

The Dean's Newsletter: October 21, 2002

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ACCESS: Safety and Accountability in Clinical Research

On Monday October 7th, ACCESS [<http://clinicaltrials.stanford.edu/>] hosted an extremely well attended symposium on Safety and Accountability in Clinical Research at Stanford. Given the enormous attention that has been focused in the press and by communities nationally on the conduct of clinical research, it is imperative that leading academic medical centers like Stanford critically review their programs and performance to assure that patient safety and the public trust is assured. Thankfully, Stanford has taken these matters very seriously and has done an outstanding job in this important but challenging area. This is especially important given the School's commitment to research and the affirmation, through our ongoing Strategic Planning Process, that translational clinical research is one of our highest priorities in the years ahead, serving as a means to bring knowledge from the laboratory to the bedside and as a vehicle to align our basic and clinical research students and faculty.

This year's Keynote Symposium Speaker was Greg Koski, MD, PhD, who has served as Director of the Office for Human Research Protection in the Department of Health and Human Services since September of 2000*. Dr. Koski reviewed the progress that he observed taking place throughout the nation as academic medical centers have responded to the public concern about human subject safety in clinical research. He also cited Stanford as a leader and pacesetter in working diligently to assure human subject safety in clinical research.

Symposium participants, together with faculty panels, reviewed three mock cases to discuss issues in the recruitment of subjects to clinical trials, the informed consent process, conflicts of interest, the role of the Institutional Review Board, and the importance of assuring patient privacy as well as creating an environment of safety and accountability. Special thanks go to Dr. Steve Alexander, Professor of Pediatrics (Nephrology) and Medical Director of the ACCESS Clinical Trials Office and Mary Sweeney, Program Manager, along with the Planning Committee, for putting together an excellent program.

*Of note, Dr. Koski resigned from position of Director of OHRP on October 16th.

"Bench-Side" Consults

We generally tend to think of consultations regarding biomedical ethics as taking place in the hospitals or related medical settings. However, they are also very important in the research laboratory. Dr. Hank Greely, C. Wendell and Edith M. Carlsmith Professor in Law and current chair of the University Academic Council, has provided the following update. According to Professor Greely, "not everyone knows...that, like the Medical School itself, the Bioethics Center [<http://scbe.stanford.edu/>] has a dual focus, working on both clinical medicine and basic biomedical science. The Center has provided ethics consultations not just to clinicians, but to basic science researchers whose projects raise ethical concerns." The Center's monthly seminar this past October 3rd provided a nice example. Professor Hank Greely from the Law School presented the preliminary report of a five person working group assembled by the Center to consider the ethical implications of some of Dr. Irv Weissman's work with human brain stem cells. Dr. Weissman wants to try to create mice with brains made up, largely or entirely, of human neurons in order to have an *in vivo* model for studying those neurons and their reactions to both insults and treatments. The group's report tries to provide clarity and guidance about the issues this research raises, both for Dr. Weissman and for others, including the public. The Center wants to provide more help to basic science researchers, whether through published reports by working groups or through short telephone or e-mail communications.

More About the Respectful Workplace

I have conveyed in past Newsletters the importance I place on having a "respectful workplace" within the School of Medicine. A number of initiatives are in place to educate and assist students, faculty and staff and it is our hope that these will help to assure that all members of our community feel valued and respected but, if they have concerns, that they know where to go for help and assistance.

At the Dean's Staff Meeting on Wednesday, October 9th, Martha McKee reviewed her role as the Ombudsperson for the School. She also described other resources available within the medical community. She highlighted that the Ombudsperson must be both impartial and independent and assures confidentiality in all interactions. The Ombudsperson is available to listen to concerns, clarify procedures and suggest options. The mission of the Ombudsperson's Office is to consider the rights and

interests of individuals but not to advocate for any individual or group but rather, to advocate for fairness and equal treatment. You should feel free to contact the Ombudsperson when you need someone to listen; when an awkward situation occurs in the workplace or uncomfortable feelings are bothering you; when you are unsure of Stanford policy or you believe a policy, procedure or regulation has been improperly applied; when you think you have been treated unfairly; when you think that someone has engaged in misconduct or what you think may be an ethical violation; when you believe you are being harassed; or when you are afraid of retaliation. The services of the Ombudsperson are available at Stanford to be a resource for faculty, students, staff, housestaff and postdoctoral fellows in the School of Medicine. If you need assistance contact Ms. Martha McKee at 650-498-5744 or by email at Martha.Mckee@leland.stanford.edu.

In addition to the Ombudsperson, the School of Medicine has other resources for problem resolution. Please note the following:

Medical Students

- Julie Parsonnet, MD, Senior Associate Dean for Medical Education
- Eleanor Antonakos, DFA/Office of Student Affairs

Interns and Residents

- Ann Dohn, Office of Graduate Medical Education

Graduate Students

- Ellen Porzig, PhD, Associate Dean for Graduate Student Affairs
- W. James Nelson, PhD, Senior Associate Dean for Graduate and Postdoctoral Education.

Postdoctoral Scholars

- Michael Cowan, Associate Dean for Postdoctoral Affairs

Staff/Staff Physicians

- Cori Bossenberry, Director, Human Resources Group
- Norma Leavitt, Associate Director, Human Resources Group

Faculty

- David Stevenson, Senior Associate Dean for Academic Affairs
- Linda Deasey, Assistant Dean for Academic Affairs
- Ellen Waxman, Director of Faculty Relations

Again, these resources are available to help us achieve the most respectful workplace that is possible.

Board of Trustees Update on the Clark Center

At the Committee on the Medical Center of the Stanford University Board of Trustees, Matt Scott, Professor of Developmental Biology and Genetics and Chair of the Bio-X

Leadership Council, gave an update on "Interdisciplinary Research in Biology" also known as the Bio-X Program [<http://biox.stanford.edu/>]. The goals of Bio-X are to foster interdisciplinary education for a new generation of students, facilitate innovative collaborations among scientists and physicians across the spectrum of the physical, engineering, biological and social sciences, and provide bridges to the community through education and concerns for public policy and ethics. To accomplish these objectives, the Bio-X program will:

- Design events and programs that foster discussion and collaboration across the boundaries of traditional fields.
- Offer programs and incentives (e.g., grants) to stimulate collaboration of teams with diverse backgrounds.
- Build an intranet to facilitate communication between Bio-X affiliates across the Stanford campus.
- Generate a planning process for interdisciplinary education.

Among the current themes of Bio-X at Stanford are:

- Biocomputation (including imaging, bioinformatics, protein folding, biomechanical stimulation)
- Biodesign (including biorobotics, device discovery)
- Biophysics
- Chemical Biology
- Genomics/Proteomics
- Regenerative Medicine

Bio-X at Stanford has unfolded as a program that now engages four Schools (Earth Sciences, Engineering, Humanities & Sciences, and Medicine) and with more than 20 departments now participating. The Clark Center will house part of the Bio-X program when it opens in June, 2003. To date, 31 faculty are planning on locating some or all of their laboratories to the Clark Center. When assembled, they will include a breathtaking array of faculty disciplines, as well as both senior and junior members, a third of which are Assistant Professors. In addition, the Clark Center will be the administrative home of the newly established Department of Bioengineering between the Schools of Engineering and Medicine, whose mission is "Create a fusion of engineering and the life sciences that promotes scientific discovery and the development of new technologies and therapies".

The emerging themes in multidisciplinary research and education at Stanford are exciting and important and are likely to distinguish our university as a unique and very special institution during the years ahead.

Faculty Senate Update on Curriculum Planning

As you know, under the leadership of Senior Associate Dean for Medical Education Julie Parsonnet, we are engaged in curriculum redevelopment for medical students with the goal of instituting important new changes for the Class entering in 2003. One of the overarching goals includes fostering parallel learning throughout the medical school in both basic science and clinical medicine in order to foster continued connectivity with

the scientific principles that are the foundations of modern clinical medicine and clinical practice. In addition, we want our students to be able to pursue independent scholarship throughout medical school through "scholarly tracks" (or medical majors) that will enable them to develop specific skills through a mentored curriculum with associated research. In order to accomplish these and related goals, it is also important to critically assess the fundamental essential knowledge that students must gather early in medical school in order to prepare them for life-time learning. Rather than adhering to the more traditional and compartmentalized medical school curriculum of "preclinical" followed by "clinical" training, we would like to find greater linearity and connectivity to both areas of learning. To accomplish this and also create opportunities to commence the "scholarly track" experience during the first year of medical school, it is important to reduce class time during the initial phases of medical school — some of which will be moved to later years of medical training. These changes are, of course, all interrelated and must be further guided by assuring that our students still have an environment that fosters flexibility and individual development. Such changes quite naturally foster both excitement and concern.

In order to benefit from the experiences of other institutions that have recently undergone curriculum change, the Medical School Faculty Senate invited David Irby, Ph.D., Senior Associate Dean for Education and Helen Loeser, M.D., Associate Dean for the Curriculum from UCSF to speak at its October 16th meeting. Drs. Irby and Loeser shared the challenges they faced in instituting the major changes under way at UCSF. One guiding principle is that the changes are continuous and require ongoing adaptation. The second is that there is always resistance to change, regardless of the nature of the change or the portion of the curriculum being modified. The third is that faculty and student engagement is critical and that a clear mandate from School leadership essential.

I am cognizant that change is difficult and that there are many stakeholders, each with an important perspective. That said, we agreed through the Strategic Planning process that began more than a year ago that the general directions outlined above were essential to the future of Stanford Medicine. I am absolutely and unequivocally committed to having these changes occur in a timely manner. I am confident that the guiding principles that will shape these changes discussed above will enrich the opportunities for our students and make education at Stanford transformational in American Medicine for the 21st Century.

Update from the Executive Committee

At the Executive Committee meeting on Friday October 18th, the changes that are now planned for the professorate were reviewed and discussed. These changes are the result of a more than yearlong planning effort led by Senior Associate Dean for Academic Affairs, Dr. David Stevenson. I will present an update about the changes in the next scheduled issue of the Dean's Newsletter on November 4th.

Among the other topics discussed at the Executive Committee were:

Working with the Office of Communications and Public Affairs. A presentation was given by Ritch Eich, Chief and Michelle Brandt who described the role of their Office in linking the faculty with the media. A strong plea was made to the Chairs that they and the faculty get to know and work with the Office of Communications and Public Affairs [<http://mednews.stanford.edu/>] and that they should feel free to call (650-723-6911) whenever there are questions or concerns.

Specifically, the Office can help faculty with:

- Counsel in responding to requests for interviews from print and broadcast reporters — including media training.
- The Office can help disseminate information that features important faculty stories and events.
- They can prepare response to sensitive and potentially negative information.
- Facilitate broadcast of photo shoots within the medical center.

Dr. Eich and Ms. Brandt also made clear that faculty could help them by:

- Contacting their office with ideas for the Stanford Report and press releases
- Providing notice (ideally two weeks) about publications that may be newsworthy.
- Alerting them to events or issues that may generate media interest.
- Letting them know if a reporter contacts you.

I would encourage you to work closely with the Office of Communications and Public Affairs — and to certainly contact them if you have any questions or need advice.

Health Insurance Benefits: We had a presentation regarding the upcoming open enrollment and the various changes in health care coverage. As you likely know, health care inflation is occurring nationally — and locally — with increases in rates exceeding 25-30%. These and other changes are impacting the choices available for Stanford University employees. You should have received information about the options and if you have questions you should contact the Benefits Office at 650-736- 2985 or visit the website at <http://benefitsu.stanford.edu/>

It is important to note that if you want to have full access to Stanford faculty the options are restricted to the Blue Shield PPO and the Definity Plan. Access to Stanford physicians may be also available the Blue Shield Triple Option. Please also note that the options are different for Postdoctoral Scholars and their questions can be directed to Michael Cowan, Associate Dean for Postdoctoral Affairs at 650-725-5075.

Congratulations

- On October 14th, the Institute of Medicine of the National Academy of Sciences announced it newly elected members. Included among them were **Dr. Linda Guidice**,

Stanley McCormick Memorial Professor of Obstetrics and Gynecology and **Dr. Irv Weissman**, Karel and Avice Beekhuis Professor of Cancer Biology, Professor of Pathology, Developmental Biology and by courtesy, of Biological Sciences. This brings the number of Stanford faculty elected to the IOM to 36. Congratulations to Drs. Giudice and Weissman.

- Mr. Mike Hindery announced that **Carole Buffum** has been appointed as Assistant Dean for Finance and Administration in the School of Medicine. Carole has served for four years as the School's Executive Director of Finance and Administration and before that served in several finance and management roles in the Dean's Office. Although Carole's role and responsibilities are not changing, the new title is appropriate recognition for Carole's role and responsibilities in and contributions to the School. Congratulations Carol.
- **Dr. David Spiegel** was formally celebrated as the Jack, Samuel and Lulu Willson Professor at a lovely dinner held in his honor on October 8th. This offered an opportunity to acknowledge Dr. Spiegel's many contributions to both scholarship in mind/body interactions and resultant important programs for patients facing the challenges of cancer or stressful life situations or events. He is internationally recognized for his important contributions to psychiatry and he is the recipient of numerous honors and awards.
- **Dr. Malcom Bagshaw**, Henry Kaplan-Harry Lebeson Professor of Cancer Biology, Emeritus was awarded the Gold Medal of the American College of Radiology at its 79th Annual Meeting on October 1. He was recognized for his contributions to the field of radiology, especially the development of concepts for the treatment of prostate cancer.
- **Dr. Ted Harris**, George DeForest Barnett Professor of Medicine and past Chair has been elected to Fellowship in the Royal College of Physicians of London.

Congratulations to Dr. Harris

- On Friday, October 18th, a wonderful event was held in the Bing Dining Room to celebrate the career of **Dr. Harry Oberhelman, Jr.**, Professor of Gastrointestinal Surgery, Emeritus. Dr. Oberhelman has been a major figure at Stanford for more than 42 years, having joined the faculty within a year of the School moving to the Palo Alto campus. Since then he has been a distinguished and revered surgeon and colleague who is deeply respected for his many contributions to patients, trainees and Stanford.

Upcoming Events

- **Walk for Diabetes.** On Sunday, October 27th, Stanford Medical School students, along with others from the University and neighborhood communities will participate in the "Walk to Cure Diabetes" that will be held in Shoreline Park in Mountain View, beginning at 9AM (with registration beginning at 8:00 a.m. Our students invite you to join the Stanford School of Medicine Team and, by your participation, help in supporting research in diabetes. (The walk is only three miles). [Info: <http://www.stanford.edu/dept/news/report/news/september25/diabetes-925.html>]
- **The Fall Forum on Community Scholarship and Service**, organized by Stanford Medical Students and sponsored by the Public Service Medical Scholars Program, will

be held on Wednesday, November 6th, from 5:00-7:30 p.m. at the Frances C. Arrillaga Alumni Center. Dr. Robert Ross, CEO of the California Endowment will give the keynote address. This first-time event will showcase a wide range of service and partnership research projects undertaken by Stanford medical students in underserved communities here and around the world. If you have any questions please contact schevez@stanford.edu or call 650-736-1957 and if you are planning to attend, please RSVP to stanfordfallforum@yahoo.com or 650-736-1957.

Appointments and Promotions

- **Richard Bland** has been appointed Professor of Pediatrics (Research), 11/01/02-10/31/08.
- **Joan Frisoli** has been appointed Assistant Professor of Radiology at the Stanford University Medical Center, 10/1/2002 to 9/30/2005
- **Thomas Hsu** has been appointed Assistant Professor of Urology at the Stanford University Medical Center, 11/1/2002 to 10/31/2005
- **Mark Musen** has been promoted to Professor of Medicine (Medical Informatics) and, by courtesy, of Computer Science, effective 11/01/01.
- **Lawrence Shuer** has been promoted to Professor of Neurosurgery at Stanford University Medical Center, effective 11/1/02.