddie, Director (BERD & CSC) jricksod@uci.edu 949-824-0513
- Jodi MacGregor, Business Manager jmacgreg@uci.edu 949-824-9908
Questions

Joni Ricks-Oddie, PhD MPH

jricksod@uci.edu
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ORCID for the UCI Community

June 19, 2019

Mitchell Brown
UCI Libraries and University of California Irvine
Student Center, Emerald Bay B.
What is ORCID?

- ORCID is an open, not-for-profit organization run by and for the research community.
- We provide researchers with a unique identifier, an ORCID iD, that reliably and clearly connects them with their research contributions and affiliations.
- Hundreds of systems have now integrated ORCID iDs – from grant application and manuscript submission to CRIS to repositories, and more!
- By pooling the know-how and influence of the international research community, we can deliver a huge step forward for the openness and reliability of research information.
Why ORCiD? Researchers

1. Spend more time doing research, less time managing it
2. Improve recognition and discoverability for yourself and your research activities
3. Benefit from having a trusted, self-managed record of your research activities and affiliations that you can share with organizations and individuals you trust
Why ORCiD? Organizations

1. Ownership of your organization’s name and validation of connections with it
2. Maintain links with your researchers - past, present, and future
3. Benefit from faster, automated information-sharing through cross-system interoperability
DISTINGUISH YOURSELF IN
THREE EASY STEPS
30 Seconds to Register

1. **REGISTER**
   Get your unique ORCID identifier [Register now!](https://orcid.org/)
   Registration takes 30 seconds.

2. **ADD YOUR INFO**
   Enhance your ORCID record with your professional information and link to your other identifiers (such as Scopus or ResearcherID or LinkedIn).

3. **USE YOUR ORCID ID**
   Include your ORCID identifier on your webpage, when you submit publications, apply for grants, and in any research workflow to ensure you get credit for your work.
Mitchell C. Brown

ORCID ID
https://orcid.org/0000-0002-3366-1281

Biography
I am a librarian at the University of California Irvine. My title is Scholarly Communications Coordinator and Research Librarian for Chemistry, Earth System Science and Russian Studies. My education background includes a B.S. Physics (Carnegie-Mellon, 1988) and M.L.I.S. (University of Texas, Austin, 1994). I have worked at LSU-Baton Rouge and Princeton University prior to UC Irvine.

University of California Irvine: Irvine, CA, US
2005-07-17 to present | Research Librarian for Chemistry, Earth System Science, Pharmaceutical Science, and Russian Studies; Scholarly Communications Coordinator (Library)
Employment
Source: Mitchell C. Brown

Employment
Source: Mitchell C. Brown
ORCID Ecosystem: Interoperability

INTEROPERABILITY ENTER ONCE REUSE OFTEN

PUBLISHER
Assert authorship

CONNECT COLLECT

RESEARCHER
https://orcid.org/0000-0001-2345-6789

CONNECT COLLECT

EMPLOYER
Assert affiliation

CONNECT COLLECT

FUNDER
Assert award

CONNECT COLLECT

ORCID API
(Application Programming Interface)
Contact Information

Help with ORCiD Registration

Mitchell Brown
UCI Libraries
Scholarly Communications Coordinator
mcbrown@uci.edu
(949) 824-9732
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Federal Update

Summer QRAM
June 19, 2019
NIH-Notice of Special Interest  
NOT-OD-19-17

• Expanding the use of Notices of Special Interest (NOSI) posted in the NIH Guide for Grants and Contracts in lieu of non parent program announcements
  – NOSI’s highlight a specific area of research or program
  – Direct applicants to one or more active FOA’s for submission of applications for the initiative described in the notice

• NOSI’s require applicants to include the notice number in the Agency Routing Identifier field (4b) in the SF 424 (R&R)
  – Failure to include the information in field (4b) will result in the application being removed from consideration for the initiative
NIH – Update to Policy on ESI Application Status
NOT-OD-19-072

• NIH will automatically update the ESI (early stage investigator) status of an application within eRA Commons as follows:

  – If a PD/PI updates his/her degree or residency information after submission of an R01 or R01-equivalent application, or if an investigator requests and/or receives an extension of ESI status after submitting an R01 or R01-equivalent application, the application will be reviewed with the designation assigned at the time of submission.

• Within eRA Commons, the status of the pending application will be updated after release of the Summary Statement to acknowledge ESI-application eligibility.
If an ESI-eligible application is awarded and the same PD/PI has an R01 or R01-equivalent application pending review, the pending application will be reviewed as an ESI-eligible application. However, the status of the pending application will be updated after release of the Summary Statement to acknowledge the application is no longer ESI-eligible.

This will minimize the need for manual changes while allowing consideration of ESI status at the time of funding decision.
Update to NIH/AHRQ Policy on Post-Submission Materials
NOT-OD-19-083
Applicable to applications submitted to due dates on or after May 25, 2019

- Applications for Training Grants (T series), a list of publications up to three pages in length will be accepted as post submission materials.
  - Replaces the current on page limitation for post submission publications list
- Clarifies that Preprints and Other Interim Research Products (NOT-OD-17-050) are not accepted as post submission materials because they do not represent unforeseen events.
Update to NIH/AHRQ Policy on Post-Submission Materials NOT-OD-19-083 (cont.)

• Missing or corrected materials cannot be submitted after the application due date unless submission of that material is specifically listed in NOT-OD-19-083 as allowable post-submission material(s).

• Materials resulting from change of institution, or change of PD/PI, that occurs between application submission and peer review must be sent to the Scientific Review Officer (SRO) managing the review with a cc: to the Division of Receipt and Referral (csrdrr@mail.nih.gov); after review materials should be sent to the Grants Management Specialist (GMS) listed in eRA Commons for the application.
NIH/AHRQ-Required Use of xTRACT System to Prepare Data Tables for Training Grants Research Performance Progress Reports (RPPR) in FY 2020
NOT-OD-19-108

• xTRACT must be used to create the required training data tables for submission of RPPR’s for NIH and AHRQ T15, T32, T90/R90 and TL1 awards
  – RPPR will validate the uploaded data table pdfs to ensure they were created in xTRACT
  – Guidance on using xTRACT and this guide notice can be found on the UCI Training Grant website: https://research.uci.edu/research-development/training-grants/index.html

• xTRACT use will continue to be voluntary for new and renewal training grant applications as well as awards for career level training, education and career development awards.
USDA-National Institute of Food and Agriculture (NIFA) Indirect Cost Rate Change

2018 Farm Bill
– Except as provided in law, indirect costs against any grant may not exceed 30% of TFFA (Total Federal Fund Awarded)

• Chart - [https://nifa.usda.gov/resource/indirect-cost-chart](https://nifa.usda.gov/resource/indirect-cost-chart)
  – Now includes FAQs

Total Federal Funds Awarded (TFFA) = Field K., Total Costs and Fee, on SF-424 R&R Budget
USDA-National Institute of Food and Agriculture (NIFA) Indirect Cost Rate Change (cont.)

- Prime: Lesser of negotiated rate or 30% TFFA*
- Subs: Lesser of negotiated rate or 30% TFFA
- Add IDC for Prime plus Subs – if the amount exceeds 30% TFFA of Prime’s budget, then adjustments must be made
- *may be split between the Federal and any required match

UCOP is developing a systemwide approach to assessing this IDC limitation on USDA-NIFA proposals when subs are involved

Notify SPA or AI in advance if you have proposals or awards from USDA-NIFA that are subject to this IDC limitation
Update on Foreign Influence on Research

Reminder on concerns

1. Failure by some researchers to disclose substantial contributions of resources from other organizations, including foreign governments;
2. Diversion of intellectual property in grant applications or produced by NIH-supported research to other entities, including other countries; and
3. Sharing of confidential information by peer reviewers with others, including with foreign entities, or otherwise attempting to influence funding decisions.
NIH: Other Support

NIH has noted failure to disclose substantial foreign research support:

- Talents awards, employment, foreign grants
- Hidden transfer of information, know-how, data and person time

When in doubt, disclose everything.
NSF: Current and Pending Support

- Include all financial resources and commitments of time even if no salary support is received.
- All current and pending support, including this project, for ongoing projects, and for any proposals currently under consideration from whatever source, irrespective of whether such support is provided through the proposing organization or is provided directly to the individual.
- All projects and activities, current or proposed that require a time commitment from the individual must be reported, even if the support received is only in-kind (such as office/laboratory space, equipment, supplies, employees, students).
• The total award amount for the entire award period covered (including indirect costs) must be provided, as well as the number of person-months (or partial person-months) per year to be devoted to the project by the senior personnel involved.

• Concurrent submission of a proposal to other organizations will not prejudice its review by NSF, if disclosed.

• If the project (or any part of the project) now being submitted has been funded previously by a source other than NSF, provide the required information describing the last period of funding. For example, Federal, State, local, foreign, public or private foundations, non-profits, industrial or other commercial organizations, consulting, or internal funds allocated toward specific projects.
NSF: New Bio Sketch format

Designated the National Institutes of Health’s SciENcv (Science Experts Network Curriculum Vitae) as an NSF-approved bio sketch format and is encouraging its use.

Beginning with the next PAPPG (anticipated effective date, January 2020), NSF will only accept PDFs for bio sketches generated through an NSF-approved format. A description of NSF-approved format(s) will be posted on the NSF website when the PAPPG is issued: https://www.nsf.gov/pubs/policydocs/pappg19_1/pappg_2.jsp#IIC2f

Multiple training resources are available on the SciENcv website: https://www.ncbi.nlm.nih.gov/sciencv/

• SciENcv Background
• YouTube Video: SciENcv Tutorial
• YouTube Video: Integrating with ORCID
• SciENcv Help
DOE internal memo published June 7, 2019

DOE Order 486.1 – Department of Energy Foreign Government Talent Recruitment Programs.

Applies to internal DOE elements and Management & Operations (M&O) contractors.

No external guidance provided yet.
Guidance on Foreign Relationships/Affiliations

Official communication and guidance is posted to our website and will be updated as we receive specific information from the federal government regarding policies and procedures.

https://research.uci.edu/ref/export-controls/basics/foreigninfluences.html
Questions??
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Training Grants Website

https://www.research.uci.edu/research-development/training-grants/index.html
Starting point

- NIH T32 grants
- Document the intricacies and nuances of training grants – pre & post-award
- Point of reference – updates/SOP’s
- Broader goal – improve these various processes
- Landing page has
  - General overview
  - Links/resources
  - Announcements
POST-AWARD

• Highlighted by Beata at last QRAM

• Post award sections
  – Quick Facts
  – Budget Categories
  – Reporting & Close-Out
  – Re-budgeting
Data tables – prep

- Main driver for creating this resource
- Starts with overview, links, and general advice from seasoned administrators
Data tables - requests

• Processes for requesting data from various groups on campus
Data tables – guidance/tips + tricks

• Goes into each data table
• Campuses processes
• Tips/tricks from seasoned submitters
• Work in progress – please contribute
Reports/data

• Going along with the data tables...

• Compiled resource
  – Info from different sources in one place
  – Housed on Google Sheets

• Just one example... open to more ideas!

• Applicable campus tools
Program plan

- Things to note for the rest of the application
- Campus processes
  - Biosketches
  - Responsible Conduct of Research
  - Letters of Support
ERA & xTRACT

- ERA roles and who that person is at UCI
- xTRACT and the upcoming transition
Questions?

Kristine Thai - kthai2@uci.edu
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Contracts & Grants Accounting Update

Beata Najman
• PI Report Projections are linked to ABO
### EFFECTIVE PERIOD

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<td>Instruction</td>
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<tr>
<td>PRED.</td>
<td>07/01/2016</td>
<td>06/30/2018</td>
<td>37.50</td>
<td>On-Campus</td>
<td>Other Sponsored Activities</td>
</tr>
<tr>
<td>PRED.</td>
<td>07/01/2018</td>
<td>06/30/2021</td>
<td>43.50</td>
<td>On-Campus</td>
<td>Other Sponsored Activities</td>
</tr>
<tr>
<td>PRED.</td>
<td>07/01/2016</td>
<td>06/30/2021</td>
<td>26.00</td>
<td>Off-Campus</td>
<td>Other Sponsored Activities</td>
</tr>
<tr>
<td>PRED.</td>
<td>07/01/2016</td>
<td>06/30/2021</td>
<td>10.00</td>
<td>Off-Campus</td>
<td>Intergovernmental Personnel Act</td>
</tr>
<tr>
<td>PROV.</td>
<td>07/01/2021</td>
<td>Until</td>
<td></td>
<td></td>
<td>Use same rates and conditions as those cited for fiscal year ending June 30, 2021.</td>
</tr>
</tbody>
</table>

Amended
Questions?
Agenda

- **Table Topics**
- IRB Fees
- IACUC Overview
- UCI Center for Statistical Consulting
- ORCID
- Federal Update
- Training Grant Website
- Contracts & Grants Accounting Update
- **ERA Update**
- DocuSign
- **Table Topics (3:00-3:30)**
ERA Update

Barbara Inderwiesche
Enter User Feedback and Submit Incident Reports!
The end is near...

- The Fiscal Year – end, that is.
- Zot!Portal > Decision Support > OR Decision Support > Awards by Campus Area
- Updates on July 1, 2019
- Data Page
Questions?

Come talk to ERA at the tables!
Or, email era@research.uci.edu
Agenda

• *Table Topics*
• IRB Fees
• IACUC Overview
• UCI Center for Statistical Consulting
• ORCID
• Federal Update
• Training Grant Website
• Contracts & Grants Accounting Update
• ERA Update
• **DocuSign**
• *Table Topics (3:00-3:30)*
DocuSign

Kelly Kadlec
DocuSign

Have you ever DocuSigned anything?

• Fast, secure, trackable, paperless

• Number of departmental accounts increasing
DocuSign

UCI’s Enterprise DocuSign Subscription

• DFA and OIT collaboration

• For campus and health sciences employees, excludes UCIMC

• Accounts available later this month
  – For departments, units, individuals—any group size
  – Convenience of Single Sign-On using UCInetID
Add Documents to the Envelope

Add Recipients to the Envelope

As the sender, you automatically receive a copy of the completed envelope.

Import a bulk list: Send copies of this envelope to many people at once.

Set signing order:

Name *
Kolby Knipec - whalenRGucci

Message to All Recipients

Custom email and language for each recipient

Email Subject:
Please DocuSign
Characters remaining: 100

Email Message
Enter Message
Characters remaining: 10000

Advanced Options
• Recipients can sign on paper
• Recipients can change signing responsibility
• Incomplete envelopes expire 150 days after send date
• Recipients are warned 8 days before request expires
• Comments are enabled
• Senders can use either quick send or advanced edit
...to very sophisticated
UCI’s Enterprise DocuSign Subscription

• Guiding Principle: make DocuSign available as if departments had purchased it themselves

• Building a Community of Practice
  – Peers helping peers as we transform business processes at UCI
  – Office of Research, Human Resources, Student Affairs, OIT, DFA
  – DocuSign Momentum 2019 Conference
Questions?
Final Questions?
See you next time...

September 11, 2019
Moss Cove AB
1:30-3:30
Agenda

• *Table Topics*
• IRB Fees
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• ORCID
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• *Table Topics (3:00-3:30)*