

UNIVERSITY OF MINNESOTA

## Reflections on “Vulnerability”

*By Debra DeBruin, PhD*

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Recent years have brought increased attention to ethical issues in research involving human participants, and a good deal of activity to achieve the appropriate oversight of such research. In this country, President Clinton’s Advisory Committee on Human Radiation Experiments, various federal offices, the US Congress, an array of professional and advocacy organizations, many bioethicists, and the media have all expressed concern about the adequacy of the current system for protecting participants in research. A number of reforms have been instituted in response to these concerns, including some restructuring of the oversight system and the adoption of new initiatives for education in the responsible conduct of research. The National Bioethics Advisory Commission will soon release its comprehensive review of the system and recommendations for further reform. Congress has been following the development of the

Commission’s report with interest, and is preparing to draft legislation in response to it.

Such close scrutiny of the system helps to assure that all persons volunteering to participate in research will be treated in a manner consistent with fundamental dictates of morality. The ethical treatment of human research participants involves a complex collection of issues. I personally find questions about the treatment of so-called “vulnerable populations” in research to be particularly compelling, and thought it would be appropriate to introduce myself to readers by sharing some of my thoughts on this subject.

Traditionally, certain groups of people have been considered especially vulnerable in research, and, therefore, to require additional protections. However, current federal regulations governing research involving

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### From the Director...

## Three Parents and a Baby

*By Jeffrey Kahn, PhD, MPH*

One of the leading reproductive medicine clinics in the United States has announced the success of a technique they developed to help women whose eggs don’t seem to fertilize and develop properly. It involves injecting non-genetic material (cytoplasm) from the inside of a donated egg into the infertile woman’s egg, to give it a needed boost for fertilization and development. Mixing the “boosted” egg and sperm in a test tube fertilizes it, as with any other in vitro fertilization.

The clinic reported the first successful births using this method, along with genetic analysis of the babies born as a result. It turns out that the non-genetic material in the donated shell or injected into the egg does in fact contribute some genetic information to the babies, leading some to comment that they have three genetic parents: the two women whose eggs are mixed along with

the sperm donor. Is this the beginning of genetically engineered children? Should we be creating babies by such experimental means, and what, if any, regulations ought to be imposed on them?

Are such children really the genetic products of three different people? The genetic contribution from the donated egg is limited at best, coming only from the DNA in tiny energy-producing organelles called mitochondria. This DNA can be fingerprinted and traced back to the individual from whom it came, so there is some unique genetic contribution. But on the scale of the individual’s entire genome, it is a tiny proportion compared to the contribution from the woman whose eggs are boosted and the man whose sperm is used to fertilize it. A more



*Jeffrey Kahn*

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# Thoughts on Nursing Work

By Joan Liaschenko, RN, PhD

As this issue of the *Bioethics Examiner* goes to press, the nurses from two hospitals in the Twin Cities area who have been on strike since June 2nd are scheduled for a contract ratification vote. The strike has been a grave concern to all involved parties. As a nurse and a new faculty member of the Center, I thought it would be fitting to introduce myself to readers by sharing some of my thoughts on the matter. No one disputes that the work of nursing is indispensable to the well-being of patients and to the day-to-day operations of health care delivery. It is precisely this indispensability that has raised questions about the morality of nurses' striking. Generally, those discussions have focused on the ethical issues related to the special duty of nurses to not abandon patients. Duties are important because they lay out the minimal expectations that society can expect from specific groups, but duty is not the only domain of significance in our ethical lives. I am more interested in the ethical dimensions of the meaning of work.

Work can be analyzed in a number of ways: as a physical transformation of material reality, as a social transaction, as identity, and as an economic transformation (Wallman, 1979). It may seem odd to think of nursing work as a transformation of material reality—it is not, after all, the turning of raw material into another product. But the individual who is sick experiences changes in their body for which they seek help. They want relief from certain symptoms. Nursing work is designed to relieve, contain, or prevent these symptoms; for example, nurses change dressings for someone who has a wound, helping to change the body from one state to another. The management of nausea and vomiting is another example. Much of this body work is “dirty work.” Sociologists and anthropologists have pointed out that all societies have what is called “dirty work” by which they mean work that deals with dirty, unwanted, discarded products. The people who do that work tend to be avoided and disparaged as if they were the work. Feminists have argued that work with the human body has always been considered dirty work and that throughout history it has been done consistently and primarily by women. They have pointed out that, in general, this work, (for example, elementary education, nursing, care of the elderly, and child care) has less official status and a claim to less of society's resources. However, even if not recognized as “dirty,” people clearly see nursing as physical work.

In addition, nursing work entails emotional work that is a kind of social transaction. Patients distressed by a diagnosis and anxious about coping with treatments, patients worried about who will care for their children, spouses, or pets call for a response. Responding to this kind of distress requires time, but in an efficiency-driven system, the work that is legitimated is body work, not emotional work. Because emotional work is a social transaction and not a product, it is invisible in a product-driven society. New nurses learn very quickly what the ‘official’ work is and what the unofficial work is. Emotional work is extra, frequently coming out of the personal time of nurses.

Nursing work also involves other invisible social transactions critical to health care. The amount of information to be communicated between multiple people, departments, and agencies is nothing short of monumental. Nurses do the overwhelming majority of this “in-between” work. An organizational theorist, Roy Jacques (1994) who studied nurses documented that the majority of their time is spent doing this work. Examples include transferring patients from one place to another, explaining to a physician what a patient has said about the treatment, clarifying orders, talking with families, keeping supervisors informed, requesting services and supplies, etc. In the absence of emotional work, health care is inhumane, uncompassionate, even brutal. In the absence of this information-exchange work, health care is chaotic, dangerous, even impossible.

Work is a central factor in how cultures value and imbue with status and privilege different kinds of work. Therefore, it is central to how people identify and define themselves and their value within society. In the United States, this is particularly salient since we routinely ask people about what they do. How they respond reveals the value society places on that particular work. For high status categories, such as lawyers, physicians, professors, engineers, architects, and high-level business, people readily disclose their occupations. Others are more reticent and some even apologize. “I’m just a nurse,” is commonly heard and such a description of identity reflects the embarrassment of doing “dirty work,” emotional work, and, perhaps, the working class origins of nursing. The development of organized nursing was a response to changing conditions of the times. Young women were moving from rural areas to towns and cities in search of work. But since “good” women didn’t work

Nursing work also involves other invisible social transactions critical to health care.

# Faculty Profile

## Joan Liaschenko, RN, PhD

Joan Liaschenko joined the Center for Bioethics and the School of Nursing as an Associate Professor in January of this year having come from the University of Wisconsin, Milwaukee. In addition, Dr. Liaschenko is an adjunct Associate Professor at the University of Calgary, School of Nursing. Recently, she was appointed as the first Associate to the International Centre for Nursing Ethics at the University of Surrey, England. She received her PhD from the University of California, San Francisco, where she also did post-doctoral work on the moral dimensions of nursing work with home care nurses and psychiatric nurses. She continues her interest in nursing work. A current project is looking at the correlation of American Nursing Association (ANA) and political action committee (PAC) money and voting records of incumbents in terms of their support of health related legislation. She is also exploring the ethical issues that arise in the work of nurses running clinical trials. She is the co-editor of *Nursing Philosophy* and the ethics

section editor of *Home Care Provider*. She has published widely, presents at numerous international conferences and has been a visiting scholar at the Joint Centre for Bioethics at the University of Toronto and the School of Nursing, Flinders University, Adelaide, Australia.

### Selected Publications

#### ARTICLES

Liaschenko J. Nursing Work, Housekeeping Issues, and the Moral Geography of Home Care. In Thomasma D, Weisstub D, Kushner T (eds.) *Volume on Aging, International Library of Ethics, Law, and the New Medicine*. Dordrecht, The Netherlands, Kluwer Academic Press, forthcoming.

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Joan Liaschenko

Joan Liaschenko, RN, PhD is Associate Professor, Center for Bioethics; School of Nursing, University of Minnesota.

## Recent Faculty Publications

#### BOOK CHAPTERS

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vulnerable populations are plagued with difficulties. What do we mean by vulnerability and who ought to be considered vulnerable? The regulations provide a list of examples to clarify which groups should be so classified: “children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons” (45 CFR 46.111(a)(3) and (b)). While the list may be illustrative, it is not exhaustive. Others could also be considered vulnerable. The Belmont Report, which provides the philosophical foundation for the regulations, also lists “racial minorities, . . . the very sick, and the institutionalized,” for example (National Commission 1979). Moreover, the claim that all of these groups are vulnerable is controversial; for example, many find the suggestion that pregnant women are vulnerable to be quite sexist. Unfortunately, the regulations do not supply any definition of vulnerability nor any analysis of the sorts of characteristics that render research participants vulnerable. In my view, the regulations ought not to speak of groups as being categorically vulnerable at all. For example, while economically disadvantaged persons may face troubling risk of exploitation in research that offers financial incentives or valuable medical care to which they may otherwise lack access in return for participation, they may be no more vulnerable than economically privileged persons in certain sorts of survey research. Vulnerability ought not to be conceived of as a characteristic of groups. Rather, certain traits may render certain persons vulnerable in certain situations.

**Of course,** absent a reasonable account of the nature of vulnerability, the regulations cannot offer defensible prescriptions about how we ought to treat those who may be vulnerable. Basic Department of Health and Human Services (DHHS) regulations—dubbed “The Common Rule” since they have been widely adopted across the federal government—offer very little guidance in this matter. They stipulate two requirements concerning those who are vulnerable, both unhelpfully vague. The first demands that “the selection of subjects is equitable,” but states only that those charged with the review of proposed research “should be particularly cognizant of the special problems of research involving vulnerable populations” (45 CFR 46.111(a)(3)). The second requires that “when some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as children, prisoners, pregnant women, mentally disabled persons, or economically or

educationally disadvantaged persons, additional safeguards have been included in the study to protect the rights and welfare of these subjects,” but offers no guidance about suitable safeguards (45 CFR 46.111(b)). Additional DHHS regulations—that have not been widely adopted—do specify more detailed protections for pregnant women and fetuses, prisoners, and children. But this is only a subset of those identified in the Common Rule as vulnerable. Thus, we need much more robust and uniform guidance than the current system provides.

**In addition,** the more detailed protections articulated for the particular groups just mentioned fall into two categories: they impose more stringent requirements for informed consent or limits on levels of risk to which the vulnerable may be exposed. While such paternalistic safeguards may be appropriate responses to particular varieties of vulnerability (for example, those to which young children are susceptible given their relatively undeveloped decision making abilities), we need to develop a broader array of strategies suitable for the full spectrum of diverse types of vulnerability. For example, economically underprivileged adults are susceptible to different vulnerabilities than are young children; while the former may be at increased risk of exploitation, they do not lack decision making capabilities, as the latter do. The ethical treatment of vulnerable participants in research is not a “one size fits all” affair.

**Unfortunately,** the paternalistic nature of the regulations’ “protections” for vulnerable participants has prompted some resistance against the use of the concept of vulnerability in the research context, except in very limited cases. If we think of the vulnerable as being unable to make informed decisions for themselves, and so as needing to be shielded from the risks of research, then we should not apply the concept as widely as it traditionally has been used. Consider, for example, members of undervalued groups in our society—persons who, because of their race, ethnicity, gender, age, socioeconomic status, and so on, are stereotyped, marginalized, exploited, subordinated. To insinuate that such persons are incapable of making informed decisions for themselves and so in need of our protection is to compound the injustices they face by further insulting and stigmatizing them. In addition, routinely excluding them from research in an effort to protect them from risk deprives them of whatever benefits research may offer.

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# Faculty Profile

## Debra DeBruin, PhD

Debra DeBruin joined the Center for Bioethics and the Department of Medicine, University of Minnesota Medical School, as Assistant Professor in December 2000. She received her BA from Carleton College magna cum laude with distinction in philosophy, and her PhD in philosophy from the University of Pittsburgh. She recently completed a Greenwall Postdoctoral Fellowship in Bioethics and Health Policy at Johns Hopkins University School of Hygiene and Public Health and Georgetown University.

In addition to teaching philosophy and bioethics, Dr. DeBruin has served as a health policy fellow for Senator Edward Kennedy (D-MA) in the Democratic office of the Health, Education, Labor and Pensions Committee of the United States Senate. Her responsibilities there encompassed diverse concerns, including Medicare reform and other health-related policy initiatives for senior citizens, pain management and end-of-life care, physician-assisted dying, and mental health and substance abuse issues. She has also worked as a consultant to the National Academy of Science's Institute of Medicine and the National Bioethics Advisory Commission on issues relating to the ethics of research. She is Project Director for the Robert H. Levi

Leadership Symposium on the ethics of Medicare reform, a forum designed to bring together eminent scholars with influential policy makers for extended discussion of fundamental moral issues concerning Medicare reform. Her areas of interest include the ethics of research involving human participants and public health policy.

### Selected Publications

#### BOOK CHAPTERS

Carse A, DeBruin D. Transforming Resistance: Shifting the Burden of Proof in the Feminist Classroom. In Cudd A, Superson A (eds.) *Theorizing Backlash: Philosophical Reflections on the Resistance to Feminism*, forthcoming.

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Debra DeBruin

Debra DeBruin, PhD, is Assistant Professor, Center for Bioethics; Department of Medicine, University of Minnesota Medical School.

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important issue may be genetic disease caused by defects in mitochondrial DNA, even though they are quite rare. Whatever genetic heritage is passed on from the egg donor to the resulting child will also be inherited by successive generations of children. So while the genetic change is neither controlled nor intended, it is permanent. How can we be sure that such heritable changes aren't harmful? We lack sufficient information and experience to be able to answer the question, so why not limit such experimental reproduction until we can?

It is very difficult to regulate research in assisted reproduction technologies because it is almost all done in the private sector, and research performed solely in the private sector is beyond the reach of most federal regulation. A researcher and physician at the clinic quoted in the *New York Times*, said he did not seek review by the federal oversight panel on DNA-related research such as gene therapy "because they didn't give us federal funds. I would be happy to talk to them if they

gave us funds." He's right that they were under no obligation to seek government approval, but that leaves consideration about the impact of the research up to the researchers themselves—the equivalent of leaving the foxes to guard the henhouse. Most researchers are people of great integrity, but they should not try to serve what may be conflicting interests.

Mixing the contents of two women's eggs is likely to be just the beginning of our efforts to manipulate eggs and sperm to help overcome infertility, to avoid disease and maybe even to enhance the characteristics of our children. These new abilities also bring serious responsibilities, but we lack the policy processes to link the two. It is time to close the loopholes that allow research on new reproductive technologies to avoid research oversight and regulation, especially when the success or failure it brings will be passed on to future generations.

*A version of this article appeared in an "Ethics Matters" column on CNN Interactive ([www.cnn.com/health](http://www.cnn.com/health)).*

outside the home, a compromise was struck between the cultural demands for specific womanly virtues and a workplace structure that would ensure their development—women could work outside the home as long as the hospital was structured like the home. Hospital organization was a Victorian family model in which nurses lived under the authority of the physician just as wives were subordinate to the authority of their husbands. While much has changed, much has remained the same. Nursing provided an option for women in Victorian times, opening doors to independence and an acceptable social identity. Today nursing is no longer one of a few options for women and, in fact, no longer affords a social identity that women seek. Indeed, it may be the “spoiled identity” described by Goffman 1963.

**Health care** is a huge industry—it makes money for some, provides services, and employs others. Even though the work of nursing has become more onerous with fewer nurses to do it, with more and more body work passed down the social hierarchy, nurses are more essential than ever. The body work is dirtier, the social transactions more complex, and identity less fulfilling. The in-between space in which nurses work is bigger and more crowded. Nurses are further from the patients, which they profoundly resent. The administrative structures now in place are huge corporate bodies that have replaced physicians and hospital administrators. The irony can't be escaped that it was physicians who, throughout the 20th century, fiercely resisted every effort to have a national health care system on grounds that it would interfere with medical practice. But it has come anyway through the corporatization of health care in the sector that they endorsed, the private sector. Under corporatization, nursing work has become even more invisible. There is the problem that even as nurses become more indispensable to the actual running of institutions, the knowledge necessary to this work is not currently commodified. Typically, commodified knowledge is knowledge that can be bought and sold. It is expert, skilled, highly specialized knowledge that is necessary to the production of some goods and services. Those persons who have commodified knowledge are indispensable to health care and those who do not are easily replaced and of limited use to corporations.

No one doubts, for example, the indispensability of surgeons. Death rates are visible. But because much of nursing work is invisible, the economic structures do not have to recognize or acknowledge the contribution of nurses in the same way.

**These issues** are important to ethics because they are concerned with the ethical domains of character and way of life. There is no clear dividing line between the ways in which work can be analyzed and the ethical issues they raise. Rather, there is much overlap but the categories do raise relevant questions of ethical significance. Regarding body work, there is the general issue of gendered work, gender relations at work, and cultural values and expectations regarding the body and how it is cared for. There is the issue of the kind of practitioners we can become and be in systems that fail to acknowledge the importance of our emotional lives by disallowing time to attend to the emotional work in health care. What are the implications for patient care when the self-identity of practitioners changes from someone holding certain values to someone constrained in acting on those values? The issues of concern to the striking nurses are health benefits, salary, and more control over the conditions effecting the kind and quality of their work. Historically strikes have addressed grave injustices under various degrees of industrialization. We do not yet know the harms that may accrue to nurses, patients, physicians, families, and others in the shift to a knowledge economy in the new social organization of corporatization under advanced capitalism. What will the injustices be in this system? How will they be experienced in day to day work? Who will be allowed to work and who will be denied? Strikes may or may not address the injustices in the new model. However, attention to nursing work is, and will remain, critical for the foreseeable future.

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Visit the Center's Resource Center at N504 Boynton, 410 Church Street SE, Minneapolis, MN; online at [www.bioethics.umn.edu](http://www.bioethics.umn.edu); or contact Gay Moldow, RN, MSW, Resource Center Director, 612-625-1610, or e-mail: [moldow04@tc.umn.edu](mailto:moldow04@tc.umn.edu).

## Center News

### FACULTY & ASSOCIATES

**Jeffrey Kahn, PhD, MPH**, has been promoted to Full Professor, Department of Medicine, University of Minnesota Medical School.

**Raymond DeVries, PhD**, and his colleagues were awarded an NIH grant of \$1,250,000, for a four year project entitled "The Ethical Problems of Deep Brain Stimulation (DBS)."

**Steven Miles, MD**, was nominated for the 2001 Healthcare Foundation of New Jersey Faculty Humanism in Medicine Award by the Minnesota Medical Foundation.

**N. Yasemin Oguz, MD, PhD**, has been awarded the 2001-02 Post-Doctoral Fellowship in the Center.

**THE CENTER FOR BIOETHICS** helps meet its general costs of operation, research and education projects by raising money from individuals, corporations, and foundations, and through grants from public and governmental sources. You can help support the work of the Center by providing tax-deductible charitable support. For more information call Carmela Kranz with the Minnesota Medical Foundation at (612) 625-1114 or reference the enclosed gift envelope.

*Vulnerability continued from Page 4*

However, members of such groups do face special risks of unjust treatment in the research context as in society more generally. Indeed, many of the most outrageous abuses in research have involved the unethical treatment of such persons. To adequately capture the vulnerability such persons may face in certain types of research, we must reform our understanding of the concept of vulnerability. Our current paradigm focuses too narrowly on difficulties with informed consent; we should instead think of vulnerability as involving special risk of unethical treatment in research more generally. Such a broader understanding of vulnerability should

## Calendar of Events

### JUL 14

Jeffrey Kahn, PhD, MPH, will speak on "Increasing Organ Availability and Compensation for Organs," at the Second Chance for Life Annual Educational Program, University of Minnesota Second Chance Foundation, Minneapolis, MN. For information, call 612-624-0123.

### JUL 30

Dianne Bartels, RN, MA, will participate on a panel discussion "The Future Legal Issues of Biotechnology," at the World Future Society's 2001 Annual Conference, Minneapolis, MN. For information, call 301-656-8274.

### AUG 3

Steven Miles, MD, will speak on "Organizational Ethics," at the Queen of Peace Hospital Ethics Committee, sponsored by Queen of Peace Hospital, New Prague, MN. For information, email: pangelucci@qofp.org.

### AUG 6

Jeffrey Kahn, PhD, MPH, will speak on "Individual Rights and Scientific Research: Protecting Human Subjects," at the American Bar Association Annual Meeting, Chicago, IL. For information, web site: [www.abanet.org/annual/2001](http://www.abanet.org/annual/2001).

### AUG 22

Steven Miles, MD, will speak on "Consumer Focused Services and Patient Rights," at the Minnesota Age Odyssey, sponsored by the State of Minnesota, St. Cloud, MN. For information, call 651-297-2989.

### SEPT 8

Steven Miles, MD, will speak on "New Topics in Clinical Ethics for Critical Care," at the Critical Care/Intensive Care Conference, sponsored by the University of Minnesota School of Medicine, Minneapolis, MN. For information, call 612-626-7600.

### SEP 10

Jeffrey Kahn, PhD, MPH, will speak on "Creation of a Stem Cell Donor," for the United Resource Networks' 10th Annual National Clinical Conference, Minneapolis, MN. For information, call 800-847-2050.

### SEP 14

Peter Ubel, PhD, Ann Arbor VAMC and University of Michigan will speak at the Center for Bioethics seminar series on the University of Minnesota campus, 12:15-1:30 pm. For information, contact the Center.

### SEP 28

Jeffrey Kahn, PhD, MPH, will speak at the Minnesota Association of Blood Banks Annual Meeting, Bloomington, MN. For information, call 612-871-3300.

### OCT 12

Debra DeBruin, PhD, will speak on research ethics at the "Professional Ethics in Health Care and Beyond" Conference sponsored by Minnesota State University, Mankato, MN. For information, call 507-389-6022.

enable us to better identify types of vulnerabilities and strategies to help offset them. Paternalistic protection is not always what is needed. In some cases, perhaps, we would do better to think in terms of empowerment—for example, giving some persons or groups greater voice in setting research agendas and designing studies. The ethical treatment of all persons in research requires such expanded vision.

### REFERENCES

National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. 1979. *The Belmont Report: Ethical Principles and Guidelines in the Protection of Human Subjects*. Washington, DC: DHEW.

Bioethics courses offered in fall semester at the University of Minnesota can be found on the Center's website at [www.bioethics.umn.edu](http://www.bioethics.umn.edu).

Center publications can also be accessed at the Center's website or contact the Center for information.

# Faculty and Staff at the Center

The Fall 2001 Bioethics

Examiner submission deadline is September 5. Submissions should be addressed to:

*Bioethics Examiner*, Center for Bioethics, University of Minnesota, Suite N504

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Telephone: 612-624-9440

Fax: 612-624-9108

E-mail: holmb006@tc.umn.edu

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## CENTER FACULTY

Jeffrey Kahn, PhD, MPH  
*Director, Center for Bioethics; Professor, Department of Medicine, University of Minnesota Medical School; Division of Health Services Research and Policy, School of Public Health; Department of Philosophy, College of Liberal Arts, University of Minnesota*

Dianne Bartels, RN, MA  
*Associate Director*

Debra DeBruin, PhD  
*Assistant Professor, Center for Bioethics; Department of Medicine, University of Minnesota Medical School*

Carl Elliott, MD, PhD  
*Director of Graduate Studies, Center for Bioethics; Associate Professor, Department of Pediatrics, University of Minnesota Medical School; Department of Philosophy, College of Liberal Arts, University of Minnesota*

Joan Liaschenko, RN, PhD  
*Associate Professor, Center for Bioethics; School of Nursing, University of Minnesota*

Steven Miles, MD  
*Professor, Center for Bioethics; Department of Medicine, University of Minnesota Medical School*

John Song, MD, MPH, MAT  
*Assistant Professor, Center for Bioethics; Department of Medicine, University of Minnesota Medical School*

Susan M. Wolf, JD  
*Faegre & Benson Professor of Law; Professor of Law and Medicine, Law School and Center for Bioethics; Director, Joint Degree Program in Law, Health & the Life Sciences; Chair, Consortium on Law and Values in Health, Environment & the Life Sciences, University of Minnesota*

## FACULTY ASSOCIATES

Muriel Bebeau, PhD  
*Professor, Department of Preventive Sciences, School of Dentistry, University of Minnesota*

Dan Burk, MS, JD, JSM  
*Professor, University of Minnesota Law School*

Ronald Cranford, MD  
*Professor of Neurology, University of Minnesota Medical School; Associate Physician, Department of Neurology, Hennepin County Medical Center*

Rosalie Kane, DSW  
*Professor, Division of Health Services Research and Policy, School of Public Health; Member of the Graduate Faculty, School of Social Work, College of Human Ecology, University of Minnesota*

David Mayo, PhD  
*Professor, Department of Philosophy, College of Liberal Arts, University of Minnesota, Duluth*

Gregory Plotnikoff, MD, MTS  
*Assistant Professor, Internal Medicine and Pediatrics, University of Minnesota Medical School; Medical Director, University of Minnesota Center for Spirituality and Healing; Staff Physician, Community-University Health Care Center*

Edward Ratner, MD  
*Assistant Professor, Department of Family Practice and Community Health, University of Minnesota*

Beth Virnig, PhD, MPH  
*Assistant Professor, Division of Health Services Research and Policy, School of Public Health, University of Minnesota*

## EMERITUS FACULTY

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Patricia Crisham, PhD, RN  
Muriel Ryden, PhD, RN

## VISITING FACULTY

Raymond DeVries, PhD

## POST-DOCTORAL FELLOW

N. Yasemin Oguz, MD, PhD

## RESOURCE CENTER DIRECTOR

Gay Moldow, RN, MSW, LICSW

## ADMINISTRATIVE STAFF

Candace Holmbo  
*Administrator*

LeeAnne Hoekstra  
*Administrative Aide*

Karen Howard  
*Principal Secretary*

Sarah Zins  
*Senior Office Specialist*

Jacob Larson  
*Information Technician*

## RESEARCH ASSISTANTS

Alicia Hall  
Ramona Ilea  
Josie Johnston  
Remo Ostini  
Susan Parry  
William Vann

University of Minnesota  
Suite N504 Boynton  
410 Church Street SE  
Minneapolis, MN 55455-0346

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