



Stanford Bioethics

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New project: ethics of comparative effectiveness research

In May of this year, a planning meeting was convened at SCBE to generate joint CTSA/VA efforts concerning the ethics of comparative effectiveness research (CER) using Point of Care Clinical Research (POCR) as an example. Currently, comparative effectiveness research faces a dilemma. Retrospective studies are relatively easy to do, but the results are not epistemologically ideal. In contrast, prospective studies offer the potential for very strong evidence of what works, but the studies are expensive and difficult to carry out. POCR offers a way for prospective CER studies to take place with greatly reduced costs by randomizing patients as they seek care in cases where there is little to no evidence that one clinical option is better than another (and their physician does not have strong feelings about which option is better). The main vision for POCR is to impact clinical care and foster a learning system within the healthcare field, and that has the potential to change the way physicians view patient care.

Several ethical issues were identified that will be further developed by a larger group. These include clinician engagement in research, consent issues (e.g. specific vs. blanket consent), equipoise, boundaries for minimal risk, safety reporting, and interpretation of study endpoints. Plans were made for a future meeting to further discuss the ethical issues, scientific limitations, legal aspects, and implementation of this research.

New Clinical Ethics Training Program

SCBE has started a new training program for clinical fellows who have protected research time to do qualitative and quantitative clinical ethics research with guidance, support, and mentorship at SCBE. Two projects are underway.

Alisa Van Cleave, MD, pediatric critical care fellow at LPCH, is studying physician communication with families during pediatric ICU care



conferences. Little is known about best practices for pediatric ICU physicians to use while communicating bad news or difficult information during these conferences, and no curricula exist to formally teach these skills to physicians-in-training due to the lack of data. To

learn more about how currently practicing pediatric intensivists communicate with families, pediatric ICU care conferences are being audio recorded, transcribed, and analyzed using the principles of grounded theory. Families are also filling out a short questionnaire afterward rating their level of satisfaction with the communication, their level of understanding, and their overall opinion of how well the conference met their needs, which we will analyze in conjunction with various communication styles. Dr. David Magnus is the faculty sponsor for this project.

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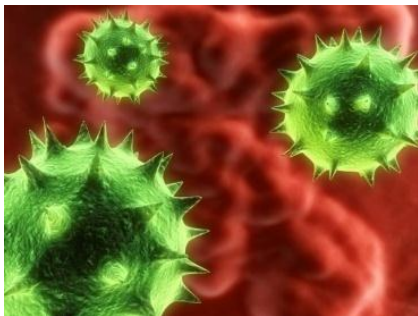
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David Chooljian, MD, JD, a pulmonary and critical care medicine fellow at SUMC, is beginning a project on advance care planning in the Advanced Lung Disease Clinic (ALDC). There is a vast unaddressed need for advance care planning in this patient population due to the nature of their diseases, which tend to be chronic but with the constant possibility of acute worsening that will make them unable to make their own health decisions. Previous research shows that advance directives are more likely to be completed via multiple dedicated sessions devoted to their facets, such sessions are unrealistic given the (ever-increasing) demands on the time of both clinicians and patients. Therefore, validating an intervention that can be performed both in the outpatient setting and in a single visit would be an important development in the field. This project will establish the prevalence of advance directive completion among patients presenting to the ALDC, which will include patients with interstitial lung disease, COPD, CF, and other chronic lung diseases. It will also include patients referred for transplantation. Following this, there will be an intervention phase where patients are randomized to standard care vs. two prompting questions about who their surrogate decision-makers should be and what their caregivers and surrogate decision-makers should think about when deciding for the patient. The second purpose of the project will be to examine whether or not this intervention improves the prevalence of advance directive completion in a significant way. Dr. David Magnus is the faculty sponsor for this project.

New Grant: ELSI and Microbiome



The project, *Toward a Framework For Policy Analysis of Microbiome Research*, aims to understand the kinds of ethical, legal, and social issues raised by the new field of human microbiome research. The aim of the project is to analyze how risk and benefit are conceptualized in research contributing to the understanding of the human microbiome and its applications, through content analysis of scientific and lay articles about microbiome-related research. We are particularly interested in determining the relationship between microbiome research questions or design, concepts of risk and benefit, and societal values. To that end, we also aim to conduct extended, structured interviews with experts in microbiome research. The products of our work will be a categorization of microbiome research, including the values and ethical issues associated with these types of research; a research agenda for ELSI and microbiome researchers, as well as more generalizable contributions to ELSI research, science and technology assessment through development of a mechanism for engagement of biomedical and other researchers in dialog about ethical and social implications of their work and through development of an overall framework for technology assessment that incorporates both values and social context to assess and proactively adapt scientific research design.

INVEST program through P50 funded Center for Excellence

CIRGE will implement a new program, the Integrating Values and Ethics in Science and Technology (INVEST) Forum, based on the concept of constructive technology assessment (CTA). The premise of CTA is that the implications of scientific research and development are not only a function of characteristics of technology, but of the interaction between science and its social and moral context. CIRGE's innovation will be in developing a process for coordinating ELSI research agendas around specific focus areas in genomic research, with the goal of translating the ELSI research findings into design features of genomic research and technology and informing policy. Our role will be to translate ELSI research not only in the sense of informing or developing health, research or social policy, but to translate the currency of values and ethics into the currency of scientific research.

CIRGE will serve as an intermediary between stakeholders and end-users of the research on the genomics of behavior, the scientists who conduct that research, and the ELSI research community. We will create a forum for integrating ethical and social considerations into specific areas of genomic research through 1) “prognostic” normative analyses that identify the values, principles and assumptions that are implicated by research and technology and its application 2) empirical analysis to map relevant genomic research and technology and identify stakeholders, 3) empirical analysis to assess relevant features of the ethical, legal or social context, such as how different stakeholders think genome information or technology will be used, should be used, perceived, or who it might benefit or harm, 4) “diagnostic” normative analyses to assess whether and how genomic research and technology supports or undermines stakeholder values, and 5) feeding

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back normative and empirical ELSI findings into research and development priorities, design criteria or requirements. These feedback processes are intended to inform the design and application of genome research in a way that enhances benefit and utility to end-users.

CIRGE is implementing a new program, the Integrating Values and Ethics in Science and Technology (INVEST) methodology, based on the concept of constructive technology assessment (CTA). The premise of CTA is that the implications of scientific research and development are not only a function of a technology's abilities, but of the interaction between science and its social and moral context. CIRGE's innovation will be in developing a concrete process for coordinating Ethical, Legal and Social Implications (ELSI) research agendas around individual technology areas, with the goal of integrating ELSI research findings into the design and development of research and technology and informing policy. The INVEST methodology therefore involves mapping and engaging with a wide variety of stakeholders along the translational pathway, conducting normative analysis of their viewpoints and feeding this information back to technology developers and funders. A

central feature of the process is the INVEST Forum, an online portal where stakeholders are invited to engage with hypothetical scenarios about the possible applications of a technology as well as the views and opinions of other stakeholders. The values and priorities thus revealed form an important part of the INVEST deliverables.

New R01: Race and Ethnicity in Gene-Environment Interaction Studies

Sandra Soo-Jin Lee is a Co-investigator on a new study led by Janet Shim, Ph.D. at UCSF entitled, *Conceptions of Race and Ethnicity Used in Gene-Environment Interaction Studies*. The goals of this study are to identify and understand the major theoretical and conceptual trends, methodological debates, and issues related to the organizational and funding contexts of gene-environment interaction research. The project focuses on the interpretation of population differences and investigates epidemiologists' perspectives on the use of race and ethnicity in genome and epidemiologic science. The 4-year study is funded by NHGRI/NIH (#1R01HG005848-01).

Center News

21st Annual Jonathan J. King Lectureship



SCBE has had an extraordinary group of speakers for our annual Jonathan J. King lecture and 2011 is no exception. Chris Feudtner, MD, PhD, MPH, will be speaking at 5:30 pm on October 5, 2011, in the Lucile Packard Children's Hospital Auditorium, Stanford University.

Chris Feudtner is associate professor of pediatrics and attending physician, director of research for the Pediatric Advanced Care Team and the Integrated Care Service, and co-scientific director of PolicyLab at The Children's Hospital of Philadelphia. In these roles, Dr. Feudtner both provides care to children with complex chronic conditions and investigates ways to improve the quality of life for these children and their families. In 2008, he assumed the responsibilities of director of the new Department of Medical Ethics at Children's Hospital and holds the Steven D. Handler Endowed Chair of Medical Ethics.

The 2011 Jonathan J. King Lecture is free and open to the public. No reservations are necessary. LPCH Hospital is located at 725 Welch Road, Palo Alto. A map and parking information can be found at <http://bioethics.stanford.edu>.

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Mildred Cho Promoted to Full Professor

SCBE's Associate Director, Mildred Cho, was recently promoted to full professor of Pediatrics. SCBE held a celebration in her honor at the Garden Court Hotel in Palo Alto on June 20, to toast her many accomplishments.



Dr. Cho's overall research program has focused on the study of the ethical, social and policy implications of genetic research and its applications. Her early work studied the impact of genetic testing on potential patients and communities and on how clinical genetic testing was affected by patent and licensing policy.

In the last five years, the goals of her work have shifted towards facilitating the integration of ethical and social considerations into genetic research and generating data to inform science policy. This work has addressed ethical and policy issues that have been faced by genetic researchers as they are in the process of designing research. Her work on the use of racial and ethnic categories in genetic research was in part inspired by her participation as an invited member of the International HapMap Consortium, which included genome scientists and ELSI researchers who worked together to design the NHGRI HapMap Project in a way that took ethical and community concerns into account. This work also led to policy recommendations and changes in editorial policy at scientific journals. The modus of working closely with biomedical scientists to address ethical and social issues specifically raised by their research led to development of the concept of research ethics consultation into an institutionalized practice.

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In 2004 Dr. Cho secured a Center for Excellence in Ethical, Legal, and Social Implications (ELSI) Research Grant (CEER). This grant was one of four that were initially awarded by the NHGRI, and two more have been awarded since then. The CEER was recently renewed for another five years. With this award, she was able to implement and expand on some of the ideas she had been developing about integrating ELSI considerations with biomedical research.

Under this grant, she established the Benchside Ethics Consultation Service (BECS) at Stanford University. It was initially envisioned as a service for genetic researchers at Stanford but quickly evolved, providing consultation to local biotechnology companies, researchers at other universities nationally, and NIH institutes. Stanford is now seen as the leader in research ethics consultation, with the “Stanford Model” now being adopted by dozens of research institutions throughout the country, primarily through the Clinical and Translational Sciences Award (CTSA) Program. The Ontario Genome Institute is also building a service on this model. In addition, BECS has also been cited as a model to serve scientists in other fields, such as nanotechnology research.

For the next five years of CIRGE, Dr. Cho is developing a new program, Integrating Values and Ethics into Science and Technology (INVEST), which will build on the ideas developed for research ethics consultation and is based on the conceptual framework of constructive technology assessment. This is an innovative program, unlike any other in this country, which aims to closely link the design of genomic research and technology with the needs of a variety of stakeholders. The intent of INVEST is to facilitate the translation of basic research to application and uptake by broader communities of downstream users and decision-makers, such as clinicians, patients, health insurers, policy-makers, researchers, and the general public.

Dr. Cho’s goals for the next few years are to test and refine the ethics consultation model and the INVEST method for facilitating the integration of ethical and social considerations into genetic research, and to expand them into other areas of biomedical science. She hopes to test the exportation of these models internationally.

Bioethics in Film:

It has been a busy past six months for the Program in Bioethics and Film, with two new ground-breaking films, a trip to the Sundance Story Lab, and the development of several new partnerships!

In their soon to be released film entitled *Rare*, Dr. Maren Grainger-Monsen and co-director Nicole Newnham demonstrate how individual determination can literally alter the course of research for a rare genetic disorder. In this moving feature documentary, Donna Appell, a dedicated mother, races against time as she unites people from around the world in a quest to cure her daughter’s rare genetic disease. This stunning documentary reveals the personal journey of individuals dealing with Hermansky Pudlak Syndrome (HPS), which includes albinism, blindness, a bleeding disorder and pulmonary fibrosis.

In conjunction with preparations for public distribution and a nationwide PBS broadcast, a special screening of *Rare* was held on July 13th at Stanford’s Clark Center Auditorium. The film was incredibly well received by a standing room only crowd.

Philip A. Pizzo, Dean of the School of Medicine, praised *Rare* and its ability to deepen our understanding by exploring ethical challenges and human illness. In his newsletter following the screening, Pizzo declared that “Dr. Grainger-Monsen, her colleagues and the Stanford Center for Biomedical Ethics provide a unique resource for Stanford, the nation and the world.”



Drs. Magnus, Grainger-Monsen, and Raffin at reception following the screening of Rare at Stanford.

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Coupled with their film distribution and broadcast endeavors, filmmaker's Grainger-Monsen and Newnham recently completed a thirty-minute version of *Rare* to meet further outreach objectives. They have partnered with the Northwest Association for Biomedical Research (NWABR) and are currently writing a national curriculum for high school teachers that will incorporate the film. Because of its teenage characters and intimate human story, *Rare* is an ideal vehicle for sparking awareness and interest in medical research among youth.

Grainger-Monsen and Newnham also have another film underway with astounding promise. Earlier this summer, their film, *The Revolutionary Optimists*, was one of only five films selected for the Sundance Documentary Edit and Story Lab. In this truly inspiring experience, seven Academy Award winning directors were flown in to work alongside the filmmakers, offering critical feedback during the rough cut of the film.

The Revolutionary Optimists is a documentary work-in-progress that brings attention to the urgent need to solve public health problems in the developing world. The film follows Amlan Ganguly, a Bengali visionary who has transformed some of Calcutta's poorest slums by educating and empowering children through theater, dance, and data. Pushing at the limits of optimism, Amlan and his youth have helped cause malaria and diarrhea rates to drop, and neighborhoods to transform. Amlan has been selected as the 2011 Ford Fellow by the Ford Motor Company Corporation. He is truly an emerging leader!

The Revolutionary Optimists is also fortunate to have been included in the ITVS Women and Girls Lead program. This initiative is designed to educate and connect women, girls, and their allies across the globe to address the challenges of the 21st century. We are in great company with other remarkable programs and it is humbling to see women and girls stepping into leadership roles and working to improve their communities, making innovations in science, the arts, business, and governance. Other important announcements for *The Revolutionary Optimists* include a recent partnership with Global Fund for Children. Their Video Active Girls Project helps young girls around the world participate in learning how to use media, and aligns with the aims of our film and outreach.

Because of the great work of so many individuals, we had the opportunity to make the keynote presentation for the Bay Area Video Coalition Producer's Institute on June 11th. Not only are these films making a difference within the medical world, but we are able to share our multi-platform approach with other filmmakers. Grainger-Monsen also has a new book chapter forthcoming in the new Health and Humanities Reader published by Rutgers University Press.

Program on Stem Cells in Society

Christopher Thomas Scott, Director of the Program on Stem Cells in Society and Senior Research Scholar at SCBE is the PI on the *Workforce Development in Stem Cell Research* grant funded by the NSF, which made great progress this year. They completed the materials for the first unit, From Embryo to Beating Heart. This course presents stem cell biology, emerging technologies, laboratory skills, and social issues as a unified body of knowledge designed to launch professional careers. The curriculum was tested at Stanford and three partner colleges including City College of San Francisco, UCSF, and Middlesex. The pilot was so successful that the class has been picked up by the Institute for Stem Cell Biology and Regenerative Medicine, to be taught again this Spring. To read an article about the success of the Stanford seminar, follow this link: <http://med.stanford.edu/ism/2011/june/stem-class-0606.html>.

Scott also worked with a group of Stanford researchers to raise ethical issues in the process for donating frozen IVF embryos to research. They describe a two-stage consent process that is designed to help couples make informed decisions while minimizing conflicts of interest and respecting patient choice. The study was published in *Cell Stem Cell* this April.

Scott worked with Jen McCormick, a former CIRGE scholar, Mindy DeRouen, a PSCS postdoctoral fellow, and Jason Owen-Smith at the University of Michigan to ask how the development of human induced pluripotent stem cells (hiPSCs) affected the trajectory of stem cell research. By analyzing co-authorship networks of stem cell research articles and use of stem cell lines, they found that hiPSCs are not a substitute for human embryonic stem cells. Rather, hiPSCs are a complement, and restricting funding for human embryonic stem cell research could have negative affects on the field of hiPSC research. This study was published in *Cell* in June.

Faculty Profile: Laura Roberts



Paula Bailey interviews Laura Roberts, MD, MA, Chairman and Katharine Dexter McCormick and Stanley McCormick Memorial Professor in the Department of Psychiatry and Behavioral Medicine at the Stanford University School of Medicine. She is a nationally recognized scholar and leader in ethics, psychiatry, medicine, and medical education.

Dr. Roberts has performed numerous empirical studies of contemporary ethics issues in medicine and health policy and has been funded by the National Institutes of Health, the Department of Energy, the National Alliance of Schizophrenia and Depression, the Arnold P. Gold Foundation, and other private and public foundations. In 2003, Dr. Roberts was appointed Editor-in-Chief for *Academic Psychiatry*. Additionally, she has recently developed several books.

Dr. Roberts, welcome to Stanford! It's really an honor to have you here. What are your impressions so far?

Oh, I'm so thrilled to be here! You know I've worked in a few different systems doing a combination of psychiatry, administration, ethics, and research, and to be here is just a wonderful opportunity.

Well, we're really thrilled to have you here. Let's start with some background. How did you get into this work?

I guess I was a typical “humanities kid” in college, and I was the first student to graduate from a new program in history, philosophy and social studies of science and medicine—one of these wonderful interdisciplinary programs at the University of Chicago. Before medical school, I also received my master's degree in another interdisciplinary program there—the “Conceptual Foundations of Science”—a combination of intellectual history, psychology, and also philosophy of science, more broadly. In this context I studied different theories in moral philosophy and learned about new approaches to ethics as linked with work in biology and sociobiology. I thought a lot about the kind of evolutionary pressures that would drive the emergence of altruism in different species. Probably a lot like other young people, I was very interested in questions around what makes us distinctly human—would conscience and moral approaches in life be part of what makes us distinctly human, I wondered? That was the kind of intellectual work I was doing. I studied Freud and Darwin, lots of emerging biology and neuroscience, and I worked in animal behavior laboratories and did field work studying bird behavior in Australia. These were really phenomenal, formative experiences for me intellectually and personally.

My father was a physician and my mother was a nurse, so at the time I thought that there was no way I was going into medicine! One of my teachers in college recommended I work at a school for emotionally disturbed kids, however, which changed my path. I learned a lot, both negative and positive, in that time. My work with the kids really inspired me to go into medicine to understand the medical and biological underpinnings of mental illness. In that experience I also learned that people who are too ideological, too dogmatic, and not self-reflective enough can actually begin to do harm to others, even though they cannot see it. What I saw at the school was a group of people who had acquired a certain mindset, a certain perspective. Despite their dedication to the well-being of the children, they were blind to the medical issues in the kids. The staff did their work with passion and effort and good hearts, but operated from a certain very limited ideological perspective. It was a perspective that overvalued certain considerations and neglected what I now know to be important neurodevelopmental and medical issues. At the time, I wasn't quite sure what was “wrong,” but I knew that something was. Their theoretical framework didn't allow neurobiological and medical factors to come into their thinking.

This experience taking care of children with mental illness really made me keenly aware of how, even with the best of intentions, people can do things that they do not intend. It also made me attentive to the situation of people who are vulnerable. And children and children with mental illness are very vulnerable populations. I have always felt that this experience made me a

Faculty Profile (continued)

physician-scientist, as well as an ethicist. It made me understand that you've got to know your science, you've got to be an accurate observer, you've got to be willing to be wrong, you've got to be willing to test your ideas in the context of real lives, and you've got to be humble about your ideas when they are applied in the real world.

When I was in medical school, I had the wonderful problem of loving everything I did! I loved surgery, I loved psychiatry, I loved working in communities, I loved being in the clinic, I loved working in a lab. Everything was great, and I thought about several different specialties, but I think I really wanted to stay true to my original motivation, which was working with vulnerable populations. I really wanted to work in this amazing and rapidly developing field of psychiatry.

I met a wonderful mentor during my medical training—a general medical internist, Mark Siegler. At that time, I had my first child and I took a year off from medical school and worked with him in setting up the Center for Clinical Medical Ethics at the University of Chicago. That was in 1984 and 1985. It was amazing to be so young and to feel a part of the whole new developing field of clinical ethics. I participated in ethics seminars and ethics committee work, and learned a lot about how to analyze the ethical aspects arising from the care of individual patients. The teachers were brilliant, and they were also plainspoken and modest individuals. It was a privilege to work with people who were social scientists as well as outstanding thinkers in the areas of law, policy, literature, and clinical medicine. In that time, I learned about the methods that could be used to investigate questions of ethical importance.

My first empirical work really had to do with ethical issues encountered by medical students with health issues. In my case, I had a child as a medical student. This was a wonderful, normal, healthy kind of development in my life, but it taught me a lot about how awkward it is to be both a medical student and a patient in my training institution. Classmates with health issues surrounded me—really serious health issues that went unrecognized, denied, untreated. I will never forget going to the ICU searching for patients to interview so that I could practice my history-taking skills in the middle of the night. I discovered one of my classmates had been hospitalized after taking an overdose of antidepressants in a suicide attempt. I left right away, and I didn't tell anyone, and he was transferred to another hospital before morning. I had another classmate who had terrible GI symptoms, and he was told by an attending that he needed to learn to handle the stress of medical training better. It turned out that he had ravaging

Crohn's Disease. He dropped out of medical school later that year. These experiences taught me a lot. By paying attention and being aware, I could see complex ethical and clinical issues that arise for people who are trainees and patients at the same training institution. I was also struck by the irony of it—if there was a group of people who ought to be able to access health care, it was health care providers and trainees! I didn't have the words for it, but I was beginning to understand how dual roles create ethical vulnerabilities.

That was my first original work—beginning to look at ethical issues in health care for physicians and physicians-in-training. The literature had a bit about psychiatric issues and addiction in residents, for example, but nothing that looked at the spectrum of illnesses that medical students might naturally experience. That was the time of HIV and the fear of needle sticks, too—an occupational hazard that medical students and residents feared, because we drew all of the bloods, put in lines, and handled a lot of the specimens in the hospital. This work also had a very positive piece to it, too. I learned that medical students and residents who had been ill, or who had loved ones who had experienced serious health issues, were amazingly compassionate. They never treated patients like objects or “~~hits~~” or burdens. Physicians-in-training who had been patients, who had walked in the shoes of a person dealing with illness, were always kind and did not become cynical. From this, I also learned that dual roles not only create vulnerability but can inspire empathy and consolidate the identity of a young physician in a very positive way. My work in this area really became a “~~labor~~ of love.”

I went from the University of Chicago to New Mexico, and I entered the field of psychiatry. Given the opportunities I had, everyone around me thought that these were unusual choices, to say the least! I am glad that I followed my intuition. I wanted to be in an exceptionally innovative educational environment, to be in a place that had a profound sense of “~~ealing~~,” and to be somewhere where I felt it would be possible to make a difference while I gained my skills. It was humbling and often overwhelming and always amazing to care for the very ill patients we had—underserved populations from many different ethnic and cultural backgrounds in New Mexico, a border state with Mexico. There was extreme poverty. We often saw patients with very advanced neuropsychiatric disease who had never received any treatment. Their families cared for them, against all odds and with almost no resources. I learned how to do good with nothing. I learned how to make a difference with only your own knowledge and your ability to problem-solve or engage others to use their strengths to get through another day. I met the most courageous patients and families. I learned that as a physician you should talk with people, listen in an

Faculty Profile (continued)

open-hearted way, and to try to address problems. But you can't fix certain things. Even when you can't make things right, though, you can help people bear their suffering by being with them and not turning away. That is often our greatest responsibility.

After my training I stayed on as faculty at the University of New Mexico. I worked as a consultation-liaison physician in the hospital and as the associate director for medical student education. I was writing a lot, mostly inspired by my patients and by major ethical and policy controversies in American medicine. I became very interested in end-of-life care practices and the vulnerability of seriously ill individuals with unrecognized mental illnesses, including delirium, in medical settings. Around then, I received two Young Investigator Awards from the National Alliance for Research on Schizophrenia and Depression to study ethical issues in psychiatric research. Mine was the first ethics grant funded by this organization. I proposed to do something that was quite simple, namely, asking people with schizophrenia about their attitudes and experiences in research, rather than paternalistically assuming that they were too vulnerable or unaware to have views on this topic. These projects were inspired by my experiences as an intern, and later, in taking care of people living with schizophrenia.

I then performed studies funded by the NIMH and NIDA with several wonderful colleagues in which we compared perspectives of people with HIV, cancer, schizophrenia, PTSD, and other illnesses to see how they approach the research situation to help sort out the ethics issues that were big public policy debates at the time. I knew from my clinical work that there were times when my patients who were enrolled in the clinical trials of my colleagues clearly understood what they were getting into. They very generously gave of themselves to these research projects to help others in the future and to help science. On the other hand, I could also tell that there were times when patients really didn't understand. They had misplaced hopes that distorted the choices they were making about research participation, or they were very decisionally compromised. I wanted to use empirical methods to understand this, and I wanted to begin understanding the assumptions that existed in the literature. One assumption, for example, was that a person with depression might be alright to consent to be in research, but a person with schizophrenia would be too vulnerable, by definition, to ethically participate. Similarly, there was an assumption that a person with HIV or with cancer could be in an extremely aggressive clinical trial and that this wasn't only ethically permissible, it was considered to be a "patient's right" to access these innovative treatments. This was all illogical to me. I knew amazingly insightful and altruistic people with schizophrenia and I knew desperate

cancer patients. I knew that ethical participation in human research was governed by many factors beyond the nature of the illness. It was also clear that consent was not a simple, rule-based phenomenon: I figured there had to be a "break point" in the capacity for consent for certain kinds of studies, and a different "break point" in the capacity for consent for other kinds of studies, and that diagnosis alone was not the determining factor. In fact, the assumptions I saw in the literature struck me as prejudicial and as damaging to the very people they were intended to help. This was an old and familiar theme to me at this point.

Then I started studying rural health disparities, particularly in the context of stigmatizing illnesses. I came to understand how stigma works in small communities—how stigma itself becomes a barrier to care, which is particularly tragic in rural and frontier areas. These insights from clinical and health care systems administrative work led to an extensive collaboration with people in Alaska and New Mexico and a longstanding project funded by NIDA. We have now gone on to study many different potentially vulnerable and disadvantaged populations, all inspired from this original work and collaboration. More recently, I have turned to studying genetics ethics issues in the workplace and in psychiatric research. This work has been funded by the DOE, NIMH, and NHGRI, and we are now writing up our findings.

Increasingly I find that I am drawn to doing studies that help to understand the distinct concerns of people who have multiple and overlapping sources of vulnerability—the rural runaway with addiction and medical illness, the person with schizophrenia who is nearing the end of his life, the severely ill individual who has exhausted all of her treatment options, the impaired physician who is too scared to seek help, the mentally ill prisoner who wishes to participate in research. This is the work I feel most compelled to pursue and will be continuing to do in the future.

I've always been involved with IRBs and patient care ethics committees, and have done professional reviews around professionalism issues for national organizations and local organizations. I've been reluctant to do this much of the time, because I think it's wrong for ethicists to become the "conscience" of their institutions. We are just people who are practiced at thinking through certain complex problems, who are knowledgeable about relevant literature, evidence, and best practices, and who are willing to struggle through the imperfections of real-life situations to arrive at a next step. Most of us do this with a good deal of humility. It really helps to have common sense and to be prepared for the next set of ethical issues that will inevitably follow from the initial set of ethical issues.

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You also have to be prepared for things that are unimaginable and for contradictory views when you are in novel situations. This is absolutely true in psychiatric ethics. We have really hard and really unexpected ethical issues. For example, I once took care of a patient with schizoaffective disorder who had been severely ill. His arm was scarred because several years previously he had had auditory hallucinations that had directed him to saw off his arm, as terrifying as that sounds. He did begin to saw off his arm. Fortunately, he was discovered and taken to the hospital by his sister. Though the patient was ambivalent about the procedure, the surgeons reattached his arm. Afterward there was a debate about whether he had adequately consented to the reattachment and whether his rights had been violated by this surgery. Basically, this was an actively psychotic person with symptoms that caused life-threatening self-harm. This was a disease-driven behavior, and the need for surgery was great and the outcome was time-sensitive. In my view, it was absurd to question the surgeons' good sense in helping this patient by reattaching his arm. This argument might make sense in the courtroom, but for physicians in the emergency room or the surgical suite, or for the psychiatrists who "clear" the patient for immediate intervention, it is another matter. Another example is end-of-life care issues with people who have undiagnosed mental illness. These are complicated questions that you can't approach in a naïve way, and it is especially wonderful that we now have evidence to help understand and resolve these questions. The data are that, for example, people living with cancer who request physician assisted suicide are commonly depressed or in extreme physical pain; when they receive adequate clinical treatment for depression and/or pain, their desire to live is restored. This scenario is an example of something that has the appearance of an ethical problem but is really a clinical care problem. When we perform outstanding care, many—not all—of the seemingly "ethical" problems of medicine resolve themselves very quickly.

How do you see the role of empirical and interdisciplinary work in bioethics evolving?

Bioethics as a field has really evolved. Early on, the entire field was really grounded in philosophical argument—really elegant philosophical argument. In the late 1970s and 1980s, there were fiery debates around technology and medicine, mostly around ventilator support. Henry Beecher's *New England Journal* paper described how vulnerable patients were routinely exploited in the name of science, and the "It's Over, Debbie" narrative in which a physician described euthanizing a patient was published in *JAMA*. Stories of Baby Doe, Baby Fae, Barney Clark, and others filled the popular media. These accounts riveted the country. The issues became very real. New ways of conceptualizing ethical issues in medicine emerged, and people were beginning to apply these theoretical

models to real life situations. Then what happened was the emergence of empirical work — scientific inquiry in which one could take these ideas and begin to explore patterns. Then the NIH doubling period occurred, and NIH began investing in topics of ethical relevance such as informed consent in the context of research. The Human Genome Project was getting launched. The NIH carved out a portion of their budget to be dedicated to ethics questions and the implications of the human genome project for society.

Data-driven work does not replace elegant conceptual work; both are needed for our field to thrive. It is just that certain questions are addressed by data, whereas other questions are inherently different. The world gives us both, and there is a great mutualism in the contributions of conceptual and empirical bioethics. It all fits together.

You have made seminal contributions to the field of informed consent and capacity assessment. What are the most critical problems with the way patients are assessed?

I've done a lot in informed consent and capacity assessment. This has been my clinical work for many years, and some of my research has centered on these clinical ethics practices. Most of my work has been focused on subtler aspects of decisional capacity, such as the capacity for appreciation, on the context for consent, and the capacity for voluntarism. For example, voluntarism has been seen historically as, in essence, the absence of coercion. I view voluntarism as a much more positive capacity, with multiple dimensions to it. An authentic expression of one's wishes, an expression of one's self. Decisional capacity has more factual and rational components to it, but there's also a notion of appreciation. This is a more cognitively complex process that goes beyond knowledge, reasoning, and simple logic to integrate one's personal values and self-reflection to arrive at a decision, an insight, a choice that's true to you. That's the kind of work that I do. It is a murky area, not easily amenable to study or rigorous understanding. That makes it all the more interesting. I really like these murky areas and midwifing clarity where you can.

As co-chair of the American Psychiatric Association task force on research ethics, what are some of the major issues you addressed?

With Jeffrey Lieberman and a wonderful group of colleagues, we tried to help our field by laying out the cardinal principles in psychiatric research ethics. There were huge controversies, often involving prejudicial attitudes that were damaging to people with mental illness—whether they were capable of consent, altruism, and self-advocacy, for instance. It was assumed that people with

Faculty Profile (continued)

neuropsychiatric diseases would always be misled by the therapeutic misconception. The task force report helped articulate the issues and the guidelines of the field.

What I have learned is that people with physical and mental illnesses alike express thoughtful, altruistic, and careful views about human research. People with neuropsychiatric diseases have the same hopes as other participants of research. I have data from a series of studies—amazing work where people with schizophrenia will tell you that they understand the difference between research and clinical care, the difference between what they expect will happen, and what they wish would happen—very subtle issues. I have data derived from interviews with hundreds of severely ill individuals talking about the importance of science and their desire to help others through participation of science. Extraordinarily heroic people.

How has your training in ethics contributed to your work in psychiatry?

I would say that psychiatry has helped me more with ethics than ethics has helped me with psychiatry, because in psychiatry what you learn is to be very careful about understanding your motivations, the reasons that fuel your beliefs, the influences on the positions you take, the psychological investment in having certain positions that are not grounded in anything but your own psyche. It brings a kind of intellectual rigor, a self-honesty that is very valuable in doing ethics. I think psychiatric ethicists are very humble people, for the most part, because they understand that if they hold a belief passionately, with equal measure they should evaluate why they are holding that belief! I think psychiatric ethicists really work very hard to strip away personal motivation that might distort their work or their recommendations. Psychiatry has been a great gift to me in doing ethics work. I think attention to ethics has made me a better teacher of psychiatry and a better practitioner of psychiatry.

Let me just tell you one last piece, which is about administration. I love leadership activities and administration. Most people think administration is like Dilbert. You need a clipboard, a bad haircut, a broken computer—and most importantly you need to be clueless about what matters. For me, it is the opposite. It is wonderful work, and it is the work I feel best suited to, and certainly it is the perfect expression of ethics. You're using your best judgment, you're using your skills and experience, and you are doing all of this to help others do great professional work and to help those who need you so that they may have better lives. At a medical school, you're using what you know about all the different aspects of academic medicine to support the development of students, to build science that's going to change the future of medicine and future of society, to help patients through the creation of new methods of care. And you're helping communities, offering something in return to those who have entrusted you with such special work in this life. ✨

People News

Rachelle Roxas – Administrative Associate

Rachelle Roxas joined SCBE in November 2010 as Administrative Associate. She graduated from Hawaii Pacific University in May 2009 with an MBA in Management. Her BS is in Business Administration, with a concentration in Marketing from San Jose State University. Rachelle worked for Tosoh Bioscience as Marketing Communications and Tradeshow Events Manager for six years before moving to Hawaii to pursue her MBA. She worked for Hawaii Pacific University as Coordinator for Campus Activities and Student Center before moving back to the Bay Area.



Inna Sayfer and Rachelle Roxas

Inna Sayfer – Research Project Manager

Inna Sayfer has joined SCBE as the new Research Project Manager for the Human Microbiome Project. Inna holds a Stanford BA in Quantitative Economics and a PhD in Political Science. Her doctoral thesis looked at the political economy of Russia's dependence on trade in oil and gas. Prior to joining SCBE, Inna worked as an Associate Researcher with the Stanford Program on Energy and Sustainable Development. Her most recent publication is a co-authored chapter on Russia's gas giant, Gazprom, to be published by Cambridge University Press in November, 2011, in an edited volume entitled, *Oil and Gas: State Owned Enterprises and the World's Energy Supply*.

Sally Tobin Retires

Sally Tobin, PhD, MSW, Senior Research Scholar, has retired from Stanford, after fifteen years at SCBE. A party was held in her honor to celebrate her many contributions to Stanford and the center. Sally's most recent projects include both live and computer-mediated educational programs about the genetic revolution in medical care, the environment, and society, sparked by the rapid advances in our knowledge about genomics. She has also worked in research ethics and on use of genetic information on addictions in the legal system. Fortunately for SCBE, though Sally is officially retired, she continues to contribute to two ongoing projects and can often be spotted at SCBE events. Her view is that since she is now retired, she can participate in a wide variety of fun activities, some of which happen to occur at SCBE.



Visiting Scholar – Dr. Changwoo Lee

SCBE welcomes a new visiting scholar, Dr. Changwoo Lee, who will be collaborating with us for the next year. He is an Associate Professor in the Department of Pediatrics, in addition to managing medical student training at Wonkwang University in South Korea. His research will focus on why the number of female medical students in the U.S. is rising, with the goal of better anticipating the needs of future women doctors, resulting in the promotion of healthier medical residents, patients, and communities.

Recent Publications

Joanna H. Fanos

Fanos, J. H., S. Gronka, et al. (2011). "Impact of presymptomatic genetic testing for familial amyotrophic lateral sclerosis." *Genet Med* 13(4): 342-348.

Fanos, J., L. Wiener, et al. (2010). "Potential Impact of Genetic Information on Childhood Sibling Relationships." *Handbook of Genomics and the Family*(Issues in Clinical Child Psychology): 141-161.

Henry T. Greely

Frueh, F. W., H. T. Greely, et al. (2011). "The future of direct-to-consumer clinical genetic tests." *Nat Rev Genet* 12(7): 511-515.

Greely, H. (2010). "To tell the truth. Brain scans should not be used for lie detection unless their reliability is proven." *Sci Am* 303(6): 18.

Greely, H. T. (2011). "Reading minds with neuroscience - Possibilities for the law." *Cortex*.

Greely, H. T. (2011). "Get ready for the flood of fetal gene screening." *Nature* 469(7330): 289-291.

Greely, H. T. (2011). *Of Nails and Hammers: Human Biological Enhancement and American Policy Tools*. *Enhancing Human Capacities*. J. S. Ruud ter Meulen, Guy Kahane, Wiley Blackwell.

Greely, H. T. (2011). *Neuroscience and Criminal Responsibility: Proving "Can't Help Himself" as a Narrow Bar to Criminal Liability* *Law and Neuroscience, Current Legal Issues*. M. Freeman, Oxford University Press. 13.

Greely, H. T. (2011). "Law and the Biosciences." *The Stanford Lawyer*: 84.

Greely, H. T. (2011). "Time to Raise Some Hell." *Gene Watch*: 24.

Greely, H. T. a. A. D. W. (2011). *Reference Guide on Neuroscience*. *Reference Manual on Scientific Evidence*. Washington, D.C., National Academies Press/Federal Judicial Center.

Murphy, E. R. a. H.T.G. (2011). *What Will Be the Limits of Neuroscience-Based Mindreading in the Law?* *The Oxford Handbook of Neuroethics*. J. I. a. B. Sahakian, Oxford University Press.

Ormond, K. E., L. Hudgins, et al. (2011). "Medical and graduate students' attitudes toward personal genomics." *Genet Med* 13(5): 400-408.

Recent Publications (continued)

Katrina Karkazis

Karkazis, K. (2010). "Looking at and talking about genitalia: understanding where physicians and patients get their ideas about what's normal and what isn't." *Med Humanit* 36(2): 68-69.

Karkazis, K. (2010). "Children with Disorders of Sex Development: An Updated Approach to Optimize Care." *Pediatrics in Review* 31(11): 82-85.

Alfred T. Lane

Sbicca, J. A., E. S. Gorell, et al. (2010). "The integrity of the dermatology National Resident Matching Program: results of a national study." *J Am Acad Dermatol* 63(4): 594-601.

David Magnus

Magnus, D. and M. Allyse (Forthcoming). Biopiracy. *The International Encyclopedia of Ethics*, Hugh LaFollette

Vernez, S. and D. Magnus (Forthcoming). "Can the Dead Donor Rule be Resuscitated?" *Am J Bioeth.*

Ormond, K. E., L. Hudgins, et al. (2011). "Medical and graduate students' attitudes toward personal genomics." *Genet Med* 13(5): 400-408.

Havard, M. and D. Magnus (2011). "Beyond the IRB: local service versus global oversight." *Am J Bioeth* 11(5): 1-2.

Havard, M. and D. Magnus (2011). "Sexless reproduction: a status symbol." *Am J Bioeth* 11(3): 1.

Magnus, D. (2010). "The history of the American Journal of Bioethics." *Am J Bioeth* 10(10): 3.

Kelly E. Ormond

Ormond, K. E., L. Hudgins, et al. (2011). "Medical and graduate students' attitudes toward personal genomics." *Genet Med* 13(5): 400-408.

Lauren Sayres

Sayres, L. C., M. Allyse, et al. (2011). "Cell-free fetal DNA testing: a pilot study of obstetric healthcare provider attitudes toward clinical implementation." *Prenat Diagn.*

Chris Scott

Scott, C. T., J. B. McCormick, et al. (2011). "Democracy derived? New trajectories in pluripotent stem cell research." *Cell* 145(6): 820-826.

Kalista, T., H. A. Freeman, et al. (2011). "Donation of embryos for human development and stem cell research." *Cell Stem Cell* 8(4): 360-362.

Simon, B. M. and C. T. Scott (2011). "Unsettled expectations: how recent patent decisions affect biotech." *Nat Biotechnol* 29(3): 229-230.

Scott, C. T., J. B. McCormick, et al. (2010). "Federal policy and the use of pluripotent stem cells." *Nat Methods* 7(11): 866-867.

Scott, C. T., M. C. DeRouen, et al. (2010). "The Language of Hope: Therapeutic Intent in Stem Cell Clinical Trials." *American Journal of Bioethics Primary Research* 1(3): 4-11.

Simon, B. M., C. E. Murdoch, et al. (2010). "Pluripotent patents make prime time: an analysis of the emerging landscape." *Nature Biotechnology* 28(6): 557-559.

Murdoch, C. E. and C. T. Scott (2010). "Response to open peer commentaries on "Stem cell tourism and the power of hope"." *Am J Bioeth* 10(5): W1-3.

Murdoch, C. E. and C. T. Scott (2010). "Stem cell tourism and the power of hope." *Am J Bioeth* 10(5): 16-23.

Caulfield, T., C. Scott, et al. (2010). "Stem cell research policy and iPS cells." *Nat Methods* 7(1): 28-33.

Scott, C. T. (2010). "Teetering on the brink." *Nat Biotechnol* 28(10): 987.

Scott, C. T. (2010). "Never Again." *Nature Biotechnology* 28(2): 131.

Audrey Shafer

Gardner, C., L. Golestaneh, et al. (2010). "People say there are no accidents: Poetry and Commentary." *Journal of Medical Humanities* 31: 257-263.

Reisman, J., S. Nigliazzo, et al. (2011). "For There is Work to be Done: Poetry and Commentary." *Journal of Medical Humanities* 32: 245-250.

Shafer, A. (2011). "Carol Cassella's Healer." *Book Review CSA Bulletin* 60(1): 87-88.

Shafer, A. (2010). Charles Dickens: A Tale of Two Cities. *Osler's Bedside Library: Great Writers Who Inspired a Great Physician*. M. LaCombe and D. J. Elpem, American College of Physicians Press: 169-177.

Shafer, A. (2010). The Use of Narrative and Metaphor in Anaesthetic Practice. *Handbook of Communication Skills in Anaesthesia and Critical Care*. A. M. Cyna, M. I. Andrew, S. G. M. Tan and A. F. Smith, Oxford University Press.

Shapiro, J. and A. Shafer (2011). "It doesn't look good": Teaching end of life care through Carver's poetry. *Carver Across the Curriculum: Interdisciplinary Approaches to Teaching the Fiction and Poetry of Raymond Carver*. P. B. Grant and K. Ashley, Cambridge Scholars Publishing: 47-62.

Shafer, A. (2011). "Emergence." *Anesthesiology* 114(5): 1236-1237.

Shafer, A. (2011). "A Foot." *Anesthesiology* 115(1): 205-206.

Shafer, A. (2011). "Operating Room Suite." *Anesthesiology* 115(1): 207-208.

Maya Wolpert

Cho, M. K. and M. N. Wolpert (2010). "Not yet in sequence: Clinical, technical, ethical questions linger over personal genomics." *Modern Healthcare* November 22: 24.

Larry Zaroff

Zaroff, L. (2011). "Equanimity." *Hektoen International: A Journal of Medical Humanities* 3(1).

SCBE Upcoming Events

(More information at <http://bioethics.stanford.edu>)

October 4, November 1, December 6, 2011 7:00 – 9:30 pm

Tuesday Evening Writing Group Series
SCBE Conference Room (62)
1215 Welch Road, Modular A

October 14, 2011, 7:30 pm

Wong Flew Over the Cuckoo's Nest
Performance by Kristina Wong
Cubberley Auditorium

November 2, 2011, 10:00 – 11:00 am

CIRGE Writing Seminar
Medical School Office Building, X-303
Future schedule at <http://cirge.stanford.edu/>

March 1, 2012, 6:30 pm

Public Reading by Rafael Campo, MD, MA
Cantor Arts Center Auditorium

October 5, 2011, 5:30 pm – 6:30 pm

21st Annual Jonathan J. King Lecture
Chris Feudtner, MD, PhD, MPH
Auditorium, 1st Floor
Lucile Packard Children's Hospital

October 19, 2011, 11:00 am – 12:00 pm

CIRGE Journal Club
Li Ka Shing Center, LK 308
Future schedule at <http://cirge.stanford.edu/>

November 5, 2011, 8:45 – 4:30

November One-Day Writing Workshop
Facilitated by Sharon Bray
Home of Audrey Shafer

April 11, 2012, 5:00 – 7:00 pm

Medicine and the Muse
Sheri Fink, MD, PhD
Li Ka Shing Center: Berg Hall
Stanford School of Medicine

October 10, 2011, 3:30 pm – 5:00 pm

Classic Readings in Genetics and Ethics
SCBE Conference Room (62)
1215 Welch Road, Modular A
Future schedule at <http://cirge.stanford.edu/>

October 26, 2011, 12:00 – 1:00 pm

SCBE Brown Bag Seminar
SCBE Conference Room (62)
1215 Welch Road, Modular A

January 26, 2012, 5:30 pm

Writers Forum featuring
Pegasus Physician-Writers
Cantor Arts Center Auditorium

October 2, 2012, 5:30 pm – 6:30 pm

22nd Annual Jonathan J. King Lecture
Ira Byock, MD
Li Ka Shing Center: Berg Hall
Stanford School of Medicine

Stanford Center for Biomedical Ethics

1215 Welch Road, Modular A
Stanford, CA 94305-5417

<http://bioethics.stanford.edu>

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