



Research Administration Forum

January 10, 2019

Marcia Smith

Associate Vice Chancellor for Research

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Welcome!

Research Administration Forum

January 10, 2019 - 10:00 am to 11:00 am

Louis Jolyon West Auditorium, Room C8-183
of the Semel Institute

Meeting Agenda

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Welcome and Announcements – *Marcia Smith*

OHRPP – *Alison Orkin and Mark Mimnaugh*

- **Common Rule Update**

EH & S – *Alyssa Leiva*

- **Controlled Substances Schedule I and Cannabis**

EFM – *Yoon Lee*

- **PPS: Payroll Expense Transfer Deadline**
- **UCPath Update: Salary Cost Transfer Cleanup** – *Amanda Maninos*
- **ERS Release** – *Amanda Maninos*

Open Forum – Questions, Discussion

Welcome and Announcements

Marcia Smith

- **OCGA Presentation postponed pending new information, should anyone, PI or Dept, receive a stop work order we request they reach out to OCGA.**
- **Thanks to Mindful Music for sharing the space here Semel Auditorium!**



Common Rule Update

January 10, 2019

Common Rule - Background

- **The Current Common Rule (Current Rule, Pre-2018 Rule, “Old Rule”) was codified in 1991 and 19 Federal Agencies (including HHS) follow this rule.**
- **The “Revised Common Rule” (RCR, 2018 Rule, New Rule, or Final Rule) goes into effect for research approved on or after January 21, 2019.**
 - Note that January 21, 2019 is a National Holiday (MLK Jr. Day), and the University is closed.
 - All of the previous Federal Agencies have signed onto the New Rule, **except for the DOJ**

Common Rule – January 21, 2019

- **Beginning 1/21/2019, IRBs will be responsible for following:**
 - Pre-2018 Rule – For projects approved before 1/21/2019
 - New Rule – For projects approved on or after 1/21/2019
 - Commensurate protections – for unfunded projects
 - FDA Regulations – for projects that involve an investigational drug or device

Migrating Pre-2018 Studies to New Rule

- The regulations allow the IRB to keep studies under the Pre-2018 rule, through the life of the study
- The IRB can decide to move studies to the New Rule
 - If a study is moved to the New Rule, it would need to follow all components of the New Rule, including revised consent requirements and posting consent forms (if applicable)
- **UCLA plans to keep studies approved under the Pre-2018 rule under that rule, except on a case-by-case basis as determined appropriate by the reviewer**

Where do I find guidance?

- Written guidance is so far limited.
- OHRP (HHS) guidance as of 1/10/2019
 - Common Rule Q&As
<https://www.hhs.gov/ohrp/education-and-outreach/revised-common-rule/revised-common-rule-q-and-a/index.html>
 - Videos
<https://www.hhs.gov/ohrp/education-and-outreach/revised-common-rule/revised-common-rule-videos/index.html>
- **UCLA OHRPP will provide updated guidance and procedures documents over the next few weeks.**

*In the interim, please contact Alison or Mark, or your IRB Administrator,
if you have questions regarding a specific study*

What's Changing?

➤ Lots of considerations for IRB processes

Areas that more directly affect researchers:

- **Definitions**
- **Exempt Research**
- **Continuing Review**
- **Informed Consent**
- **Other changes:**
 - Broad consent
 - Single IRB
 - Required posting of clinical trial consents

New and Revised Definitions

- **Unchanged definitions: Minimal risk, IRB, and IRB approval**
- **New terms defined: Clinical trial, public health authority, written or in writing**
 - *Public health authority is part of description of activities excluded from the definition of research*
- **Minor clarifications made to wording:**
 - Intervention
 - Interaction
 - Private information
 - Identifiable private information

New Definitions

- **Clinical trial** means a research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of the interventions on biomedical or behavioral health-related outcomes.
 - *Use this definition for determining which studies require posting of the IRB-approved consent form.*
- **Written or in writing:** writing on a tangible medium (e.g., paper) or in an electronic format
 - *Included to clarify that the terms include electronic formats.*
 - *Aligns the Common Rule with US FDA and ICH initiatives*

New Definitions

- **Research: The RCR identifies 4 types of activities as not being ‘research’ as defined in the Rule. So the RCR does not apply to the following types of activities, as they do not meet the regulatory definition of research:**
 - Certain scholarly and journalistic activities
 - Certain public health surveillance activities
 - Collection and analysis of information, specimens, or records, by or for a criminal justice agency for certain criminal justice or investigative purposes, and
 - Certain authorized operational activities for national security purposes
- **Human Subject: The regulatory definition of Human Subject has not been changed in the RCR, but there has been a clarification.**
 - The Pre-2018 Rule referred to “*data*” obtained by an investigator through intervention or interaction ...”
 - The RCR replaces “data” with “*information or biospecimens*” for clarity

Exempt Research

- All but one category was revised; new categories were added.
 - Pre-2018 Rule had 6 exempt categories in section 46.101(b)
 - 2018 Rule includes 8 categories in section 46.104(d)
 - More detailed discussion of Exempt categories is provided in CITI resources provided here:
<https://about.citiprogram.org/en/final-rule-resources/#overview>
- **UCLA webIRB Application changes: Categories no longer listed**

Exempt Research – New Category 3

- **Benign Behavioral Interventions in Conjunction with the Collection of Information from Adult Subjects**
 - Brief in duration
 - Harmless, painless, not physically invasive
 - Not likely to have a significant adverse lasting impact on the participants
 - The investigator has no reason to think the participants will find the interventions offensive or embarrassing.

Continuing Review

- **Studies that are minimal risk will no longer need annual continuing review, unless determined by the IRB reviewer.**
- **Greater than minimal risk studies that meet certain milestones will no longer need annual continuing review, unless determined by the reviewer.**
- **UCLA will implement a process of annual reminders of responsibilities for amendments and post approval reports. It will require investigator response to confirm study is active.**

Informed Consent – “Key Information” Summary

Consent forms will need to start with a concise summary of key information - 45.116(a)(5)

Five “factors” (elements) must be included

1. The fact that consent is being sought for research and that participation is voluntary
2. The purposes of the research, expected duration of the prospective subject’s participation, and procedures to be followed in the research
3. The reasonably foreseeable risks or discomforts to the prospective subject
4. The benefits to the prospective subject or others that may reasonably be expected from the research
5. Appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the prospective subject

-- Preamble to Final Rule (HHS 2017, 7149-274)

Informed Consent

New required elements of consent (used when appropriate) related to the use of de-identified information, the use of biospecimens, potential for commercial profit and return of clinically-relevant results.

46.116(c)(7) - A statement that the subject's biospecimens (even if identifiers are removed) may be used for commercial profit and whether the subject will or will not share in this commercial profit.

46.116(c)(8) - A statement regarding whether clinically relevant research results, including individual research results, will be disclosed to subjects, and if so, under what conditions.

46.116(c)(9) - For research involving biospecimens, whether the research will (if known) or might include whole genome sequencing (i.e., sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen).

Informed Consent – Secondary Research

New required elements of consent for secondary research

46.116(b)(9)(i) -- A statement that identifiers might be removed from the identifiable private information or identifiable biospecimens and that, after such removal, the information or biospecimens could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from the subject or the legally authorized representative, if this might be a possibility.

46.116(b)(9)(ii) -- A statement that the subject's information or biospecimens collected as part of the research, even if identifiers are removed, will not be used or distributed for future research studies.

Other Changes

- **Broad Consent**
 - The Final Rule establishes a framework for “broad consent,” a new type of regulatory consent under the Common Rule for non-exempt storage, maintenance, and research use involving identifiable information and biospecimens.
 - UCLA not currently implementing
- **Clinical Trial Consent Form Posting**
 - Sponsors will be required to post consent forms for clinical trials to a public website/repository identified by OHRP
- **Single IRB of Record Policy**
 - Goes into effect in January 2020
 - Similar to NIH Single IRB policy, already in place

Questions?

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Mark Mimnaugh mmimnaugh@research.ucla.edu

UCLA Office of the Human Research Protection Program (OHRPP)

UCLA Environment, Health & Safety

Controlled Substances Schedule I & Cannabis

Alyssa Leiva
Controlled Substance Program Administrator for Research

California and Cannabis

Current Medical & Recreational USE of cannabis is legal

- 1996- 2015 - Medical use legalization
- 2016- Present - Adult use legalization

What does this mean federally?

- Schedule I prohibited drug



Cannabis Legislation
Information

<https://cannabis.ca.gov/cannabis-legislation/>

Federal Definition of Cannabis

'marihuana' means all parts of the plant *Cannabis sativa* L.

- whether growing or not
- Seeds
- Resin extracted
- Every compound manufacture
- salt, derivative, mixture, or preparation from plant, seed or resin

Does not include the mature stalks including

- Anything produced from the stalk, except extracted resins
- Oil or cake made from the seeds of such plant
- sterilized seed which are incapable of germination

2018 and CBD

FDA approval Epidiolex

- <https://www.fda.gov/newsevents/newsroom/pressannouncements/ucm611046.htm>



September - DEA announcement

- FDA approved CBD drugs with THC below 0.1% are Schedule V
- <https://www.dea.gov/press-releases/2018/09/27/fda-approved-drug-epidiolex-placed-schedule-v-controlled-substance-act>

Schedule I vs. V-

- <https://www.dea.gov/drug-scheduling>

UCLA and Research

Federal overrides State

How to conduct research?

- DEA Schedule I Registration
- Cannabis from NIDA- <https://www.drugabuse.gov/researchers/research-resources/nida-drug-supply-program>



Schedule I Registrations

Before you get started with your application:

- Schedule a consultation with UCLA's CSPA
- Have your list of approved protocols associated with your schedule I controlled substances
- Get your storage location ready

Schedule I Registrations

Start your applications process

- Start Check List -
<https://ucla.box.com/s/y1vnpp9852lv5slcag9bl71gq2694n3e>
- Complete your online DEA application only for Schedule I
- Start gather required documentation
- Submit your application to Research Advisory Panel of California (RAPC)

Contacts and Resources

Information on the Controlled Substance Program and DEA registrations

- Alyssa Leiva at aleiva@ehs.ucla.edu or (310)-794-5143

General information about cannabis at UCLA

- Ann Pollack at apollack@research.ucla.edu or (310) 794-0387

UC Policy

- Agnes Balla at Agnes.Balla@ucop.edu or (510) 987-9987.



Extramural Fund Management

January 10, 2019

Agenda

- **PPS: Payroll Expense Transfer Deadline**
- **Update on the Release of Effort Reports**
 - Salary Cost Transfer clean-up Status

PPS: Payroll Expense Transfer Deadline

Yoon Lee

Overview

- **PPS will discontinue as of July 1, 2019**
- **After PPS support discontinues, EFM standard procedure will be not to accept transfers of pre-UCPath go live payroll expenses debiting to sponsored project funds.**
- **History of communication of the procedure at RAF**
 - July 2017: UCPath go-live scheduled in December 2017
 - PPS was scheduled to discontinue as of July 1, 2018.
 - Detailed procedure was announced.
 - Target date to complete all payroll expenses transfers in PPS was January 2018.
 - January 2018: UCPath go-live scheduled in September 2018
 - PPS was scheduled to discontinue as of July 1, 2019.
 - Procedure was reminded.
 - Target date to complete all payroll expense transfers in PPS was October 2018.
 - June 2018: UCPath go-live scheduled in September 2018
 - Procedure and target completion date were reminded as shared at RAF in January 2018.

PPS: Payroll Expense Transfers

“PPS will discontinue as of July 1, 2019”

Until June 30, 2019 while PPS is maintained

- Transfer payroll expenses through WebPET.
- High risk cost transfers will be routed to EFM for approval.
- Payroll expense transfers will be processed through pay compute cycle and posted to general ledger (For high risk cost transfers, once approved by EFM)
- Downstream applications (e.g. Effort Reporting System) will be updated via the same process.

After June 30, 2019 once PPS is discontinued

- WebPET will no longer be available for payroll expense transfers.
- If payroll expense transfer is needed, it needs to be processed through a financial journal bypassing payroll sub-ledger.
- This will result in discrepancies between payroll sub-ledger and general ledger.
- Impact to downstream applications consuming payroll sub-ledger data (e.g. Effort Reporting System).
- Related benefits, GAEL, TIF, etc. need to be manually calculated to be included in a financial journal.
- No clear audit trails for payroll expense transfers.
- Manual reconciliation and off-system documentation will be required.

EFM Procedure

PPS: Payroll Expense Transfers after June 30, 2019

- **EFM standard procedure will be not to accept pre-UCPath go live payroll expense transfers debiting to sponsored project funds after PPS support discontinues.**
- **Department will be responsible for finding unrestricted funding source for these payroll expenses.**
- **If payroll expenses need to be transferred off from sponsored project funds after PPS support discontinues, EFM will require the department to submit following:**
 - Comprehensive explanation of circumstances why a delay of payroll expense transfers exceeded 9 months or more in addition to standard questions for cost transfers, signed by the PI and the department fund manager.
 - Detailed action plan on how the department will ensure manual adjustments to all affected downstream system reports
 - e.g. For effort reports, a complete list of all employees whose salaries are transferred including affected effort report periods, pay rate, pay distribution before and after, etc.)
 - Endorsement of Department CFO, CAO, Director, or an equivalent position on the explanation and action plan.

Department Actions Required

- **Do you have any awards monthly reconciliation has not yet been completed for August 2018 or prior?**
 - Review payroll expenses on projects through August 2018 (processed in PPS) now.
 - Process payroll expense transfers as soon as errors are discovered.

- **The Last Day to submit payroll expense transfer for EFM’s review via WebPET**

Pay Cycle	Pay Period	Last Day to submit expense transfer for review by EFM	Pay Compute
MO	06/01 – 06/30	06/18/19	06/24/19
B2	06/16 – 06/29	06/27/19	07/03/19

- Complete 2019 PPS schedule can be found at <https://ucla.app.box.com/v/pyrl-pdf-pps-sched19>

“Please do not wait and act now!”

Update on the Release of Effort Reports

Amanda Maninos

Delayed Release of Effort Reports

ERS Update

Spring'18 and Summer'18 quarters

- **Testing since October 2018**
 - Outstanding issues identified in UCPATH conversion
 - Central Resource Unit (CRU) Team is working with departments to resolve
- **Next Release Date: *TBD***
- **Certification Deadline: *TBD***
- **Fall'18 and Winter'19 quarters**
 - Anticipated Release: *April 2019*
 - Contingent upon resolution of outstanding issues

Issues Identified

ERS Update

- **Payroll Exceptions are not being distributed among all FAUs**
 - “Exceptions” include: vacation, jury duty, sick leave, etc.
 - Exceptions that were taken in August and September of 2018
 - Applies to employees with multiple components of pay
 - Population affected is still being determined
- **Positions with Multiple Components of Pay (MCOP)**
 - MCOP Worksheet is the control that ensures salary amounts are distributed correctly
 - An MCOP Worksheet is required in UCPath when:
 - a position is funded from more than one FAU and/or fund has a Salary Cap

Salary Cost Transfer clean-up

ERS Update

- **Issue: MCOP Worksheets are missing or incorrectly filled-out**
 - Result: Salary is being charged over the cap rate
 - Direct Retros are required to correct overages

- **Direct Retros required in UCPATH**

Description	Total Identified	Current Status
Positions missing MCOP worksheet	# 54	75% Completed
Positions with incorrect MCOP worksheet	# 31	100% Outstanding
Direct Retro / Salary Cost Transfers required	# 100 estimated	50% Completed

Resolution

ERS Update

- **Resolution is currently in progress**
 - CRU Team has identified and will contact populations affected
- **CRU Team is in the process of assisting departments to:**
 - Complete missing MCOP worksheets
 - Update incorrect MCOP worksheets
 - Process salary cost transfers/direct retros
- **Please respond to CRU's request by January 18th extended deadline**
 - Refer to emails issued on December 10th and 18th; Reminder sent January 7th
 - Subject: "MCOP Funding Worksheet – Dept # and MCOP Salary Cost Transfer"

Any Questions?

Contact Information

EFM Website

<http://ora.research.ucla.edu/efm/>

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UCPath-CRU team

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