Dean's Newsletter
January 20, 2003

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Update on Medical Education

During the past months considerable activity has been underway on the School of our Medical Education Curriculum. This important effort has been lead by Dr. Julie Parsonnet, Senior Associate Dean for Medical Education, with enormous help and contributions from numerous faculty, students and staff. As you will recall, the fundamental underpinning of the curriculum restructuring has been to develop a new path for training future physician-scholars and leaders. Central to the restructuring is the creation of ***Scholarly Concentrations,*** which will "define an area of academic focus within the overall medical school curriculum that provides an opportunity for students to engage in an in-depth study of an area pertinent for the practice or science of medicine and to develop analytical skills required for the critical evaluation of the scientific literature. As part of this program, students will engage in an original project or creative endeavor..."

Dr. Parsonnet presented the Request for Proposals for Scholarly Concentrations to the Medical School Faculty Senate on Wednesday January 15th and received both enthusiasm and unanimous approval to proceed. Accordingly, the RFP is now being sent to all Medical School Faculty with the goal of receiving "Letters of Intent" by February 7th and then full proposals by April 1st. Final decisions will be made by the Scholarly Concentration Committee by April 30th. This time frame will enable this exciting new program to be initiated in the Fall of 2003 for the next incoming class.

As described in the RFP, possible areas of scholarly concentration include, but are not limited to: Molecular and Genetic Medicine; Bioengineering; Community and Public Service Medicine; Health Services, Outcomes and Policy Research; Infectious Diseases and

Microbiology; Medical Humanities and Ethics. Within each scholarly concentration, students can elect to pursue an original research option or an investigative scholarly option.

- In the ***Original Research Scholarly Concentration Option*** students must complete the course requirements of the concentration, participate with graduate students in the research seminar program of the relevant department or consortium, and engage in an original research project directed by a member of the concentration faculty. Research projects will be reviewed and approved by a thesis committee. For some concentrations, additional work that would fulfill the requirements of a Masters degree may also be proposed. Students electing the *Original Research Scholarly Concentration Option* will ordinarily complete both the requirements of a regular medical school curriculum and the research component of the concentration in a minimum of five years.

- In the ***Investigative Scholarly Concentration Option*** students will fulfill the requirements by completing the designated concentration course requirements and by an independent study culminating in a scholarly paper that pertains to an original question developed by the student but that need not involve the collection of original data. Students who select the *Investigative Scholarly Concentration Option* can ordinarily complete both the standard medical school curriculum and the requirements of their elected concentration within four years if they so desire.

In parallel with the creation of the Scholarly Concentrations, the curriculum restructuring also addresses revising the traditionally dichotomized pre-clinical and clinical curriculum to one that includes parallel learning of both basic and clinical science and medicine throughout medical school. This requires redefining the essential knowledge that students require during their first and second years along with determining which basic science courses or mini-courses are better taught during the time when students are doing their clinical rotations. This restructuring also permits the creation of the necessary time-blocks to enable the Scholarly Concentrations to be successfully conducted.

In order to make the necessary changes for the class entering in the Fall of 2003, considerable work, accommodation and compromise is needed by faculty, students and staff. To a great degree this is being accomplished by the very successful partnership that has been forged between the Dean's Office and the Faculty Senate. I want to particularly thank Dr. Oscar Salvatierra, Chair of the Faculty Senate, and Dr. Ted Sectish, Chair of the Committee on Courses and Curriculum, whose leadership has been instrumental in assuring that the curriculum agenda stays on schedule. In addition, I want to also thank Dr. Neil Gesundheit, Associate Dean of Medical Education and Betsy Moreno, Office of Academic Research, for their major efforts. I also want to thank Dr. Gary Schoolnick and the members of the Scholarly Concentration Committee for their impressive work. Although much remains to be done, the work that has been accomplished to date is enormously gratifying and will serve well future generations of Stanford medical students.

Update on Education Facilities

In addition to curriculum restructuring, considerable work has also been underway in the planning for new education facilities and for the renovation of existing ones. The following update has been prepared by Maggie Saunders, Education Programmer/Project Planner in our Office of Facilities Planning and Management.

Stanford Medicine Information and Learning Environment (SMILE)

The Programming and Feasibility Phase of the SMILE project is fully underway. Initial discussions and planning have been initiated in each of the major program areas including: Learning Environments, Information Center (Lane Library), Office of Student Affairs, Student Life, Conference Center, and Dean's Offices. Additionally, exciting discussions have emerged related to the creation of an Immersive Learning Center, which would provide a hub for the integration of state of the art simulation technologies into the teaching and learning of clinical skills.

The focus of the current effort is to understand the types, number and relationship of spaces that would accomplish the goals of each of these program elements. Parallel to the programming effort, a second set of activities has been initiated to understand the engineering and site complexities of the current SMILE site located where Fairchild Auditorium is today (to be demolished and then replaced in SMILE) and southwest of Fairchild Science Building (currently a parking lot) in terms of the evolving program information. The combined result of these efforts will be the first and most preliminary definition of a building complex and a cost estimate. These two preliminary phases are anticipated to be completed sometime in April. An update is planned for a future Town Hall meeting. In the meantime, the Office of Facilities Planning and Management is eager to receive your thoughts and ideas. Please communicate your ideas to Maggie Saunders, madaca@stanford.edu.

Fleischmann Lab Renovation

The Fleischmann Lab renovation project is also progressing as planned. Construction drawings are complete and initial bids, which are within range, have been returned. In addition, technology specifications, furniture selection, and project schedule are being refined. Demolition of the current teaching labs is scheduled to begin May 15th with project completion planned for early September.

A primary goal of the renovation is to enable the Fleischmann Labs to be more flexible and technology-capable spaces. To accomplish this goal additional electrical service will be provided in the floors of the Labs. To complete this electrical work and to enable the installation of new technologies in the M-Wing classrooms in the Alway building, the classrooms (with exception of M104) will also pulled out of operation during the summer of 2003, beginning June 16 through end of August. An announcement has been distributed to the course directors, faculty and staff that we anticipate will be effected during the Spring and Summer terms. Primary surge space for courses and events taught during the summer term will be in the Herrin Lab building on main campus. A few larger events are being accommodated in other main campus facilities. Meetings with individual course directors are underway to accommodate the Spring courses taught in the Fleischmann Labs that will be disrupted from May 15 - June 13. Should you have any questions about this project or surge space for your course or

event, please contact Maggie Saunders, madaca@stanford.edu or Linda Gibson, lindah@stanford.edu.

Responsible Conduct in Clinical Research

Thanks to the efforts of Dr. Ellen Porzig, Associate Dean for Graduate Education, Dr. Mildred Cho, Senior Research Scholar, Center for Biomedical Ethics, and Michael Cowan, Associate Dean for Post-Doctoral Affairs, an important course for graduate students and post-doctoral scholars entitled "Responsible Conduct of Research" commenced on January 8th and extends through March 5th. Held on Wednesday evenings at 5:30 PM, in the Fairchild Auditorium, the course features presentations on scientific conduct, misconduct and mentorship; scientific record keeping; authorship, intellectual property and peer review; conflict of commitment, conflict of interest and relationships with industry; use of human subjects; social responsibility of biomedical scientists; and vertebrate animals in research.

This is an important program because it emphasizes our School's institutional commitment to fostering an environment that values scientific integrity. Indeed, as a community of scholars we are responsible not only for our individual actions but also for how they impact on and can be affected by the actions of others. Thus the interrelationship between integrity at the individual and at the institutional level is critically important. So too is the recognition that integrity in science is on a continuum with our personal and professional lives. Indeed, it is hard if not impossible to separate them. In 2002, the Institute of Medicine of the National Academies published an important monograph entitled ***Integrity in Scientific Research: Creating an Environment that Promotes Responsible Conduct***. I would encourage you to read this monograph, which can be accessed at www.nap.edu

The cover of the aforementioned monograph contains a quotation that I believe accurately captures the essence of scientific integrity: *" Many people say that it is the intellect which makes a great scientist. They are wrong; it is character."* – Albert Einstein.

When Does Clinical Care Become Research?

There can sometimes be a blur between clinical care and clinical research. This has important implications for deciding when approval from the Institutional Review Board should be sought before initiating a project or inquiry. The following information is provided by Vicki Jones with input from Kathy McCelland and Dr. Ann Arvin.

"Clinical Research"--Gray Matters

Investigators, both junior and senior, need to be aware that Institutional Review Board (IRB) review and approval must be obtained **prior** to collecting and analyzing patient data for purposes of research. These activities are different from the clinical care of the individual patient, even though the same clinical information may be used for research purposes. A lack of understanding of the human subjects regulations and what constitutes human subjects research can lead to violations of Stanford policy and federal regulations.

The IRB offers the following advice and information to assist investigators with their obligations to comply with Stanford's requirements for the protection of human research subjects. Stanford's Human Subjects Manual (http://humansubjects.stanford.edu/manual/) states that research activities involving human subjects must be reviewed by a Human Subjects Panel (part of the IRB). To determine if an activity involves human subjects research, ask yourself:

1. *Are human subjects involved in any aspect of the activity?*
2. *Is this activity direct clinical care of an individual patient only, or is it a research analysis of data from this and other patients?*
3. *Is the activity within Stanford's jurisdiction?*

Whether an activity represents research may fall into a gray area. What starts out as basic medical practice designed to help an individual patient can gradually develop into a systematic investigation to improve the quality of care for a small group of patients, and ultimately turn into a full research project intended to produce a significant body of sharable, transmittable, publishable data. The purpose of medical or behavioral practice is to provide diagnosis, preventive treatment or therapy to particular individuals. By contrast, the term *research* designates an activity designed to test an hypothesis, permit conclusions to be drawn, and thereby to develop or contribute to generalizable knowledge (expressed, for example, in theories, principles, and statements of relationships). Research is usually described in a formal protocol that sets forth an objective and a set of procedures designed to reach that objective.

The following case study is offered to assist answering the question: *When does clinical practice end and "research" begin?*

> Dr. Smith notices what he believes is a correlation between a patient's symptoms when on a relatively new prescription medicine and a food supplement some of his patients are taking. Dr. Smith asks a Resident to search the medical records of his patients to identify those who have both been prescribed the new medication and who have complained of certain symptoms. *Does this constitute research that requires IRB approval?*
>
> The Resident's review of the files nets about 15 records. Dr. Smith then asks the Resident to contact those patients and ask them if they have ever taken the food supplement in question. *Does this constitute research that requires IRB approval*?

The patient information gathered by the Resident points to a strong statistical correlation between taking the prescription medication and the food supplement concurrently, and the symptoms observed by Dr. Smith, even in the small group of patients contacted. Dr. Smith then asks some of his colleagues to review the records of their patients who have been prescribed the medication and to keep track of their symptoms and dietary supplements. ***Is this research that requires IRB approval*?**

Research, as officially defined by the Department of Health and Human Services http://humansubjects/manual/chapters/ch6_1_review_pro.html is: *…a systematic investigation, including research development, testing, and evaluation**, designed** to develop or contribute to generalizable knowledge*. So, whether an activity is research, becomes a matter of ***intent***. At the point where Dr. Smith discovers a correlation that might *develop or contribute to generalizable knowledge*,

his efforts become research-oriented. It may be that the investigation commenced with the idea of helping Dr. Smith's individual patients, but somewhere along the line Dr. Smith decided to explore the correlation further with the possible intent of contributing to general medical knowledge.

Therefore, when Dr. Smith asked the Resident to review the medical charts, if his intent was to analyze the data and eventually publish the results or use them in a larger, formal investigation, then this was research requiring IRB approval. If, on the other hand, Dr. Smith's intent was simply to help his own patients, then his actions were part of clinical practice.

The purpose of medical or behavioral practice is to provide diagnosis, preventative treatment, or therapy; and interventions are designed solely to enhance the well being of the individual patient or client. Research constitutes activities designed to contribute to general knowledge. Once a study begins, new relationships are created. Patients become subjects, doctors become researchers, students, as subjects, become respondents. The line between practice and research is often a blurred one, and confusion can arise on the part of the investigator, as well as the subject. It is the responsibility of the investigator to understand and maintain the distinction between practice and research and to inform study participants of their role as research subjects versus their role as patients.

The most efficient solution at every step of the *Dr. Smith* scenario described above would have been: *When in doubt, ask the IRB.* The IRB, in the Research Compliance Office, is available to answer questions concerning the use of research subjects and to help investigators submit research protocols for IRB approval. Stanford has four IRBs that each meet monthly to review protocols covering all aspects of human subjects research. For general information and assistance related to Human Subjects in Medical Research, please visit the Human Subjects web site http://www.stanford.edu/dept/DoR/hs/. For answers to questions, contact Jon Schwaiger (Jon.Schwaiger@Stanford.edu or 650-723-0082). For general information and assistance related to Human Subjects in Non-Medical Research, please visit the web site and then contact Juli Espinoza (Juli.Espinoza@Stanford.edu or 650-723-4526) concerning any questions

Inauguration of the Stanford Medicine National Advisory Council

I am pleased to announce the inauguration of the Stanford University School of Medicine's National Advisory Council. Given the many changes impacting academic health centers, it is imperative that the School and University periodically assess its strategic initiatives and direction. The School of Medicine's National Advisory Council will meet annually to review School-wide initiatives and strategic plans, including future programs and capital development. The NAC will report its findings and recommendations to the Dean and the Provost. The following list includes the individuals who have agreed to serve on this new Council:

Edward Benz, M.D.
President
Dana Farber Cancer Institute
Harvard Medical School

Elizabeth Blackburn, Ph.D.
Professor, Department of Biochemistry & Biophysics
University of California, San Francisco

Thomas F. Boat, M.D.
Professor and Chair, Dept of Pediatrics
Children's Hospital Medical Center
Cincinnati, OH

Donald A.B. Lindberg MD
Director, National Library of Medicine
National Institutes of Health

Susan Lindquist, Ph.D.
Director, Whitehead Institute
Massachusetts Institute of Technology

Daniel H. Lowenstein, M.D.
Professor of Neurology
Department of Neurology
University of California, San Francisco

William A. Peck, M.D.
Dean, School of Medicine
Washington University

Mr. William A. Halter
Stanford University, Board of Trustees
Washington, D.C.

David Satcher, M.D., Ph.D.
Director, National Center for Primary Care
Morehouse School of Medicine

Carla Shatz, Ph.D.
Professor and Chair, Department of Neurobiology
Harvard Medical School

Samuel A. Wells, Jr., M.D.
Department of Surgery
Duke University Medical Center School of Medicine

I am enormously pleased by the quality and depth of the individuals who have agreed to serve on this Council. They represent a breadth of knowledge and expertise that spans the School of Medicine's missions in education, research, patient care and community service.

We are planning our first meeting of the National Advisory Council for November 2003.

Congratulations

- **Dr. Stanley Falkow**: This past week, the National Academy of Sciences (NAS) has selected 18 individuals to receive awards honoring their outstanding scientific achievements. Among these is Dr. Stanley Falkow, Professor of Microbiology and Immunology, who will receive the **Selman A. Waksman Award** "for his many contributions to understanding the mechanisms by which bacteria cause infection and disease." The award is supported by the Foundation for Microbiology and has been presented since 1968. Congratulations to Dr. Falkow.
- **Dr. Carlos Esquivel:** The Northern California Chapter of the American Liver Foundation will honor Dr. Carlos Esquivel for his outstanding contribution to biotechnology and medical innovation at a gala event in San Francisco in March. Congratulations Dr. Esquivel.
- **Stanford Medical Center** has received among the highest scores in California on the first comprehensive report on hospital performance publicly released by a health plan. The Pacificare Quality Index, released this past week, evaluated 200 California hospitals on more than 60 measures of quality and affordability. Stanford achieved an overall quality score of 95%, with an overall patient safety score of 98%. Given the complexity

of the cases cared for at Stanford, these results are excellent and compare favorably to other academic medical centers (e.g., UCSF Medical Center had a score of 79% and UCLA Medical Center scored 58%). While these are gratifying, by all accounts considerable work remains in further improving the quality of patient satisfaction at Stanford – a matter that is high on the priority list of hospital leaders.

Announcements

2nd School of Medicine HIPAA Public Forum to Focus on Research

The second in the series of HIPAA Public Forums sponsored by the School of Medicine is slated for Wednesday, January 29 from 1:00pm – 2:30pm in Fairchild Auditorium.

In response to many requests for more information regarding the HIPAA privacy rules and research, this Forum will focus on research compliance and the impact of the new HIPAA regulations. A panel representing HIPAA staff from the School, Hospitals, and University will provide the most current information regarding Stanford research policies, answer faculty and staff questions, and solicit input for future training needs. Investigators and research staff are encouraged to attend.

Due to space limitations, participants are asked to pre-register for this event by using the following link: http://reggie.stanford.edu/SignupForm1.asp?670

Prior to the Forum, participants are encouraged to submit questions they would like the panel to address. Please submit general questions and common concerns to HIPAA@med.stanford.edu.

Stanford University Minority Medical Alliance's (SUMMA) Twelfth Annual Premedical Conference

As you probably already know, SUMMA is a coalition of African American, Latino, and Native American medical students committed to recruiting and retaining underrepresented medical professionals. Every year, SUMMA hosts the largest minority premedical conference on the west coast, typically drawing 400-600 attendees each year. The goal of the conference is to increase the number of minority applicants to the health professional fields so that we can better serve our communities.

Our opening speeches begin at 8 a.m., with the conference ending at 4:30 p.m. In line with our goal of increasing the numbers of underrepresented minorities in medical school, SUMMA will focus on the pre-medical process by providing workshops targeted at specific aspects of the application process, a newly revamped booklet with 65 pages of facts, advice, and tips, and invaluable interaction with medical students, physicians, and recruiters from around the country.

Please join us on Saturday, February 1, 2003 at Fairchild Auditorium. Further details about this exciting event can be found at: http://www-med.stanford.edu/osa/summa

Appointments and Promotions

- Craig T. Albanese has appointed to Professor of Surgery at the Lucile Salter Packard Children's Hospital and Professor, by courtesy, of Pediatrics at the Lucile Salter Packard Children's Hospital and Professor, by courtesy, of Obstetrics and Gynecology at the Stanford University Medical Center, effective 1/1/2003 to 12/31/2007.

- Natalie Rasgon has been appointed to Associate Professor of Psychiatry and Behavioral Sciences at the Stanford University Medical Center, effective 1/1/2003 to 12/31/2007.

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