

Department of Medicine
RSA Monthly Meeting
October 18, 2007
8:30-10:00 AM, Laurel Heights 416

Present: Chude Allen, Peggy Bartek, Olive Burk-Giovanetti, Michele Carter, Alice Chin, Helen Chuan, Ani Handajani, Catherine Hoselton, Ian Jones, Kathy Judd, Jennifer Kellen, Calvin Kwok, Anne Lawrence, Victoria Lee, Linda Lew, Samantha Lieu, Marienna Murch, Solat Navab, Lourdes Ocbena, Tajal Patel, William Rypcinski, Kate Shumate, Renuka Sippy, Kim Smith, Suzanne Sutton, Kapo Tam, Susan Vance, Bill Walzer, Joseph Wilson

Updates

Upcoming RSA Meetings

Wendy Hom from the Controller's Office will review cost-sharing policies at November's RSA Meeting. She will also discuss Attachment E's and signature requirements on cost and payroll journals. Her presentation will focus on maintaining compliance with current policies, and will introduce proposed future policies. Please forward any questions you would like Wendy to address to Suzanne or Joseph.

December's RSA meeting will comprise a short update session, followed by a gift exchange. More details will be provided at November's meeting.

New Benefit Rates

Please note that Benefit rates changed effective October 1st, 2007. The new rates are as follows:

Academics – 17%

Post-Doc – 18.2%

Staff – 25%

Please refer to the Contracts and Grants website

(<http://www.research.ucsf.edu/cg/memo/cgFringe.asp>) for further information.

Procedure for Chair's Signature

Please remember to route all documents, which require Dr. King's signature to Suzanne and Joseph for review prior to sending them to the Chair's Office. Departmental letters of support should also be drafted and signed by the Division Chief for concurrence by the Chair.

OAAIS Weblinks Archival Proposal

OAAIS (Office of Academic and Administrative Information Systems) maintains the ad-hoc tables that are used for Weblinks data requests. In response to user concerns about the amount of time reports take to run in addition to other degradations in Weblinks' performance, OAAIS is proposing that a proportion of Weblinks data be archived.

OAAIS currently proposes to archive all data older than five years for all funds. Access to archived data would require a work request to OAAIS. The proposed processing time would be 3 business days for urgent requests and 5 days for non-urgent requests.

In order for your opinions and requests to be considered, please send your concerns to OAAIS at weblinks.team@ucsf.edu. Please review the Weblinks Database Archiving proposal handout, consider the questions on the last page, and respond directly to OAAIS with questions, concerns, and ideas.

Budget Status Reports (BSRs)

Some RSAs have expressed concern about the BSR deadline so we discussed strategies for submitting the BSRs on time.

BSRs function as an important part of DOM's service agreement to PIs, PIs are financially responsible for the awards in their name so they must receive regular updates on their accounts to enable them to effectively manage their accounts. A BSR format can vary but it must reflect the projected balance after all expenses have been reconciled to be accurate and allowable to prevent the account from going into overdraft. There is no such thing as a "perfect BSR" so submission delays as a result of this is not valid. BSRs are "works in progress" with encumbered credits, expenses, pending payments and other changes noted in the report. BSRs also do not need to be submitted all at once. Please submit them as each PI's portfolio of active funds is completed.

BSRs should be submitted for all active sponsored research funds (including clinical trials, fellowships, private grants, and subcontracts). BSRs do not need to be submitted for gift funds, or discretionary accounts nor for sponsored funds that are inactive but are in overdraft.

BSRs should be submitted no less than bimonthly, if not monthly. Funds that do not have monthly fluctuations in their activity may be submitted to the Department bimonthly. Please be sure to communicate to Michele Carter the funds that will be submitted every other month. Otherwise, they will be assumed to be delinquent if not submitted monthly. The e-mail that is sent to the PI with the BSRs should be copied to Michele Carter. This verifies that the PI and the Department will have the same version of the BSR for record purposes and helps to minimize duplication of e-mails.

Starting in November 2007, the deadline for BSR submission has officially changed to be due *seven business days after the close of Weblinks*. Please direct further questions about BSRs to Suzanne and notify Michele of any submission changes to your accounts.

Organization of Industry Contracts Division

Erik Lium, Director of Industry Contracts, Jim Kiriakis, and Mora Mattingly attended to present an overview of the Industry Contracts Division (ICD) under Erik's new leadership.

General

The Industry Contracts Division (ICD) is a division of the Office of Sponsored Research (OSR), and reports to Joyce Freedman, the Assistant Vice Chancellor of the Office of Research. The ICD handles all sponsored research and material transfer agreements with commercial entities. They negotiate and execute Sponsored Research Agreements (SRAs), Clinical Trial Agreements (CTAs), Confidential Disclosure and Non-Disclosure Agreements (CDAs and NDAs), all incoming Material Transfer Agreements (MTAs) and outgoing Human Specimen MTAs.

Since Erik took the position as Director of ICD in December of 2006, the department has set up an automated system to record, track, and organize which contract documents have been received, and how far along submitted contracts are in the internal process. The database automatically responds to RSAs via email regarding which documents have been received, and which are still needed to complete the execution of the contract. Within the next year, the division intends to publish the statistics of Clinical Trial processes and turn-around times.

The mission of the ICD is to increase the volume of industry-sponsored research, and to position UCSF as the industry partner-of-choice by streamlining UCSF's internal contracting process.

In the past, the processing time of an MTA might run between 5-6 months; currently, the process takes, on average, 30-40 days after receipt of the document by ICD.

Please begin the CHR process as soon as is possible when looking to open a new clinical trial. It is not uncommon for ICD to have completed contracts that are only waiting on CHR approval.

ICD is currently in the process of developing a standardized curriculum to disseminate among department administrative personnel, which would further inform RSAs on policies and best practices. In the meantime, please feel free to approach officers directly with questions or for informal small-group training requests.

Erik has proposed to EMF that the RAS proposal number be printed on all contract checks as a component of contracting protocol. ICD believes that printing the "P" number as a unique identifier on all checks would alleviate the undistributed checks problem in EMF (currently \$25 million).

Although it may not be feasible to request monthly payments from industry sponsors, it is a good idea to negotiate an increased initial payment to at least cover the full cost of recruitment and trial start-up. The terms of a contract are, and should be, separate from the budget. The RSA/CRC should create the budget in conjunction with the PI and in partnership with an officer at ICD.

RSAs should be sure to constantly keep the lines of communication with ICD open by calling officers with questions and issues.

Although the ICD does their best to negotiate around most issues, they will not accept contracts which conflict with university policy on publication restrictions and indemnification.

Future issues that ICD anticipates revolve around the new clinical trial policy enacted by the Centers for Medicare/Medicaid, and Federal Anti-Kickback Statues.

- 1) The new policy of utilizing the V70.7 code to define all standard-of-care costs to be paid by Medicare may create a tighter, more stringent negotiation by the sponsor in regards to the contract budget; furthermore, if the V70.7 code is not used, or is used incorrectly, Medicare may audit the trial and demand reimbursement for any funds that they have paid out.
- 2) Recent enforcement of Federal Anti-Kickback Statues by Federal Prosecutors has brought many sponsors under investigation, and their behavior is being closely scrutinized. Any activity that appears to generate bias benefiting a commercial agency and charging a Federal payor will lead to swift and severe penalty.

The next RSA meeting is scheduled for Thursday, November 15, 2007 from 8:30-10:00 AM in room LHTS 416.