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Jon F. Merz on Bioethics

By Norman M. Goldfarb

Jon F. Merz is Associate Professor of Medical Ethics and Vice Chair for faculty affairs of the Department of Medical Ethics at the University of Pennsylvania School of Medicine. He received a BS degree in Nuclear Engineering from Rensselaer Polytechnic Institute in 1978, an MBA degree from the University of North Florida in 1983, a JD degree from Duquesne University School of Law in 1987, and a PhD degree in Engineering & Public Policy from Carnegie Mellon University in 1991. He was a policy analyst at the RAND Corporation from 1992 to 1995, and has been at Penn since then.

How did you become a bioethicist?

A substantial portion of my professional and academic pursuits over the years has been motivated by a fundamental interest in risk and society. This interest began as an undergraduate student, with a focus on the regulation of nuclear power plants. It then segued through topics involving chemical and natural hazards, financial risks and insurance, tort law, risk perception, and decision-making under uncertainty. For the past dozen years, I've focused on biomedical technologies, informed consent, and human subjects research.

As a bioethicist, what do you do?

Bioethics is all about public policy, so I try to understand and address ethical issues, and advance ethical standards for the public welfare.

I teach. I primarily teach medical ethics and research ethics in the medical school and research ethics in our Master of Bioethics program. I've taught science and engineering ethics in the School of Engineering and Applied Science. I give ethics-related lectures in numerous courses in the School of Medicine, the Center for Clinical Epidemiology and Biostatistics, and occasionally in other programs and at other universities. I've also taught a course on Medical Innovation in our Master's program, and I am teaching a course on Developing World Research Ethics this spring term.

I mentor. I've worked with numerous students over the last 14 years on research studies performed in fulfillment of degree requirements, for self-paced class credit, or simply to satisfy student interests. I use these opportunities to inculcate an understanding of and respect for scientific methods and ethics. Equally important, I've been privileged to know and have influenced a group of wonderful students.

I perform policy-related research. My research interests range over a number of topics and fields. As a social scientist, I bring to bear qualitative and quantitative methods to gain factual insights. I spend most of my time trying to understand what is going on and assessing the ethical issues involved. Unlike some social scientists, my law, ethics and policy perspectives enable me — no, compel me — to not just describe what I observe, but also to be normative, in other words, to recommend solutions to problems.

I consult. I provide advice to various interest groups and firms. I have served on hospital and other institutional ethics committees, institutional review boards at Penn, RAND and elsewhere, the Penn Cancer Center's clinical trials monitoring committee, and a half dozen data and safety monitoring boards. I have provided advice on the ethical conduct of research to firms, hospitals, universities, researchers, the NIH, and foundations. I have

been an expert witness in several legal cases involving FDA regulations and human subjects research. I have provided expert testimony to Congress and other federal committees related to gene patenting.

I advocate. Several of my research interests have led me to provide direct assistance to advocacy organizations in reproductive rights, medical privacy, and access to essential medicines. The problem with being an advocate, of course, is that it can undermine the reputation for objectivity I try to maintain as a good social scientist and policy analyst.

Finally, sometimes I am a lawyer, including the practice of patent law. Fortunately, this activity ties into my advocacy and research interests.

The practice of bioethics requires good descriptive data, as well as normative ethics. This can present the largest challenge to what I do, as suggested above, because taking positions and drawing normative conclusions about social policies, professional practices or the like can be interpreted as bias. Of course, science is not objective. I feel that we can overcome the surface criticisms by openness – of sources of funding and other conflicting interests or obligations – and by thorough method, subjected to stringent peer review. As such, I attempt to target my work to scientific venues. At this, I have been relatively successful, and I intend to continue this work into the future.

I distinctly recall an article in the Chronicle of Higher Education that appeared not long before I completed my PhD. It discussed a then-new NSF program funding cross-disciplinary training of scientists. The NSF program manager was quoted as saying “we’re not training multidisciplinarians — those people don’t get jobs.” Be that as it may, bioethics is a natural home for multidisciplinarians. My multidisciplinary background is very helpful in looking at bioethics problems from different perspectives, so it helped me, at least, find employment.

What is the IRB Forum?

The IRB Forum (http://www.irbforum.org) is principally a forum for discussing topics related to institutional review boards. Robert M. (Skip) Nelson created the IRB Forum in 1997. I took it over in 2003. Membership has grown to over 7,300 members, most of whom subscribe to the discussion list. Members come from some 65 countries. About 5% of members log into the site each month, contributing 20 postings per day. The jobs board, perhaps the best source for IRB-related job hunting, gets about 10 new job listings per month. Thirty percent of members receive our employment emails or check for jobs on the website.

The Forum is largely made up of two groups of people: those who staff and sit on IRBs, and those who have an academic interest in human subjects research and regulation. Many people, of course, play both rolls. Most postings thus deal with administrative matters or ethical and legal issues.

Recent discussions, for example, have focused on pragmatic issues raised by use of the Web, both for conducting IRB meetings and for performing Web-based surveys. Privacy is a touchy area in which people seek guidance, and the Web has thrown an interesting twist on the topic.

There often are differences of opinion about gray areas that are not clearly resolved by the Common Rule. The Forum is very efficient at articulating different perspectives for members to use as they wish, but we do not pretend to offer “the answer.” Nobody knows how Forum participants use these insights, except anecdotally. In one case, a detailed debate about tissue ownership and exculpatory language in consent forms was extracted, refined and published in Research Practitioner under the debaters’ authorship [1:119, 2000].

Questions and issues are posted by a relatively large percentage of members, while responses come from a vocal and generally very well-informed and experienced group of people. In a sense, the Forum is akin to a volunteer advisory group, providing insight and advice to those who ask for it. Responses are usually excellent, but sometimes they are incorrect. We do not intervene to block or remove such posts, instead leaving it to the discussion to correct misperceptions.

Members do not always check the archives before posting questions. Every few months, someone new asks if paying subjects is coercive. Almost every time, there is a flurry of posts (including by me) arguing that money or other enticements are not coercive, because coercion arises from a threat of harm. Subject payments may constitute undue influence, but they cannot be coercive. Of course, this distinction does not affect their ethical quality. Note, however, that the "undue influence" construct has been questioned because IRB-approved research only poses reasonable risks in relation to potential benefits, so subjects induced to participate by payments cannot be said to be taking undue risks. (See Emanuel, J Law Med Ethics 2004; 32:100.)

Over the past few years, two of the most popular topics have been privacy and the use of human tissues in research. Of the 28,000 posts in the IRB Forum since 1997, over 1,300 involve privacy and about half that number involve tissues. Over 8,000 posts mention "consent." OHRP is mentioned in over 2,000 posts. The archive could provide an interesting source of data on the evolution of human subjects protection over the last 12 years.

What bioethics topics are hot now?

Bioethics ranges far beyond research ethics. Healthcare reform is perhaps the most important issue to which bioethicists are contributing. Another topic that seems to be emerging after years of stability is the persistent vegetative state and the definition of brain death because of some notable recoveries from severe brain injuries. Clinical advances may well require us to rethink end-of-life care, organ transplantation, and withdrawing care from patients. Within clinical research, globalization raises very difficult questions of exploitation, especially as it relates to autonomy and different ethical norms in different countries. One of my favorite examples is whether it is ethical to conduct a Phase I study in, say, Pennsylvania for a drug intended to treat a disease that is found only in Africa; indeed, this has been required by some local IRBs in Africa. Genetic data and biosamples also raise a lot of interesting bioethics questions with respect to ownership and use.

What projects have you completed recently or are working on now?

I have done a lot of work on privacy and genetics, particularly as it relates to use of human tissue in research. I'm currently looking at the practices and policies of researchers who collect, store and study biological samples from children. For example, do they obtain new consents when the children become adults? Should there be different standards for return of results or management of incidental findings when kids are involved?

I've devoted some effort in the last few years to looking at scientific misconduct and, for example, policies and practices of retraction and its consequences for scientists. In the most interesting study, to my mind, my colleague Barbara Redman and I identified mid-career scientists found guilty by the DHHS Office for Research Integrity of misconduct in the last 10 or so years. We examined their publication productivity, and we attempted to interview them. Only about a quarter of those we could track down were willing to talk to us; folks generally had put the event behind them and didn't want to revisit it. We found that scientists found guilty of misconduct typically retained scientific careers. Those who committed plagiarism were likely to survive in academia, while those who committed

falsification or fabrication generally moved to industry or perhaps to a profession like medicine or psychology. The article appeared in Science (2008: 321:775). We're currently expanding the study to early career scientists.

Going forward, I am working with a graduate student, Francis Barchi, on a project to develop and test research ethics training materials and methods in Botswana, which has a nascent research enterprise. The country is building a new medical school, so it needs to prepare for an increase in research activity in the years to come. While Botswana's regulators are looking to U.S. and other standards to guide development of their own rules, they need to consider local mores and perhaps address other objectives, such as access to the fruits of research, in their approach. Parallel to our training in Botswana, Francis and I will be co-teaching a course next term in our Master's program on research ethics in the developing world, specifically examining the evolution of standards and methods for addressing colonial antecedents of abuse and exploitation, cultural differences, and economic disparities.

What is your prognosis for the future of bioethics in clinical research?

Prognostication is such a risky business. I think there's no shortage of issues in clinical research that will benefit from bioethical research and consideration. Some of the topics that will continue to present difficult if not intractable problems are conflicts of interest, the selling of "personalized medicine" at the forefront of genetic discovery, the ethics and practice of research in developing countries, and liability of IRBs for allegedly negligent decisions and oversight.

One issue I am highly interested in studying is the use of screening consent, where a simplified consent is used solely for the purpose of performing screening tests to qualify potential subjects for study participation. My sense is that there's a lot of pressure from sponsors, investigators and even IRBs to use these simplified consents. My fear is that the reason isn't efficiency (after all, everyone has to review and approve two different consent forms!), but, rather, to enroll subjects who would not otherwise enroll. The hypothesis is that when a person consents to screening, they are psychologically committing to the study. Once they put one foot in the water, saying, in effect, "there's no harm in getting screened," it becomes hard for them to then refuse if they are found to be eligible. This method risks undermining voluntariness. I have heard no coherent arguments for either using these methods or for dealing with the risk to a free and informed decision to take part in research. Empirical research could help resolve this concern and shed light on the ethics of this emerging practice.

Interviewer

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