Research Administration Forum
July 13, 2017

Welcome!

Marcia Smith
Associate Vice Chancellor for Research
Agenda

• Welcome and Announcements – Marcia Smith
  ▪ FY17 Year-end Data

• RSAWA News – Jennifer Perkins
  ▪ AAALAC Site Visit: August 1 – 4, 2017

• OCGA News – Kathy Kawamura
  ▪ NIH GCP Guidance Follow-Up
  ▪ Grant Updates

• RPC News – Ann Pham
  ▪ Export Controls – Cuba Update

• OHRPP News – Kip Kantelo
  ▪ Final Rule
  ▪ NIH Single IRB Policy

• EFM - Yoon Lee
  ▪ UCPath: Payroll Expense Transfers – Yoon Lee
  ▪ PAMS Update – Jennifer Aguilar
  ▪ ERS Update – Connie Brown
NIH F&A Costs

Highlights of ORA FY 2017 Research Awards

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

Rory Constancio
Director, Office of Research Data Management
## $1 Billion Awarded Dollars
### FY17, FY16 & FY15

**Awarded Dollars & Counts**

<table>
<thead>
<tr>
<th>Fiscal Year</th>
<th>Awarded Dollars</th>
<th>Award (Transaction) Counts</th>
</tr>
</thead>
<tbody>
<tr>
<td>FY 2017</td>
<td>$1,060,140,489</td>
<td>5,779</td>
</tr>
<tr>
<td>FY 2016</td>
<td>$1,049,075,841</td>
<td>5,554</td>
</tr>
<tr>
<td>FY 2015</td>
<td>$1,033,159,101</td>
<td>5,648</td>
</tr>
</tbody>
</table>
FY 2016 & FY 2017
Awarded Dollars

Research Awarded Dollars by Sponsor Type

- Federal Government
  - FY 2016: $607,906,103
  - FY 2017: $601,326,883
- Business & For-Profit
  - FY 2016: $125,814,253
  - FY 2017: $116,338,939
- State & Other Government
  - FY 2016: $110,214,470
  - FY 2017: $80,961,909
- Higher Education
  - FY 2016: $80,466,517
  - FY 2017: $136,349,671
- Charitable & Non-Profit Organization
  - FY 2016: $132,318,366
  - FY 2017: $132,318,366
FY 2016 & FY 2017
Awarded Dollars

Research Awarded Dollars by Sponsor Type

FY 2016
- Federal Government: $136.3 M (13.0%)
- Business & For-Profit: $116.3 M (11.1%)
- State & Other Government: $107.5 M (10.2%)
- Charitable & Non-Profit Organization: $80.7 M (10.4%)
- Other: $81.0 M (7.7%)

FY 2017
- Federal Government: $132.3 M (12.5%)
- Business & For-Profit: $110.2 M (10.4%)
- State & Other Government: $125.8 M (11.9%)
- Charitable & Non-Profit Organization: $90.5 M (8.6%)
- Other: $601.3 M (55.7%)

Sponsor Category
- Federal Government
- Business & For-Profit
- State & Other Government
- Charitable & Non-Profit Organization
- Higher Education
- Other
RSAWA UPDATES: 2017 AAALAC SITE VISIT

Jennifer Perkins, MA, CPIA
Director – Research Safety & Animal Welfare
Institutional Contact for Dual Use Research
Background

- Association for Assessment and Accreditation of Laboratory Animal Care, International
- Private, non-profit
- Peer-Review
- More than 980 accredited institutions in 44 countries
- UCOP requires all UC campuses to be accredited
Site Visit

• August 1-4, 2017
• Meet with IO and administration
• Meet with ARC
• Tour facilities
• Talk to lab staff
• Ask MANY questions
• In-Briefing (Day 1)
• Exit Briefing (Day 4)
Findings

- Mandatory – must correct in order to maintain accreditation
- Suggestions for Improvement – recommended upgrades to improve an already acceptable program
How to Prepare?

- Read, review, understand your protocol
- Follow veterinary orders
- Document all treatments
- Review relevant ARC Policies
- Contact ARC admin team for walk-through, protocol review
Questions?
Topics

• NIH Good Clinical Practice
• ClinicalTrials.gov
• F&A Rate Application
• TIF Rate
• NIH Notice Updates
NIH Good Clinical Practice

As presented at previous RAF (January 12, 2017), NIH issued NOT-OD-16-148 which outlines the NIH policy on Good Clinical Practice training for NIH awardees involved in NIH-fund clinical trials.

• “This policy establishes the expectation that all NIH-funded investigators and staff who are involved in the conduct, oversight, or management of clinical trials should be trained in Good Clinical Practice (GCP), consistent with principles of the International Conference on Harmonisation (ICH) E6 (R2)”

• Training may be achieved through a class or course, academic training program, or certification by other sources.

• GCP training should be refreshed at least every three years in order remain current with regulations, standards and guidelines.
NIH Good Clinical Practice

UCLA Process:

• PI is responsible for ensuring that NIH-funded investigators and staff who are involved in the conduct, oversight, or management of clinical trials are up to date with GCP training.
  ▪ New Awards: OCGA will confirm GCP training completion with department/PI

• Existing/ongoing NIH clinical trials – remind PIs to complete their training and ensure relevant staff complete training.
  ▪ Upcoming: OCGA to follow-up for completion of GCP training certification

• If previously completed training from source other than CITI; will be required to provide evidence of completion

• ePass - OCGA will review sponsor & program type based upon NIH definitions
NIH Good Clinical Practice
<table>
<thead>
<tr>
<th>Last Name</th>
<th>First Name</th>
<th>DEPARTMENT</th>
<th>DEPT</th>
<th>Learner Group or Course Taken</th>
<th>Completion Date</th>
<th>Expiration Date</th>
<th>Type of Course</th>
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</thead>
<tbody>
<tr>
<td>Bruin</td>
<td>Joseph</td>
<td>CLINICAL RESEARCH CENTER</td>
<td>1790</td>
<td>Good Clinical Practice (OPTIONAL)</td>
<td>4/8/2013</td>
<td>4/7/2016</td>
<td>GCP</td>
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<tr>
<td>Bruin</td>
<td>Josephine</td>
<td>MEDCTR-VOLUNTEERS</td>
<td>2808</td>
<td>Good Clinical Practice (OPTIONAL)</td>
<td>12/11/2009</td>
<td>12/10/2012</td>
<td>GCP</td>
</tr>
<tr>
<td>Conte</td>
<td>Lee</td>
<td>MEDICINE-HEMATOLOGY-ONCOLOGY</td>
<td>1559</td>
<td>Good Clinical Practice (OPTIONAL)</td>
<td>6/10/2013</td>
<td>6/9/2016</td>
<td>GCP</td>
</tr>
<tr>
<td>Don</td>
<td>Glen</td>
<td>CANCER PREVENTION &amp; CNTRL RESEARCH</td>
<td>1916</td>
<td>Good Clinical Practice (OPTIONAL)</td>
<td>10/27/2015</td>
<td>10/26/2018</td>
<td>GCP</td>
</tr>
<tr>
<td>Ley</td>
<td>Gay</td>
<td>MEDICINE-HEMATOLOGY-ONCOLOGY</td>
<td>1559</td>
<td>Good Clinical Practice (OPTIONAL)</td>
<td>11/18/2013</td>
<td>11/17/2016</td>
<td>GCP</td>
</tr>
<tr>
<td>Shire</td>
<td>Will</td>
<td>MEDCTR-JULES STEIN EYE INSTITUTE</td>
<td>2892</td>
<td>Good Clinical Practice (OPTIONAL)</td>
<td>6/16/2017</td>
<td>6/15/2020</td>
<td>GCP</td>
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Compliant

Non-Compliant
Pending Epass Changes (NIH Good Clinical Practice)

EPASS Section 6

<table>
<thead>
<tr>
<th></th>
<th>Does this proposal involve the use of significant IT resources (beyond basic academic infrastructure); the generation of datasets or digital assets; or a budget with over $10,000 in IT-related hardware, software, or staff expenditures? (Check additional requirements)</th>
</tr>
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<tbody>
<tr>
<td></td>
<td>Human Subjects? If yes, indicate &quot;Pending&quot;, IRB # or Exemption #: __________________________________________________________ Delayed Onset □</td>
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<tr>
<td></td>
<td>Are study related patient care costs to be billed to the award OR to a third party payor (i.e. medical insurance/Medicare)? If yes, then a Policy 915 Coverage Analysis is required (contact <a href="mailto:coverageanalysis@mednet.ucla.edu">coverageanalysis@mednet.ucla.edu</a>)</td>
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<td></td>
<td>Animal Subjects? If yes, indicate &quot;Pending&quot; or ARCI: ___________________________________________________________________________ Delayed Onset □</td>
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<td>Human Embryonic Stem Cell Research? If yes, refer to the Stem Cell Policy and Procedures.</td>
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<td></td>
<td>Non-UCLA materials/equipment to be used? If yes, indicate type: ___________________________________________________________________________</td>
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New Question:

NIH-funded Clinical Trial? If yes, have investigators and staff involved in the conduct, oversight, or management of clinical trials completed Good Clinical Practice training. Training is available through CITI Program. Please list relevant investigators and staff on page 3.

If yes, specify: ____________________________________________ |

Travelling to or doing research in a country currently under a US Trade or Economic Embargo (See OFAC Website)?

If yes, specify: ____________________________________________ |
List all of the “NIH-funded investigators and staff who are involved in the conduct, oversight, or management of clinical trials should be trained in Good Clinical Practice (GCP)”

<table>
<thead>
<tr>
<th>First Name</th>
<th>M/L</th>
<th>Last Name</th>
<th>Email Address</th>
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ClinicalTrials.gov

Compliance with FDAAA 801 Requirements (Final Rule)

• “ClinicalTrials.gov is a registry and results database of publicly and privately supported clinical studies of human participants conducted around the world”

• Based upon FDAAA 801 Requirements (Final Rule), it “requires Responsible Parties to register and submit summary results of clinical trials with ClinicalTrials.gov.”

• FDAAA 801 applies to any clinical study that meets the definition of an Applicable Clinical Trial and that was initiated after September 27, 2007, or that was initiated on or before that date and was still ongoing as of December 26, 2007.

• Definition of Applicable Clinical Trial under FDAAA

ClinicalTrials.gov FAQs
ClinicalTrials.gov
(NIH requirement)

Compliance with FDAAA 801 Requirements (Final Rule)

- Per the Deans, Directors, Department Chairs, and Administrative Officers memo issued by Interim Vice Chancellor Karagozian and Vice Chancellor Mazziotta dated June 2, 2017 (appendix) National Institutes of Health Policy on the Dissemination of NIH-Funded Clinical Trial Information (NOT-OD-16-149) went into effect on January 17, 2017.

- It requires registering and submitting results information to ClinicalTrials.gov for all studies funded wholly or in part by the NIH regardless of study phase, type of intervention, or whether they are subject to FDAAA Section 801. See: https://grants.nih.gov/grants/guide/notice-files/NOT-OD-16-149.html.
ClinicalTrials.gov

Compliance with FDAAA 801 Requirements (Final Rule)

- **Cancer Studies**: The Office of Regulatory Compliance, Jonsson Comprehensive Cancer Center: jcccorc@mednet.ucla.edu. The process of registering trials and results reporting is managed by the JCCC in collaboration and consultation with the investigator, using investigator-supplied information and documentation. Investigators *do not* need to maintain individual user accounts for cancer studies.

- **Non-Cancer Studies**: The Office of Regulatory Affairs, Clinical and Translational Science Institute (CTSI): ctsiora@mednet.ucla.edu. Each Investigator receives a user account under the “UCaliforniaLA” organization name to be able to log in to register and maintain their own studies. CTSI staff can view and edit all records in the organizational account and can provide guidance on registration and results-reporting requirements and the Protocol Registration System (PRS) data entry process. Study support staff and co-investigators may be given access to view and edit a study record, but only the Responsible Party can release the record to ClinicalTrials.gov.

- Per NIH ([https://grants.nih.gov/clinicaltrials_fdaaa/certify-compliance.htm](https://grants.nih.gov/clinicaltrials_fdaaa/certify-compliance.htm)), AOR’s signature on a competing application or RPPR assures compliance with FDAAA.
Pending Epass Changes
(ClinicalTrials.Gov)

PI Certifications

10. Accepts Responsibility
The Investigator(s) certifies to the following: (1) that the information submitted within this application is true, complete and accurate to the best of their knowledge; (2) that any false, fictitious, or fraudulent statements or claims may subject the Investigator(s) to criminal, civil or administrative penalties; (3) agrees to accept responsibility for the scientific conduct of the project and to provide the required progress reports if a grant is awarded as a result of the application; and (4) that you are not currently debarred, suspended or ineligible to receive federal or non-federal funds. When multiple investigators are proposed in an application this assurance must be obtained by all named investigators.

<table>
<thead>
<tr>
<th>Principal Investigator (Required)</th>
<th>Date</th>
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<tbody>
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</table>

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<thead>
<tr>
<th>Chair/ORU Director/Dean/Medical Center Director (Required)</th>
<th>Date</th>
</tr>
</thead>
<tbody>
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</tbody>
</table>

INSERT:

(5) all Clinical Trials based upon FDAAA 801, will be registered in ClinicalTrials.gov.
Technology Infrastructure Fee (TIF)


- FY 18 TIF Rate: $41.22
- Effective July 1, 2017
- TIF based upon paid FTE

TIF Fee FAQs

https://www.it.ucla.edu/support-training/campus-billing-help/general-billing-faqs/technology-infrastructure-fee-faqs
# F&A Rate

<table>
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<tr>
<th>Sponsored Activity</th>
<th>Effective Period</th>
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</thead>
<tbody>
<tr>
<td></td>
<td>FY 2017</td>
</tr>
<tr>
<td></td>
<td>July 1, 2016</td>
</tr>
<tr>
<td></td>
<td>To</td>
</tr>
<tr>
<td></td>
<td>June 30, 2017</td>
</tr>
<tr>
<td>Organized Research</td>
<td>54%</td>
</tr>
<tr>
<td>Other Sponsored Activities</td>
<td>35%</td>
</tr>
<tr>
<td>Instruction</td>
<td>37%</td>
</tr>
<tr>
<td>Off-Campus (all functions)</td>
<td>26%</td>
</tr>
<tr>
<td>Intergovernmental Personnel Agreement (IPA)</td>
<td>8%</td>
</tr>
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</table>

UCLA F&A Rate Agreement

http://www.research.ucla.edu/ocga/Documents/F_A_Rate_Agreement_5-3-17.pdf
### Split F&A Rates

**Budget Period 1: 1/01/18 – 12/31/18**

<table>
<thead>
<tr>
<th></th>
<th>Total Direct</th>
<th>Total Exclusion</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>1/1/18 - 6/30/18</strong> (6 months)</td>
<td>137,500</td>
<td>75,000</td>
</tr>
<tr>
<td><strong>7/1/18 - 12/31/18</strong> (6 months)</td>
<td>137,500</td>
<td>75,000</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th></th>
<th>Total Direct</th>
<th>Total Exclusion</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>UCLA F&amp;A Rate</strong></td>
<td><strong>55%</strong></td>
<td></td>
</tr>
</tbody>
</table>

- **Total Direct Exclusions**: 37,500
- **Base**: 100,000
- **Indirect**: 55,000
- **Total Cost**: 192,500

<table>
<thead>
<tr>
<th></th>
<th>Total Direct</th>
<th>Total Exclusion</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>UCLA F&amp;A Rate</strong></td>
<td><strong>56%</strong></td>
<td></td>
</tr>
</tbody>
</table>

- **Total Direct Exclusions**: 37,500
- **Base**: 100,000
- **Indirect**: 56,000
- **Total Cost**: 193,500
NIH Notice Updates

NOT-OD-17-048
NIH Continuing Resolution
- Non-competing awards issued ~90%

NOT-OD-17-086
FY17 passed May 5, 2017
- $2B increase from FY16 budget ($34.3b)

“in general reductions will be fully restored”
NIH Notice Update

**NOT-OD-17-084**
- NRSA Predoc Increased Stipend Levels FY17
- NRSA awards with PreDocs will be amended if issued from FY17 funds
- Amended Appointment Forms must be updated via Xtrain (eCommons)
  - **Reminder**: Stipends noted on Statement of Appointment Forms must match Stipends paid

**NOT-OD-17-003** (Postdoc NRSA FY17 Levels)
NIH Updates

**NOT-OD-17-062**

New NIH “FORMS-E”

For proposal due dates on or after 1/25/18

Forms-E to be released ~October 2017

- Consolidate Human Subjects Information
- Expand Clinical Trial Information
  - Align with ClinicalTrials.gov
JULY

Post Submission Pre-Award

Wednesday, July 26, 2017
10889 Wilshire Blvd., Conf Room 820-20
9:30am-11:00 am

UCLA Office of Contract & Grant Administration is the central point of contact for all pre-award actions related to sponsored projects to be funded upon receipt of satisfactory compliance. This session will focus on NIH Just-in-Time (JIT), DOD pre-award process, Reps and Certs, other authorizations (Federal, State, County) and sponsor requests.
MASTER TRAINING
http://ora.research.ucla.edu/OCGA/Pages/Training-Resources/training-calendar.aspx

August
NSF FastLane and Research.gov

September
What Constitutes a Complete Proposal Package?
Questions
Appendix: NIH Definition of Clinical Trial

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 those interventions on health-related biomedical or behavioral outcomes.

See Common Rule definition of research at 45 CFR 46.102(d)

See Common Rule definition of human subject at 45 CFR 46.102(f)

The term "prospectively assigned" refers to a pre-defined process (e.g., randomization) specified in an approved protocol that stipulates the assignment of research subjects (individually or in clusters) to one or more arms (e.g., intervention, placebo or other control) of the clinical trial.

*Source: https://grants.nih.gov/grants/glossary.htm#ClinicalTrial*
Appendix: NIH Definition of Clinical Trial

An *intervention* is defined as a manipulation of the subject or subject's environment for the purpose of modifying one or more health-related processes and/or endpoints. Examples include, but are not limited, to: drugs/small molecules/compounds, biologics, devices; procedures (e.g., surgical techniques); delivery systems (e.g., telemedicine, face-to-face); strategies to change health-related behavior (e.g., diet, cognitive therapy, exercise, development of new habits); and, treatment, prevention, and diagnostic strategies.

A *health-related biomedical or behavioral outcome* is defined as the pre-specified effect of an intervention on the study subjects. Examples include positive or negative changes to physiological or biological parameters (e.g., improvement of lung capacity, gene expression); psychological or neurodevelopmental parameters (e.g., mood management intervention for smokers; reading comprehension and/or information retention); disease processes; health-related behavior; and, well-being or quality of life.
Appendix: NIH Definition of Clinical Trial

Biomedical clinical trials of an experimental drug, treatment, device, or behavioral intervention may proceed through four phases:

**Phase I.** Tests a new biomedical intervention in a small group of people (e.g. 20-80) for the first time to determine efficacy and evaluate safety (e.g., determine a safe dosage range and identify side effects).

**Phase II.** Study the biomedical or behavioral intervention in a larger group of people (several hundred) to determine efficacy and further evaluate safety.

**Phase III.** Study to determine efficacy of the biomedical or behavioral intervention in large groups of people (from several hundred to several thousand) by comparing the intervention to other standard or experimental interventions as well as to monitor adverse effects, and to collect information that will allow the interventions to be used safely.

**Phase IV.** Studies conducted after the intervention has been marketed. These studies are designed to monitor the effectiveness of the approved intervention in the general population and to collect information about any adverse effects associated with widespread use.
Dear Colleagues:

This guidance is issued to remind the campus clinical research community of the longstanding requirements to register and report results of clinical trials on the Federal database, [www.ClinicalTrials.gov](http://www.ClinicalTrials.gov). It supplants campus guidance distributed in 2008.

Several changes to relevant federal regulations took effect in January 2017. They are:


- National Institutes of Health Policy on the Dissemination of NIH-Funded Clinical Trial Information (NOT-OD-16-149) went into effect on January 17, 2017. It requires registering and submitting results information to ClinicalTrials.gov for all studies funded wholly or in part by the NIH regardless of study phase, type of intervention, or whether they are subject to FDAAA Section 801. See: [https://grants.nih.gov/grants/guide/notices-files/NOT-OD-16-149.html](https://grants.nih.gov/grants/guide/notices-files/NOT-OD-16-149.html).

- Additionally, the International Committee of Medical Journal Editors (ICMJE) requires prospective registration in ClinicalTrials.gov as a precondition of consideration for publication of research results generated by a Clinical Trial in their journals [http://www.icmje.org/recommendations/browse/publishing-and-editorial-issues/clinical-trial-registration.html](http://www.icmje.org/recommendations/browse/publishing-and-editorial-issues/clinical-trial-registration.html).

Under the FDA regulations and NIH policy, the entity or individual responsible for registering a clinical investigation and submitting Clinical Trial information to ClinicalTrials.gov is known as the Responsible Party.

UCLA has established two institutional accounts in the Protocol Registration and Results System (PRS) for ClinicalTrials.gov to support UCLA investigators who serve as the Responsible Party on a clinical trial:

- For cancer studies: The Office of Regulatory Compliance, Jonsson Comprehensive Cancer Center. [jcom@mednet.ucla.edu](mailto:jcom@mednet.ucla.edu). The process of registering trials and results reporting is managed by the JCCC in collaboration and consultation with the investigator, using investigator-supplied information and documentation. Investigators do not need to maintain individual user accounts for cancer studies.

- For all non-cancer studies: The Office of Regulatory Affairs, Clinical and Translational Science Institute (CTSI): [ctsi@mednet.ucla.edu](mailto:ctsi@mednet.ucla.edu). Each Investigator receives a user account under the “UCaliforniaLA” organization name to be able to log in to register and maintain their own studies. CTSI staff can view and edit all records in the organizational account and can provide guidance on registration and results-reporting requirements and the Protocol Registration System (PRS) data entry process. Study support staff and co-investigators may be given access to view and edit a study record, but only the Responsible Party can release the record to ClinicalTrials.gov.

Complying with the regulations is mandatory. Please forward this information to relevant individuals in your units. We urge all investigators to avail themselves of the support provided by the CTSI and JCCC to make reporting and registration easier, and to reduce the risk of monetary penalties that can be imposed by the FDA and/or the NIH for failure to comply.

For additional information see: [http://researchgo.ucla.edu/clinicaltrials.gov](http://researchgo.ucla.edu/clinicaltrials.gov).

Sincerely,

*Ann Karagozian, Ph.D.*  
Interim Vice Chancellor for Research

*John Mazziotta, M.D., Ph.D.*  
Vice Chancellor of UCLA Health Sciences
Identifying an “Applicable Clinical Trial” under FDAAA

- This flowchart presents basic guidance on determining if a trial is considered an “applicable clinical trial” under FDAAA. It maps out the guidance provided in the “Elaboration of Definitions of Responsible Party and Applicable Clinical Trial”, and is also available as an interactive flowchart at http://grants.nih.gov/ClinicalTrials/FGAAA/index.htm

- This flow chart may not address every situation. The grantee’s sponsored research office, general counsel, or other similar official should be involved in determining whether or not the grant supports an applicable clinical trial that needs to be registered under FDAAA.

Does the trial include a drug, biologic or device?

- Yes, a drug or biologic.
- Yes, a device.

Does the device meet all of the following 4 criteria:
1. Is it a clinical investigation?
2. Is it a controlled clinical investigation?
3. Is it other than a Phase I clinical investigation?
4. Does it investigate a drug (including a biological product) subject to section 505 of the Federal Food, Drug, and Cosmetic Act (FDCA) or section 551 of the Public Health Service Act?

- Yes
- No

Review the following criteria to determine if the applicable clinical trial (ACT) needs to be registered under FDAAA:

- If the trial was initiated or before 9/27/2007 and involves a serious or life threatening disease or condition.
- If the trial was initiated or before 9/27/2007 and involves a serious or life threatening disease or condition and was completed (meaning, not ongoing) by 12/26/2007.
- If the trial was ongoing as of 9/27/2007, did involve a serious or life threatening disease or condition and was completed (meaning, not ongoing) by 12/26/2007.

- Then the ACT must be registered not later than 21 days after the first patient is enrolled, or by 12/26/2007, whichever is later.
- Then the ACT must be registered by 12/26/2007.
- Then the ACT must be registered by 9/27/2008.

- Then the ACT is not subject to FDAAA, although if it is a drug clinical trial, it may be subject to pre-existing registration requirements under the Food and Drug Administration Modernization Act (FDAMA) of 1997.
- Then the ACT is not subject to FDAAA, and even if it is a drug clinical trial, it is also not subject to pre-existing registration requirements under FDAMA.
EXPORT CONTROLS

The **federal laws and regulations** that have been established by the U.S. government to control:

- The export of sensitive equipment, software, and technology
- Trade and financial transactions

These controls are in place to promote national security interests and foreign policy objectives.
REGULATING AGENCIES
U.S. Department of the Treasury
Office of Foreign Assets Control (OFAC)

- Sanctions Programs and Country Information
  https://www.treasury.gov/resource-center/sanctions/Programs/Pages/Programs.aspx

- Cuba Sanctions
  https://www.treasury.gov/resource-center/sanctions/Programs/pages/cuba.aspx
12 CATEGORIES OF AUTHORIZED TRAVEL

1. Family visits;
2. Official business of the U.S. government, foreign governments, and certain intergovernmental organizations;
3. Journalistic activity;
4. PROFESSIONAL RESEARCH AND PROFESSIONAL MEETINGS;
5. EDUCATIONAL ACTIVITIES;
6. Religious activities;
7. Public performances, clinics, workshops, athletic and other competitions, and exhibitions;
8. Support for the Cuban people;
9. Humanitarian projects;
10. Activities of private foundations or research or educational institutes;
11. Exportation, importation, or transmission of information or informational materials;
12. Certain export transactions that may be considered for authorization under existing Department of Commerce regulations and guidelines with respect to Cuba or engaged in by U.S.-owned or -controlled foreign firms.
PROFESSIONAL RESEARCH & MEETINGS

GENERAL LICENSE

- Authorizes attendance at professional meetings or conferences in Cuba related to a traveler’s profession, professional background, or area of expertise.

- Schedule of activities: NO free time or recreation in excess of that consistent with a full-time schedule.

- Traveler: Retain receipts and records demonstrating a full-time schedule of authorized activities.
EDUCATIONAL ACTIVITIES

GENERAL LICENSE

- Authorizes faculty, staff, and students at U.S. academic institutions to engage in study abroad programs, academic exchanges, and joint non-commercial academic research.

- Includes *people-to-people* educational activities in Cuba.

- Traveler: Retain receipts and records demonstrating a full-time schedule of authorized activities.
JUNE 16, 2017

- President Trump wants to end individual people-to-people travel.

- Individual people-to-people travel: educational travel that does not involve academic study pursuant to a degree program, and does not take place under the auspices of an organization that is subject to U.S. jurisdiction that sponsors such exchanges to promote people-to-people contact.
CONCLUSIONS

- The announced changes do not take effect until OFAC issues the new regulations. **WHEN?? Stay tuned.**

- No changes for UCLA . . . for now.

- Travel: Contact RPC prior to traveling to Cuba (and Iran, North Korea, Sudan, and Syria)

- EPASS: If PI has intentions of traveling to Cuba, please indicate this in the Export Control section
CONTACT

Ann Pham
Export Control Administrator
ann.pham@research.ucla.edu  |  310.206.3727

Joanna Arias
Export Control Analyst
joanna.arias@research.ucla.edu
310.794.2642

Claudia Modlin
Assistant Director, ORPC
cmodlin@research.ucla.edu
310.794.2642
OHRPP Updates

Kip Kantelo, Director
July 13, 2017
NIH Policy on Single IRBs

- Policy coming this month
  released in June ‘16
- Effective for Jan May Sept Jan 25
- Domestic sites of multi-center
- Proposals to identify cIRB
  - Coordination plans & personnel
  - Certain direct costs allowable
NIH Policy on Single IRBs

- IRBrely *SmartIRB* framework
  - National agreement now in place
    - 200+ institutions (including UCLA)
    - Some institutions coming up with additional agreements
  - Online tool for communication

- More detailed guidance and tools coming

- irbreliaice@research.ucla.edu
Final Rule

- Released January 19
- Effective next January (maybe)
- Key changes
  - Broadening exemption categories
  - Eliminate continuing IRB review for expedited studies
  - Consent - key info up front
  - Broad consent for secondary use
  - Single IRB mandate (3 years delay)
- Planning rollout, more to come
Thank you!

❖ For questions:
  • Reliance
    ❑ irbreliance@research.ucla.edu
  • North & South General IRBs
    ❑ x57122
    ❑ gcirb@research.ucla.edu
  • Medical IRBs
    ❑ x55344
    ❑mirb@research.ucla.edu
RESEARCH ADMINISTRATION

Extramural Fund Management

July 13, 2017
Today’s Topics

- UCPath: Payroll Expense Transfer
- PAMS Update
- ERS Update
UCPath: Payroll Expense Transfers

Yoon Lee
UCPath Go Live

- December 2017 remains go–live target

- Transition readiness in process
  - Campus Advisory Group have been attending transition readiness workshop since October 2016
  - Assessing each unit’s business processes, plan, and execute relevant activities to ensure successful transition to UCPath

- Testing in process
  - EFM participated in salary cost transfers testing through Integrated Testing Cycle 2
  - Integration testing Cycle 3 will be performed from July 17, 2017 through September 11, 2017
  - User Acceptance Testing is scheduled from September 25, 2017 through November 3, 2017
Payroll Expense Transfers: Pre-UCPath Go Live Data

- UCLA elected not to convert payroll data from PPS to UCPath.

- After UCPath Go Live, UCLA will maintain Payroll Personnel System (PPS) for the limited time.

- While PPS is maintained,
  - PPS current process to update the Financial System and ERS will be supported.
  - WebPET (Payroll Expense Transfers) will be supported.

- Currently UCLA plans to discontinue PPS as of July 1, 2018.
Payroll Expense Transfers: Pre-UCPath Go Live Data

After UCPath Go Live, transfer of payroll expenses processed in PPS while PPS is supported:

- 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 as of today
Payroll Expense Transfers: Pre-UCPath Go Live Data

After UCPaPath Go Live, transfer of payroll expenses processed in PPS after PPS support discontinues:

- As PPS support discontinues, WebPET will no longer be available to transfer payroll expenses.

- If payroll expense transfer is needed after PPS support discontinues, it needs to be processed through a financial journal bypassing payroll sub-ledger.
  - No clear audit trails for payroll expense transfers.
  - 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.
Required Actions by the Department

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

- If there are any awards where monthly reconciliation has not been completed, review payroll expenses now and process payroll expense transfers as soon as errors are discovered.

- Target to complete all transfers of payroll expenses processed in PPS before UCPath Go-Live: by January 1, 2018.
  - Only payroll expenses processed in December 2017 should be left for review after UCPath Go-Live.
EFM Procedure

- EFM standard procedure will be not to accept pre-UCPath go live payroll expense transfers debiting to sponsored project funds after PPS support discontinues (currently scheduled to be July 1, 2018).
- Department will be responsible for finding unrestricted source of funding 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 payroll expense errors could not be corrected timely 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.
Post Award Management System (PAMS)

Jennifer Aguilar
RAPID Closeout Packet Upload Tool

- Effective July 1, 2017, the RAPID closeout packet upload tool in the ORA portal is no longer available.
- All RAPID closeout packets along with supporting documentation are to be submitted via PAMS.
- This change will help the department:
  - View real-time status of closeout packets in PAMS by using the approval workflow.
  - Easily locate closeout packets and documents submitted in PAMS.
PAMS Pilot

- Pilot users actively provided extensive feedback to enhance the system
- The PAMS Team made system improvements and documented wide-ranging list of enhancements
- In order to focus on the development of these enhancements, effective July 1, 2017, pilot has stopped
- Completing closeout packets in PAMS is temporarily not available during this development phase
- Campus will be notified once system is back for all to use
- All other functionalities in PAMS will continue to be available
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PAMS Training

- In-Person Training Session:
  - Wednesday, July 19th 9-11am in the Wilshire-Glendon building
  - To register, complete the Doodle poll: http://doodle.com/poll/5yr96mf9hmavi9nw
Resources

- PAMS Help Team
  - (310) 794-0008, pamshelp@research.ucla.edu
  - Questions on access to PAMS

- Visit the [PAMS](http://ora.research.ucla.edu/EFM/Pages/PAMS/Overview.aspx) website for more information including:
  - Training materials, Quick Guides, Videos
Effort Reporting

Connie Brown
Effort Reporting Statistics

As of July 12, 2017

- **Fall 2016 & Winter 2017 (7/31/17 Deadline)**
  - Generated: 10,186
  - Certified: 5,245
  - Open: 4,941
  - On-Time Rate – 51%

- **Spring 2006 to Summer 2016 (Prior Quarters)**
  - Generated: 257,219
  - Certified: 256,271
  - Open: 948
  - Current Rate – 99%

- **Spring’06 - Winter’17 (All Quarters Rate)**
  - 97% Certified
Past Due and Current Due Reports

- Notification automatically sent to departments on the 15th of the month
  - Current Due Reports included until 7/31/17

### Past Due Effort Reports for [Name] (as of 6/14/2017)

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**Count:** 91
ERS Reminders

- Fall 2016 & Winter 2017 Effort Reports Deadline
  - Monday, July 31, 2017 (until mid-night)

- ERS Notifications
  - To subscribe: Send an e-mail to: ers-subscribe@lists.ucla.edu or ora-news-subscribe@lists.ucla.edu. The subject line and body of the e-mail can be blank

- Off-Campus Access Update
  - Cisco SSL AnyConnect
  - Download software at https://www.bol.ucla.edu/services/vpn/all.html. Contact the BOL Help Desk at (310) 267-4357 or email consult@ucla.edu for assistance

- ERS Training Course
  - September 6 and 7, 2017

- ERS Help Desk:
  - Connie Brown at ershelp@research.ucla.edu
“SEE YOU ALL AT …!"
Contact information

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

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