

Commentary: Refusing to Give up on Forensic Research

John L. Young, MD

Increasing regulation may soon cost forensic patients the opportunity to benefit from participating in research. A wise preventive strategy is the institutional use of quality assurance and related processes for regulating its internal research. Candilis and colleagues provide abundant useful information for this purpose. Additional models to consider include a centralized Institutional Review Board, study coordinators, and services researchers. Research needs to be done on the regulation of forensic research.

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It was a very popular study among our patients. Participants received a special watch programmed to provide a beeper tone at random times, and when it sounded they were to enter answers to a brief questionnaire about their thoughts and feelings at that moment. Later, the responses were entered into a protocol aimed at defining risk factors for violence.^{1,2} However, the investigators were restricted from recruiting any participants among the patients referred by the Department of Correction (DOC). Practical considerations precluded any serious hope of satisfying the DOC's requirements for recruitment of research subjects. However, the demand for enrollment was so strong that the investigators relented and permitted DOC-referred patients to go through the procedure, except that, of course, their data were ignored.

Yet there was no deception. We informed the DOC patients that we were not permitted to use their data, but they refused to be put off, so much did they desire to gain the obvious benefits of participation. The DOC patients still enjoyed, at least vicariously, the enhancement of self-esteem that comes from having a share in a project aimed at making a contribution to the general benefit of society. They also had an opportunity to learn that altruistic behavior has its own rewards. Still, lingering questions about the fairness of the DOC regulations were of

concern. Now these questions pale in comparison to the specter raised in the article by Candilis et al.³ Are all our patients being placed at risk of losing the genuine benefits of being research participants? Will we have to discard all data to continue offering such benefits?

The American Academy of Psychiatry and the Law (AAPL) Committee on Institutional and Correctional Forensic Psychiatry takes the position that forensic mental health research is far too important to be allowed to sink into a sea of oversight requirements.⁴ The sheer number of patients involved, some 300,000 at any given time and 700,000 cycling through prisons and jails over the course of each year; the costs of their care; the severity of their illnesses; and several additional realities call out for research. While the committee underscores the importance of proper protection of subjects, it expresses concern about the paucity of such research, emphasizing that this group of patients has unique problems and needs. Their double stigma—incarceration along with mental illness—renders them particularly vulnerable to the consequences of the systematic neglect of their researchable problems and needs.

Trends of Concern

The protection of research subjects is becoming a dominant concern for several valid reasons that transcend jails, prisons, and forensic hospitals. Misconduct of investigators has led to several tragedies that gained prominence when unexpected deaths proved attributable to failures in the protection of the sub-

Dr. Young is Clinical Professor of Psychiatry at Yale University School of Medicine, New Haven, CT, and Attending Psychiatrist, Connecticut Valley Hospital, Middletown, CT. Address correspondence to: John L. Young, MD, Connecticut Valley Hospital, Box 70, O'Brien Drive, Middletown, CT 06457. E-mail: john.young@po.state.ct.us

ject.⁵ Some clinical trials have been exported, leading to abuses of subjects' rights.^{6,7} Gag clauses in clinical trial agreements between sponsors and investigators still significantly hobble efforts to protect patients from the consequences of negatively perceived data.⁸ Manufacturers continue to conceal risks from patients and their physicians.^{9,10} Even academic medical centers vary widely in their standards for agreements with industry sponsors of drug studies.¹¹ A related concern is the sheer cost of maintaining an institutional review board (IRB), now reaching an annual median of \$750,000.¹²

This trend toward ignoring basic patient rights in the pursuit of new information and the development of new technology is triggering a responding trend that supports these rights without threatening research. Journal editors are requiring registration in a public trial registry as a condition of later consideration for publication¹³ and are already refining their procedures for clarity and fairness.¹⁴ The National Institutes of Health (NIH) is experiencing a strong response to its efforts to encourage recipients of its grants to make their results public voluntarily.¹⁵ Finally, Candilis and his colleagues³ are right to focus positive attention on the emergence of HIPAA regulations and their potential impact on research. Although the precise impact remains somewhat difficult to evaluate at this stage, our hospital's research committee is taking its potential seriously and constructively.

Our Debt to the Authors

Candilis and colleagues³ provide a well-organized account of the several key acronyms that must now enter the awareness of forensic researchers and their administrators. The authors arrange them in their proper hierarchy so that it becomes unmistakably clear that an increasing responsibility is now being placed at each forensic institution's gate.

We can expect to be held to account for protection of the basic rights of research subjects. This accountability applies to every stage of any investigation. We now must take our mastery of quality assurance and continuous quality improvement from clinical care and apply it to research. Thanks to careful sorting out provided by Candilis *et al.*,³ we can see clearly that the Institute of Medicine has the most encompassing approach and that its contributions seem to offer the most parsimonious path to achieving compliance with relevant standards in the near term. This is es-

pecially applicable to the predictable long-term issue of having to assure the effectiveness of efforts to assess an institution's success at reviewing its own compliance.

The article marks two ends of a spectrum of options for a forensic institution that is striving to keep its research efforts afloat. At a minimum, it can monitor developments in the protection of research subjects, planning to implement processes to comply with new expectations before they become requirements. Or, maximally, an administrative group might decide to take on a leadership role by encouraging its researchers' efforts to develop and explore models for forensic research of exemplary sensitivity to subjects' rights and interests. Some may find wisdom in an intermediate position. The information needed to make a clear decision is now available.

Suggestions for Staying Afloat

As much as any other institution, our hospital has to strive against various obstacles, including regulatory concerns, to sustain its forensic research. It has proven profoundly helpful to develop mutually supportive contacts with our international colleagues. It is easily done, beginning by taking part in professional organizations with international memberships and then by following up the individual contacts that naturally develop. Visiting with these colleagues in their home settings never fails to be mutually satisfying.

Connecticut's Department of Mental Health and Addiction Services has recently established a central IRB with jurisdiction over research conducted at any of its facilities. Once made, the adjustment to its workings may prove worthwhile and give buoyancy to our forensic research efforts. The hospital's research committee now undertakes to assist prospective investigators to meet the central IRB's standards and may, with experience, become adept at doing so. This experience should transfer to have a confidence-building effect on both the committee members themselves and the researchers who approach them with their ideas, aspirations, and proposals. The hospital research committee may then have more time than previously to focus on monitoring the progress of approved studies. Importantly, centralizing the IRB functions should enhance the assurance of rigor and objectivity.

Aside from what can be done centrally, it is also possible to advance the protection of research sub-

jects by adding attention at the local level. One proposal involves use of a study coordinator who collaborates in various ways to bridge the gap between abstract procedural safeguards and the individuals whom they are meant to direct and to protect.¹⁶ Another model brings services researchers to support clinicians in defining and sustaining interventions whose efficacy they have decided they would like to test clinically.¹⁷

Of course, it is also possible to conceptualize research projects to improve our adaptation to the advances of research regulation. Candilis and colleagues³ offer a useful model for a project to study the financial costs of research regulation. Their model could readily be expanded to address the matter of other costs and the possible benefits. In particular, the recent revision of a classic work on informed consent¹⁸ marks this area as ripe for further investigation.^{19,20}

Conclusion

There is no disputing that we are living in an age of surging interest in matters of ethics. Whether ours will be a golden age in this regard remains to be seen. In another article, Candilis *et al.*²¹ proposes that narrative approaches will make important contributions to professional ethics. The same may be true for research ethics, as well.

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