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In 1956 the faculty of Harvard Medical School instituted carefully formulated regulations governing the use of medical students as research subjects. The regulations established several echelons of review for projects involving students, a class of subjects for whom the faculty felt it had a special responsibility. No such extra consideration was granted to other adult participants in research. The regulations, issued in a memorandum entitled "Rules Governing the Participation of Medical Students as Experimental Subjects," were formulated by the Administrative Board, the body then responsible for approving the use of medical students as research subjects.

Several concerns motivated the faculty to adopt the new policy. The Administrative Board observed that there had been a "rapid increase in research involving medical students in recent years."[1] More important, the Board noted that "unfortunate practices had crept in" and that students were "being used too frequently as guinea pigs" in risky experiments. Of special concern to the Board was the potential of increased exposure to radioactive isotopes. It did not want the students to be put in "jeopardy."

Nevertheless, many faculty members reiterated their support for the "great tradition of human experimentation in medicine" and declared that the intent of the regulations was neither to counter this tradition nor "to handicap important investigations seriously." Indeed, the faculty noted that participation as a research subject was of potential educational benefit to students. Such ideas were incorporated into part of the Rules: "The contact between investigator and student is recognized as an excellent opportunity for the investigator to demonstrate to the student both his personal responsibility for the student's health and safety and an active interest in furthering the student's education."[2] The statement about faculty "responsibility" is especially noteworthy because it recognized the dichotomous nature of the position of the faculty: they were committed both to human investigation and to the safety of their students. Thus, the intent of the 1956 Rules was to support research and at the same time protect students from the risks of such research.

Except for minor administrative details, the 1956 guidelines have not been changed. However, the Administrative Board continued to consider the advisability of medical student participation, according to the guidelines, only until 1974, when our IRB, the Harvard Medical School-Harvard School of Dental Medicine (HMS-HSDM) Committee on Human Studies, was established. Our IRB is charged with reviewing all research involving either (1) HMS-administered funds, or (2) HMS facilities, or (3) HMS students as subjects. One of the primary charges of our IRB is thus to review projects involving medical students to ensure the special consideration mandated by the Rules. Our committee has recently considered, however, whether it is appropriate for protocols involving students to be subjected to review by parties other than the IRB and, indeed, what special protection, if any, students should be afforded by our committee.

The regulations, it turns out, have been so protective that students are largely prohibited from being subjects in research. Indeed, several investigators from affiliated hospitals recently told our IRB that the obstacles to their use of medical students are so numerous that they "avoid using students altogether because of the cumbersome, time-consuming procedures required by HMS." These investigators have questioned whether there should be more obstacles to the involvement of medical students in research projects than there are for the general public. Indeed, research involving students usually receives the approval of two IRBs: that of the sponsoring hospital or institution (if other than HMS), and that of the Committee on Human Studies. The investigators did not object to this double approval as much as to the review by several other parties required by the Rules.

The Rules outline a number of special requirements for the use of medical students. A copy of this document, signed by the Dean of the Medical School, is distributed to the students at the beginning of the academic year. The basic statement of policy in the 1956 edition, as in the present one, declares: "The guiding principle in

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considering the participation of medical students as subjects is the belief that no students should be exposed to risk as far as their health and well-being are concerned." In addition, the statement stipulates that "students' time should not be invaded to the extent of creating conflicts with their scheduled work," and that "payment should not ordinarily be made to the student for participating as a subject in an experiment." These policy statements are intended to protect students from health risks, time conflicts, and undue monetary inducement.

With respect to administrative procedure, the research protocol must, as usual, first be approved by the head of the investigator's department; but the department head must be specifically informed of the intention to use students as subjects. "Subsequent to such approval," the present policy dictates, "a detailed protocol must be submitted to the Director of Medical Area Health Service (MAHS) and to the Dean's office. In experiments involving the use of radioactive materials, a copy of the protocol shall be submitted also to the Secretary of the Committee on Medical Research in Biophysics. Following review and commentary by these parties, the protocol must be presented to the Committee on Human Studies for discussion and for approval or disapproval of student participation."

Of particular import is the fact that parties other than the IRB—that is, the Dean's Office and the Health Service Director—approve the participation of medical students. In addition, implicit in these guidelines is the possibility that the IRB might disapprove medical student participation, but still give a green light to the protocol itself, though this has very rarely occurred. This possibility, however, illuminates the special mandate of our IRB: it is on occasion supposed to determine separately the permissibility of a study and of medical student participation.

Potential subjects must also, according to the Rules, be referred to MAHS for medical clearance before beginning the experiment with the result of the medical examination being sent in writing to the investigator. Finally, MAHS "must maintain records of the research projects in which medical students participate," and "the investigator must report to MAHS any significant medical observations that are made during the course of a given experiment." These regulations are presumably meant to fulfill the faculty's "responsibility" for the health and well-being of the students.

Changes under Consideration

Changes under consideration are meant to redress many of the problems some feel are present in the current system. Specifically, the changes seek to eliminate both the perceived paternalistic attitude toward medical students in the existing guidelines and, most important, the double standard that exists between the consideration given to the participation of medical students versus the public at large. This double standard arises both from the extra review by other parties given to protocols involving students and from the special consideration given to student participation within the IRB itself—for example, the requirement that "no students be exposed to risk."[3] Incidentally, the whole process would be streamlined, thus achieving the investigators' original desire.

The specific modifications being contemplated by our IRB include: (1) The definition of acceptable risk will be changed to state that "no student should be exposed to risk different from that considered generally acceptable for normal adult subjects by the Human Studies Committee." (2) The requirement for a special medical exam of the student prior to participation in the experiment will be eliminated. (3) Protocols will be submitted to the IRB for actual "consideration," and to the Dean's office and MAHS Director's office only for their "information." And (4) MAHS will be notified if any significant medical observations are made only "upon assent of the student involved."

Opponents of the proposed changes point out that problems that motivated the formulation of the original guidelines have not recurred. They insist that to tamper with the present system and remove some of the obstacles to faculty use of medical students amounts to putting the "fox in charge of the chicken coop." Students might be subject to inappropriate and undue pressure and might participate in studies in an attempt to garner better recommendations, better grades, or other favors (such as summer employment). The rules for medical students are more stringent, they insist, because a medical student is less free than a random adult to refuse the request of a faculty investigator to be a research subject. They point out that the autonomy of a student is unavoidably compromised by the very nature of the student/faculty relationship and that special consideration must thus be given to medical students.

This argument confounds the two issues at stake. The Rules at present protect the *health*, not the *liberty*, of medical students. The basic questions are thus: (1) Does the University have a special obligation to the health of its students? And (2) how are students, in fact, to be protected from undue coercion by faculty to participate in research? Is an IRB the right agency to afford this protection?

Protection from Coercion

With regard to the latter question, the Belmont Report of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research spelled out its concern in 1976 in its initial formulation of guidelines for the protection of human subjects. The report states that "certain groups, such as racial minorities, the economically disadvantaged, the very sick, and the institutionalized may continually be sought as research subjects, owing to their ready availability in settings where research is conducted. Given their dependent status and their frequently compromised capacity for free consent, they should be protected against the danger of being involved in research solely for administrative convenience, or because they are easy to manipulate as a result of their illness or socioeconomic condition."[4]

Medical students certainly are "readily available in settings where research is conducted," a feature that makes them relatively easy to monitor. Their interest in medicine will also tend to make them more reliable and willing subjects, especially with respect to reporting the effects of the experimental intervention. Largely for such reasons of "administrative convenience," medical students may be very desirable as research subjects. However, the same ready availability that makes medical students a desirable subject pool also makes them a captive population, a status that can only decrease their autonomy.

It is often argued that medical students, because of their increased understanding of the science and procedures involved in the experiment, have greater ability than the average subject to give informed consent. This is true. In fact, this is another feature that has made medical students desirable subjects. The problem, of course, is that while medical students may be more able to give informed consent, they are less able to give free consent. It is the latter that is key with respect to any protection they deserve. The Belmont Report recognizes that

"unjustifiable pressures usually occur when persons in positions of authority or commanding influence—especially where possible sanctions are involved—urge a course of action for the subject." Since an obvious conflict of interest arises if the investigator is also the student's professor, medical students may be construed to be a group deserving special consideration. Indeed, the Report clearly stipulates that for informed consent to be truly voluntary, there must be "conditions free of coercion and undue influence."

Many different classes of potential subjects are susceptible to coercion. How can students in particular be protected from possible coercion from faculty investigators? One way, suggests Thomas Shannon of the University of Massachusetts, is to require that students be recruited only through a general invitation, not individually.[5] Indeed, many drug companies, concerned about potential abuse of employees, have such a regulation in effect.[6] In addition perhaps a special grievance committee, consisting of student and faculty members, could be established to deal with alleged violations of the rule. The existence of such a committee should be well publicized and its deliberations kept confidential.

Should the IRB field allegations of coercion? Shannon points out that it is a "proper task" for an IRB to consider issues of unfair coercion of subjects to participate. Indeed, the Belmont Report stipulates that those likely to be unduly coerced, those with diminished autonomy, should be protected, presumably by the IRB. But while it is appropriate for an IRB to take the possibility of coercion or abuse of special groups into account, the IRB should avoid the responsibility of policing its decisions. The problem of enforcement of IRB decisions is a serious one, but beyond the scope of the present discussion. Suffice it to say, as argued by Robert Levine of the Yale University School of Medicine, that "if the IRB is obliged to function as a police force, it can only indicate to the community of investigators that it is operating from presumptions of mistrust. Presumptions of mistrust cost a lot in time and energy of IRB members, most of whom have no training in police work in the first place."[3 at p. S100] IRB responsibility, at least at present, is simply to assess whether a given protocol has proper safeguards for its subjects.[7]

Are the deliberations of the IRB and the rule against individual solicitation sufficient to protect students from coercive situations? If we assume good faith on behalf of faculty investigators, I believe so. After all, this is the specific charge of an IRB: to protect people from coercion or other abuses to which they are particularly susceptible. For example, the IRB rightly takes the possibility of coercion into account when reviewing whether a recent victim of a myocardial infarction, wheeled into the emergency ward, can truly give free consent to be in a trial of a new, potentially superior, fibrinolytic agent. Or, for instance, the IRB might properly seek extra protection of the confidentiality of subjects of an investigation into the activities of patients recently released from a mental health institution.

That is, special protection is uniformly extended by IRBs to vulnerable groups. Efforts are ordinarily made to protect people from situations they might find coercive or otherwise abusive. Students, too, would be granted special consideration, in light of their special position, in the normal course of IRB deliberations. This is why our committee is specifically informed when students are to be in the subject pool. For example, in one case, an IRB saw fit to modify a procedure granting extra academic credit to students participating as research subjects; such an offer was felt to be unacceptably coercive, in light of the students' position.[8] Another example involving students was reviewed by our IRB: a national testing agency sought to administer tests to medical students in an attempt to predict their future ability as clinicians. Our IRB required special protections of confidentiality in view of the potentially compromising data generated by the study. In this case, medical student participation was felt to warrant special consideration because the special position of the students made them subjects in the first place.

Confidentiality was also of tantamount importance in our review of a study of the sexual habits and substance abuse history of medical students. Indeed, the problem of confidentiality is a significant one in the close community of a medical school, and our IRB often takes this into account. Aside from breaches of confidentiality, students are also especially susceptible to certain other abuses, such as being used as subjects in behavioral research involving deception.[9] Students deserve IRB protection of their liberty, autonomy, and integrity. Indeed, there is good reason for student membership on IRBs precisely to represent the interests of the student subjects.[10]

IRBs function by design and mandate to protect subjects of research. An IRB is no less capable of protecting students than any other vulnerable group. The IRB can insist that the regulation regarding individual solicitation and the existence of the grievance committee be part of the informed consent document. It can consider student participation in its deliberations. And naturally, a protocol involving students would be subjected to the same assessment of the risk/benefit ratio as would any other proposal, thus ensuring that students, like other adults, are not involved in unjustifiably risky procedures.

Monetary Inducement

And what of the possibility of monetary inducement that the Rules seek to eliminate? It is well recognized that the promise of too great a reward may constitute an undue inducement, may cause a person to act against his or her best interests.[11] The Administrative Board evidently feared that a student, ordinarily having a low income (and, these days, being greatly in debt), might be unduly induced by monetary rewards. It therefore prohibited monetary compensation. This is quite remarkable for it is unclear why a student would willingly be a subject under such circumstances. The Rules state that the student's "motivation should stem from an opportunity to learn and to contribute, rather than from a financial inducement *per se*."

I doubt very much whether investigators could conduct their research if curiosity or altruism were the only motivations of their subjects. It is for this reason that payments are offered in the first place. The prohibition of payment under the Rules, in an attempt to eliminate undue inducement, is again a factor discouraging medical student participation. At another medical school, in fact, exactly the opposite policy has been adopted and students are singled out to be offered money: the "policy is to recruit subjects from among medical students, and there is a general suspicion of efforts to solicit subjects from among community residents because of the fear that monetary payments will serve as an undue inducement."[12] That is, at this school money is not felt to be an inappropriate or undue inducement for medical students.

Others disagree with the idea that, without monetary compensation, few will be research subjects and argue against money as a motive for participation. Lisa Newton, of Fairfield University, argues that monetary

inducements should be kept to the point where they are but one factor, not in and of itself sufficient to explain a person's desire to be a subject. She argues that there is another "justification for keeping payments low and subject pools restrictive. We want volunteers who are aware of the value of the research, able to understand it, willing to cooperate in carrying it through ...."[13] That is, Newton argues that only those "who might be expected to understand what is going on" should be subjects. Medical students certainly fit this description. But Newton nevertheless maintains that money should be offered. It seems appropriate that payment given to other normal adult volunteers also be given to students because medical students are no more likely to be induced by money than any other group of comparable means. In any case, the IRB should be given details about payment so as to arrive at some determination of whether the amount involved is proper.

Time Commitment

Should the time commitment involved in a protocol enter into the IRB's consideration of whether to let medical students participate? Arguing that the IRB is "charged with protecting people from research in which the risks outweigh the benefits,"[14] Shannon maintains that an IRB should have a role in deciding whether a given protocol requires too much time away from a subject's "primary goals," this loss of time constituting a "risk" of the research. Hence, students might be denied access to a given research project on the grounds that, in the IRB's judgment, too much time away from schoolwork would be required. In a sense, the research would be deemed too risky for students. As already mentioned, such a stipulation is, in fact, present in the Rules.

But the question again arises why students *in particular* should be given special consideration with respect to time lost being a research subject. Medical students, as autonomous adults, should be able to decide for themselves about their schedules. Or, indeed, if a protocol were deemed too time-consuming, then blanket protection should be extended to all adult volunteers. "Excessive or unjustified paternalism may lead to intervention into areas that are not particularly problematic. It may be best left to the discretion of the individual subject as to whether or not he or she wishes to invest time in a research protocol that carries modest risk with it, but also does not provide very many personal benefits."[7]

The IRB's Responsibility

We have considered the problem of coercion of medical students and the ability of an IRB to take under advisement the special issues involving student subjects. With respect to protection of their *health*, it is unclear whether students differ in any significant way from other adults. Do adult medical students deserve any more protection of their health than other individuals? Why should not graduate students, postdoctoral fellows, lab technicians, or, indeed, the general public be similarly protected? IRBs should avoid developing "institutional policies that impose inconsistent procedural requirements on classes of research projects that do not differ in any morally relevant fashion. Double standards create within the institution the often accurate impression that the procedural requirements—in the view of the institution—have no inherent value and, therefore, are to be evaded."[3] at p. S99

The inconsistent procedural requirements for the use of medical students that create the double standard are the no-payment rule, the special medical exam, the several echelons of review, and the no risk criterion. These requirements should be eliminated. Of course, there will still be an IRB to protect students from excessive health risks, undue inducement, and coercion. The IRB should have the principal responsibility for protecting medical students. Indeed, the special review by other parties mandated by the present Rules may dilute IRB power and effectiveness.

The original guidelines, which essentially protected students from any health risks whatsoever—by, in effect, making it very difficult for them to be subjects at all—were drawn up at a time when there was no IRB. The faculty thus sought to protect its students, for whom it felt it had a "special responsibility." However, such guidelines seem out of place with the subsequent establishment of an IRB to protect all human subjects. Indeed, the "special responsibility" of the faculty now seems anachronistic and excessively paternalistic. This is not to say that medical students, who have a "compromised capacity for free consent" and a "dependent status," and who are "readily available," should not have special IRB protection from the consequences of these attributes. Their diminished autonomy should be taken into consideration. But review by additional parties and virtual elimination of health risks do not seem warranted. The modifications to the Rules under consideration seek to take into account the standing of our IRB and its responsibility for all human subjects of research.

REFERENCES

[1]Minutes of Faculty Meeting, Harvard Medical School, February 10, 1956.

[2]"Rules Governing the Participation of Medical Students as Experimental Subjects," Office of Sponsored Research Administration, Harvard Medical School.

[3]See Levine, R.J.; "The Impact of Institutional Review Boards on Clinical Research" *Perspectives in Biology and Medicine.* 23:S98-S114, 1980, pg. S107, for a brief case involving a "zero risk" standard.

[4]National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research; *The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research,* DHEW Publication No. (OS) 79-12065, Washington, 1979.

[5]Shannon, T.A.; "Case Study: Should Medical Students Be Research Subjects?" *IRB: A Review of Human Subjects Research.* 1(No. 2): 4, April, 1979. See also letter by K.A. Nolan; "'Protecting' Medical Students from the Risks of Research" *IRB: A Review of Human Subjects Research.* 1(No. 5): 9, August/September, 1979, and response by T.A. Shannon in same issue.

[6]Meyers, K.; "Drug Company Employees as Research Subjects: Programs, Problems, and Ethics: *IRB: A Review of Human Subjects Research.* 1(No. 8): 5-6, December 1979.

[7]Nevertheless, some IRBs are taking a more active role in ensuring subjects' autonomy; see Shannon, T.A. and I.S. Ockene, "Case Study: Approving High Risk, Rejecting Low Risk: The Case of Two Cases" *IRB: A Review of Human Subjects Research.* 7(No. 1): 6-8, January/February 1985, for an example of an IRB's "own oversight process."

[8]Gamble, H.F.; "Case Study: Students, Grades, and Informed Consent" *IRB: A Review of Human Subjects Research.* 4(No. 5): 7-10, May 1982. See also Shannon and Ockene for another example of an offer of extra credit to students.

[9]Schmutte, G.T.; "Case Study: Using Students as Subjects Without Their Knowledge" *IRB: A Review of Human Subjects Research.* 2(No. 10): 5-6, December 1980. See also commentary by T.H. Murray, "Was This Deception Necessary?" in the same issue.

[10]Nolan, K.A.; "The Evolution of IRB Composition: Student Members: 'Informed Outsiders' on IRBs" *IRB: A Review of Human Subjects Research.* 2(No. 8): 1-4, October 1980.

[11]See R. Macklin; "'Due' and 'Undue' Inducements: On Paying Money to Research Subjects" *IRB: A Review of Human Subjects Research.* 3(No. 5): 1-6, May 1981; see also *The Belmont Report*.

[12]R. Macklin; Macklin recognizes that even this policy has its problems "since students, at the time they are students, may well have a lower income than the working poor ...." This paper is a good examination of the problem of inducement in general.

[13]L. Newton; "Inducement, Due and Otherwise" *IRB: A Review of Human Subjects Research.* 4(No. 3): 4-5, March 1982, with response by R. Macklin in same issue.

[14]Shannon, T.A., in response to K.A. Nolan's letter.