

RESEARCH ADVISORY BOARD

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

AGENDA

Topic	Presenter	Time
1. Clinical trial definition	MC Gaisbauer	8:30 – 8:45am
2. Award verification project (an alternative to effort reporting)	MC Gaisbauer	8:45 – 9:45am

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*

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

Present: Clarice Estrada, John Ellis*, David Erle*, MC Gaisbauer, Julene Johnson, Laurie Herraiz*, Jim Kiriakis*, Gretchen Kiser, Synthia Mellon, Teresa Moeller, Suzanne Murphy, Michael Nordberg, Christine Razler, Jon Rueter, Brian Smith, James Sorensen, Matthew Springer, Paul Volberding, Winona Ward. Irene Broderick (staff). Sharon Anderson (guest). *=by phone

1. Clinical trial definition**

MC Gaisbauer

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)**

MC Gaisbauer

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 general 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.



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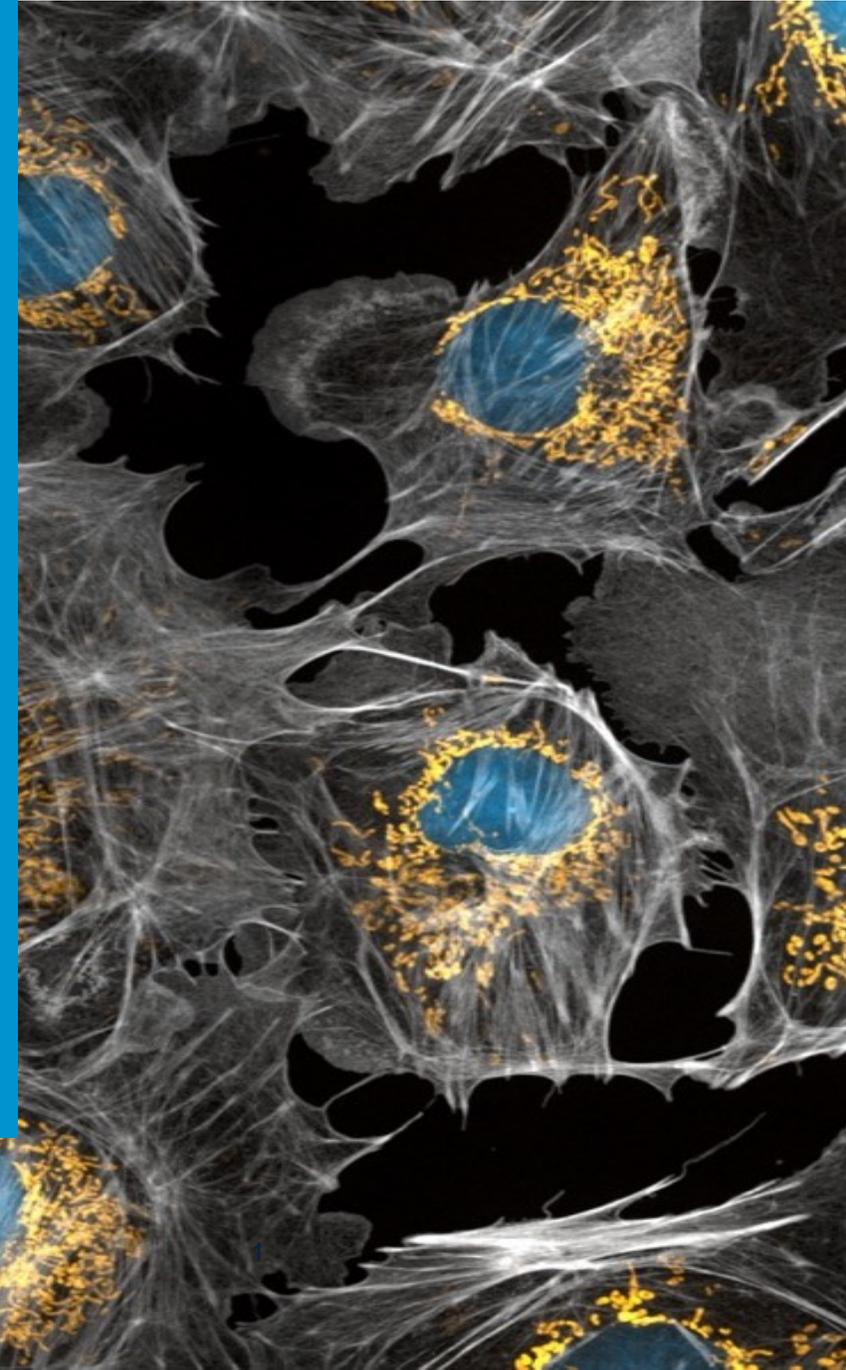
Proposal to Reclassify Federally Funded Clinical Trials as Organized Research

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

January 8, 2019



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.

Clinical Trials

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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.

Clinical Trials

F&A Impact of the Discrepancy between UCSF and NIH Clinical Trial Definitions

NIH GENERAL CASE STUDY	CT PER NIH DEFINITION	CT PER UCSF DEFINITION	F&A RATE APPLIED
<p>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.</p>	N	Y	35.0% MTDC
<p>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.</p>	Y	N	59.5% MTDC

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Clinical Trials

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

Year	Rate Type	F&A Rate
FY 2017-2018	Organized Research (OR)	59.50%
FY 2017-2018	Other Sponsored Activities	34.00%
	Rate Difference	25.50%
FY 2016-2017 Clinical Trials Federal (CTF) On-Campus (On) MTDC		5,747,532
	CTF On ICR at OR Rate at FY 2016-2017 MTDC	3,419,781
	CTF On ICR (FY 2016-2017)	2,013,579
	ICR Potential Annual Increase	1,406,202
FY 2013-2014 (Base Year)		
OR Base		329,706,059
CTF On-Campus MTDC		5,747,532
OR Base including CTF On-Campus MTDC		335,453,591
Calculated OR Rate		69.33
OR Rate including CT Federal On-Campus MTDC in OR base		68.61
	Rate Difference	(0.72)

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Clinical Trials

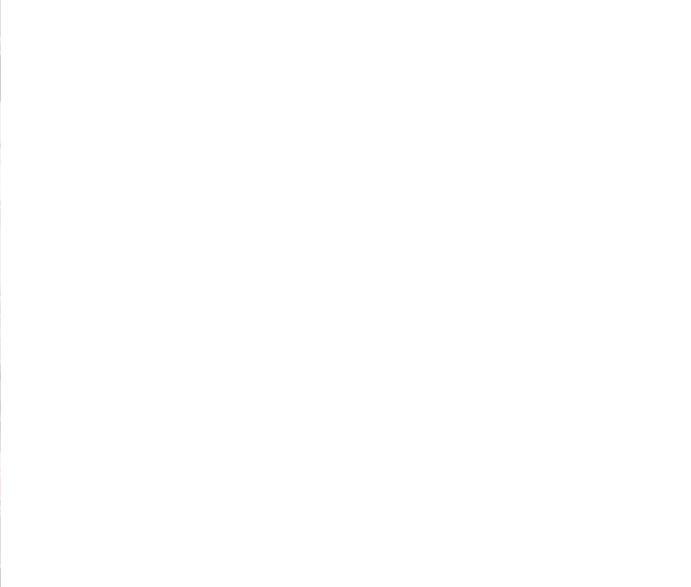
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Recommendation

UCSF should reclassify federally funded Clinical Trial awards to Organized Research effective 7/1/2019.

UCSF administrative offices 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.





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San Francisco

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

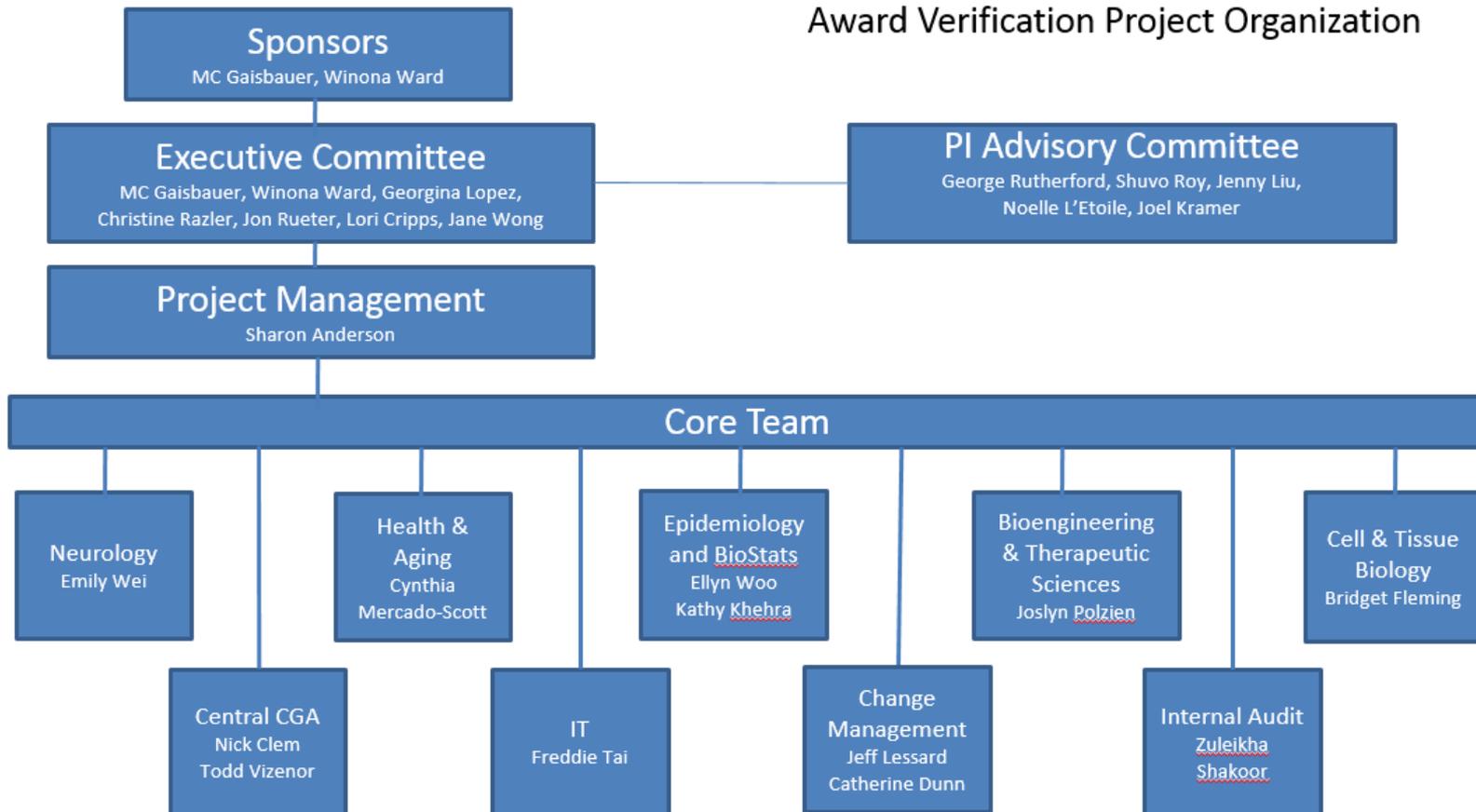
Project Overview (continued)

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

Project Overview (continued)

Award Verification Project Organization



Award Verification Design Demo

- 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?



UCSF

