Ethical Issues in Human Research

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Ethical issues in research involving human subjects have been a matter of concern both to the lay public and to researchers in private and public enterprises. In earlier times safeguards for human subjects were left entirely to the judgment of the investigator, and the extolled value of research was such that a research topic may have been deemed more important than the welfare or dignity of the human subject. After some important milestone legislation (which will be discussed shortly), the pendulum may have swung in the other direction to such a degree that some now believe the integrity of traditional experimental research design models is often compromised because of safeguards proposed by an overzealous lay public. In other noteworthy instances, political and social concerns have abridged the freedom of inquiry, and certain lines of inquiry have become sensitive and controversial. These ethical issues in human research may not be uniformly distributed across various disciplines, but some of these issues do affect the research activities of many of us in the Academy and our profession as a whole.

A Short History of Ethical Issues

As early as 1937 the National Institutes of Health often denied funding proposals when the risks were deemed to be excessive. On an international level, the protocols recommended by the Nuremberg Code (Nuremberg Military Tribunals, 1949) and the Declaration of Helsinki (World Medical Association, 1966), both of which addressed medical research done on patients, raised the issue of ethical conduct in human research. Although the Nuremberg Code does mention that the research “should be conducted only by scientifically qualified persons,” it states that “medical experiments on human beings [should] conform to the ethics of the medical profession [italics added] generally” (cited in Katz, 1972, p. 305). In a similar fashion, the Declaration of Helsinki cites “the health of the patient” and the “doctor in clinical research,” noting that “the standards as drafted are only a guide to physicians all over the world” (p. 32).

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The Nuremberg Code of 10 moral, ethical, and legal concepts was formulated in 1947 as a result of a court opinion involving 20 Nazi physicians and 3 scientific researchers for war crimes and crimes against humanity. The now infamous research activities at concentration camps included studies on exposure to high altitude conducted in a low-pressure chamber where prisoners were subjected to atmospheric pressures up to 68,000 feet, freezing experiments where prisoners were forced to be in a tank of ice water for up to 3 hours, malaria studies where prisoners were used to test several different immunizations, sulfanilamide experiments where prisoners were deliberately wounded and the wounds aggravated by such procedures as tying off blood vessels to produce gangrene or forcing ground glass or wood shavings into the wound to test the effectiveness of different drugs. Other studies looked at jaundice, spotted fever (typhus), and various poisons; prisoners were intentionally infected or poisoned and then followed with various research protocols. Some prisoners, for example, were given poisons in their food; those who died were autopsied, and others were intentionally killed so they could be autopsied. The exact number of deaths and grievous injuries remains a mystery, although it is known that at least 200 Jews, 50 Gypsies, 500 Poles with tuberculosis, and 1,000 Russian prisoners were involved, with only a few survivors (Katz, 1972). The defendants argued that they had conducted ethical human research, which the court refuted on the basis of medical ethics.

The Nuremberg Code was a starting reference point for future international and national clinical research ethics codes. The importance of the Nuremberg Code for future efforts at the control of human experimentation becomes obvious when one reviews the key provisions of the code and compares them against those seen today in various informed consent documents. The Nuremberg Code is presented here in a slightly abbreviated form:

1. The voluntary consent of the human subject is absolutely essential.
2. The experiment should be such as to yield fruitful results for the good of society, unprocurable by other methods or means of study, and not random and unnecessary in nature.
3. The experiment should be so designed and based on the results of animal experimentation and a knowledge of natural history of the disease or other problem under study that the anticipated results will justify the performance of the experiment.
4. The experiment should be so conducted as to avoid all unnecessary physical and mental suffering and injury.
5. No experiment should be conducted where there is an a priori reason to believe that death or disabling injury will occur; except, perhaps, in those experiments where the experimental physicians also serve as subjects.
6. The degree of risk to be taken should never exceed that determined by the humanitarian importance of the problem to be solved by the experiment.
7. Proper preparations should be made and adequate facilities provided to protect the experimental subject against even remote possibilities of injury, disabilities, or death.
8. The experiment should be conducted only by scientifically qualified persons. The highest degree of skill and care should be required through all stages of the experiment of those who conduct or engage in the experiment.
9. During the course of the experiment the human subject should be at liberty to bring the experiment to an end if he has reached the physical or mental state where continuation of the experiment seems to him to be impossible.

10. During the course of the experiment the scientist in charge must be prepared to terminate the experiment at any stage, if he has probable cause to believe, in the exercise of the good faith, superior skill, and careful judgment required of him that a continuation of the experiment is likely to result in injury, disability, or death to the experimental subject.

The subsequent Declaration of Helsinki in 1964 added the distinction of therapeutic versus nontherapeutic research, stipulating that "the interest of science and society should never take precedence over considerations relative to the well-being of the subject." In a 1966 policy statement on the principles of medical ethics, the American Medical Association also distinguished between clinical investigations designed "primarily for treatment" from those "primarily for the accumulation of scientific knowledge." These and other policy statements by influential public and professional groups made it clear that the principles of the Nuremberg Code set out in language appropriate for medical research should also apply to scientific investigations involving human subjects of a nonmedical nature.

The National Institutes of Health drafted a 1965 memorandum to the United States surgeon general recommending the need to formulate policies for extramural funding on human subjects. The result was the first Public Health Service Policy and Procedure Order relating to extramural research with human subjects. In 1966 the National Institutes of Health, the Federal Drug Administration, and the Department of Health, Education, and Welfare started to issue detailed regulations to govern human subject research in supported projects; these regulations applied to both medical and nonmedical research supported by the agencies. The Food and Drug Administration added provisions in 1962 requiring researchers to inform subjects about placebo and control group protocols and to stipulate any alternative forms of therapy. In 1971 the Department of Health, Education, and Welfare issued its detailed International Guide to DHEW Policy on Protection of Human Subjects and extended risk protocols to include possible psychological and social harm. Ethical principles for the conduct of psychological research with human participants are covered in detail by the American Psychological Association (1973), and the issue of deception and misrepresentation has been addressed recently by Landers (1979).

Public awareness of the need for protection of human subjects was heightened by several news stories in the 1960s that resulted in national and international indignation. Researchers at the Jewish Hospital and Medical Center of Brooklyn injected live cancer cells into geriatric patients without first securing informed consent. At a New York State institution for the severely retarded (Willowbrook), children were allegedly exposed to a hepatitis virus to test a vaccine under controlled conditions, without adequate information being provided to parents for an informed consent. And in Tuskegee, Alabama, black male subjects with syphilis were studied longitudinally by the U.S. Public Health Service to document the course of the untreated disease from the 1930s. No informed consent had been obtained, and even after 1945 when penicillin was known to be a safe and effective cure, the Department of Health, Education, and Welfare failed to practice
its own stated research safeguards and continued the study with an untreated control group.

These often-cited cases of improper research with human subjects were by no means isolated examples. A news story came out about the Central Intelligence Agency’s use of the drug LSD and other behavior modification techniques without proper informed consent and human subject safeguards. Beecher (1966) cited similar troubling examples in research conducted by “leading medical schools, university hospitals, private hospitals, governmental military departments (the Army, the Navy, and the Air Force), governmental institutes (the National Institutes of Health), Veterans Administration hospitals and industry.” Revelations such as these made it obvious that safeguards for human subjects were necessary regardless of the research sponsorship.

As considered in more detail by Liemohn (1979), the Department of Health, Education, and Welfare formulated The Institutional Guide to DHEW Policy on Protection of Human Subjects (DHEW, 1971). After some interim recommendations, finalized protocols were published in the Federal Register (DHEW, 1974) and in the National Research Act, Public Law 93-348 (1974). The National Research Act also established the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research and contained a key provision charging institutional review boards (IRBs) with reviewing research proposals involving human subjects. Subsequently various regulations and interpretations have been recommended by many public and private organizations extending policies of informed consent and protection of human subjects to any and all investigations, not just to projects supported by DHEW. These organizations include the American Alliance for Health, Physical Education, Recreation and Dance, the American College of Sports Medicine, the American Psychological Association, the National Academy of Sciences, and the Royal College of Physicians for all hospitals in England, as well as most major institutions of higher education.

**Basic Elements of Informed Consent**

As a result of the various forces acting to protect human subjects, the National Research Act, Public Law 93-348 (1974) formulated a set of basic elements to be included in an informed consent document. These elements are by now familiar to all engaged in research conducted with human beings as subjects; they are presented here for review:

- A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject’s participation, a description of the procedures to be followed, and identification of any procedures that are experimental
- A description of any reasonably foreseeable risks or discomforts to the subject
- A description of any benefits to the subject or to others that may reasonably be expected from the research
- A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject
- A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained
- For research involving more than minimal risk, explanations as to whether any compensation will be provided in case of injury and whether any medical treatments are available if injury occurs and, if so, what they consist of or where further information may be obtained.
- An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject.
- A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.

In addition, other elements of informed consent are recommended depending on the exact nature of the research and the population being tested. These include such items as the investigator's terminating the investigation earlier than stipulated (as stated in the Nuremberg Code), significant new findings developed during the investigation that may influence the subject's willingness to continue participation, and special protocols when the investigation involves use of fetuses, pregnant women, prisoners, children, or wards of the state or any other agency, and research requiring greater than minimal risk or deception. These as well as many other specific protocols have been established not only by federal agencies but by professional societies as well.

**Difficulties With Informed Consent**

Although various professional organizations have endorsed federal guidelines and adopted policy statements that have been well circulated, difficulties with adequate compliance exist. These difficulties have been substantially increased with numerous court rulings that have amplified the "informed" condition and increased the difficulty of legally complying with the notion of informed consent. It is likely that no informed consent document could present all the relevant information required to constitute a legally impregnable satisfaction. Some relevant information may require a sophisticated level of understanding beyond what can reasonably be expected in naive subjects. Ingelfinger (1972) stated that the protocols suggested for an adequate informed consent document do not adequately address the issue of educated consent and that the layperson simply cannot understand the importance of much research without a sufficient background in the topical area. It should also be noted that the mere fact that an informed consent form was signed does not automatically sanction the research as ethical. The research itself must be ethical. For example, even if the Nazis had obtained some form of consent by the prisoners involved in the freezing studies, the studies themselves were unethical.

Because of court decisions that legal consent must be informed consent, a need arose to determine what specific kinds of information should be provided in an informed consent document. Rosoff (1981) suggests that the information provided must either meet the "professional community standard" or the "reasonable patient standard." Under the professional community standard, the investigator would provide all information that represents current professional custom.

The reasonable patient standard, a more influential practice as well as a more commonly employed rule in a legal context, requires that the patient be
provided the information necessary to make an informed decision. Herbert (1990) refers to the standard as the "patient's need for information doctrine," which has been adopted in over a dozen litigations. Needless to say, both of these standards fail to offer much comfort to investigators wishing to comply legally with the doctrine of informed consent.

Proxy consent. Another disturbing issue relevant to the informed consent principle involves proxy consent. A confusing and contradictory body of literature exists dealing with the appropriateness of research done on children. One view—as stipulated by the Medical Research Council of Great Britain (1963)—holds that a strict interpretation of the law would make it impossible for parents or guardians to give permission for research studies on minors "which are of no particular benefit to them and which carry some risk of harm." As quoted in Medical World News (June 5, 1973), Dr. Donald T. Chalkley of the National Institutes of Health said that if given research does not produce something of benefit to the child, neither the parent nor legal guardian has the right to give legal consent for participation. The key elements in this ethical (and legal) issue are the promise of benefit to the minor coupled with the element of a significant risk factor to the subject. If the research holds no promise of a benefit to the participant and there is a significant risk factor involved, minors would simply be excluded from all such research, regardless of parental consent.

One might suppose that the issue of research involving children without any beneficial outcomes is resolvable on the basis of establishing a no-significant-risk condition. But based on the issue of what constitutes an adequate informed consent document, it could be concluded that establishing such a condition is not easy. Because every study undoubtedly produces some risk, the task is to establish that the risks present are not significant ones. It is not clear, furthermore, if the minor must be informed (and perhaps educated) about the risks involved or whether the parent alone must be provided adequate information for an informed (and perhaps educated) consent.

Would the taking of a blood sample, for example, which always carries the risk of a hematoma, be a significant risk? Simple finger-stick devices that are commonly used in cholesterol-screening programs and to assess hemoglobin levels prior to blood donations have a known risk of hepatitis B transmission (Polish et al., 1992). Following several outbreaks of hepatitis B infection, the Food and Drug Administration released a nationwide alert about improper use of such devices.

Exercise and Exercise Tests. Are there significant risks in exercise and exercise testing? The American College of Sports Medicine (ACSM, 1991) weighs the risk of death against the benefits from exercise and concludes that "the overall risk-benefit ratio for an active way of life is favorable" (p. 28). The rationale presumably comes from a comparison of death rates being "transiently increased during the actual exercise period" but decreased for the remainder of the day. Thus, a "slightly higher" risk of cardiac arrest of 21 events per 1 billion person-hours during exercise compared to 18 events in sedentary men is considered reasonable. But the ACSM guidelines for exercise testing also include a statement in the sample of an informed consent document for a health-related exercise test that the risks include "abnormal blood pressure, fainting, disorder of heart beat, and, in rare instances, heart attack, stroke, or death" (p. 30). It is also stated that in a recent survey of over 2,000 clinical exercise testing sites
where more than 600,000 tests were administered, a death rate of about 0.5 per 10,000 exercise tests resulted. Rochnis and Blackburn (1971), however, had earlier reported a mortality rate of 1 per 10,000 tests and an overall combined mortality–morbidity rate of about 4 per 10,000 tests based on a survey of 73 medical centers and 170,000 tests. The ACSM guidelines also note that regardless of the precautions taken "there is no way to eliminate absolutely the risk of a serious event during exercise testing or exercise participation" (p. 31). And as Herbert (1990) has pointed out, there are 29 different professional organizations with standards of guidelines and practices. Many of these guidelines that relate to exercise and fitness are not uniform, nor is sports medicine recognized as a medical specialty by the American Medical Association. For example, Herbert points out a difference between the ACSM guidelines and the American Heart Association guidelines as to who may prescribe exercise. Given such a state of affairs, competent professionals from one area of expertise may disagree on what is a reasonable risk-to-benefit ratio.

Children and Exercise. What are the defined health risks associated with strenuous exercise in children? The ACSM guidelines and a position statement (ACSM, 1988) encourage exercise in children, note that fitness testing of children has a long history, list a number of common fitness test batteries, and recommend procedures be practiced similarly to adult fitness testing. They decline to discuss accepted methods of fitness testing and provide no information on risks involved in testing or exercise.

Control Groups. Intrinsic to the origins of the informed consent document in medical practice and research is the principle of a risk-to-benefit ratio. The original idea was that a subject (patient) would undergo an experimental clinical treatment regimen that might surpass the benefits associated with a traditional treatment regimen. The potential added benefit, however, had to be weighed against possible risks associated with the new treatment regimen. In a medical context such a principle had a certain degree of face validity. If the new treatment regimen possessed the potential of only a slight increase in benefits but was coupled with an increased risk factor, the proposed investigation might be deemed inadvisable on the basis of the risk/benefit principle.

One situation where the risk/benefit ratio comes into play involves the use of a control group. The evaluation of a new therapeutic regimen (or exercise practice) typically includes a comparison of the clinical effectiveness of the new regimen against a traditional regimen, or a control group. Experimental design considerations could call for control subjects' being administered an active placebo. The placebo itself must be safe and not contribute to any increased risk for the subjects. But should the placebo have any beneficial effects? Kabat (1975) has argued that in clinical drug trials a placebo should be chosen for the control group "which is known to be of value against some other infectious disease so that they derive some benefits from their participation" (p. 505). In this manner, every research participant receives some benefit, and the integrity of the research design is not compromised. At the very least, Kabat argues, the placebo should not alter the risk compared to nonparticipation in the research study.

In many studies conducted in exercise physiology and fitness laboratories, a particular exercise system or device may be tested for effectiveness against a more traditional one. Such a practice would garner support from Kabat's point of view because the control group is being given the benefit of the traditional
exercise. However, it is often the case that the control group is a sedentary control, expected, and indeed required, to remain sedentary throughout the course of the study. Is the sedentary control group being treated ethically? One might argue that sedentary subjects accrue no additional risk because they are sedentary to begin with and are merely maintaining an adopted lifestyle. But are they receiving any benefits from participation in the study? Because most fitness proponents profess the positive values of exercise, are not the sedentary control subjects being penalized? If assignment into the exercise and sedentary groups is made from an initial group of sedentary subjects, are the subjects receiving equivalent benefits from participation? Giving subjects a choice between exercise and sedentariness could bias the results. And, finally, what information needs to be included in the informed consent document to adequately inform the research subjects about benefits and risks?

New Ethical Conflicts

Quite recently, and attended by much national publicity and even sensational exposes, a new set of ethical conflict issues has emerged. The Public Health Service (PHS) ruled in 1990 that any university seeking National Institutes of Health (NIH) funding must certify that it has formal regulations for research misconduct. The NIH then established an Office of Scientific Integrity (OSI) with jurisdiction and power of investigation over alleged improprieties in sponsored research. It is still too early to know the full range of the OSI's activities and operating protocols, but its initial definition of scientific misconduct included items such as plagiarism, falsification of data and results, and "other practices." The other practices are those "that wrongly deviate from those that are commonly accepted within the scientific community for proposing, conducting, and reporting research." Observers believe that the OSI will involve itself with issues of conflict of interest as well as scientific misconduct because the two are difficult to distinguish. The OSI and PHS avoid the term fraud in research because it has a different meaning from civil fraud in a legal context (Goodstein, 1991).

Scientific misconduct and fraud are certainly ethical issues in human research, but I will leave them aside here in favor of the conflict of interest question. Although researchers often engage in activities that can be of economic benefit, a conflict of interest may occur when an employee’s outside activities influence the university’s business or other decision-making activities in such a way that personal gain results for the employee or the employee’s family or associates. A conflict of interest may occur, for example, when a university professor who has developed some product sets up a company with private funding, and the private corporation then funds research in the university professor’s lab on campus. Here the issue would be the objectivity of research when there is a personal and financial interest.

In 1989, the PHS issued preliminary guidelines to guard against conflict of interest in federally funded research. The NIH recommended rules that would have prohibited researchers from having any financial investment or receiving money from a corporation whose service or product they were researching and would require them to disclose any potential conflict of interest to their administrators. Well-meaning as it may have been, the recommendation brought a storm of protest from researchers, and the NIH withdrew its conflict of interest guidelines.
Despite the withdrawal of this first attempt, the agency seems committed to formulating suitable guidelines (Palca, 1990). Because conflict of interest disclosure appears to be an inevitable requirement for federal funding, universities and other research establishments will be forced to comply with such directives as they now do concerning informed consent and human subject review.

The following examples from a University of Massachusetts-Amherst draft of guidelines for conflict of interest policies illustrate some potential conflict of interest situations.

- A professor directs student research activities that are designed primarily to serve the professor's entrepreneurial activities rather than the student's personal academic goals.
- A researcher has a contract from the manufacturer of Brand A exercise device. The contract includes remuneration for the researcher and research assistants as well as permanent possession of the exercise device. One study compares the effectiveness of Brand A against Brand B using volunteer university students.
- A researcher develops an exercise device that is patented and marketed for sale. The researcher conducts a study with the device using students enrolled in a fitness course he or she teaches and compares the effectiveness of the exercise device against another, perhaps rival, device.
- A sport psychologist is developing a competitive anxiety scale and tests a large number of age-relevant subjects as part of the scale refinement to establish internal consistency and test-retest reliability.

In each of these examples it might be asked what information should be included in the informed consent document. For example, should subjects be informed that an investigator is receiving remuneration from a private corporation to do research? Should subjects receive a remuneration for their participation in a study inasmuch as they are contributing to the marketability of a product? Are given research studies important contributions to the body of knowledge in exercise science or a more specific contribution to the marketability of a product? Is it reasonable to accept that such research will be free of bias? Indeed, are the benefits primarily to the entrepreneurial researcher and the corporation instead of to the subjects? Are there any direct benefits to the subjects being administered the anxiety scale?

Consider another example of a study not infrequent today. A group of subjects are asked to volunteer to undergo muscular atrophy and concomitant consequences of disuse produced by inactivity induced by some form of external intervention (e.g., casting a limb or remaining horizontal in bed). Certainly such studies are of importance because of anticipated space travel or the medical treatment of paresis or paralysis. It is acknowledged, of course, that disuse atrophy is a negative phenomenon and entails some element of risk. In this case the benefits of participation in the study are not likely to be claimed for the research participants. Instead, the benefits realized will be for other humans, for the space effort, or for medical practice. Because such research is conducted it is obvious that some subjects are motivated to participate in a study with negative benefits and with some degree of risk factor in order to benefit others rather than themselves.
Should, as Bok asked (1978), research ever "place specific persons at risk in order to benefit others" (p. 116)? What information would be provided in the informed consent document detailing the risks involved with disuse atrophy? What safeguards should be taken to insure proper recovery after the atrophy has been produced?

The conflict of interest issue has also arisen in publication practices of scientific journals. The *Journal of the American Medical Association* now asks every author to sign a statement dealing with potential conflict of interest: "I certify that I have no affiliation with or financial involvement in any organization or entity with a financial interest in the subject matter or materials discussed in the manuscript (e.g., employment, consultancies, stock ownership, honoraria) except as disclosed in an attachment." After review of the confidential financial statement submitted by the author or authors, the editor may ask the author to include a footnote in the article about the potential conflict of interest. It seems likely that other scientific and professional journals will consider similar disclosures as, for example, policies adopted by the *Journal of the American Geriatric Society* and the *New England Journal of Medicine*. Recently, for example, *Medicine and Science in Sports and Exercise* (Vol. 24, No. 1, pp. 144-147) published a letter to the editor followed by a response dealing with a claim that a potential conflict of interest may have occurred in regard to review of work submitted for publication. Conflict of interest concerns are likely to increase as academia and the corporate world interface in mutual endeavors.

**Abridgement of Freedom of Inquiry**

The interface between scientists and the public has historically been beset with difficulties. Galileo suffered from dictates of the Inquisition that forbade certain kinds of inquiry based on religious doctrine. Other social and political concerns have consistently produced friction between scientific inquiry and societal concerns. As we have seen, society's concern over safeguards for human subject research has led to many legislative acts and public policies. But as these safeguards came to be enforced, many scientists complained of infringements on academic freedom and distortion of scientific inquiry.

Consider the number of ethical issues that have resulted in confrontations between science and the social welfare: germ warfare and armaments, nuclear energy, cosmetics, microwave towers, genetic work on intelligence, race and ethnicity, and recombinant DNA, to mention only a few. Research on fetuses was the first issue in which the U.S. Congress declared a moratorium on a specific line of research, in conjunction with legislation establishing the National Research Act of 1974. The issue was tied closely to the battle over abortion rights and saw both the House of Representatives and the Senate deadlocked in deliberations.

There is little question that social responsibility and sensitivity to human rights must be recognized in scientific inquiry. But the general principle is plagued with difficulties regarding decisions on specific issues. External control of scientific inquiry has resulted in researchers' decrying the intrusion of politically motivated lay groups who make decisions about the direction and content of research. Institutional review boards (IRBs), in particular, have come in for sharp criticism because many legislated policies are difficult to interpret consistently given the heterogeneous grouping of IRBs, with representation by citizens, clergy,
politicians, administrators, and scientists with a specialty different from the research under review. It has been the unhappy experience of most researchers studying the reviews of a submitted research article that not everyone can understand its importance, significance, or selected methodology. An IRB composed of individuals less familiar with a research study than the reviewers of a professional journal can hardly be expected to conduct reviews that are deemed fair and reasonable on a topic about which perhaps only a handful of other researchers in the world are informed.

The responsibilities of an IRB, however, do include assessing the suitability of proposed research to fulfill its promise of valid results on a topic of sufficient importance to justify the risks involved. Rutstein (1978) put it quite straightforwardly in stating that scientifically unsound studies are unethical. This IRB responsibility inevitably requires attention to methodology of the study and the significance of the topic. If research is poorly designed and methodology faulty, it is unlikely to produce results worthy of the subjects' risk taking. And it is here that IRBs have indicated serious questions about a study's mandate and competencies. Gray (1975) has argued that the scientific soundness of a study must be a relevant issue for an IRB even though its members may feel ill-equipped to judge scientific importance and methodologies. IRBs have been known, furthermore, to disapprove studies on the basis of poorly qualified investigators. One wonders how the journal practice of blind reviews would be evaluated by an IRB. In blind review authors are unknown to reviewers to prevent 'halo effects' wherein well-known investigators may have articles accepted simply on the influence of their reputations. Inherent in the blind review process is the principle that articles should be reviewed on their scientific merits without regard to the reputation of their authors.

In another example of IRB jurisdiction in nonscientific aspects of a study, the board requires an estimate of the amount of time each human subject will be expected to devote to the study. One can only surmise that the IRB is empowered to decide what a reasonable time commitment is for human subjects and to disapprove those studies it determines take too much time. IRBs also require information about the amount of any compensation provided to subjects. Such a provision must lead to decisions about appropriate amounts of compensation, though the original intent was probably to discourage subjects from accepting more than minimal risks in order to earn financial stipends. Numerous related examples could be cited, but it seems safe to suggest that IRBs as well as policies of federal agencies often intrude on researchers' autonomy and make value judgments about the conduct of science, which can be challenged as being beyond their scientific expertise or intended charge.

And it is precisely to this issue that most complaints about institutional review boards have been directed. The IRB often makes recommendations and conditions for approval that transcend simple attention to possible risks and safeguards. The IRB often assesses the scientific worth and methodology of a study under review. So too sensitivity to the needs of society extends to prescriptions for research methodology. Consider the priority announcement for clinical research involving biomedical and behavioral studies of diseases and disorders. The NIH/ADAMHA policy is that applicants must include minorities and women in study populations 'so that research findings can be of benefit to all persons at risk.' If women or minorities are not included or inadequately represented,
"a clear and compelling rationale should be provided." If such information is
not clearly provided, the initial review group is to request such information; if
it is not provided, the application is deferred or returned to the applicant.

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