



Against Special Protections for Medical Students

Author(s): Nancy R. Angoff

Source: *IRB: Ethics and Human Research*, Vol. 7, No. 5 (Sep. - Oct., 1985), pp. 9-10

Published by: The Hastings Center

Stable URL: <http://www.jstor.org/stable/3564191>

Accessed: 08/01/2009 11:19

Your use of the JSTOR archive indicates your acceptance of JSTOR's Terms and Conditions of Use, available at <http://www.jstor.org/page/info/about/policies/terms.jsp>. JSTOR's Terms and Conditions of Use provides, in part, that unless you have obtained prior permission, you may not download an entire issue of a journal or multiple copies of articles, and you may use content in the JSTOR archive only for your personal, non-commercial use.

Please contact the publisher regarding any further use of this work. Publisher contact information may be obtained at <http://www.jstor.org/action/showPublisher?publisherCode=hastings>.

Each copy of any part of a JSTOR transmission must contain the same copyright notice that appears on the screen or printed page of such transmission.

JSTOR is a not-for-profit organization founded in 1995 to build trusted digital archives for scholarship. We work with the scholarly community to preserve their work and the materials they rely upon, and to build a common research platform that promotes the discovery and use of these resources. For more information about JSTOR, please contact support@jstor.org.



The Hastings Center is collaborating with JSTOR to digitize, preserve and extend access to *IRB: Ethics and Human Research*.

<http://www.jstor.org>

Against Special Protections for Medical Students

by Nancy R. Angoff

In his article "Do Medical Students Need Special Protection?" Nicholas Christakis concludes that IRB review of research involving medical students as subjects is sufficient to safeguard the students' rights and well-being.¹ He feels that special guidelines like the "Rules Governing the Participation of Medical Students as Experimental Subjects" in effect at Harvard since 1956 are excessively paternalistic and restrictive. I agree with Mr. Christakis's viewpoint; furthermore, I believe that this sort of protection is really overprotection and serves to foster a distorted image of medical students having diminished autonomy.

Harvard's rules were formulated originally in response to an apparent escalation in the use of medical students as research subjects in "risky" experiments in the 1950s. The appropriateness of the rules at that time is not an issue since there were few review committees resembling present-day IRBs. However, given IRBs and other institutional safeguards for protecting the rights of all research subjects and encouraging ethical and professional behavior on the part of investigators, the rules seem extraneous in 1985. Their existence contributes to an incorrect view of medical students as a special population more in need of protection than the general population. In fact, the rules specify protections even greater than those afforded groups such as children and the mentally infirm, groups recognized as needing special consideration owing to their decreased capacity to evaluate fully the research experience.

At Harvard, research protocols in which students might be used as subjects must be approved by the Dean of the medical school and the Director of Medical Area Health Service (MAHS) in addition to the IRB. Student subjects must undergo a physical exam by MAHS and a record must be kept by MAHS of the student's research activities including any "significant medical observations" made by the investigator during the course of research. Proposed modifications of these rules could do away with their most troubling aspect, that they serve as a mechanism for invasion of a student's

privacy. The proposed modifications require the agreement of the student before the investigator may give any information to MAHS.

The need for special protections for medical student research subjects is based on a perception that "...while medical students may be more able to give informed consent, they are less able to give free consent." The proponents of these rules seem to believe that this decreased autonomy is the result of an interplay of selfish motivations on the part of students and faculty inherent in the highly competitive medical school environment. Students might try to insinuate themselves into the good graces of their professors by selling themselves as research subjects, and faculty investigators may take advantage of their students by applying undue pressure to get them to participate in "risky research" against the students' better judgment. All of this unchecked behavior could pose threats to a student's health and ability to manage his or her time carefully.

The basic question to be decided is whether medical students as a group are, in fact, "less free" than the general population by virtue of being "a captive population." Since I do not believe that they are, I shall argue that they ought to be left to evaluate freely any demands on their health or time and make decisions about participating in research accordingly. Of course, the IRB must assess the risks of particular research protocols as acceptable.

The Autonomy of Medical Students

There are several telling reasons to consider medical students highly autonomous. These are people who have maneuvered successfully through a system that includes many hurdles to their present status. They were selected by Harvard because they demonstrate "...evidence of integrity, maturity, concern for others, leadership potential, and an aptitude for working with people."² Such strong candidates do not just lose their good judgment upon entering the hallowed halls. Medical students in 1985 are individuals with rich and diverse backgrounds; some of them have already established impressive credentials in other occupations and professions. Even the most unsophisticated medi-

cal student has a sense of direction and purpose that ought to be respected. Certainly, people who will be entrusted with making judgments about the health and well-being of others should be allowed to make choices about managing their own time and health.

How real a threat does research pose to a medical student's health? Probably not so great a threat as exposure to formaldehyde in gross anatomy lab or to infections incubating in a pediatric ward. In fact, Robert J. Levine writes, "On the basis of all of the empirical evidence of which I am aware, it seems proper to conclude that the role of research subject is not particularly hazardous in general. It follows that attempts to portray it as such and arguments for policies designed to restrict research generally because it is hazardous are without warrant."^{3,p.26}

How real is the problem of overly aggressive faculty pressuring students to participate in research against their wishes? Faculty who behave this way become known very quickly to medical students and those who are reluctant to be pressured will steer clear of them. In any case, behavior of this sort should not be tolerated by the institution whether it occurs with students, employees, or patients. But a policy to prevent it should be aimed at curbing the behavior, not limiting the choices available to students.

The IRB's Role

If it is agreed that IRB review of research involving medical students is sufficient to protect their welfare, the question then arises whether IRBs should impose more rigid criteria for participation of students than for the general public. The IRB at the University of Massachusetts adopted a policy that students may participate as subjects when "1) the experiment has minimal risks; 2) there is no major physical or surgical intervention; 3) there is a minimal interruption of one's daily routine."⁴ In the case that gave impetus to the adoption of this policy, several students who had participated in research complained to the IRB that since they had experienced side effects they were not "in the best shape for classes and examinations."

If representatives of any other group complained to an IRB that side effects of a study treatment were more disabling than they had been led to believe, the most likely action of the IRB would be to insist that the investigator modify the consent form to reflect more accurately the apparent side effects.

Nancy R. Angoff is Associate Chairman, Human Investigation Committee, Yale University School of Medicine.

The information that the study may result in stomach irritation that could prevent one from performing as usual for a few days is material to anyone's decision about whether to participate, not just students. It is unlikely that any other adult group's complaints would result in an exclusionary policy. Do special considerations of this type lead to what Harvard calls "the development of highly qualified physicians capable of providing leadership in their chosen fields"?

A Case In Point

One IRB decided differently. A research protocol involving multiple catheterizations, infusions of drugs, and radiation exposure equivalent to an amount received from two chest x-rays and an upper gastrointestinal series was approved by the Human Investigation Committee (HIC) at Yale School of Medicine.⁵ Given the complexities of the procedures and the attendant risks, the HIC decided that participation should be limited to those subjects who could comprehend and evaluate the information shared with them by the investigators. The HIC informed the investigators that, in its view, any component of this study could be explained satisfactorily to most normal volunteers. However, in the aggregate, the sheer volume of risk information seemed likely to overwhelm the average prospective subject.

The research clearly would not fit the criteria allowing medical student participation set by the University of Massachusetts IRB. Students would not be allowed to participate under the Harvard rules either. The HIC, however, directed the investigators to describe a proposed subject population that would assure their familiarity with the procedures, assure their capacity to assess the risks and discomforts of the procedures, and afford confidence that they could appreciate the importance of the knowledge being sought. The HIC suggested that one category of subjects that would fit this profile would be third- and fourth-year medical students. One of the co-investigators on this protocol was a fourth-year medical student. It seems ironic to protect students from participating fully and under the same conditions in an experience such as one which they may one day request others to accept.

The HIC approved payment to subjects on this protocol of \$100 for approximately seven hours of their time, not an unreasonable amount for a day's work involving so much dis-

comfort. One concern of proponents of Harvard's rules, which also exclude payment to student research subjects, is that students "... might participate in studies in an attempt to garner better recommendations, better grades, or other favors (such as summer employment.)" It seems logical that direct payment to students for a job well done would somewhat dispel any expectations by students that any other form of reward would follow. Earning money from participation in research is at least as reputable a way as a variety of others available to students such as selling their blood, tending bar, or babysitting for a faculty member's children.

Finally, treating medical students differently by applying different standards to their participation in research than to the participation of the general public has the flavor of elitism. One may wonder why it is acceptable to ask the masses to accept risk in the name of science but not the very people whose futures are linked to the successful perpetuation of biomedical research. Medical schools that create this impression are acting somewhat like parents who profess a belief in public education but send their children to private school.

If medical schools really are interested in training competent and sen-

sitive future investigators, exposure to the total research experience should be available to students. How better to know what information truly is relevant to informed consent; how better to understand the difference between words on a consent form and a consent process; how better to appreciate what it feels like to be made a "thing" whose "being is reduced to that of a mere token or 'sample'";^{6,p.250} how better to know what it is like to be a subject than to be one! We should not be making it more difficult for medical students to participate in research; rather, we should be making it easier.

REFERENCES

- ¹Christakis, N: "Do Medical Student Research Subjects Need Special Protection?" *IRB: A Review of Human Subjects Research*. 7 (No. 3): 1-4, May/June 1985.
- ²Brochure to prospective medical school applicants, Harvard Medical School. May, 1985.
- ³Levine, R.J.: *Ethics and Regulation of Clinical Research*. Urban and Schwarzenberg, Baltimore, 1981.
- ⁴Shannon, T.A.: "Case Study: Should Medical Students Be Research Subjects?" *IRB: A Review of Human Subjects Research*. 1 (No. 2) 4, April, 1979.
- ⁵Levine, R.J.: "Case Study: What Kinds of Subjects Can Understand this Protocol?" *IRB: A Review of Human Subjects Research*. 6 (No. 5) 6-8, September/October 1984.
- ⁶Jonas, H: *Philosophical Reflections on Experimenting with Human Subjects*. pp. 1-31. In: *Experimentation with Human Subjects*, ed. by P.A. Freund, George Braziller, New York, 1970.

ROBERT S. GORDON, JR.

With profound sorrow we note that in early August, Robert S. Gordon, Jr., M.D. died of cancer at the age of 59. Bob was best known to the world as a distinguished clinical investigator who in 1961 helped establish a cholera research program in East Pakistan (now Bangladesh) and who in 1972 shared in a prize from the Vernon Stouffer Foundation for his research on the role of fatty acids in the development of arteriosclerosis.

Virtually all of his long and productive professional career was spent in various capacities at the National Institutes of Health. In recent years as Special Assistant to the Director, NIH, Bob concentrated on developing improved understandings of the scientific, practical and ethical problems of randomized clinical trials. It is in this capacity that he became well-known and highly respected by those who are interested in the ethics and regulation of clinical research. He contributed generously and skillfully to our publications—e.g., by writing articles for *IRB*—and programs—e.g., through frequent appearances as a faculty member at PRIM&R meetings. As one of the founders of the Society for Clinical Trials, he worked hard and successfully to make ethical considerations a prominent part of their programs and publications. With patience and a gentle sense of humor, he strove diligently and persistently to harmonize the requirements of science and ethics. We shall miss Bob Gordon.

—RJL