RESEARCH ADVISORY BOARD

January 8, 2019 8:30-10:00 a.m.
Medical Sciences Building: Conference Room S-30 & Zoom

AGENDA

<table>
<thead>
<tr>
<th>Topic</th>
<th>Presenter</th>
<th>Time</th>
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<tbody>
<tr>
<td>1. Clinical trial definition</td>
<td>MC Gaisbauer</td>
<td>8:30 – 8:45am</td>
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<tr>
<td>2. Award verification project (an alternative to effort reporting)</td>
<td>MC Gaisbauer</td>
<td>8:45 – 9:45am</td>
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2019 Meetings: 2nd Tuesday of each month
- January 8
- February 12
- March 12
- April 9
- May 14
- June 11
- July 9
- August 13
- September 10
- October 8
- November 12
- December 10

1. Clinical trial definition**

In October 2014, the NIH revised its definition of “Clinical Trial” which applies to applications submitted on and after January 25, 2015 as follows: “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 effect of those interventions on health-related biomedical or behavioral outcome”.

The key difference between UCSF & NIH definitions is that interventions is broader than UCSF’s definition. Note that this is a financial classification change; programmatic requirements of the sponsor will not change. Application requirements will also not change; however, if the NIH determines something is/isn’t a clinical trial, UCSF would adhere to the NIH’s decision.

Impact on the F&A rates:

- OSR reviewed the costing policy guidance provided by the NIH; the reclassification of CTF awards as Organized Research will provide potentially $1.4 million in additional indirect cost recovery annually because of the higher F&A rate for OR awards.
- The potential negative impact of the reclassification is the increase in the OR base that will cause a downward impact on the calculated OR rate used for negotiations with the federal government

Recommendation: UCSF should reclassify federally funded Clinical Trial awards to Organized Research effective 7/1/2019 (including renewals), and align with the NIH for federal, not private, clinical trials. UCSF administrative offices should categorize Federal Clinical Trials as Organized Research and will apply the higher indirect cost base to all new, renewal, resubmission, revision, and transfer-in applications submitted on or after the implementation date. Applications submitted prior to the implementation date and associated awards, will not be affected.

Action: MC will communicate the above via ReSearch ReSource and other newsletters. MC will send the RAB a summary on UCSF’s rate classifications.

2. Award verification project (an alternative to effort reporting)**

This project is an alternative to effort reporting and will hopefully replace the University’s existing effort reporting system. The project goal is to develop a process and technical solution that leverages existing controls to verify all project expenses on an award with efficiency and transparency. Project objects include elimination of duplicative efforts, reduction of administrative burdens, and increase in compliance with Uniform Guidance. The funding request is with IT Governance now and the proposal is due January 25, 2019.
Resources from the Effort Reporting System (ERS) will fund this as the ERS will retire. Current expectation is that Award Verification will go live in Fall 2020, after UCPath.

Representatives from each school, and others with large or small effort reporting portfolios were included in the Award Verification Project. The intuitive new tool is available in My Access and works on the web and mobile devices. The tool allows financial and personnel data to be viewed instantly; it replaces a significant amount of work (2 effort reports, 12 monthly reviews with quarterly reports) and is may eventually replace budget status reports.

The system requires verification of only federal award data; general ledger ledger data is available for verification if desired. Everyone with access to an award can see the data. Other features/functionality include:

- salary distribution of a given employee across multiple grants; personnel data can be run by award and by project,
- monthly spend and running balance available at the person level,
- view levels include award PI, sponsored project as PI, project PI; project manager will be added, and
- the tool is auditable.

An internal pilot group will test the tool before it is rolled out to campus; all are welcome to be testers. Matt Springer and Julene Johnson volunteered. Members added the following suggestions: add a definitions page; reconsider naming conventions; build in pie charts.

**Issues:** The School of Medicine must begin using the PI Projection Tool - change management will be required to get people using the projection tool. People will also need to start entering vacation leave balances.

**Recommendations:** Contact Mike Kincaid (School of Medicine): he is creating another (competing) app that may be adopted at a higher rate.

**Contains excerpts from PowerPoint; see PowerPoint for detail.**
Proposal to Reclassify Federally Funded Clinical Trials as Organized Research

Submitted by the UCSF Costing Policy Group

- Winona Ward, Director, Office of Sponsored Research (OSR)
- MC Gaisbauer, Assistant Controller, Contracts and Grants Accounting (CGA)

January 9, 2019
NIH revised its definition of “Clinical Trial” in October 2014, which applies to applications submitted on and after January 25, 2015:

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 effect of those interventions on health-related biomedical or behavioral outcome.
NIH revised its definition of “Clinical Trial” in October 2014, which applies to applications submitted on and after January 25, 2015:

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 effect of those interventions on health-related biomedical or behavioral outcome.

The new NIH definition differs from the UC clinical trial definition in two key areas:

- unlike the University’s definition, the NIH definition includes clinical interventions; and
- unlike the University’s definition, the NIH definition does not include the testing of investigational or approved devices, only the study of the manipulation of the subject or the subject’s environment.
# F&A Impact of the Discrepancy between UCSF and NIH Clinical Trial Definitions

<table>
<thead>
<tr>
<th>NIH GENERAL CASE STUDY</th>
<th>CT PER NIH DEFINITION</th>
<th>CT PER UCSF DEFINITION</th>
<th>F&amp;A RATE APPLIED</th>
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<tbody>
<tr>
<td>C.S. #7A The study involves the recruitment of research participants with disease X to test an investigational in vitro diagnostic device (IVD). It is designed to evaluate the ability of the device to measure the level of an antibody in blood.</td>
<td>N</td>
<td>Y</td>
<td>35.0% MTDC</td>
</tr>
<tr>
<td>C.S. #14 The study involves the recruitment of healthy volunteers for a respiratory challenge study; participants are randomized to receive different combinations of allergens. The study evaluates the severity and mechanism of the immune response to different combinations of allergens introduced via inhalation.</td>
<td>Y</td>
<td>N</td>
<td>59.5% MTDC</td>
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</table>
**Clinical Trials**

**Basis for Change**
NIH revised its definition of “Clinical Trial” in October 2014, which applies to applications submitted on and after January 25, 2015:

*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 effect of those interventions on health-related biomedical or behavioral outcome.*

**Impact**
The new NIH definition differs from the UC clinical trial definition in two key areas:

- unlike the University’s definition, the NIH definition includes clinical interventions; and
- unlike the University’s definition, the NIH definition does not include the testing of investigational or approved devices, only the study of the manipulation of the subject or the subject’s environment.

**Assessment**
UCSF’s Costing Policy unit surveyed UC campuses with medical centers for their treatment of federally funded Clinical Trial awards. UCLA, UCSD, UCI, UCD, and UCB all classify federally funded Clinical Trial awards in their Organized Research (OR) base and were applying the OR F&A rate to these awards. The reason noted was that these awards were more associated with basic research than clinical trials.
BRM Impact Analysis of the Reclassification of Federally Funded Clinical Trials (CTF) from Other Sponsored Activity (OSA) to Organized Research (OR)

- The reclassification of CTF awards as Organized Research will provide potentially $1.4 million in additional indirect cost recovery annually because of the higher F&A rate for OR awards.

- The potential negative impact of the reclassification is the increase in the OR base that will cause a downward impact on the calculated OR rate used for negotiations with the federal government.

<table>
<thead>
<tr>
<th>Year</th>
<th>Rate Type</th>
<th>F&amp;A Rate</th>
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<tbody>
<tr>
<td>FY 2017-2018</td>
<td>Organized Research (OR)</td>
<td>59.50%</td>
</tr>
<tr>
<td>FY 2017-2018</td>
<td>Other Sponsored Activities</td>
<td>34.00%</td>
</tr>
<tr>
<td></td>
<td>Rate Difference</td>
<td>25.50%</td>
</tr>
<tr>
<td>FY 2016-2017</td>
<td>Clinical Trials Federal (CTF) On-Campus (On) MTDC</td>
<td>5,747,532</td>
</tr>
<tr>
<td></td>
<td>CTF On ICR at OR Rate at FY 2016-2017 MTDC</td>
<td>3,419,781</td>
</tr>
<tr>
<td></td>
<td>CTF On ICR (FY 2016-2017)</td>
<td>2,013,579</td>
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<tr>
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<td>ICR Potential Annual Increase</td>
<td>1,406,202</td>
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<tr>
<td>FY 2013-2014 (Base Year)</td>
<td>OR Base</td>
<td>329,706,059</td>
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<tr>
<td></td>
<td>CTF On-Campus MTDC</td>
<td>5,747,532</td>
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<tr>
<td></td>
<td>OR Base including CTF On-Campus MTDC</td>
<td>335,453,591</td>
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<tr>
<td></td>
<td>Calculated OR Rate</td>
<td>69.33</td>
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<td></td>
<td>OR Rate including CT Federal On-Campus MTDC in OR base</td>
<td>68.61</td>
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<tr>
<td></td>
<td>Rate Difference</td>
<td>(0.72)</td>
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<tr>
<td>Basis for Change</td>
<td>Impact</td>
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<td>A <em>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 effect of those interventions on health-related biomedical or behavioral outcome.</em></td>
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<table>
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<tr>
<th>Assessment</th>
<th>Recommendation</th>
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<td>UCSF’s Costing Policy unit surveyed UC campuses with medical centers for their treatment of federally funded Clinical Trial awards. UCLA, UCSD, UCI, UCD, and UCB all classify federally funded Clinical Trial awards in their Organized Research (OR) base and were applying the OR F&amp;A rate to these awards. The reason noted was that these awards were more associated with basic research than clinical trials.</td>
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Award Verification Project
Research Advisory Board Meeting

January 8, 2019
Agenda

- Project Overview  
  MC
- Award Verification Design Demo  
  Sharon
- Next Steps  
  MC
Project Overview

Goal:
Develop and implement a process and technical solution that leverages existing controls to verify all project expenses on an award in an efficient and transparent manner

Objectives:

- Reduce the administrative burden felt by PI and RSA
- Retire **Effort Reporting System** and expand verification beyond payroll expense
- Meet compliance and audit requirements of Uniform Guidance
- Leverage PI knowledge to validate expense on all projects across an award
- Increase the effectiveness and rate of compliance with Uniform Guidance
- Ensure appropriate integration with GLV process and leverage other UCSF systems
Project Status:

- Business Requirements and Design were developed by a PI and Staff Working Group over the past year
- Financial data will include award expenses and payroll data
- ITG Funding request is underway
A PI will be able to review all activity and verify sponsored award expenses from prior closed periods at least quarterly.

Collaboration capabilities will be included for a PI to communicate with their key staff.

Web and mobile versions of award verification will be available.
Next Steps

- Secure project funding
- GL Verification enhancements underway
- Commence Award Verification build when IT resources become available in 2019
- Current expectation is that Award Verification will go live in Fall 2020, after UCPath
Questions?