

Research as a Profession

Robert Wachbroit

There is good reason why most medical research is conducted by practicing physicians: their experience and judgment are often valuable assets in the design and execution of a research protocol. But physician-researchers are caught in a conflict of interest. This conflict is due to basic differences in the goals and practices of medicine and research. The physician's goal is to care for the patient, to promote and maintain his or her health, whereas the researcher's goal is to produce "generalizable knowledge." These distinct goals lead to practices and methods that are not only different, but also sometimes contrary: researchers regularly employ the techniques of double-blinding or randomization, while a physician who dispenses treatment in a double-blind manner would rightly be seen as irresponsible. Such common observations have led many scholars to wonder: How can one be a responsible physician *and* a responsible researcher?

The Unsteadiness of 'Equipose'

The frequent if not standard response to this problem is to invoke the concept of equipose. If the physician-researcher is *equally* uncertain about all the arms of a study—the different treatment conditions to which subjects are assigned—then he is in equipose, and he can assign a research subject to any arm without believing that he is shortchanging the subject in terms of medical care. The physician-researcher can thus seek generalizable knowledge without undermining his duty to provide the best known care.

Despite its popularity, this response is unsatisfactory for a variety of reasons. As several commentators have remarked, achieving or maintaining a state of equipose is both unrealistic and unstable. It is difficult to believe that the researcher, conducting a clinical trial, is equally uncertain between the experimental treatment and the control because by the time the study has reached this stage of investigation, the researcher has already performed or is familiar with various preliminary studies that presumably justify the considerable time, effort, and expense needed to continue the research. This does not suggest the mind of someone who believes that it is a toss up, a flip of the

coin, whether the experimental treatment or the control is better.

Furthermore, even if the researcher began the study in a state of equipose, it would almost always be undermined as the study progressed: if the data suggested even a slight trend favoring one arm of the study, equipose would be destroyed and, according to the common view, the physician-researcher could no longer ethically continue the experiment.

There have been several responses to these concerns, including shifting the focus of equipose from the researcher to the research subject or from the individual researcher to the research community. But none of these proposals address the most important objection to appealing to equipose. They concern only one type of research activity: research in which the subject might benefit medically from participating in the research, the most common example of which is the randomized clinical trial (RCT). But medical research consists of more than RCTs. A good deal of research is exploratory, offering little or no likelihood of therapeutic benefit. Consider, for example, a study of some cancer treatment in which subjects in an advanced stage of the disease are given different doses of the treatment in order to determine the appropriate dose for further studies. The researchers, the research subjects, and the professional community know that most people will not derive any therapeutic benefit from participating in this research. Some might benefit therapeutically from participating, but most will not; either because the dosage will be too low and thus ineffective or else too high and possibly harmful. The concept of equipose has no purchase in such settings. But without appeal to equipose, how can the *physician-researcher* pursue such dosage determination studies—or research on healthy volunteers—without conflict with the physician's goal of caring for and promoting the health of the patient?

A Profession in its Own Right

There are three responses to the problem of different goals. (1) We could try to identify those cases where the two goals overlap and restrict research to those sit-

uations. This is the strategy of appealing to equipoise. The difficulty, as we have noted, is that this overlap is not sufficiently large and stable to sustain medical research. (2) We could try to revise the goals so as to avoid a conflict. For example, we might consider the physician's goal to be the maintenance and promotion of health, without any mention of promoting what is in the patient's best medical interests. The difficulty here of course is that it radically alters if not undermines the physician-patient relationship. How can the patient trust or follow his physician's recommendations if he does not believe that his best medical interests are being promoted? (3) We could acknowledge that medical care and medical research differ in goals, methods, and, consequently, ethical requirements. But what does such an acknowledgement consist in? Just arguing that a clear understanding of the difference between research and medicine care renders the concept of equipoise unnecessary (as medical ethicists F.G. Miller and H. Brody argue) is not enough. We need to move from regarding research on human subjects as an activity that some physicians perform to regarding such research as a profession in its own right, distinct from the profession of medicine. Thus, the tension between being a physician and being a researcher is not a tension within a profession but a tension between two different professions.

Tensions or conflicts between professions are not uncommon, nor are they unexpected in light of their different missions. The lawyer's duty to advocate for his client's rights does not always mesh with the physician's duty to provide medical care to his patient or with the journalist's duty to inform the public. This remains true even if the same person belongs to more than one profession. So, for example, choosing the same person as one's doctor and lawyer would likely create a serious problem—any conflict between professions would automatically become a conflict of interest for the individual professional. As they say, you should wear only one hat at a time.

If biomedical, human subject research is a profession, then the people conducting the research are wearing the hat of the (professional) researcher, regardless of what other professions they might also belong to, including the medical profession. This of course does not mean that the researchers should be indifferent to the health conditions or needs of research subjects, but their concerns and duties are not those of a physician. They have a duty to ensure that research subjects are not exposed to unreasonable risks and to ensure (not necessarily administer) appropriate medical care for conditions that are a consequence of the research. While I am not proposing here a specific code of conduct or professional ethics for researchers, distinct from the code governing physicians, constructing one would not be difficult. It is at least implicit in the

increasingly elaborate requirements and guidelines for conducting human subject research. Applying the discussion of professional ethics—sometimes called “role morality”—to research as a profession can offer insights into the obligations, responsibilities, and special social role of medical researchers. More work needs to be done in this area.

Treating human subject research as a profession in its own right not only eliminates the need to employ the concept of equipoise, it also addresses certain confusions research subjects might have that go under the name of “the therapeutic misconception.” The misconception occurs when research subjects believe that the study in which they are participating is therapy and that their relationship towards the investigator is that of patient to physician. Although investigators and their consent forms make an effort to disabuse research subjects of this misunderstanding, it persists. If it were clear to everyone that research was a different profession from medicine, it seems less likely that research subjects would regard a study as treatment, the investigator as a physician, and the subject as a patient. Even if your lawyer happens to belong to the medical profession, you don't confuse his legal advice with medical advice.

What would it mean to treat biomedical research on human subjects as a profession? Although there are no universally recognized criteria that distinguish a profession from other skilled vocations or activities, many professions are associated with three institution-related features: (1) specialized education and training, (2) licensing or certification, and (3) some sort of oversight

Treating human subject research as a profession in its own right not only eliminates the need to employ the concept of equipoise, it also addresses certain confusions research subjects might have. . . .

over members through professional standards. When we consider research as a profession, the applicability of (1) is straightforward and uncontroversial. Everyone acknowledges that biomedical research requires training that is distinct from the training required for medicine, even if overlapping. Although the other two features are less well-recognized, recent developments seem to point in their direction.

For some years the National Institutes of Health, one of the most important sources of funding for biomedical research in the US, have required researchers to provide in effect certification that they can conduct responsible research. While this is not as demanding as the licensing requirements in medicine or law, it does suggest a recognition that there are professional stan-

dards to which practitioners must certify their competence and compliance. Furthermore, any research that hopes to be supported by the federal government or accepted by the FDA must be approved by an Institutional Review Board (IRB). While not the same as State Licensing Boards, IRBs, whose membership will include researchers, do have the power to bar individuals from acting as biomedical researchers in their institution. In some respects, therefore, research is beginning to be treated, at least implicitly, as if it were a profession. Treating it explicitly as a profession may not be so radical a step.

Research as a Profession: A Problem and a Compromise

Nevertheless, let me acknowledge an important problem with research as a profession—or, in fact, with any approach that maintains a sharp distinction between medical care and medical research: If biomedical research as a profession distinct from medicine, it becomes questionable whether physicians should refer or recommend patients to research studies. It would seem inappropriate—an abuse of the patient's trust—for a physician, acting in his professional capacity, to refer a patient to his banker, lawyer, or realtor; if the physician were compensated for these referrals, it would certainly have the appearance of a conflict of interest. Accordingly, one might hold that, if biomedical research were a distinct profession, physician referrals of their patients to researchers would be similarly inappropriate. This conclusion, however, would place a significant burden on the recruitment of subjects for important studies.

It is worth exploring whether this problem can be solved with a compromise—perhaps we should replace physician referrals with information displays in hospitals and in the physician's office? Treating biomedical research as a profession, distinct from medicine, does not mean ignoring their interdependencies.

While distinct from the other health professions, biomedical research still needs to be coordinated with these professions. And yet, treating it as a distinct profession can help us better understand what is being asked of us when we perform or participate in research.

Robert Wachbroit
Research Scholar
Institute for Philosophy and Public Policy
University of Maryland
rswa@umd.edu

I am indebted to David Wasserman for helpful comments and suggestions. I also wish to acknowledge support of FIC/NIH 1R25 TW007090-01 in writing this article.

Sources: S. Hellman and D. Hellman, "Of Mice But Not Men: Problems of the Randomized Controlled Trial," *New England Journal of Medicine* 324 (1991), 1585-89; C. Fried, *Medical Experimentation: Personal Integrity and Social Policy* (Amsterdam:North Holland), 1974; B. Freedman, "Equipoise and the Ethics of Clinical Research," *New England Journal of Medicine* 317 (1987), 141-14; F.G. Miller and H. Brody, "A Critique of Clinical Equipoise: Therapeutic Misconception in the Ethics of Clinical Trials," *Hastings Center Report*, 33 (2003), 9-28;; on role morality, see D. Luban, "Professional Ethics," which is found in *A Companion to Applied Ethics*, (Blackwell Publishers, 2003) edited by R. Frey and Christopher Wellman; for information on certification required by the National Institutes of Health, see: <http://grants2.nih.gov/grants/guide/notice-files/NOT-OD-00-039.html> (accessed for article July 7, 2005).

