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Project Title: A PRACTICUM IN RESEARCH ETHICS

Description:

Background: *The Ideal of Informed Consent in Practice*

An emerging empirical literature on research participation has provoked a constructive re-evaluation of the standard of informed consent and an awareness of its practical limitations. Since regulations are often silent as to the meaning of capacity to consent to research, researchers are left with a “heroic standard” of decisional capacity that often cannot be met by many patients and in many settings. Patients with schizophrenia, for example, often have profound deficits in their awareness of their illness and need for care. They may be delusional about critical aspects of the study being considered, they may have attention and information processing deficits, or they may evidence profound ambivalence or passivity. Patients with depression may evidence despair and hopelessness that may influence decision-making, or simply make them “not care” about the risks associated with a protocol. The poor may be unable to resist significant cash incentives or offers of otherwise unavailable medical care, and so on. The hospitalized patients’ “therapeutic misconception” or the desperate solutions sought by the terminally ill reveal the complexities of the concept of informed and voluntary consent in actual clinical circumstances.

Furthermore, neither research nor regulation has significantly influenced the development of *procedures* for informed consent. Traditional approaches to consent have to be considered inadequate given the greater emphasis on the many dimensions of “vulnerability” and the greater demand for information disclosure. While it remains vitally important to focus awareness among researchers on barriers to informed consent in specific populations, if we are to protect vulnerable patients while furthering worthwhile scientific inquiry, we most devote more attention to efforts to translate the ideal of consent to meaningful practice.

Course: *A Practicum in Research Ethics*

We have developed a course in applied research ethics for clinical investigators and members of institutional review boards. The program addresses an unmet need at our medical center, and initiates a valuable collaboration between the faculty and staff of the New York State Psychiatric Institute and the Center for the Study of Society and Medicine at Columbia University. The curriculum, taught by established clinical investigators and ethicists, is designed to familiarize program participants with core principals and seminal events in the history of the ethics of human experimentation with a focus on work with vulnerable populations. The syllabus draws upon the theoretical and empiric literature in research ethics to educate participants on informed consent and the assessment of capacity. Research with ethnic and racial minorities and immigrant populations will be discussed to underscore often overlooked matters of ethical and social importance. The course structure and content is tailored to the needs and interests of those actively involved in research and research oversight; the program takes a practical and clinical approach. Methods to enhance the informed consent process will be presented in small, case-oriented workshops. *A practicum in research ethics* aims to promote the ethical conduct of clinical investigation by teaching core ethical principles, by increasing awareness of the vulnerabilities of special populations, by providing consensus training in the assessment of capacity, and by encouraging discussion and debate.

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