

YOU DID IT AGAIN! DOM RANKS #1 IN NIH FUNDING FOR FY 04
by Suzanne Sutton, Director of Research Administration

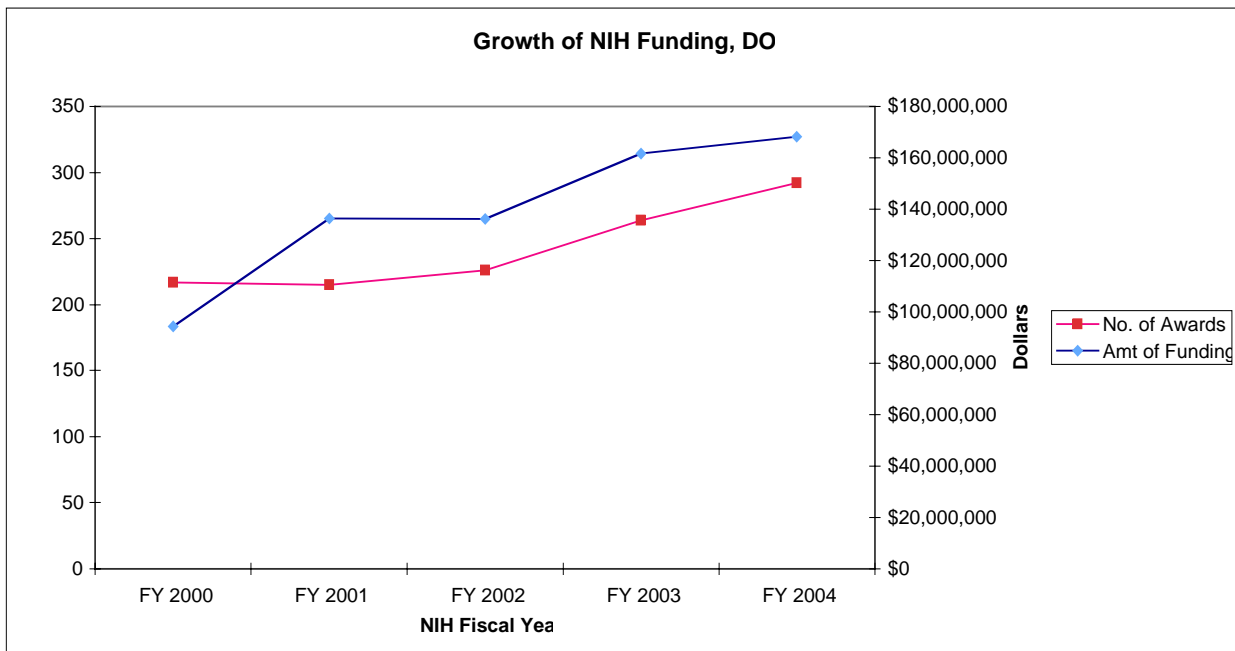
CONGRATULATIONS to all faculty and RSAs! It was recently published by the National Institutes of Health that, for the second year in a row, our department ranked Number One in FY 2004 as the highest funded Internal Medicine Department in the nation. The other institutions in the top five (in sequential order) were: Johns Hopkins, Duke University, University of Washington, and University of Pennsylvania. We were the highest funded in terms of dollars, although we received 61 fewer awards than Johns Hopkins. This is due, in part, to the higher amount of funding per award we received on average than did the other top five institutions in this year's ranking. It is also due, in large part, to the considerable amount of our

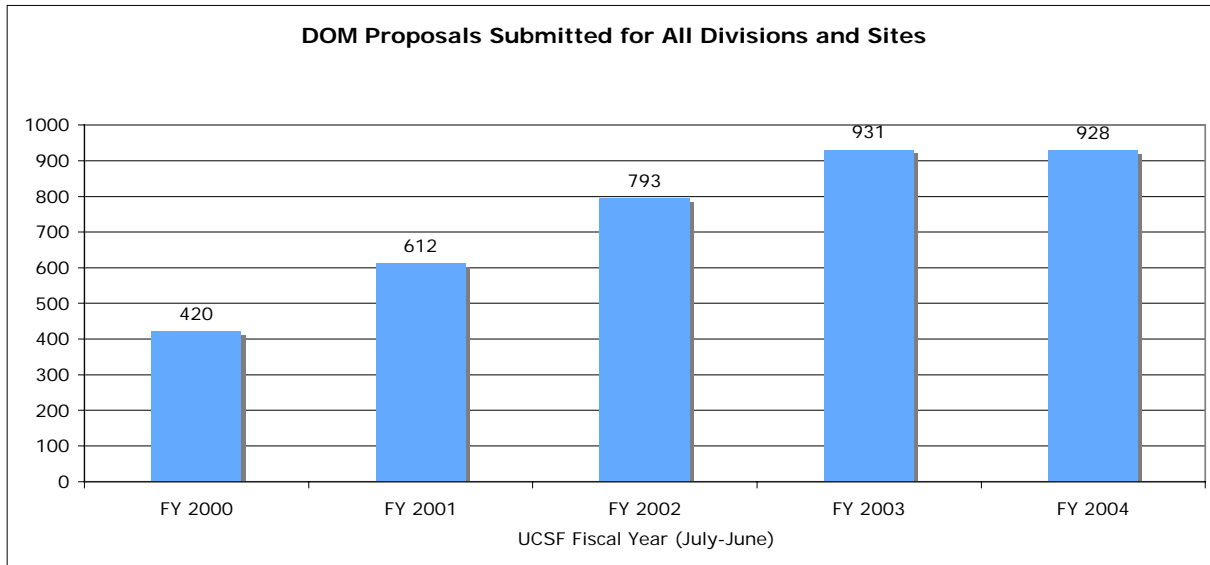
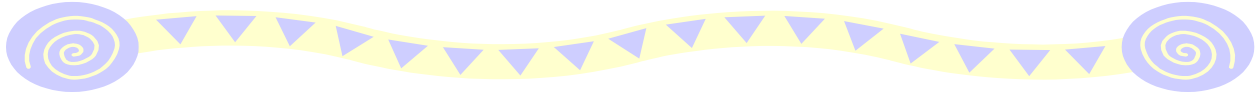
Research and Development contract funding.

Our department was granted \$27.7 million in Research and Development contract dollars in FY 2004. In comparison, Johns Hopkins was awarded a little over \$2 million; Duke, \$311K; University of Washington, \$522K; and UPenn, \$599K.

The number of awards and amount of overall funding per year has continued to increase since FY 2000. This is commensurate with the increasing number of proposals the Department submits each year. Proposals submitted from the Department of Medicine for all Division across all sites show that the number submitted has increased by 121% from five years ago, with an average increase each year of 23%.

As you may know, the Labor, Health and



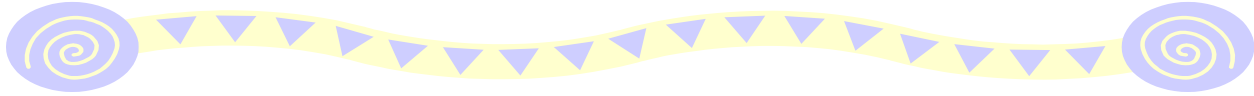


Human Services and Education (L/HHS) Appropriations Subcommittee recently marked up its FY 2006 bill. Chairman Ralph Regula (R-OH) provided NIH with \$28.5 billion, an increase of \$145 million over NIH's FY 2005 budget and roughly in line with what the President proposed. However, this increase is the smallest the agency has received in 36 years.

If the Subcommittee bill passes, it will translate into 505 fewer research grants for all applicants in FY 2006 than were funded in FY 2004. The Department is aware of how critically this may affect our ability to continue our growth trend. In response, we will continue our endeavors to ensure quality and continuous research administration services to investigators and a stronger infrastructure to facilitate the successful application of funds.

GRANTS WRITING IN THE DEPARTMENT OF MEDICINE
by Steve Glotzbach, Grants Development Coordinator

I am pleased to be a new member of the UCSF Department of Medicine Research Administration team as of May 2005. During my time as a scientist and PI at Stanford University School of Medicine and as a consultant, I have had ample opportunities to hone my skills as a grant writer in the never-ending quest for extramural funding. In my current position, I look forward to learning about your research interests and in helping to match those interests with relevant sources of funding so that your research programs can be successfully implemented. I have already had the pleasure of working with Drs. Kirsten Fleischmann and Kirsten Johansen on their NIH proposals.



In the newly created position of Grants Development Coordinator in the Department of Medicine, I am a resource for faculty and fellows who are planning, writing, or revising grant applications. Most of my work will focus on assisting faculty with applications for funding to NIH through a variety of mechanisms, including RO1, R21, K-series, Center Grants and Program Projects. Complementing the work of the Departmental RSAs, I will concentrate on the Research Plan/Narrative portions of proposals. In my position, I can act as an additional set of critical eyes for established investigators, or can work more closely with junior faculty and their mentors in strategizing, structuring, and wordsmithing proposals. I am also available to help with non-NIH proposals or with the writing-related aspects of other fundraising efforts.

As many of you know, there are three NIH funding cycles per year, with the dates dependent on the specific funding mechanism. A summary of these deadlines and anticipated award dates is found at: <http://grants1.nih.gov/grants/dates.htm>. If you would like my help writing a new proposal or anticipate substantial revisions to an existing application, please contact me earlier rather than later to allow sufficient time for us to work together effectively. I have found that 3-6 months is an optimal time period for preparing a proposal from scratch, although material can be repurposed from existing sources and a proposal can be synthesized within a much shorter temporal window. For work on revised proposals, I find that attention to reviewers' comments in

the summary sheets is essential. It would help me to work from these comments.

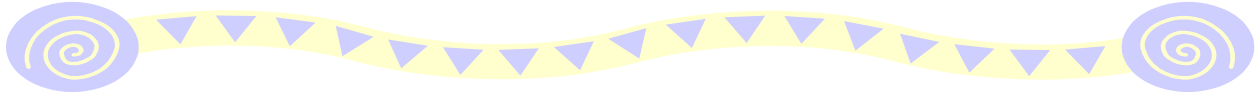
I hope you will contact me to let me know how I can help you with your grant proposals. I can be reached at 502-1569 or at sglotzbach@medicine.ucsf.edu.

EDITING IN THE DEPARTMENT OF MEDICINE

by Deborah Airo, Principal Editor

By now, many of you have heard about my services and the new editorial office that opened this March in the Department of Medicine. When I heard that a service to help PIs with their manuscripts would be offered, it was easier to think of other institutions where the investigators were more obviously in need of help. My hesitation was because DOM investigators produce papers that are among the best in terms of quality of writing and science that I've seen in my past 5 years at The American Journal of Medicine, and I wondered if the need and the interest would be there.

As an editor at the AJM, I saw many submissions that could have benefited from aid, such as the manuscript that was typed partially in English and partially in ideograms, the one written entirely as a table, or the one based on observation of one subject and one control. Most problems are much less dire—just following instructions to authors can help considerably and may prevent the return of a manuscript—but it becomes obvious after working at a journal



that many papers could be improved before submission.

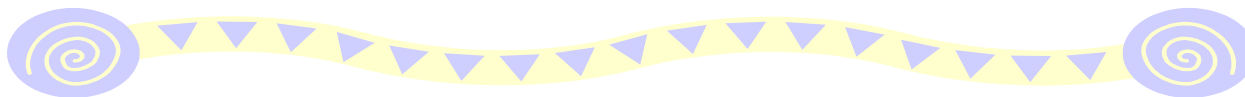
There are things that all writers overlook, whether they're writing fiction, cookbooks, or the results of studies. In science, authors may not know whether their writing is clear to readers outside the research group, or, after sitting with the data for so long, may not notice that the results, tables, or figures could be confusing. People who are experienced in searching for these and other problems take some of the burden off authors and their colleagues and allow them to focus on the substance of their manuscript.

From the journal editor's viewpoint, it's discouraging if potentially interesting data are overlooked because of unclear writing or 'unique' presentation. Although editing won't improve the chances of acceptance for manuscripts that are lacking or uninteresting scientifically or that don't meet the journal's needs, it can help when the problem is clarity, presentation, or style rather than substance. Most journals accept less than 20% of submissions, and some of the more popular ones accept less than 10%. Choosing from the thousands of manuscripts they receive each year is a demanding job for journal editors, and the purpose of the editorial office is to make their work and yours simpler. By editing with an eye to what's important to journals, from an insider's perspective, we can help make it a bit easier for them to accept your paper.

For all of these reasons, I was glad to participate when the editorial office was set up in March. It's also been encouraging to

see the degree of interest. In the last three months, 25 pieces have been sent in for editing. You've asked for work on word count, accuracy, adding or removing tables or text, clarity, abstracts, formatting, and styling to requirements. There have been requests for help with manuscripts, cover letters, resubmissions, and revisions; I hope book chapters and other writings will come soon. I've heard from seasoned PIs, post-docs, fellows, and graduate students. The quality of the writing and science and the dedication of the investigators in producing a superior manuscript have been impressive, and the topics have been interesting, too. The only thing that could make it even better would be to hear from more of you.

Everyone could use a break from reading that manuscript again, including your co-authors, and the Department has three free services that you can't pass up: the editing office for manuscripts and other writings (dairo@medicine.ucsf.edu), the grant writing service (sglotzbach@medicine.ucsf.edu), and the biostatistical consulting service (the first hour is free) at http://www.biostat.ucsf.edu/biostat_consult.html.



SBIR AND STTR PROGRAMS

Did you know that the NIH sets aside a percentage of its extramural budget each year to foster research and development collaborations between small business and academic institutions? The Small Business Innovation Research (SBIR) program and the Small Business Technology Transfer (STTR) program are set-aside programs (2.5% and 0.30%, respectively, of an agency's extramural budget) that seek to increase the participation of small businesses in Federal R&D and to increase private sector commercialization of technology developed through Federal R&D. To apply for these funds, small businesses (defined as less than 250 employees) must formally collaborate with a research institution during Phase I and Phase II research. Twelve federal agencies currently participate in the SBIR program. The agencies most relevant to us are the Departments of Health and Human Services (DHHS), Defense (DOD), Education (DoED), the National Aeronautics and Space Administration (NASA), and the National Science Foundation (NSF). Five Federal agencies participate in the STTR program: DOD, DOE, DHHS (NIH), NASA and NSF.

In what areas is NIH interested? The National Institutes of Health (NIH) welcomes SBIR and STTR applications from small businesses in any biomedical or behavioral research area that falls within its mission to improve human health. The amount and duration of funding for SBIR/STTR Programs depends on the phase of research proposed. Specific topics of interest to individual Institutes at NIH are found in Part 1 of the annual SBIR/STTR Omnibus Solicitation, accessed through the website listed below.

UCSF would be awarded SBIR/STTR funds via a subcontract with the small business. Deadlines for submission of SBIR and STTR grant applications are April 1, August 1, and December 1. For more information, click on <http://grants2.nih.gov/grants/funding/sbir.htm>

POLICY/PROGRAM UPDATES

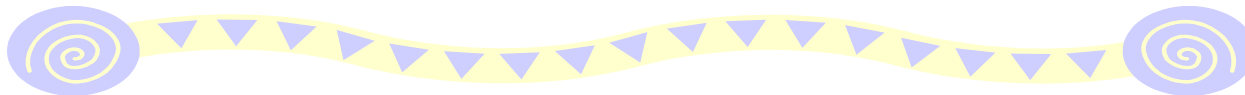
NIH Salary Limitation on Grants, Cooperative Agreements, and Contracts
New Salary Cap \$180,100
<http://grants1.nih.gov/grants/guide/notice-files/NOT-OD-05-024.html>

Ruth L. Kirschstein National Research Service Award (NRSA) Stipend and Other Budgetary Levels Effective for Fiscal Year 2005

T32, F32, etc. grants <http://grants1.nih.gov/grants/guide/notice-files/NOT-OD-05-032.html>

Updated Frequently Asked Questions on the DOM RSA Webpage

Proposal and Manuscript Development/Editing; Systems Access and Passwords; Pre-Award; Post-Award
<http://medicine.ucsf.edu/research/about/faq2.htm>



**CLINICAL TRIALS IN THE
DEPARTMENT OF MEDICINE**

*by Maria Lourdes Novellero, Assistant
Director of Research Administration*

Clinical trials are a vital component of the research chain. They bridge the gap between the laboratory and the clinic, measuring the value of scientific information in enhancing health care. Without the credible and substantive data that clinical trials generate, therapeutic decision-making would not be as advanced as it is today.

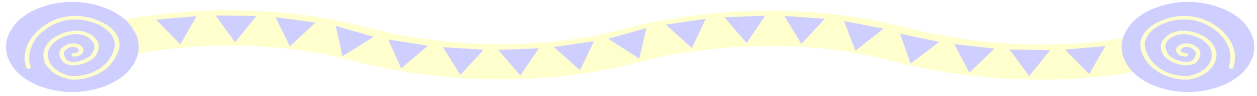
In the Department of Medicine (DOM), there have been more than 300 clinical trials over the past five years, about 100 of which are still ongoing. The Divisions of Hematology/Oncology, Cardiology, Gastroenterology, and Rheumatology have been most active in conducting clinical trials.

The set-up and financial management of a clinical trial can be challenging due to its unique complexities. Contract negotiations with the sponsor can be a long, arduous process. Moreover, unlike grants where payments follow a specific schedule regardless of deliverables, clinical trial revenues are based on milestones such as patient enrollment and/or completion of case report forms. The success of a clinical trial hinges, therefore, on having the study up and running expeditiously, negotiating a budget that covers all costs, and receiving timely payments.

Realizing these key factors, the Research Administration Unit has been proactive in developing templates and streamlining procedures to assist PIs with pertinent administrative and financial tasks, in addition

to providing regular and *ad hoc* training sessions for RSAs on the pre- and post-award management of clinical trials. Templates for budget preparation and enrollment status update have been generated, and a budget status report is now being tailored to address the variations in payment schedules. Invoicing procedures are also being clarified and modified for more efficient revenue collection. To evaluate the usefulness and applicability of these templates and procedures, a Clinical Trials Working Group, comprised of seasoned Clinical Research Coordinators and RSAs from several DOM divisions, is being put together. It is expected that the Group members will draw on their own experiences with clinical trials and share best practices with others.

Recently, upfront revenues for industry-sponsored clinical trials have been enhanced by the implementation of a pre-clinical trial cost agreement. The rationale for a pre-clinical trial cost agreement is two-fold: 1) to support start-up costs of a clinical trial, and 2) to ensure that non-refundable expended fees are covered in the event the clinical trial does not proceed. Pre-study costs include Institutional Review Board (IRB) preparation and application, budget analysis and preparation, training of staff and ancillary departments involved in the study, travel and attendance at the Investigators Meeting, and IRB review fee. Overhead costs at 22% are also included in the requested pre-study funding. In short, the pre-clinical trial cost agreement serves as a mechanism to ensure that we will be appropriately reimbursed for all preparatory work even when the sponsor decides to



cancel the project or when the main contract cannot be executed for such reasons as disagreement with terms and conditions. The agreement is now being piloted within DOM with the goal of using it across the School later this year.

MEET PHYLLIS TIEN, MD, Asst. Adjunct Professor of Medicine, VAMC

by Wendy Ng, RSA at the VAMC



WN: What made you decide to attend medical school?

PT: I decided to attend medical school after taking a semester off during college to take care of my grandmother, who had been diagnosed with metastatic breast cancer. I first considered becoming a doctor in junior high school. I was deeply affected by some of the poverty and political suppression I witnessed in different countries I visited with my parents while growing up. I very much wanted to help the people and I thought being a doctor would be a good way to help.

WN: Why did you choose Infectious Diseases to be your specialty?

PT: I chose Infectious Disease, because infectious diseases are a major public health problem globally. In addition, social, political and environmental conditions have a major impact on infectious diseases. That is a major reason why I became particularly interested in caring for patients with HIV during medical school.

WN: I know you're involved with the WIHS and FRAM studies. Can you explain what these studies are?

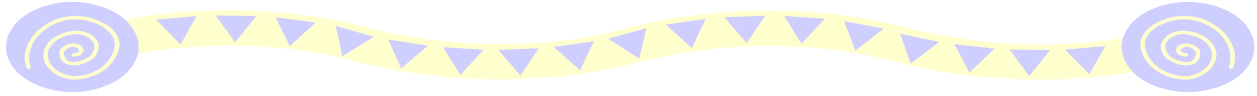
PT: WIHS stands for "Women's Interagency HIV Study." WIHS was established in 1994 at 6 sites across the US to study the natural history of HIV infection in women with and at risk for HIV. FRAM is also a multi-site study with 16 study sites across the US. FRAM studies Fat Redistribution and Metabolic Change in HIV infection—hence the name FRAM.

WN: Are you also involved with other studies?

PT: Both WIHS and FRAM are large cohort studies that have collected a lot of data, allowing me to develop independent research questions involving participants from WIHS and FRAM. For example, I am studying liver abnormalities in participants from WIHS and FRAM who have both HIV and HCV coinfection.

WN: What do you do outside of work?

PT: When I'm not at work, I enjoy spending time relaxing with my family, taking care of



our two chickens, and tending to our beehives. Every summer, we collect the honey from our bees to enter in the honey contest at the County Fair. I also love traveling and exposing my kids to different cultures. Last year, we went to Zimbabwe to visit family, so that my kids could meet their new cousin.

WN: I know you have 2 children, would you encourage them to go into Medicine?

PT: I would most certainly encourage them to go into Medicine. I think it is a wonderful and fulfilling profession.

Phyllis/Wendy Chat

PT: How do you like working for the Department of Medicine?

WN: I've been with the Department for five years and each day seems different. There are days I wish I was home with my two kids but through it all I'm glad I'm working at UCSF and with the Department of Medicine. Department of Medicine has a very strong research administration team that is committed to excellence in providing service to their faculty in support of their research activities and I'm proud to be a part of that team.

PT: What made you decide to work for UCSF?

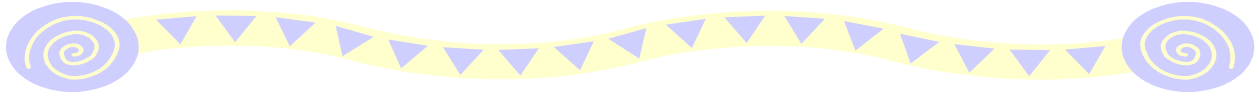
WN: It all started with the work-study program from high school. I was assigned to work with the Medical Center Director's Office. I was in the executive suite surrounded by people who held high positions within the medical center. That experience was fascinating, memorable, and delightful. I

left UC after I graduated from high school but felt UC was definitely a place I wanted to come back to.

PT: What do you do outside of work?

WN: Because I have two small children, my time outside of work is spent mostly with my family. We try to take at least one vacation each year. On weekends, we take our bicycles to Golden Gate Park or hang out by the beach. My husband goes to the golf course every weekend and so at the age of 3 my children had their very first set of golf clubs. They pretended to have fun at the golf course. I've sat through their music lessons, swimming lessons, and whatever lessons they may have without falling asleep.





MEET TONY BARLOW, Division Administrator, Rheumatology
by Maria Novello, Assistant Director



MN: How important is research to your division?

TB: Research is core to our divisional operations. Although our clinical services generate revenues, the bulk of our funding is research-related, particularly from NIH and private sources. The services provided by the Department's Research Administration (RA) unit are, therefore, vital to our operations.

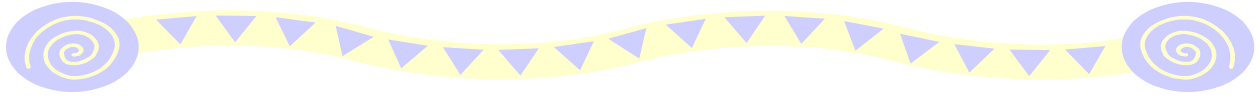
MN: What specific RA services or tools are most helpful to you?

TB: The introduction of the DOM Post-Award Express has made my review and analysis of divisional finances easier. I use it

more often than Weblinks, as it provides a simple yet comprehensive view of accounts. Recently, a tertiary function has also been incorporated into the system that has made a difference: I can now view online my Medical Center cost centers, in addition to having paper reports from the Medical Center. I also rely on the RA unit for information that I cannot readily obtain on my own. For instance, Division Administrators were recently provided a report summarizing the different types of K awards available from the NIH. Such reports are much appreciated by faculty and staff. The Newsletter is also a rich resource for learning about the Department's research-related projects.

MN: How can the RA unit serve your division better?

TB: Recently, the increased communications from the unit have been extremely helpful. I expect that we will be more informed about issues in the future. I also think that the unit is moving in the right direction by streamlining the reporting structure for RSAs. It makes sense to me that RSAs report directly to the Division Administrators and that when possible they are physically located within their respective divisions. This eliminates confusion. Overall, our division has been satisfied with the support services that we have been receiving. It certainly helps that we have a very competent RSA in the person of Bill Walzer. He plays a key role in responding to both the pre- and post-award needs of our faculty and in generating financial status reports that assist me in financial planning.



MN: What makes an outstanding RSA, from your perspective?

TB: An excellent RSA knows how to exercise balance between pre- and post-award activities. He/she is well versed with departmental, University, and funding agency requirements for proposal submission. The RSA also interacts with PIs regularly and communicates information to them on a timely basis. This helps us to keep 11th hour requests to a minimum. While completing pre-award tasks, the RSA consistently provides accurate financial status reports and discusses post-award issues with PIs.

MN: How has your Division evolved over the past few years?

TB: The Division has been undergoing several significant changes. One has been the integration of the Clinical Trials Center into the division. Another is taking under our wing the MSTP Program, a 7-8-year MD/PhD program under the leadership and direction of our Division Chief, Arthur Weiss. Lastly, we are now entering the 6th year of the UCSF Lupus Program, a collaborative effort among multi-disciplinary health care professionals to find safer, more effective therapies for lupus and to improve the quality of life of patients living with lupus. All of these developments have been learning opportunities for the division and for me.

MN: What do you like most about your job?

TB: I like the fact that there is no such thing as a typical day. Because of its wide range of activities, my job is far from being an “assembly line” type of position. In addition, all my PIs are a pleasure to work with and the team approach of the department is unparalleled. Lastly, working for UCSF per se is rewarding as we do good things here. I believe in the University’s multi-layered mission of patient care, healthcare research, student training, and community service.

STAFF NEWS

Tuyet Tran was promoted to Analyst II in the Division of Cardiology as the new RSA. She was previously in the Division of General Internal Medicine as a Research Assistant III in the Research Administration unit.

Steven Glotzbach, PhD started on May 16th as the new Grants Development Coordinator. Steve’s role is to help investigators focus the scientific portions of the proposal narratives to increase the chances of being awarded. He can help with all proposal types for any investigator in the Department of Medicine across all sites.