UCLA Research Administration

# Research Administration Forum

Marcia Smith

October 10, 2019

# Agenda

- **Welcome and Announcements –** *Patti Manheim*
- **Extramural Fund Management**
  - UCPath Updates – *Will Murdoch*
  - ERS Update – *Will Murdoch*
  - Ascend: Expense Approval Workflow – *Yoon Lee*
- **Research Safety and Animal Welfare Administration –** *Jennifer Perkins*
  - RSAWA Updates
- **Office of the Human Research Protection Program** – *Kristin Craun*
  - OHRPP Updates – *Moore Rhys*
    - Single IRB
    - Consent Templates
- **Research Policy and Compliance –** *Ann Pollack*
  - Cannabis
- **Office of Contract and Grant Administration –** *Patti Manheim*
  - Trending Topics: Intellectual Property – *Jim Fong*

UCLA Research Administration

# Extramural Fund Management

October 10, 2019

UCLA Research Administration

# Agenda

- UCPath updates
- ERS update
- Ascend: Expense Approval Workflow

# UCPath Updates

Will Murdoch & Andrew Merki

UCLA Research Administration

# UCPath Updates



- **What is the current status of outstanding UCPath issues?**
  - EFM is aware of roughly 33 outstanding issues reported to UCPath Center by various UC campuses that are in queue for resolution as of October 2019
    - Includes both C&G-impacting issues and non-C&G issues
- **What is being done to address outstanding UCPath issues?**
  - Weekly meetings with the workgroup formed to address these issues with support from AVC Marcia Smith (ORA), AVC/Controller Allison Baird-James (CFS), and Executive Director Omar Noorzai (BTO).
    - Individuals from UCLA UCPath Central Resource Unit (UCPath CRU), CFS (General Accounting), BTO, and ORA (EFM) are participating.
  - Bi-weekly calls with UC Controllers and UCPath Center in Riverside to discuss and prioritize issues across UC campuses.
  - Weekly calls with UCPath Center and other UC campuses to discuss issues that are specifically impacting ERS/effort reporting.

UCLA Research Administration

# UCPath Updates

Key Resolved Issues

| Key Resolved Issue* | Current Status / Next Steps |
|---|---|
| GAEL incorrectly charged** | • Resolved. Fund Manager will be contacted by EFM if revision is required for previously submitted financial deliverable |
| Duplicate Direct Retros** | • Resolved. Fund Manager will be contacted by EFM if revision is required for previously submitted financial deliverable |
| UCPath preventing funding setup for funds with future start dates | • Resolved. Departments can now set up funding using funds with future start dates |
| Direct Retros blocked for MCOP employees when VAC offset is present | • Resolved. Departments now able to process Direct Retros for MCOP employees when VAC offset is present |
| Departments unable to process Direct Retros for employees that had department change | • Resolved. Departments now able to process Direct Retros for employees that had a department change |

*Includes key issues that have been resolved. Not a comprehensive list of all UCPath issues that have been resolved.

**Resolution included historical data cleanup component for GAEL & Duplicate Direct Retros

UCLA Research Administration

# UCPath Updates

Key Outstanding Issues

| Key Outstanding Issue* | Current Status / Next Steps |
|---|---|
| Exception Earn Codes (VAC, SKL, etc.) for employees with MCOPs are being applied to only 1 FAU vs. full funding distribution | • Fix for new transactions: Resolved.<br>• Fix for historical transactions: UCLA CRU reviewing impacted funds and will communicate cleanup effort to campus. |
| Exception Earn Codes (VAC, SKL, etc.) distributing to current month funding distribution vs. funding distribution at time exception was taken | • Fix for new transactions: Issue still ongoing and in queue for UCPC to resolve. Resolution date TBD.<br>• Fix for historical transactions: UCLA CRU reviewing all impacted funds and will communicate cleanup effort to campus. |
| Recall and Limited Employees Accruing Vacation (VLA) | • Fix for new transactions: Issue still ongoing and in queue for UCPC to resolve in October 2019.<br>• Fix for historical transactions: Fund Manager will be contacted by EFM if any revisions are required once issue is corrected in UCPath. |

*Includes key outstanding issues. Not a comprehensive list of all outstanding issues.

UCLA Research Administration

# UCPath Updates

Key Outstanding Issues

| Key Outstanding Issue* (continued) | Current Status / Next Steps |
|---|---|
| Inability to report benefits by person by earn period | • UCPC developing UCPath enhancement to break out benefits by earn period. UCPC target resolution date is November 2019. |
| Benefit Cost Transfer (BCT) not available yet | • Per CRU, target date for BCT release is mid-November 2019 pending successful testing.<br>• In the intermediate, please submit benefit journal requests to CRU following guidance from CRU newsletter sent 8/26/19 – Volume 1 Issue 7<br>  • Link: https://centralresourceunit.ucla.edu/s/article/CRU-Newsletter-Volume-1-Issue-7 |
| Incorrect derived effort % | • EFM is aware of cases where derived effort % is incorrect.<br>• Issue has been reported to UCPC as high priority. Resolution date TBD. |

*Includes key outstanding issues. Not a comprehensive list of all outstanding issues.

UCLA Research Administration

# UCPath Updates

Key Outstanding Issues

| Key Outstanding Issue* (continued) | Current Status / Next Steps |
|---|---|
| Purged recycled funds | • In certain cases, funds that were purged after UCPath Go Live and have been recycled for use on new awards are preventing users from entering funding and/or processing Direct Retros.<br>• Issue being researched by EFM, Central Resource Unit, and ITS<br>• Workaround has been identified. Please contact EFM accountant if you encounter an issue related to effective dating in UCPath. |
| Federal Flow Through High Risk Direct Retros not routing through EFM | • Per UCPC, UCPath fix is currently underway and on track for mid-October 2019 delivery. |

*Includes key outstanding issues. Not a comprehensive list of all outstanding issues.

# ERS Updates

Will Murdoch & Andrew Merki

UCLA Research Administration

# ERS Updates

Current Certification Rate

- **Current campus certification rate is 80% as of 10/10/19 (6% increase from last RAF meeting)**
- **All outstanding reports are now past due and need to be certified ASAP**

| | Fall | | | Winter | | | Spring | | | Summer | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Academic Year | Cert Rate | Cert # | Open # | Cert Rate | Cert # | Open # | Cert Rate | Cert # | Open # | Cert Rate | Cert # | Open # |
| 2005-2006 | N/A | N/A | N/A | N/A | N/A | N/A | 100% | 6683 | 0 | 100% | 6984 | 0 |
| 2006-2007 | 100% | 6112 | 0 | 100% | 6050 | 0 | 100% | 6195 | 0 | 100% | 6575 | 0 |
| 2007-2008 | 100% | 5828 | 0 | 100% | 5872 | 0 | 100% | 5997 | 0 | 100% | 6498 | 0 |
| 2008-2009 | 100% | 5830 | 0 | 100% | 5877 | 0 | 100% | 6128 | 0 | 100% | 7394 | 0 |
| 2009-2010 | 100% | 6434 | 0 | 100% | 6681 | 0 | 100% | 6899 | 0 | 100% | 7798 | 0 |
| 2010-2011 | 99% | 6573 | 3 | 100% | 6621 | 0 | 99% | 6772 | 1 | 99% | 7081 | 2 |
| 2011-2012 | 99% | 6211 | 2 | 99% | 6278 | 6 | 99% | 6273 | 4 | 99% | 6606 | 1 |
| 2012-2013 | 99% | 5773 | 3 | 99% | 5843 | 3 | 99% | 5815 | 1 | 99% | 6117 | 4 |
| 2013-2014 | 99% | 5372 | 2 | 99% | 5335 | 3 | 99% | 5503 | 2 | 99% | 5898 | 4 |
| 2014-2015 | 99% | 5265 | 2 | 99% | 5340 | 3 | 99% | 5344 | 6 | 99% | 5859 | 6 |
| 2015-2016 | 99% | 5223 | 4 | 99% | 5265 | 4 | 99% | 5388 | 4 | 99% | 5697 | 7 |
| 2016-2017 | 99% | 5120 | 9 | 99% | 5176 | 9 | 99% | 5231 | 45 | 98% | 5730 | 67 |
| 2017-2018 | 97% | 5067 | 121 | 97% | 4994 | 134 | 80% | 5015 | 1249 | N/A | N/A | N/A |

**Note**: Academic Year 2017 - 2018 Spring effort reports include a modified effort reporting period of: April to July 2018 for 11/12 Academics, April to July 2018 for Non-Academics, and March to July 2018 for 9/12 Academics

UCLA Research Administration

# ERS Updates

General Announcements

- **Next effort report release**
  - Test data is being generated for next round of effort reports. Release schedule pending review of data.
- **ERS Past Due and Open Effort Report Listserv**
  - Previously shared that starting October 15th 2019, Past Due and Open Effort Report listserv will be automated to only include ERS Coordinators. **Transition is slightly delayed until November 15th, 2019**.
- **Next ERS Class scheduled and available for registration – please sign up!**
  - Session 1 (Lecture): Tues, Oct 22, 8:30 a.m. - 12:00 a.m.
  - Session 2 (Lab): Wed, Oct 23, 8:30 a.m. - 12:00 p.m. or 1:00p.m. - 4:30 p.m.

UCLA Research Administration

12

# Ascend: Expense Approval Workflow

Yoon Lee

# Expense Approval Workflow

Non-payroll expenses

- **Change from Post Authorization to Prior Approval.**

| Current | Ascend |
|---|---|
| PAN (Post Authorization Notification)<br>→ Prior Approval in system is not required. | Prior Approval will be required.<br>→ Requisitions for purchase, invoices for payment, expense reimbursements, cost transfers, etc. |

- **Ascend: Different approver(s) depending on whether it is a charge to GL funds vs. PPM Projects.**

| GL funds | PPM C&G projects |
|---|---|
| **Financial Unit Manager**<br>• It can be an individual or a group of approvers. | **PPM project manager**<br>• An individual. It cannot be a group of approvers.<br>• Note: Subaward POs and invoices will have a different workflow. |
| **For expense reimbursement**<br>• The same **Financial Unit Travel Approver Group** is planned for both GL funds and PPM projects. (Please note that this is not a final decision yet) | |

UCLA Research Administration

# PPM C&G Project Manager

- **Current design of approval workflow in PPM**
  - Requisitions, invoices, and cost transfers are routed to the PPM Project Manager.
  - Self-approval is not allowed.
- **This model may not fit for certain departments where**
  - The person most equipped to approve transactions is the one who initiates a transaction.
  - The person most equipped to approve requisitions and invoices is different from the person responsible for approving cost transfers.
  - Other scenarios?
- **Grant team is gathering information to provide feedback to Ascend Access Security and Workflow team to develop most appropriate design that meets the campus need.**

UCLA Research Administration

# PPM C&G Project Manager

- **Questions to identify appropriate individuals for the right set of tasks to properly design access security and approval workflow for non-payroll expenses:**
  - Who creates a requisition?
  - Who would be the most appropriate person to approve the requisition (except for sub-award)?
    - This may be one of recipients of PANs.
    - Availability of the approver must be considered for timely approval. Until approval is obtained, a transaction will not be processed.
  - Who would be the most appropriate person to approve the invoices (except for sub-award)?
  - Who prepares and submits cost transfers?
  - Who currently approves cost transfers if the department has an approval in place?
- **If you believe the delivered approval workflow is not adequate for your departments, send your scenarios highlighting gaps to Yoon Lee at yoon.lee@research.ucla.edu.**
  - Your response by Wednesday October 23rd would be appreciated.

UCLA Research Administration

# Any Questions?

## Contact Information

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

**ERS Help Desk**
Email: ershelp@research.ucla.edu

**Yoon Lee**
Phone: X40375
Email: yoon.lee@research.ucla.edu

**Will Murdoch**
Phone: X65151
Email: Wallace.murdoch@research.ucla.edu

UCLA Research Administration

# RSAWA Updates

Research Safety & Animal Welfare Administration

- **RSAWA Systems**
  - ARC: New RATS development
  - IBC: SafetyNet continuing review (CR) process
  - RSC: SafetyNet RUA process
- **RSAWA Staff Changes**
  - ARC and IBC
- **NEAVS FOIA and PRR**
- **AAALAC**
  - Due in Summer 2020

UCLA Research Administration

# RSAWA Updates

- ARC Staff: arc@research.ucla.edu or 310-206-6308
- IBC Staff: ibc@research.ucla.edu or 310-794-0262
- RSC Staff: rsc@research.ucla.edu or 310-206-5601
- RSAWA Director: jperkins@research.ucla.edu or 310-794-9645

UCLA Research Administration

# OHRPP Updates

October 10, 2019

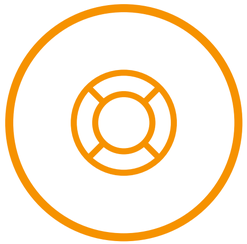
# OHRPP Updates

- Single IRB Mandate
- Consent Templates Update
- Subscribe to HRN
- OHRPP Training & what's on the horizon

# sIRB Mandate

**NIH grants (with grant application due dates from January 25, 2018 onward) for multi-site human subject research require that a *single IRB ("sIRB")* review for all participating sites. The NIH has prepared a FAQ on the NIH sIRB requirement.**

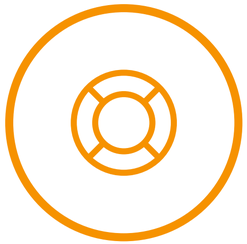
# sIRB Mandate



**The revised common rule *expands this mandate* to require sIRB review for IRB review of cooperative research funded or conducted by *any* Federal agency/department in the US.**

- **This part of the revised common rule *goes into effect on January 21, 2020***

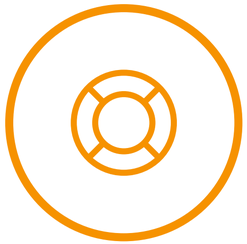
# sIRB Mandate



## Exceptions to the sIRB mandate:

- When more than single IRB review is required by law (such as tribal law passed by the governing body of an American Indian or Alaskan Native tribe)
- When the federal department/agency conducting or supporting the research determines that sIRB is not appropriate (this is expected to be RARE)

# sIRB Mandate



## sIRB recommendations:

- **If an investigator wants a UCLA IRB to be the sIRB, *contact OHRPP early* *reliance@research.ucla.edu***
- **The UCLA IRB *may or may not* be able to act as the sIRB for your cooperative project**
- ***If* the UCLA IRB cannot act as the sIRB for your cooperative project, we can direct you to alternative IRBs (including commercial IRBs)**

# Consent Template Updates

## The OHRPP updates consent templates when:

- There are *changes in the regulations* (such as the revised common rule)
- *OHRP and/or FDA issue guidance* that impact the consent template verbiage or instructions
- There are *changes in UC or UCLA policy* that impact the consent template verbiage or instructions

# Consent Template Updates

**With the *revised common rule*, a number of changes were made to required elements of the consent form:**

- **"Key information" summary at the beginning of the form**
- **Whole document must be written to "facilitate understanding"**
- **Statement about possible secondary use of data/specimens**
- **Statement about potential commercial profit and whether the participant will or will not share in that profit**
- **Statement about return of clinically-relevant individual test results**
- **Statement about whether or not the research will include whole genome/whole exome sequencing (as applicable)**

# Consent Template Updates

**History:**

- **The last update of the consent templates was in 2011**
- **The revised common rule relevant to consents went into effect on January 21, 2019**
- **Since then (in the absence of a revised template), the IRB has been sending investigators study-specific consent change requests, based on our revised common rule implementation page, to meet the requirements of the new regulations**

# Consent Template Updates

**We have been waiting for OHRP guidance/tools for "key information" before issuing the updated consent templates.**

- *We are no longer waiting, as guidance does not appear to be forthcoming*
- We anticipate rolling out the new templates ***within the month***
- If OHRP issues guidance at a future date that is not aligned with our template, we will modify the template again

# Consent Template Updates

## Roll-out of revised consent templates:

- New templates will be uploaded to the ORHPP website
- Informational/training session(s) on this new consent content will be provided by OHRPP to the research community
- A notice will be sent out through the OHRPP listserv (a.k.a. "Human Research News") to announce the availability of the new templates and time/location of training session(s)

# OHRPP “Human Research News” - Reminder

**To be the first to know when OHRPP releases guidance and other updates, please subscribe to our listserv**

- ***To subscribe, send an email (blank subject and body) to: investigators-l+subscribe@lists.ucla.edu***

# OHRPP Training Opportunities

- ✓ **OHRPP Quality Improvement Unit *will come to your division/department for IRB-related training*, customized to your needs.**
- ✓ **"*Learn at Lunch*" training series will re-launch in early 2020. Please send in your suggestions for topics.**

➢ *To request a custom training or suggest a Learn at Lunch topic, please contact: OHRPP Assistant Director, Education & Quality Improvement Moore Rhys (310) 794-6339*

# OHRPP "on the horizon"

- The *annual PI* (and faculty sponsor) *assurance* function in webIRB is coming for certain types of studies
- The PAR application is being revised in webIRB

# OHRPP "on the horizon"

***OHRPP is hiring!***

- **One position to support the Quality Improvement Unit of OHRPP (education, post-approval monitoring, and quality improvement)**
- **One position to support the Director including for special projects (such as AAHRPP accreditation)**

# Any Questions?

## Contact Information

**Website URL**

http://ora.research.ucla.edu/ohrpp

**Kristin Craun, OHRPP Director**

Phone: x33150

Email: kristin.craun@research.ucla.edu

**Moore Rhys, OHRPP Asst. Director, Education & QI**

Phone: x46339

Email: moore.rhys@research.ucla.edu

October 08, 2019

UCLA Research Policy & Compliance

# Cannabis Research and Other Related Activities

Research Administrators Forum

Ann Pollack
Assistant Vice Chancellor – Research

# Cannabis - Legal Landscape

- State law:
  - Proposition 215 (1996) – Medical Marijuana
  - State Bill 566 (2013) – Legalized Cultivation of Industrial Hemp
  - Proposition 64 (2016) – Adult Recreational Use
- Federal law:
  - Controlled Substances Act (CSA) of 1970 – regulates Marijuana (*Cannabis Sativa L*)
    - Most possession, distribution, cultivation (manufacturing) is prohibited under the CSA
  - Drug-Free Schools and Communities Act (1989)
  - 2018 Farm Bill

# Cannabis – UC Guidance

- UC guidance on use and possession of marijuana on UC property (https://www.ucop.edu/marijuana-and-drug-policy)

- UC Memo 18-01 “Updated Information for Researchers on Conducting Marijuana Research at the University of California” (https://researchmemos.ucop.edu/php-app/index.php/site/document?memo=UlBBQy0xOC0wMQ==&doc=3743)

- UC Memo 19-02 “Pilot Approach when Considering Funding from the Marijuana Industry” (https://researchmemos.ucop.edu/index.php/site/memoDetail/memo_id/RPAC-19-02)

# Cannabis – UCLA Guidance

- FAQs Concerning Cannabis (Marijuana) Research and other Cannabis-Related Activities (last updated April 2019)
  (http://ora.research.ucla.edu/RPC/Documents/UCLA_Cannabis_FAQs.pdf)

- Memo from EVC/Provost Scott Waugh (May 15, 2019)
  (http://ora.research.ucla.edu/RPC/Documents/Waugh-memo-Cannabis-research-at-UCLA.pdf)
  - Established Research Policy and Compliance (RPC) as the administrative home for the development and dissemination of campus policy

# Cannabis Use

- With limited exceptions* possession, distribution, and cultivation of *Cannabis sativa L*. (aka marijuana) *is still prohibited* under the federal Controlled Substance Act
- UC Guidance on Use and Possession of Marijuana on UC Property states **marijuana use remains prohibited on UC property and at UC events *except for approved academic research***
- All research conducted under the auspices of the University of California (regardless of where the research is conducted) that uses Cannabis must comply with all federal, state, and local regulations, as well as UC policies. Researchers must also comply with a California requirement for review by the Research Advisory Panel of California (RAPC)

*including certain research conducted in compliance with applicable regulations and policies of the Drug Enforcement Agency (DEA), the Food and Drug Administration (FDA), and the National Institute on Drug Abuse (NIDA)

# Cannabis Research

- Cannabis research involves the use, cultivation, distribution, possession, procurement, or administration of Cannabis
- Includes derivatives of *Cannabis sativa L,* extracts and purified constituents
- Federal controlled substances law regulating *Cannabis sativa L* also applies to controlled substance analogs intended for human use even if prepared through a *de novo* chemical manufacturing process
- It does *not* include research where there is no direct use, cultivation, distribution, possession, procurement or administration of Cannabis, such as observational studies, policy research, or review of public records related to marijuana use

# Hemp

- Hemp is defined as Cannabis sativa L. with a THC concentration of not more than 0.3% on a dry weight basis
- The Farm Bill of 2018 removed hemp and hemp derivatives (extracts and cannabinoids) from the definition of Cannabis under the Controlled Substance Act
- Thus, hemp and hemp derivatives are no longer regulated as Schedule I Controlled Substances
- Under the 2018 Farm Bill and current conditions, not all entities are legally permitted to cultivate hemp
- UC campuses may only acquire hemp from a grower that has applied for and obtained a license directly from the federal USDA

# Hemp

- Cultivation of hemp (NOT YET BEING DONE) at UCLA (or under campus auspices) would require an approved plan that includes:
  - Maintaining, for three years, relevant information regarding the land on which hemp is to be grown
  - Obtaining certified hemp seeds or cultivars with testing report certifying that seeds contain no more than 0.3% THC from suppliers
  - A procedure for testing, using post-decarboxylation or other similarly reliable methods, delta-9 THC concentration levels of the hemp produced
  - A procedure for effective disposal of plants (growing or not) and their derivatives, that are produced in violation of the rules (e.g., that exceed 0.3% concentration of THC)
  - A mechanism for affirming that the individuals who will participate in the cultivation program do not have Cannabis related felony convictions

# Use of Cannabis in Research

- Cannabis research requires DEA Schedule I registration
- Use of Cannabis in human subject research also requires approval from the IRB and the FDA (animal research requires ARC approval)
- Marijuana product for use in research must be obtained from a DEA approved grower (currently the University of Mississippi which is funded by NIDA)
- Under State law, any planned research to be conducted on humans in California requiring the use of a Schedule I or Schedule II Controlled Substance as its main study drug, must also be reviewed and approved by the Research Advisory Panel of California (RAPC) of the California Attorney General's Office

# Use of Cannabis in Research

- Campuses are expected review proposed support for Cannabis research and other related activities to ensure that UC is not inadvertently violating laws on money laundering, or is accused of aiding and abetting an illegal activity. Concerns about potential optics and risks will be managed as follows:
  - Support derived directly from illegal Cannabis-related activities - Will not be accepted
  - Support from entities or individuals who want to provide support derived from separately identifiable streams of revenue some of which are directly tied to illegal Cannabis-related activities and some of which are from other activities - May be accepted with due diligence and with written declaration under oath from the donor/supporter that the funds were not derived from an illegal source
  - Support from entities or individuals whose activities are indirectly tied to the marijuana industry -May make local decisions about whether to accept such funds based on individual evaluations of each situation, and conducting due diligence as appropriate

# Open Issues

- Questions about UC's risk tolerance
- Questions about accepting support from individuals or entities in the Cannabis industry
- Questions about UCLA student involvement in projects supported by and/or focused on the Cannabis industry
- Concerns about participation by individuals who are actively engaged in the Cannabis industry in conferences, classes, or as lecturers/mentors

# Cannabis Review Board

- Campus committee established by EVC/Provost Scott Waugh
- Co-Chaired by AVC Ann Pollack and Michael D. Roth, M.D., Professor of Medicine
- Advisory to the Vice Chancellor for Research
- Research Policy and Compliance unit of the UCLA Office of the Vice Chancellor for Research serves as the administrative home for the development and dissemination of campus policy

# Contacts

For guidance, policy interpretation and questions about reviews by the Cannabis Advisory Board (CAB) contact

**Ann Pollack,** Assistant Vice Chancellor – Research

apollack@research.ucla.edu | (310)794-0387

For assistance with DEA registrations to use Controlled Substances (including Cannabis) at UCLA, contact

**Alyssa Leiva**, UCLA EH&S

controlledsubstances@EHS.ucla.edu | (310)795-5013

# References

- RPAC Memo 17-01 “Information for Researchers on the Effect of Proposition 64 on Marijuana Research at the University of California”: https://researchmemos.ucop.edu/php-app/index.php/site/document?memo=UlBBQy0xNy0wMQ==&doc=3663
- COGR Cannabis Research Frequently Asked Questions: https://www.cogr.edu/sites/default/files/FAQ.pdf
- UC Guidance on Use and Possession of Marijuana on UC Property: https://www.ucop.edu/marijuana-and-drug-policy/