

# Expanding of Informed Consent at University Medical Centers to Include Trainees as Subjects of Social-Science Research: Implications for Science Editors

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Protecting human subjects in research has been a prominent issue in recent years. In the late 1990s, highly publicized cases of adverse events, including the deaths of patients while they were participants in clinical studies, raised questions about the handling of their involvement. Fairly or unfairly, the investigators and their institutions were brought under scrutiny on several matters, including informed consent. Recent changes in government guidelines for human-subjects protection have expanded the scope beyond the clinical setting usually associated with such guidelines in medical schools, other health-professions schools, and teaching hospitals. For the first time social and behavioral scientists who conduct research on health-professions trainees will find themselves falling under some of the same human-subjects regulations as their clinical colleagues. Some of the new requirements will result directly from specific changes in the guidelines, but more will probably result from universities' desires, in the present climate, to be cautious in interpreting the guidelines and then to apply them consistently in different disciplines and components of the university.

The changes created by the new gov-

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ernment guidelines will affect researchers in the social sciences in several ways. Those who do health-policy research or management studies, social-policy studies, or health-professions education research at all levels are probably already feeling the effects. For convenience this article will use medical education as its context because the field produces the largest volume of social-science research in the university medical center and because the bulk of that research is done on medical students and residents. It is important to keep in mind, however, that the issue affects similar researchers in related settings throughout the university medical complex.

Social-science researchers will need to obtain approval from their institutional review board (IRB) for many, perhaps all, of their studies at university medical centers; this has not been the case. An IRB is a committee or similar formal body charged by the institution—such as a university, a private hospital, a government clinic, or a university medical center—to review proposals for research that involves human subjects, to approve them or not, and to monitor them in accordance with the regulations of the US Food and Drug Administration and the US Office for Protection from Research Risks (OPRR) and with the institution's own guidelines in relation to these regulations. The researchers may also need to get informed consent from participants—for example, medical students and residents—who have seldom been asked to give formal consent. Most far-reaching, however, is the discussion and approval process that arises from the need to distinguish between types of social-science research studies, applicable

protections, and approvals needed. Such discussions of protections are overdue in the medical-center setting, where trainees are studied intensively but often have none of the protections that patients in even the simplest study would have. For example, trainees might be given no option not to participate even in studies on highly sensitive personal issues, or a study might be conducted by a person who has great power and influence over the trainees' future. In some cases, information will be reported in such a way that a knowledgeable reader could easily determine the identity of some minority-group participants. Those problems are inherent in some kinds of social-science studies or ones conducted with trainees, but the studies in medical education are not often designed to mitigate them. This would not be allowed in studies with patients.

Medical students and residents have not had the informed-consent protections that are required by the major social sciences—such as sociology and psychology—and practiced in their university departments. The codes of ethics for such disciplines would have required different approaches to informed consent, greater protection of the trainees as a special population, and special attention to the nature of the power relationship inherent in faculty research that uses student participants. Yet those requirements would all have rested on the codes of ethics for the academic disciplines involved, not on federal regulations. It is the collective ethic of the researchers' academic peers that protects participants when an anthropologist or sociologist conducts a study. In biomedical research, patients in clinical studies have had a wealth of protections;

across the campus at the medical center, it has not been common practice, much less a requirement, that trainees receive either the patients' protections or the protections that the sociologist or psychologist on the main campus would give.

In recent years, ensuring that journal articles document appropriate protection of research subjects has become an increasingly explicit concern of the journals' editors-in-chief. That concern is in line with a variety of their ethical concerns about articles, such as authorship and the role of the editors in disputes about research data between authors and between authors and their institutions. Once the biomedical community came under greater scrutiny in the 1990s, not only did research institutions review or revise their regulations, but some peer-reviewed journals began to require authors of clinical-research papers to affirm or document that the reported research had been conducted with IRB approval. Once adopted by a few leading journals, this new requirement began to spread (although probably it is still required by only a minority of clinical-research journals). Once the policy had been adopted, manuscript editors and managing editors at journals became responsible for ensuring that authors complied—and author's editors of clinical research reports had another concern to raise with their authors.

This article is intended to present an overview of the change, comment on aspects of the differences between the situation at the university medical center and at the rest of the university, and comment on issues for editors at all levels and of all responsibilities to consider.

### **Informed Consent: The Context**

#### *A Half-Century of History*

In biomedical research, informed consent is a concept and practice applied primarily in clinical settings. Researchers want patients or volunteers to participate in studies, and as part of that process the researchers explain the nature of the research, discuss the potential risks and benefits (if any), and give other information. Patients who agree to participate after receiving this information are said

to have given informed consent. Some categories of patients, such as young children and people with mental retardation, cannot give consent, but their guardians can do so on their behalf. Throughout the second half of the 20th century, concerns arose repeatedly in North America and Western Europe over the nature and extent of human-subjects research, including concern about informed consent. Some of the concerns grew from events within biomedical research, such as the Tuskegee experiments in the United States, and from events outside, such as medical experiments during World War II by the German and Japanese governments and the treatment of political prisoners in Russia under the Soviet Union government. Those concerns led to international consensus statements, national laws, and provincial and state laws designed to protect human subjects and to ensure that informed consent was truly informed.<sup>1</sup>

In the United States, major mechanisms for protecting human subjects were stipulations attached to federal research funding. The US Department of Health and Human Services (DHHS), primarily through the Public Health Service, sponsors the overwhelming majority of biomedical research conducted at academic institutions in the United States. DHHS policy and regulation of its funding affect virtually all academic and research institutions, which tend to receive some DHHS money at some time.

#### **The Revised DHHS Policy**

The biomedical-research community has been operating under 1991 DHHS regulations for human-subjects protection (45 CFR 46).<sup>2</sup> In the late 1990s these were revised, partly as a result of the high visibility of the issue during the decade and partly as a response to the usual need for clarifications or for adjustments to meet new circumstances. Throughout the 1990s OPRR issued letters of guidance to assist institutions in interpreting the regulations. The Office for Human Research Protection, the successor to OPRR, reviewed the new policies, as did the incoming Bush administration. The final revised regulations

became effective in December 2001.<sup>3</sup> The 2001 revised regulations had few changes, all having to do with pregnant women, fetuses, and neonates. Therefore, almost all research still falls under the familiar 1991 regulations, and much of the difference is the climate in which institutions are interpreting and how broadly they are applying the 1991 regulations. Much of the difference in interpretation and application of the regulations lies in the area of social science research, the definitions of research, and the protection of special populations (young children and people with mental retardation or dementia). It is not the regulations that have changed, but rather the viewpoints of the administrators responsible for overseeing research and funding at universities.

#### **Extension to Medical Students**

Because the proposed revisions of the 1991 regulations did not affect informed consent, researchers at university medical centers were not concerned about the issue. Clinical researchers knew what they needed to do, and although there were sometimes problems, they were at least on familiar ground.

The new regulations about informed consent did affect other researchers, however, even if they and their institutions did not know it. When university administrators, including those at university medical centers, studied the 1991 regulations in the climate of greater government scrutiny and an awareness of the sensitivity of human-subjects research, they read some of the existing 1991 language differently from before. A prudent, inclusive reading of the regulations makes it clear that students and other trainees who participate in social and behavioral science research must give informed consent in many circumstances. When the administrators asked for guidance from their own or the government's specialists, they learned that the government considered the language to mean exactly what it said—the protection extended to all human subjects in research, including trainees in internal social science studies.

Most affected by the new interpretation are medical schools, teaching hospitals, and

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their affiliates. Unlike counterparts in the main university, most who have conducted social science research in these institutions have done so with the understanding that, for example, the students do not need to give consent or they give blanket consent at enrollment when they sign general documents, such as a statement agreeing to participate in all student activities or in educationally related studies while they are students at the school.

These health-professions institutions will need mechanisms to screen the social science research. The regulations allow expedited review and waivers of informed consent in specific circumstances. A major part of any new system will be to determine which studies require informed consent and which are exempt according to the regulations. Important distinctions might be, for example, whether risk is minimal, whether the research cannot practicably be conducted without a waiver (as when the participant's awareness defeats the purpose of the study), and whether the study is conducted and approved by a state or local government to examine public programs.

At some institutions decisions about exemption can be made by a department head or upper-level administrator. But because the distinctions involved could be difficult and because the institutions want to be prudent, some medical schools and teaching hospitals are requiring that all studies, of whatever type, involving human subjects must be submitted to the IRB. The IRB, however, decides on how it wants to handle studies in the social and behavioral sciences, which are quite different from the clinical studies it is used to handling. It may even face the prospect of needing a separate IRB for these studies.

### **The Medical Center and the Rest of the University**

Looking at the experience of medical students and residents is a good way to see the gap between informed consent as conceived at the university's social science departments and the way it has been handled at the same university's medical schools and teaching hospitals. Medical students, for example, are tested and probed

for 4 years with respect to their scientific and clinical skills, opinions about a wide range of topics, psychosocial backgrounds, personal habits, behavior, and innermost thoughts. Recent articles derived from such probing have covered topics as varied as, for example, medical students' perceptions of academic vulnerability associated with personal illness,<sup>4</sup> why medical students felt embarrassed in taking a sexual history and how that embarrassment was related to their personality traits,<sup>5</sup> and the nature and frequency of faculty members' unethical conduct that the students have witnessed.<sup>6</sup> Yet until recently trainees in such studies would seldom have been asked to give consent. It was accepted as part of the culture that they participate in all the studies presented to them.

### **Ethical Norms in the Social Sciences**

The medical school researcher's conception—or lack thereof—of the need for informed consent from medical students and residents has often been a surprise to a social scientist coming in from the main university campus. The surprise results from the different emphasis placed on informed consent and therefore on the nature of the relationship between researcher and subject. It also reflects the fact that research in the medical school is done both by social scientists on the faculty who specialize in the health professions setting and by health professionals who also do social science research (sometimes with specialized training in the subject, often without).

The importance of informed consent in research is firmly established in the ethics codes of major social science societies. A look at two of the largest disciplines, sociology and psychology, makes the point easily.

The "Code of Ethics" of the American Sociological Association, the oldest and largest professional organization for sociologists in the United States, devotes a section to informed consent.<sup>7</sup> In the opening general statement, this section states:

Informed consent is a basic ethical tenet of scientific research on human populations. Sociologists do not involve a human being as a subject

in research without the informed consent of the subject or the subject's legally authorized representative, except as otherwise specified in this Code. Sociologists recognize the possibility of undue influence or subtle pressures on subjects that may derive from researchers' expertise or authority, and they take this into account in designing informed consent procedures.

A detailed subsection deals with the scope of informed consent; its gist is that it is almost always needed, that waivers must come from institutional boards, and that any questions about any part of informed consent in a study should be discussed and worked out with a board. A separate subsection deals with students and subordinates: "When undertaking research at their own institutions or organizations with research participants who are students or subordinates, sociologists take special care to protect the prospective subjects from adverse consequences of declining or withdrawing from participation."

The "Ethical Principles of Psychologists and Code of Conduct"<sup>8</sup> of the American Psychological Association (APA), the major professional organization of psychologists in the United States, also address the issues. In describing part of basic research responsibilities, the code says:

Prior to conducting research (except research involving only anonymous surveys, naturalistic observations, or similar research), psychologists enter into an agreement with participants that clarifies the nature of the research and the responsibilities of each party.

The section on informed consent contains provisions such as "When psychologists conduct research with individuals such as students or subordinates, psychologists take special care to protect the prospective participants from adverse consequences of declining or withdrawing from participation" and "When research participation is a course requirement or opportunity for extra credit, the prospec-

tive participant is given the choice of equitable alternative activities.” The section also deals with how the psychologist is to “consider applicable regulations and institutional review board requirements” before determining that planned research does not require informed consent.

The section on informed consent is less detailed and forceful than the counterpart in the code for sociologists, but it covers the same basic points. What is important is that APA officially considers these to be enforceable standards, not guidelines or aspirations.

The American Anthropological Association also has a detailed “Code of Ethics”, perhaps the subtlest of the three mentioned here.<sup>9</sup> In many ways, it is like the codes for sociology and psychology, but in an important respect it is deeper in how it directly affects informed consent for students. This point will be taken up later.

The American Educational Research Association (AERA) does not have a code of ethics, although it is a large and active body of researchers. (The American Education Association is a professional association for teachers. It deals with workplace issues but not with research and scholarly ones, which are in the purview of AERA, a separate organization.) A point to note is that many of those who do educational research do so after coming from another discipline, such as psychology or statistics; nonetheless, the majority have their professional training in education, which does not have a code of ethics for its practitioners as researchers and academics.

### Roots of Differences at University

#### Medical Centers

Some medical school faculty have always obtained informed consent from medical students and residents—perhaps because the studies were funded by federal grants, perhaps because of the ethics codes of their scholarly disciplines. But a great deal of social science research involving medical students and residents at university medical centers is conducted as part of normal faculty activities and therefore requires no funding, or it might be supported by

general funds from the administration. In any case, this larger number have followed what might be called the “local tradition”, that is, the idea that students either do not need to give consent or have already given it by signing general documents at the beginning of each school year. This local tradition would make no sense in a department of sociology or psychology, but it did not grow in a vacuum or out of callousness.

Roberts and others<sup>10</sup> wrote an essay exploring ethical and policy issues in the dual roles of teaching and doing research. They give a useful insight, which hinges on the distinction between *investigation in medical education* (which has a primary goal of advancing scientific knowledge) and *scholarly practice in medical education* (which seeks to improve students’ knowledge and skills and includes evaluation of programs). Both involve systematic inquiry and research but for different benefit. But there is another difference. Education research involving human subjects is intended for dissemination throughout the scholarly community and to advance scientific knowledge and therefore is subject to federal regulation (and usually IRB approval). As the authors explain, inquiry into scholarly practice in education, which aims to improve students’ learning, tends to be guided by, for example, institutional procedures, accrediting guidelines, and local values.

The distinction between investigation in education (with the goal of advancing knowledge) and scholarly practice in medical education (seeking to aid students) would, in theory, apply to any discipline. But education seems to be the prime example, with health-professions education being the most highly developed. This is not the place to examine why education became the focus, but understanding why education research in the health professions is highly developed is much simpler. The education stakes and correspondingly the social investment are high for society, which wants to be assured that graduates are competent and can do what society expects of them (whatever that is for each

health profession). Therefore, education research became a prominent feature of medical schools (and other health-professions schools), primarily because only education research could demonstrate whether applicants or matriculants or graduates could perform appropriately.

Although Roberts and others do not draw this inference, it is interesting that over recent decades the main social science departments moved in one direction and the medical schools in another. Ironically, the social science departments moved toward greater human-subjects protection in line with the protections given in the clinical setting, while the medical schools cast the cloak of scholarly practice research over all social science research done in the institution. As a result, perhaps, a culture grew up in which no stronger protection was given to medical students when they participated in studies of drug abuse, for example, than in studies of comparative teaching methods in anatomy. Over time it seemed natural to the university departments that students needed special protections and to medical schools that they did not.

### Medical-Center Norms Expressed in Two Journals

In their essay on the implications of the dual role of teaching and doing research, Roberts and others included the results of a study they conducted. They examined the extent to which ethically important elements of research were noted in published articles in one leading US journal and one leading British journal—*Academic Medicine* and *Medical Education*, respectively—that together publish the large majority worldwide of research in medical education. (Truth in labeling requires a comment that I was editor of *Academic Medicine* when the study was done, although I was not aware of its being done.)

The journals proved to be clearly lacking. The researchers hypothesized that six ethically important safeguards—review by an IRB or by an education review committee, protection of confidentiality, informed-consent processes, incentives for

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participation, and source of research funding—would rarely be mentioned in the published articles. And they hypothesized that the six safeguards would be documented no more often in 1998 and 1999 than in 1988 and 1989. In their final results (based on 424 empirical articles that met all selection criteria), both hypotheses were soundly upheld. No article documented all six safeguards, and 47% mentioned none of the six. Statistical analyses showed only modest increases over the 10 years, with only the increase in reporting of an IRB or an education committee being statistically significant (at  $P=0.02$  and  $P=0.03$ , respectively). Cross tabulations by years and by journal showed that the journals differed little, with *Academic Medicine* showing statistically significant increases in the mention of IRBs and incentives and *Medical Education* showing a “reliable increase in reporting of confidentiality”.

The authors point out that these results are similar to those of an earlier study in the geriatrics literature that used the same method. In the earlier study, 23% of the published reports mentioned informed consent and 5% mentioned IRB approval. Further review of the reports showed that some authors gave detailed descriptions of the safeguards and others essentially no information.

### **Toward a Unified Approach to Protection**

#### Implications for Researchers

Social-science researchers at university medical centers were initially apprehensive when they became aware that their universities would begin to apply DHHS regulations to their studies. The prospect of undergoing IRB review and similar requirements was daunting. Furthermore, they thought of potential problems, such as decades-old databases (and the absence of any grandfather clause in the regulations) and the impact of students' withdrawal on studies that involved differential impact on ethnic and racial minorities and on men and women. They know how difficult it is to entice medical students and residents to take time from their schedules to participate in studies, and they foresaw

steep dropout rates if elaborate informed consent procedures were required.

To a great extent the early fears have lessened. It is clear that whole categories of studies will not require informed consent and that many may not require IRB approval. Studies based on longitudinal databases in which all identifying information has been removed and all data are aggregated, for example, will not normally require consent. Also, studies of minimal risk and never to be used for publication can easily receive a waiver, although the possibility that any part of the study results might eventually be part of future research that might be published could lead researchers to seek approval. Many schools, to be safe, are requiring that all studies be submitted to IRBs, but they are also setting up expedited review systems for all that qualify. Therefore, a combination of expedited review and exemption from informed consent will substantially lower the number of studies wholly affected.

As noted above, however, one of the most valuable aspects of the stricter application is the extent and level of discussion raised between fellow researchers, among colleagues, and between faculty and administrators about the important issues of human-subjects protection in social sciences studies in general and of protecting students in particular.

Beyond that general hope, however, lie specific steps and programs that have been suggested.

Research faculty must understand that they will always face the problem of dual-purpose activities (or of “wearing two hats”) as they conduct research and teach or as they conduct research and treat patients. And they must teach students and residents about this difficult situation and how to deal with it properly and ethically. The social science faculty conduct studies in which medical students participate. The studies themselves can be used as a focus for teaching about human-subjects protection and related issues so that students learn about human-subjects protection through direct experience. Later clinical faculty should teach the issues in the clinical setting, preparing the students

to become physicians who must both treat patients and sometimes use them as research subjects.

The American Anthropological Association's “Code of Ethics” explicitly takes up the problems of inherent ethical conflicts — particularly those caused by the dual (or more) roles — and sets high standards for anthropologists to meet.<sup>9</sup> First, the code accepts as a basic tenet that ethical conflicts underlie all anthropologic work and that the task is to deal with the issues openly and to the best of the individual's and the group's ability.

Anthropological researchers must expect to encounter ethical dilemmas at every stage of their work, and must make good-faith efforts to identify potential ethical claims and conflicts in advance when preparing proposals and as projects proceed.

Further, this code is particularly strong in its injunctions as to what teachers are responsible for in the ethical education of their trainees:

Teachers/mentors should impress upon students/trainees the ethical challenges involved in every phase of anthropological work; encourage them to reflect upon this and other codes; encourage dialogue with colleagues on ethical issues; and discourage participation in ethically questionable projects.

The association's code deals more explicitly and thoroughly with conflicting values than the sociologists' and psychologists' codes. And at the end, the code sums it up very well:

Anthropological research, teaching, and application, like any human actions, pose choices for which anthropologists individually and collectively bear ethical responsibility. Since anthropologists are members of a variety of groups and subject to a variety of ethical codes, choices must sometimes be made not only between

the varied obligations presented in this code but also between those of this code and those incurred in other statuses or roles.

Henry and Wright<sup>11</sup> discuss a medical-school curriculum based on teaching about the dual role—the teacher-student and the doctor-patient relationships. This established program is taught by clinical faculty.

Henry and Wright also recommend ways to strengthen institutional policies to protect students as research subjects in social-science studies. Their five recommendations are (1) that the institution require that all institutional evaluations that use study data and that constitute research have IRB approval, (2) that the medical-education research profession as a whole set explicit policies and maintain standards through journals, funding agencies, and professional societies, (3) that faculty inform students during orientation about the school's institutional database, how their data will be used, and the safeguards to protect their privacy, (4) that IRBs help faculty to develop procedures to get students' informed consent for evaluations based on student data, and (5) that institutions give their IRBs sufficient support and resources.

Similarly, Roberts and others<sup>10</sup> discuss the inherent conflict in the dual role of teacher and researcher, examining the implications for medical faculty, academic medical institutions, students, and editors and peer reviewers. They also make recommendations. Whereas the first three groups are not unusual in such an article, the fourth (editors and peer reviewers) is. The overall implication is that only rigorous safeguards can protect student participants in research. The authors make a series of recommendations linked to the implications for the four groups. The list is too long to detail here, but these will illustrate:

*Academic medical faculty*—Carefully consider the potential issues surrounding the source of funding for the project you wish to undertake.

*Training institutions*—Develop and implement a mechanism of appeal for students who have ethical concerns regarding education-research participation.

*Students*—Seek student representatives on education committees and your institution's IRB to address ethical issues that may arise.

*Editors and peer reviewers*—Require documentation of ethically important features and safeguards in the body of the manuscript or in a cover letter accompanying the submission.

(The article contains a table listing the authors' recommendations for ethically sound practices for members of each of these four groups.)

### Recommendations for Science Editors and the Community of Editors

Strengthening protection for medical students, residents, and all health-professions trainees when they are research subjects in social science and behavioral science research is long overdue. Treating them as they are expected in the future to treat their patients is not only the right thing to do, it is the best way to teach the complexity of the dual roles they have as physician-researchers.

This complex of issues has direct consequences for editors throughout science publishing. Because I am most familiar with journals, my comments will apply primarily there, although not exclusively.

First, editors-in-chief should work with their editorial boards, the oversight boards of their sponsoring societies, or internal working groups to examine the ethical issues of protecting trainees as human subjects of social science research. The editors should then develop the policies deemed appropriate to set and maintain high ethical standards for their journals. The editors in each research community should discuss the possibility of shared standards, working as far in that direction as possible even if initially the progress is slow. The Council of Science Editors can play an important

role here as it has in promoting discussion and adoption of other standards. The World Association of Medical Editors, with its eclectic membership and electronic reach, can also be useful.

Second, managing editors and manuscript editors in editorial offices or publishing houses need to be ready for required documentation of IRB or similar approval of research that involves trainees as subjects. In some ways this is parallel to the late 1980s, when journals began to require documentation (usually statements) about authorship and the editor's office or the publishing house began to collect file after file of the new forms. The new policy will require a considerable changeover period and will involve educating and calming authors, many of whom will be alarmed at the thought that their research may suddenly become ineligible for publication after the fact. Also, the editors need to become knowledgeable about the issues so that they can discuss problems with the editor-in-chief and with authors and can be involved in creating and troubleshooting the early procedures.

Third, author's editors should be prepared for such a documentation requirement to arise at leading biomedical journals. Such a requirement is common now with clinical studies, so the concept will not be foreign to some authors (MDs who also do social-science research, for example), although it will be surprising to some who have never had to meet such requirements at their institutions. Here as elsewhere, the author's editor's responsibilities are to inform and assist tactfully—the author must solve the basic problem.

There is no question but that science editors in their professional duties can and will deal well with any new issues and requirements related to human-subjects protections for trainees. Beyond that is the question of what the community of editors as a whole could do. It would help readers and researchers to have a consensus as to the most important or core elements of such an ethical statement. The recent study of two journals<sup>10</sup> looked at six safeguards, but these might not be the ones that the research community or the ethi-

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cists, for example, consider most important. Furthermore, is the desired outcome mainly for the primary author to tell the editor that the study has IRB approval and for a statement to that effect to appear in the published report? Or is it to have explanations in the published report of what was done, similar to the six safeguards used in the recent journals study? If any research community wants the latter, the editors-in-chief in that community need to begin working with the community toward a consensus on what is needed, taking into account the differences between disciplines and the research traditions. 

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