Research Administration Forum
January 11th, 2018

Welcome!

Marcia Smith
Associate Vice Chancellor for Research
Agenda

- **Welcome and Announcements** - Marcia Smith
  - FDP Update
  - Travel Charge for Carbon Assessment

- **OHRPP** – Kip Kantelo
  - Revised Common Rule Update
  - Connecting CITI to Single Sign-On – Jon Orlin

- **EFM** – Yoon Lee
  - UC Path: Payroll Expense Transfers
  - NIH “Unilateral Closeout”

- **OCGA** – Patti Manheim
  - OCGA Master Training on January 17th - Evan Garcia & Yessenia Sarmiento
    - “Compliance at the Proposal Stage: Prepare Now to Avoid Headaches Later”

- **ORDM** – Rory Constancio
  - Q2 Proposal/Award Update
On-time Reporting of Grants and Contracts

- NIH recurring themes: Need for On-Time Reporting
  - Dr. Michael Lauer is NIH's Deputy Director for Extramural Research serving as the principal scientific leader and advisor to the NIH Director on the NIH extramural research program.
- Ongoing emphasis on on-time technical reports
- This means that the awardee submits acceptable final research progress reports, expenditure reports, cash transaction reports, and invention reports within the required timeframe.
- Failure to correct recurring reporting problems may cause NIH to take on or more actions that may include, but are not limited to, corrective actions, withholding of further awards, suspension or termination.
- Need to submit Final RPPR on time – report on whatever is completed to date
- Emphasis on clinical trial reporting
  - 58% of NIH Clinical Trials don’t report or don’t report on time
  - $3 billion in funding for CTs each year – needs better reporting
- Any feedback on our recent implementation of automated tech report reminders?
- More later on our near-term expansion of efforts to increase UCLA compliance in this area
Travel Office Charges for Carbon Mitigation

- 12/14/2017 announcement from the Administrative Vice Chancellor
- Charges are unable on C&G awards because the costs do not benefit the funded projects
OHRPP Updates
Revised Common Rule

Kip Kantelo, Director
January 11, 2018
Revised Common Rule

- Released January 19, 2017
- Effective January 19, 2018
- Uncertainty so far
  - Congressional review
  - Administration review
    - October Delay Proposal
    - January Delay Proposal
  - No clarifying guidance
  - Agency variation
So...if it goes into effect...

- Four key changes for you
  - Consent Content
  - Continuing Review
  - Exemptions
  - Single IRB (effective 2020)
  - But NIH mandate effective 2018

- Awaiting further guidance
  - Consent Form Posting
  - Broad Consent

- Changes behind the scenes
How It Affects You...

- **Existing studies (approved or certified exempt before 1/19)**
  - Stay under pre-2018 regulations
  - Spring ‘18: transition opportunities

- **New studies (approved or certified exempt on or after 1/19)**
  - Depends on a few factors- we’ll come back to this at the end
Consent Content

❖ Concise summary of key info
  • Franken-section
  • Short SBER forms already meet

❖ Additional consent elements
  • Whether or not info/specimens will be deidentified and re-used
  • Whether clinically-relevant results will be provided and how
  • Possible commercial profit from specimens
  • Whole genome sequencing
Consent: What Next?

- OHRPP releasing
  - Updated templates
    - Regulatory changes
    - Certificate of Confidentiality language
    - OHRPP contact information
    - Simplifications and other changes
  - Targeted edits checklist
    - Limited to first 3 items above

- Transition - we’ll come back to this at the end
Continuing Review

- Eliminated for studies…
  - Approved via expedited review OR
  - With remaining activities limited to
    - Analysis of data/specimens, or
    - Accessing clinical follow-up data

- ...But!
  - FDA and DOJ still require CR
  - IRB can require CR
  - You must still submit amendments, PARs and study closures
Continuing Review

What will it look like for you?

- No change to application process
- New state in webIRB
  - “Approved- No CR Required”
  - No expiration date on approval notice or stamped documents
- Opportunities to transition existing studies may come this Spring
- Annual Ping
  - Still working on webIRB changes
  - Reminder of responsibilities
  - Simple confirmation that study active
Exemptions

❖ Summary
- New categories
- Changes to existing categories
- “Limited IRB review” for certain categories

❖ What will it look like for you?
- No outward change yet
- Staff will start using new criteria
- Simplified webIRB pathway coming this spring
Your new studies...

<table>
<thead>
<tr>
<th>Study Characteristics</th>
<th>FDA-Regulated</th>
<th>Not FDA-Regulated</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Federal support</strong></td>
<td>• Consent: New Regs</td>
<td>• Consent: New Regs</td>
</tr>
<tr>
<td><em>(except Dept of Justice)</em></td>
<td>• Continuing Review: No Change</td>
<td>• Continuing Review: New Regs</td>
</tr>
<tr>
<td></td>
<td>• Exemptions: No Change</td>
<td>• Exemptions: New Regs</td>
</tr>
</tbody>
</table>

- **Dept of Justice support**
  - Consent: Flex
  - Continuing Review: No Change
  - Exemptions: No Change

- **No Federal support**
  - Consent: Flex
  - Continuing Review: No Change
  - Exemptions: No Change

“No change” means pre-2018 regulations continue to apply
Consent for New Studies

On or before 3/1 deadline

- **Consent: New Regs** either:
  - Make changes according to targeted edits checklist
  - Use the new consent templates

- **Consent: Flex** means:
  - You may use the targeted edits checklist or the new templates
  - But IRB can approve without new requirements
Consent for New Studies

- Any new study submitted after March 1 must use the new consent templates
Takeaways

❖ You do not need to do anything different now for:
  • Existing approvals/exemptions
  • New Continuing Review rules
  • New Exemption rules

❖ For new studies:
  • You may need to make targeted edits to consent forms
  • You will need to start using new consent templates (March 1)

❖ webIRB changes this Spring
Questions?

- Look for announcements today or tomorrow
  - Human Research News
  - OHRPP website
- If delayed, we’ll announce in the same places
- Contact special e-mail
  irbregs@research.ucla.edu or your friendly IRB contacts
Connecting CITI to UCLA Single Sign-On (SSO)

Jon Orlin
OHRPP Special Projects Coordinator
January 11, 2018
You may have heard...

- This morning, announcements were sent out over multiple listservs describing CITI and UCLA Single Sign-On integration.
- The announcements included links to guidance documents with step-by-step instructions for connecting existing CITI accounts and creating new CITI accounts with UCLA Single Sign-On.
What is CITI Program?

- The Collaborative Institutional Training Initiative (CITI) Program is a leading provider of research education content.
- UCLA, like many institutions, uses CITI Program for several research training requirements.
What is single sign-on?

- Single sign-on (SSO) is a way to log into multiple related, yet independent, software systems utilizing a single ID and password.

- Example: Using your UCLA Logon ID account, you can sign into numerous UCLA web resources with the same ID and password.

Note: Mednet IDs are not the same as UCLA Logon IDs.
Why would I want to connect CITI to my UCLA SSO?

- UCLA SSO eliminates the burden of creating and managing separate CITI Program credentials
- Identifies who you are to ensure accurate tracking and reporting of training records
- Facilitates more efficient research compliance reviews
How do I connect my existing CITI account to UCLA SSO?

- Go to https://www.citiprogram.org
- Click the “Log In” button
- Click the “LOG IN THROUGH MY INSTITUTION” link
Locate and click “University of California, Los Angeles (UCLA)” in the list. You will be directed to the UCLA CITI Program disclaimer page.

University of California, Irvine
University of California, Los Angeles (UCLA)
University of Central Florida

Read the disclaimer and click “I AGREE” to proceed.
When directed to the UCLA SSO page, enter your UCLA Logon ID and password to sign in.

Upon successful login, the CITI Program website will display the message below. Read the message and click "Continue".
When the "Associate your SSO account with a CITI Program account" dialog box appears, select "I already have a CITI Program account."

The "Link to an existing CITI Program account" dialog box will appear. Enter your CITI Program Username and Password, and click "Log In"
That’s it!

- You have now linked your UCLA SSO account to your CITI Program account, which automatically adds the UCLA affiliation to your existing account, and you will be able to log into CITI Program using your UCLA SSO going forward.
For more information, visit the OHRPP website, stay tuned for additional announcements or contact mirb@research.ucla.edu.

http://ora.research.ucla.edu/OHRPP/Pages/CITITraining.aspx

Guidance documents for connecting existing and creating new CITI accounts using UCLA SSO are available on our website.
If you would like to subscribe to announcements from the Human Research News mailing list, please send an e-mail to:

investigators-l+subscribe@lists.ucla.edu

The subject line and body of the e-mail can be blank.
Thank you!

❖ For questions:
  • North & South General IRBs
    ❑ x57122
    ❑ gcirb@research.ucla.edu
  • Medical IRBs
    ❑ x55344
    ❑ mirb@research.ucla.edu
Today’s Topics

- UCPath: Payroll Expense Transfers
- NIH Unilateral Closeout
UCPath: Payroll Expense Transfers

Yoon Lee
Pilot campuses (UC Merced, UC Riverside and ASUCLA) are now live in UCPath as of Tuesday, January 2, 2018.

UCLA’s new go-live date is September 1, 2018.
- UCLA will partner with UCSB as part of the UCLA/UCSB pilot
- Pilot lessons-learned and next steps will be shared with Campus Advisory Group at UCLA.
Payroll Expense Transfers: Pre-UCPath Go-Live Data

What was shared at RAF in July 2017:

- UCLA elected not to convert payroll data from PPS to UCPath → Transfer of payroll processed in PPS cannot be done in UCPath.

- After UCPath Go Live, UCLA will maintain PPS for the limited time to allow transfers of payroll expenses processed in PPS via WebPET → Processes will remain the same as today.

- After PPS support discontinues, if payroll expense transfer is needed, it needs to be processed through a financial journal bypassing payroll sub-ledger → This will create complex yet unnecessary reconciliation between payroll sub-ledger, general ledger, effort reporting system, and any other downstream applications consuming the data from payroll sub-ledger.
Payroll Expense Transfers: Pre-UCPath Go-Live Data

What was shared at RAF in July 2017:

- It is important for the department to complete all necessary transfers of payroll expenses in PPS before PPS support discontinues.

- After UCLA discontinues PPS support;
  - Transfers of payroll expenses in PPS debiting sponsored project funds will not be allowed.
  - If payroll expenses in PPS need to be transferred off from sponsored project funds, additional documentation besides cost transfer questions will be required including detailed action plans for manual reconciliation and adjustments.
Actions Required

- Continue to review payroll expenses every month and upon discovery of errors, process payroll expense transfers through WebPET timely.

- Stay current with all transfers of payroll expenses processed in PPS until UCPath Go-Live (September 1, 2018).
  - Only payroll expenses processed in August 2018 should be left for review after UCPath Go-Live.
NIH Enforcement of Closeout Policies

Yoon Lee
NIH Unilateral Closeout


- **Purpose:** To alert that NIH is strengthening enforcement of closeout requirements (NIH GPS Section 8.6)

- **Recipient Responsibilities**
  - Submit timely and accurate final grant expenditure reports (FFR)
  - Reconcile cash transaction reports to the HHS PMS with expenditure reports (FFR)
  - Submit Final Research Performance Progress Report (F-RPPR), and Final Invention Statement and Certification (FIS) within 120 calendar days of the end of the period of performance
NIH Unilateral Closeout


- When recipients fail to submit timely reports, NIH will initiate unilateral closeout.
  - For financial closeout, if a recipient fails to submit a final expenditure FFR, NIH will close the grant using the last accepted Federal Cash Transaction Report’s cash drawdown amount.
    - Expenses incurred after the last FCTR will be disallowed (FCTRs are quarterly so costs for up to three months can be unrecovered) or
    - This may result in debt to be refunded.
  - Failure to correct recurring reporting problems may cause NIH to take further actions including corrective actions, withholding of further awards, suspension or termination.
NIH FFR Approval and De-obligation

What was shared at RAF in February 2017:

- We noted significant improvement in NIH’s turnaround times to review FFR: generally within 1 month after FFR submission.

- With transition to subaccounts, we also noted prompt de-obligation of funds in PMS upon NIH’s approval of FFR.

- Additional expenses not reported in the original FFR is not likely to be reimbursed after the deadline even if the revised FFR is submitted.

- Timely submission of accurate COP to EFM will ensure reimbursement of all allowable costs incurred for the project.
Fund Closeout Procedure

- EFM fund closeout procedure remains the same to ensure timely submission of the final financial deliverable to the sponsor.
- Under the current procedure, in absence of a complete and accurate closeout packet, EFM initiates and communicates analysis on the final expenditures based on expenses per general ledger excluding unsupported questionable costs.
- Untimely or no response to EFM’s analysis will likely result in under-reporting of expenses and incomplete recovery of costs incurred for the project.
- Submission of an accurate and complete closeout packet to EFM by the deadline will ensure full recovery of costs. For more information on the procedure, visit http://ora.research.ucla.edu/EFM/Pages/CLOSEOUT/CLOSEOUTOverview.aspx
Contact information

EFM Website
http://ora.research.ucla.edu/EFM/

Yoon Lee
X40375
yoon.lee@research.ucla.edu
Compliance at the Proposal Stage: Prepare Now to Avoid Headaches Later

ORA Research Administration Forum
January 11, 2018
Our Presenters

- Yessenia Sarmiento, CRA
- Contract & Grant Officer
- University of California, Los Angeles
- yessenia.sarmiento@research.ucla.edu

- Evan Garcia, CRA
- Contract & Grant Officer
- University of California, Los Angeles
- egarcia@research.ucla.edu
Presentation Overview

• This session will provide a basic overview of how compliance is a key factor in submitting a proposal.

• This session will cover the **Who**, **What**, **When**, **Why** and **How** compliance is a key part at the proposal stage.

• We will discuss the steps that we can take to not only ensure that a proposal submission is successful, but to make sure that pre-award and award acceptance run efficiently.
Compliance - What is it?

- The act of conforming to a rule, specification, policy, standard or law

- UCLA makes an effort to certify that we are abiding by federal/regional regulations, government legislation, prescribed rules and regulations, specified standards, or the terms of a contract

- Series of directives United States federal agencies established that summarize hundreds of laws and regulations applicable to federal assistance
Compliance - What is it?

- Certification of a proposal:
  - That the information submitted within the application is true, complete and accurate to the best of their knowledge
  - That any false, fictitious or fraudulent statements or claims may subject the Investigator(s) to criminal, civil or administrative penalties
  - Agree to accept responsibility for the scientific conduct of the project and to provide the required progress reports if a grant/contract is awarded as a result of the application
  - Not currently debarred, suspended or ineligible to receive federal or non-federal funds
Compliance – When is it done?

U. of Washington:

Compliance – Who is responsible?

- Principal Investigator/PI
- Department Chair/Director
- Dean
- OCGA - Authorized Official
- Other Offices
  - OHRPP
  - RSAWA
  - RPC
Compliance – Who is responsible?

• Principal Investigator/PI
  - Responsible for ensuring the preparation, conduct, and administration of the project is in accordance to sponsor and institutional policies and federal law and regulations
  - When multiple investigators are named, each investigator is responsible and accountable for the project
  - Certification is required by the Principal Investigator prior to submission
Compliance – How do we comply?

- PI Eligibility
- Sponsor Guidelines
- Budget
- Subawards
- COI
- Human/Animal Subjects
- Biosafety
- Export Control
- Tools: EPASS and Sponsor Checklists
Compliance – How do we comply?

- PI Eligibility
  - Policy driven, outlining different categories of employees that are authorized to serve as PI on extramurally funded projects
  - Per UCLA Policy 900: Eligibility to act as a PI with primary responsibility for the scientific, technical, and fiscal direction of the project resting with that individual; may be contingent upon continuation of employment or other status under which eligibility was initially determined; and compliance with all applicable policies of the University and the funding agency
    - [http://www.adminpolicies.ucla.edu/pdf/900.pdf](http://www.adminpolicies.ucla.edu/pdf/900.pdf)
Compliance – How do we comply?

- PI Eligibility
  - What is required if individual does not fall under the policy but want to serve as PI?
    - Request for PI Exception:
      - Submitted through a form or letter and is signed by a delegated authority
      - Acknowledge space and facilities are available for the PI
      - Supports that the proposal meets the best interest of the University
      - Approval for individual to serve as PI on a per project basis should accompany each proposal
      - Policy 900 lists officials with authority to approve exceptions
Compliance – How do we comply?

- **Sponsor Guidelines**
  - General sponsor proposal requirements
    - Specific instructions for formatting and required attachments, which forms to use, etc.
    - NIH: SF424 (R&R) Application guide
    - NSF: Proposal & Award Policies & Procedures Guide (PAPPG)
  - Specific program announcements/solicitations
    - May provide additional instructions supplanting general sponsor requirements
Compliance – How do we comply?

- **Tools: Sponsor Checklists**
  - Sometimes included by sponsors to ensure that all required components are present
  - **NSF:**

```markdown
Project Description:

[ ] The Project Description must not exceed the 15-page limitation, the limit specified in a specific program solicitation, or the limit provided in the instructions for types of proposals (e.g., RAPID, EAGER and Ideas Lab).

[ ] Project Description contains, as a separate section within the narrative, a section labeled “Broader Impacts”.

[ ] Project Description is self-contained, and Uniform Resource Locators (URLs) have not been included.

[ ] Results from Prior NSF Support have been provided for PIs and co-PIs who have received NSF support with a start date in the past five years. Results related to Intellectual Merit and Broader Impacts are described under two separate, distinct headings, and are limited to five pages of the Project Description.
```
Compliance – How do we comply?

- **Tools: Sponsor Checklists**
  - **NASA:**

  | Team            | All investigators must indicate participation via NSPIRES, except proposals submitted via grants.gov. If any team member doesn't confirm their participation the AOR will get an error that prevents submission. |
  | Team            | Paid team members may not be collaborators, they should be given a role permitted to receive funds, such as Co-I. |
  | Team            | A critical partner with a sustained, continuing role is a Co-I, not a collaborator, even if unpaid. |
  | Project Summary | Project Summary (abstract) must be in the text box in the cover pages, not the main body of the proposal. It has a built in 4000-character limit. |
  | DMP             | For most programs, the Data Management Plan (DMP) or explanation of why it is not needed must be provided in the 4000-character text boxes in the cover pages, unless otherwise stated in the program element. See Section II(c) and the ROSES FAQ for important information. |
  | Budget          | List all costs. Include all salary and indirect costs in the NSPIRES cover page budgets. |
Compliance – Why is it necessary?

- Federal Policies
- Proposal submission to Federal agencies are assurances of compliance
- Certifying to agencies that we have verified accuracy of statements in application and current compliance with Federal regulations
Compliance – Why is it necessary?

- **Internal Compliance**
  - Delay of proposal submission
    - Missing signatures
    - Missing COI forms
    - Missing/incomplete proposal forms
    - Revisions to proposal documents
      - Can be time-consuming
  - Front line of protection
    - Identify compliance risks and take action before they become compliance violations
Compliance – Why is it necessary?

• **Consequences**
  - Proposal rejection
  - Delays in award acceptance and set up
  - Negative impact of PI and/or institution’s reputation and professional standing
  - Suspension of the project indefinitely or until corrective actions are in place.
  - Termination of award
  - Repayment of funds/ Re-budgeting
  - Audit issues and/or disallowances.
  - Debarment/suspension
  - Violations of federal regulations and University policies (civil, criminal disciplinary, and administrative penalties)
  - Fines, criminal charges and/or other penalties
Any Questions?

RESEARCH ADMINISTRATION, SAME THING. EITHER YOU ARE COMPLIANT 'YES' OR YOU ARE COMPLIANT 'NO'

YOU ARE COMPLIANT 'GUESS SO'. SQUISH LIKE GRAPE.
Master Training session

Wednesday, January 17, 2018
9:30am – 11:00am

UCLA Wilshire Glendon
Conference Room 820-20
10899 Wilshire Blvd.
Los Angeles, CA 90095

RSVP: http://ora.research.ucla.edu/OCGA/Pages/Training-Resources/training-calendar.aspx
Highlights of ORA FY18 through Q2
Research Proposals & Awards

http://portal.research.ucla.edu/

Rory Constancio
Director, Office of Research Data Management
Fiscal Year 2018 through Q2
Comparison to FY 2017 & FY 2016
Requested Dollars & Proposal Counts

<table>
<thead>
<tr>
<th>Fiscal Year Period</th>
<th>Requested Dollars</th>
<th>Proposal Record Counts</th>
</tr>
</thead>
<tbody>
<tr>
<td>FY18 to Q2</td>
<td>$1,732,800,188</td>
<td>2,600</td>
</tr>
<tr>
<td>FY17 to Q2</td>
<td>$2,004,568,355</td>
<td>2,834</td>
</tr>
<tr>
<td>FY16 to Q2</td>
<td>$1,857,197,780</td>
<td>2,620</td>
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</tbody>
</table>
### Fiscal Year 2018 through Q2
Comparison to FY 2017 & FY 2016

Awarded Dollars & Counts

<table>
<thead>
<tr>
<th>Fiscal Year Period</th>
<th>Awarded Dollars</th>
<th>Award (Transaction) Counts</th>
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</thead>
<tbody>
<tr>
<td>FY18 to Q2</td>
<td>$532,240,529</td>
<td>2,811</td>
</tr>
<tr>
<td>FY17 to Q2</td>
<td>$489,108,144</td>
<td>2,446</td>
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<tr>
<td>FY16 to Q2</td>
<td>$481,574,347</td>
<td>2,406</td>
</tr>
</tbody>
</table>
Through Q2, FY 2016 to FY 2018
Awarded Dollars by Sponsor

<table>
<thead>
<tr>
<th>Federal Government</th>
<th>Higher Education</th>
<th>State &amp; Other Government</th>
<th>Business &amp; For-Profit</th>
<th>Charitable &amp; Non-Profit Organization</th>
</tr>
</thead>
<tbody>
<tr>
<td>FY16: $304 M</td>
<td>FY17: $302 M</td>
<td>FY18: $321 M</td>
<td>FY16: $30 M</td>
<td>FY17: $39 M</td>
</tr>
<tr>
<td>FY16: $30 M</td>
<td>FY17: $39 M</td>
<td>FY18: $48 M</td>
<td>FY16: $25 M</td>
<td>FY17: $27 M</td>
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<td>FY16: $67 M</td>
<td>FY17: $61 M</td>
<td>FY18: $66 M</td>
<td>FY16: $56 M</td>
<td>FY17: $56 M</td>
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Through Q2, FY 2016 to FY 2018
Awarded Dollars by Sponsor

FY16 to Q2: $481,574,347
FY17 to Q2: $489,108,144
FY18 to Q2: $532,240,529
FY 2016 to FY 2018 through Q2
Awarded Dollars by Date

FY17 Total: $1,060,140,489
FY16 Total: $1,049,075,841

FY18 to Q2: $532,240,529