

UNIVERSITY OF MINNESOTA



Reflections on "Vulnerability"

By Debra DeBruin, PhD

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



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...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.

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.

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.

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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

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

Bioethics courses offered in fall semester at the University of Minnesota can be found on the Center's website at www.bioethics.umn.edu.

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

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.