A message from the Center’s DIRECTOR....

In our Medical Center system, he was identified simply as a “John Doe.” He was brought in by ambulance, the ambulance having been called for by Eddy, a “friend” of John Doe’s. “Friend” is an interesting word to use because we really don’t know much about Eddy other than he encountered John Doe regularly enough on the street that, having not seen him for several days, he went to the alley where he knew John Doe had a mat and a few boxes.

The alley where John Doe lived was behind a strip mall in one of the many neighborhoods that form the grid of communities constituting Los Angeles. Eddy found John lying on his mat, delirious, incontinent and with evidence of vomit. Eddy thus called for an ambulance, relating the above. The ambulance brought John Doe to us, where he remained until he died due to a combination of cardiac, hepatic, renal, and respiratory failure. He never regained consciousness and his identity remained unknown.

Every major medical center in the nation takes care of patients such as John Doe. In fact, even our own hospital has taken care of so many John Does that “John Doe” by itself is not used; unidentified patients are given some sort of moniker which combines “John Doe” or “Jane Doe” with a series of numbers, thereby reflecting just how many John or Jane Does have ended up on our doorstep. Many do eventually get identified and hence their names replace the anonymity of “John Doe.”

But many are never identified, forever remaining simply “John Doe.” There is a sadness in knowing that individuals can become so estranged – from family, from friends, from community – that at the end of their lives they die so alone that even their names are lost.

Perhaps not as sad, but still troubling, is knowing that there are people such as Eddy. “Eddy” isn’t actually this person’s name. That’s my creation. Yes, there was a person who called the paramedics for John Doe, and he was familiar enough with John Doe to suspect that something may be amiss, knew where to look for him, and so checked on him and discovered he was ill. But Eddy didn’t want to give his name to the paramedics, he simply gave his report, then left. Since there was no indication that John Doe’s condition was the result of some sort of criminal activity, it seemed as if Eddy simply didn’t want to leave a trace between him and John. In so doing, we not only lost the ability to find out, possibly, who John Doe was, but also how to express our gratitude to Eddy for showing his concern for a man such as John Doe.

Instead, all we’re left with is a moment, a flash of recognition of some sort of effort to help another, a moment, upon reflection, for which we should be grateful.

When Louis Kutner published his landmark article, “Due Process of Euthanasia: The Living Will, A Proposal” [Indiana Law Review 1969; 44(4):539-54], his aim was simply to provide patients with a mechanism to refuse unwanted treatments at the end of life. But 45 years later, Advance Directives need not be solely focused on limiting treatment. They also serve as a means for formally identifying who should make decisions on one’s behalf when one is unable to make one’s own decisions. They also serve as an important means by which a person can articulate deeply cherished goals, values and preferences in light of which decisions about his or her healthcare may be made, and in the process, help all better understand this person who is now a patient.
A GLIMPSE INSIDE...
Serving as a Member on IRB Committees

Here at Cedars-Sinai, we love to answer questions. Some of these are rather simple and mundane – “Where is the coffee shop?” – while others are more complex – “Why do women experience heart disease differently than men?” Some of these more complex questions often relate to the research mission of the Medical Center. Indeed, the research endeavors of Cedars-Sinai involve many people in multiple departments. This research may involve basic science investigation – laboratory scientists advancing knowledge at its most basic levels – however, as an institution caring for patients, we also have the ability to perform clinical investigations as well. Clinical investigation involves testing of new medications, diagnostic tests and an array of therapeutic techniques, all of which aim to improve the way we take care of patients.

Because of the many tragedies in the past due to unethical conduct in the context of clinical research, Cedars-Sinai, as must all institutions receiving federal research funds, follows standards set by the Federal Government for clinical trials. This includes, at the core, having an Institutional Review Board which is tasked with insuring that potential human subjects are not taken advantage of. To satisfy this task, there are four separate IRB committees, each of which meets monthly to review protocols for new drugs, devices, and tissue banks.

Each Committee is comprised of researchers, physicians, nurses, statisticians, as well as members of the community. The CSMC staff members who serve on these Committee, moreover, come from many different departments and thus bring distinct points of view to the deliberations. As for the non-scientist community members, they are some of our hardest working members as they tread through mountains of scientific protocols all the while keeping human subject protections as their primary focus.

Using these unique perspectives, the IRB committees jointly ensure that research is done to minimize risk to research participants. Risks must also be balanced by the potential benefit of the participants. It is important to remember that these may include non-physical risks, such as emotional, psycho-social, economic or legal considerations. For example, advances in genetic testing have created the risk for discrimination based on one’s genetic history. IRB committees help assure that potential research participants are given clear, complete and correct information about the trial in which they consider enrolling; given the great diversity of Southern California, the IRB encourages study documents to be translated into the most common languages spoken in our area.

Consent must be obtained from potential research participants in a process that allows them to clearly understand what is going to be done in the research. Enrollment of research participants should be equitable as much as possible – obvious exceptions are made for conditions that only occur in certain populations, for example, in the elderly or among women. Information about the participants who are participating in research studies must be kept confidential and only information needed to complete the trial may be obtained. In certain protocols, Certificates of Confidentiality are obtained so that participant information cannot be disclosed in any legal proceeding, whether at the federal, state, or local level. The IRB also ensures that, as research is ongoing, data are reviewed on a routine basis and reviewed for new or unexpected side effects. Also the IRB requires that data monitoring evaluates the outcomes as the clinical trial goes forward.

Given these multitude of considerations and the diversity of persons involved in IRB reviews, it might not be surprising that occasionally significant differences of opinion occur. These always relate to an overwhelming desire to protect human subjects. Passionate discussions are, hopefully, always balanced by respect for, and deference to, each member of an IRB committee and what they bring to the table; still, discussions can, at times, become testy.

I have the distinct pleasure of being a pediatrician on one of the IRB Committees and for that Committee and others, I am asked to provide consultation on studies involving children. Regulations of research...
involving children are stricter for this vulnerable population. Children must give assent for any pediatric re-
search which must be documented formally. Those obtaining assent of the child must take into account the 
age, maturity, and psychological state of the child. Parents or guardians must also provide permission for the 
child to participate in the trial. Usually, both parents must provide permission for research that involves greater 
than minimal risk AND that does not have the potential for direct benefit to the pediatric research participant. 
However, if one parent is unavailable due to death or other significant circumstance, then only one parent may 
be able to provide the permission. Children who are in foster care have additional regulations for the consent 
process, ensuring the rights of this even more vulnerable group.

Overall, we, on the IRB, take great care in approving 
clinical research and get great satisfaction in this work. 

Christopher E. Harris, M.D. 
Associate Professor of Pediatrics 
Director, Pediatric Pulmonary Medicine 
Cedars-Sinai Medical Center 
Los Angeles, CA

September 17, 2014
“Autonomous Decisions and the Ethics of Nudging”
Jennifer S. Blumenthal-Barby, Ph.D., is an Assistant Professor of Medicine and Medical 
Ethics with the Center for Medical Ethics and Health Policy at Baylor College of Medicine and 
has an adjunct appointment in Philosophy at Rice University. Her research focuses on the 
ethical issues related to human judgment and decision-making (e.g., decisional biases and 
heuristics), especially in the context of healthcare decision-making.

October 15, 2014
“Stewardship of Medical Care”
Neil Wenger, M.D., is a Professor of Medicine and Health Services Research in the David 
Geffen School of Medicine at UCLA as well as the Director of The UCLA Health Ethics Cen-
ter and chair of the Ethics Committee at the UCLA Ronald Reagan Medical Center. An ac-
tive general internist, he also carries out research in the empirical study of clinical ethics, 
care of and decision making for the older patient, and quality of health care.

November 19, 2014 - Weinberger-Vermut Lecture in Genetics & Ethics
“Should We Extend the Human Life Span?”
S. Jay Olshansky, Ph.D., is a Professor of Epidemiology and Biostatistics in the School of 
Public Health at the University of Illinois at Chicago. The focus of his research to date has 
been on estimates of the upper limits to human longevity, exploring the health and public pol-
cy implications associated with individual and population aging, and global implications of 
the re-emergence of infectious and parasitic diseases.

December 17, 2014
“Public Trust and Biomedical Research: Do Research Institutions Deserve the Trust They Enjoy?”
Mark Yarborough,, Ph.D., is the Dean’s Professor of Bioethics in the Program of Bioethics at 
the University of California Davis Medical School. His primary area of scholarship and re-
search is ethical issues in biomedical research, with a special focus on matters related to 
trustworthiness in the biomedical research enterprise. He directs the ethics-related teaching 
and consulting activities of the University’s Clinical and Translation Science Center.
**Fall 2014: Educational Sessions & Meetings**

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*ENC = Ethics Noon Conference  
*ICU Ethics = ICU Ethics Roundtable for all Residents/Fellows assigned to an ICU during the given month  
*SICU Ethics = Surgical ICU Residents/Fellows Ethics Case Conference

For descriptions of the Ethics Seminar and Ethics Forum, please visit either our Intranet or Internet websites and go to the link “Educational Opportunities.”

For more information about any of the above events, please call the Center at 310-423-9636

**Good Reads...**

**Healing to All Their Flesh:** Jewish & Christian Perspectives on Spirituality, Theology, & Health. Edited by Jeff Levin and Keith G. Meador (Templeton Press, 2012). The editors of this collection have gathered together the writings of leading Jewish and Christian theological, pastoral, ethical, and religious scholars who explore the relationship between religion and health by examining issues of theology and meaning that lie at the foundation of religion’s supposed beneficial function.

**Critical Decisions:** How You and Your Doctor Can Make the Right Medical Choices Together. By Peter A. Ubel. (Harper Collins, 2012). In this passionate plea for patient empowerment, Ubel, a physician with backgrounds in bioethics and behavioral science, promotes ways to assist people in making medical decisions. The best choices must always take into account a patient’s particular values in which physicians “need to offer recommendations with humility and in a manner that invites divergence of opinion.”

**Ethics, Aging, and Society.** Edited by Martha B. Holstein, Jennifer A. Parks, Mark H. Waymack (Springer, 2011). The first major work in ten years to critically address issues and methodologies in aging and ethics, this book integrates well-developed philosophical arguments with empirical research, humanistic scholarship, and insights gained from practical experience to offers new ways of thinking about ethics that can handle the complexities and realities of aging in particular social contexts.

**Hippocratic, Religious, and Secular Medical Ethics.** By Robert M. Veatch (Georgetown Univ Press, 2012). Veatch challenges the presumption that professional groups have the authority to declare codes of ethics for their members. To the contrary, he contends that rule-specific duties must be derived from ethical norms having their foundations outside the profession, in religious and secular convictions. Further, these ethical norms must be comprehensible to lay people and patients.

Books featured in “Good Reads...” are available in the Medical Library. Please call 310-423-3751 for book availability and reserve a copy today!

If you have missed one of our Ethics Noon Conferences (ENC) Series and are interested in viewing them, the Medical Library has copies of the series dating back to November 2007. We invite you to check them out!

**Note from the Center’s Faculty...**

We would like to thank Chris Harris for his insightful contribution to this issue’s “A Glimpse Inside” as well as for his ongoing service as an original member of the Center for Healthcare Ethics’ Internal Advisory Board.

**C.H.E. Newsletter is a publication of Cedars-Sinai Medical Center.**

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Assistant Director: Virginia L. Bartlett, Ph.D.  
Associate Director: Kenneth Leeds, M.D.  
Management Assistant: Susanne Tiffer

We welcome your feedback.