From the Editors

It is easy to take for granted the standards set internationally for informed consent in healthcare. In theory, with respect to research, essentially none can be conducted without proper attention to informed consent for human subjects. The Nuremberg Code and the later Helsinki Accords make this crystal clear. With respect to clinical practice, informed consent to treatment plans has come into play largely with the patient's rights movement and was not a feature of traditional medical paternalism. However, increasingly respect for patient decision-making capacity has been seen as an intimate part of the process of healing and the goals of healthcare provider and patient interaction.

Sometimes it is important, then, to reexamine issues of consent to see not only how medicine is doing with respect to international standards, but also to deepen our understanding of the implications of consent in areas in which it has not been previously fully considered. As this issue demonstrates, the standards of informed consent are accepted with a great deal of variability, and their appropriateness is still being debated.

This issue also demonstrates that we have come a long way over the past half-century regarding informed consent. Yet we still have a long way to go. As proof of this, the recent publication in the United States of the Government Radiation Panel Report reexamined commitments to informed consent.[1] Although President Clinton apologized to the thousands of nonconsenting subjects and their survivors for the decades-old research on radioactivity[2] done mostly right after the Second World War during the Cold War years, for those who insist on current standards of research, an apology is not enough. Yet the Panel, whose report is controversial, had to wrestle with the fact that universally accepted standards had not yet been set when much of the research was done. Also its primary task was to determine if restitution was in order. Hence, the ethics of its report concerned an economic form of justice rather than a moral one.

We still have a long way to go, nonetheless. In making its recommendation for compensation, the Panel argued that a "legacy of mistrust" has built up around the disclosures of government wrongdoing. Even though "wrongs were done" throughout the radiation experiment program, the report in effect argues (and this is the controversial point) that one is only *harmed* (monetarily speaking) if one has been subjected to serious medical interventions against or without one's consent, rather than seeing *harm* done by the very act of intervening without consent. Today that higher standard would seem to apply to medical research and clinical practice itself. The Panel determined that only 18 persons out of hundreds had been subjected to sufficient radiation to cause physical harm (they were injected

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with plutonium without their knowledge). Only these people were to receive monetary compensation from the government. The rest got their public apology from a government that supposedly is no longer in the business of conducting research without consent.

It is often said that the winners write the history. If the Nazis had won World War II, we would suppose that this research and the very prominent physicians and institutions that conducted it, would have been condemned in a public tribunal. At least the Advisory Committee panel found "serious deficiencies" in current ethical policies today. This means that the Report represents an opportunity to begin a major public campaign to educate physicians and researchers about the importance, indeed, requirement for informed consent.

Our Special Section on the Issues in Consent, opens with the advancement of informed consent to the clinical practice, in this instance, of psychiatry. Edmund Pellegrino explores the ethics of a biography about Anne Sexton, a poet who committed suicide. Her odyssey included psychiatric treatment that her biographer judged essential to understanding her poetry and her life. Neither Sexton nor her therapist ever conceived of the tapes of their session being used later, nor was any consent to do so ever given. After her suicide, her daughter, the executor of the estate, ordered the tapes to be given to the biographer, causing some harm to survivors. Does consent end with our death? If we cannot be harmed, does it matter if others close to us might be?

Barry Furrow takes up a very different aspect of consent. When the physician becomes a "possible pathogen," exposing patients to risks from transmissible disease or personal shortcoming, what ought to be required in terms of disclosure? How much weight should informed consent doctrine be made to bear?

Two philosophers look at informed consent in the articles by Barbara MacKinnon and Amnon Goldworth. MacKinnon examines whether informed consent is as important as we think it is for controlled clinical trials. A controlled clinical trial is a kind of "in-between" medical research protocol, because it combines research on therapy for one randomized group, and for the other, nontherapeutic experimentation (the second group get standard therapy or even a placebo). Exactly what are clinically ill patients consenting to, then, when asked to participate in such research? And how can therapists willingly put chronically ill patients, with say Parkinson's disease, on such protocols? It creates a conflict of interest for them.

Amnon Goldworth explores in more critical depth the skepticism that still surrounds informed consent in the clinical setting. He addresses ways of disclosing and offers a proposal as to how it should be generally applied. The need for the kind of discussion raised by Goldworth is clearly demonstrated in the study by Chris Ciesielski-Carlucci, Nancy Milliken, and Neal Cohen that illustrates problems in disseminating information regarding a procedure as frequently performed as circumcision.

Joan Porter widens the focus and addresses some of the issues in seeking informed consent in international collaborative research. Some suggestions are offered for designing a relevant informed consent process, especially in developing countries.

Another paper with implications for consent is Lawrence Schneiderman and Nancy Jecker's continuing study of the implications of futility and their discussion whether a treatment can be portrayed to the patient as beneficial, experimental, or futile. The authors focus on the pressure on physicians to offer patients "the newest treatment" in the erroneous assumption that what is

newer is necessarily better. This pressure has a direct impact on the consent by the patient because there is almost too much trust in the physician and medicine's falsely perceived limitless abilities.

Although exploring a range of issues and questions of informed consent in both research and clinical settings, what the papers in this issue have in common is the recognition that the *informed* part of *informed consent* does not modify patients or subjects—it modifies health providers and researchers. And, by examining the duties of when, under what circumstances, and in what manner there is a duty on the part of those working with patients and subjects to make disclosures, the Special Section underscores a critical distinction often forgotten, as history demonstrates, to the detriment of patients and subjects.

Notes

1. Advisory Committee on Human Radiation Experiments. Final Report. Washington, DC: United States Government Printing Office, October 1995.
2. Scripps Howard News Service. Clinton apologizes for the wrong done in human radiation testing. *Chicago Tribune*, 1995; Oct 4:§1:9.