Obstacles to Research in Forensic Psychiatry

Marc Hillbrand, PhD

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From 1987 until 1996, the Human Investigation Committee of the Whiting Forensic Institute (WFI), the maximum-security hospital of the State of Connecticut, reviewed and approved 52 research protocols. Most (45/52 or 87%) were implemented, resulting in the completion of five master's theses, three doctoral dissertations, and more than 36 publications in peer-reviewed journals, including the *American Journal of Psychiatry* and the *Journal of Consulting and Clinical Psychology*. Between 1997 and the present, one research protocol has been approved and is about to be conducted.

While the reasons for this dramatic discrepancy are multiple and defy easy categorization, it appears that the decrease in approved protocols is not attributable to personnel changes, as favorable working conditions have resulted in low professional staff turnover. However, one factor may be the challenge that researchers face to obtain Institutional Review Board (IRB) approval in recent years, a phenomenon certainly not unique to forensic research or to Connecticut.[1,2]

As was the case in many other states, several public psychiatric hospitals were closed in Connecticut during the nineties. In 1997, the WFI was merged with Connecticut Valley Hospital. In the wake of the statewide reorganization of public mental health services, regional hospital-based IRBs were disbanded and replaced by a statewide IRB. The previous hospital-based research protocol review process was replaced by a multi-tiered one. This complexity may have caused fewer protocols to be submitted, fewer to be completed, and fewer to be approved. (Note: the author served as chair of Whiting Forensic Institute Human Investigation Committee (1987–1996), and as a member (1997–2005) and co-chair (2005) of the CVH Research Committee.)

The review process needs to be examined more closely to understand why researchers find it daunting. They must first apply to the hospital-based Research Committee for approval of their investigation, filling out a five-page application. It is similar to those used throughout the country, reflecting federal and regional statutory guidelines as well as local requirements. A primary reviewer examines the application, typically suggesting clarifications and other changes. The hospital-based Research Committee that meets monthly then reviews the application, often more than once if the study description is either complex, insufficiently specific, or otherwise incomplete. Approval by the hospital-based committee may thus take several months. It is then followed by prompt reviews carried out by the hospital's Chief of Professional Services, Chief of Fiscal Affairs, and finally the CEO, who forwards it to the Commissioner of the Department of Mental Health and Addiction Services (DMHAS). Only then is the protocol forwarded to the DMHAS IRB.

The mission of the IRB is to examine the scientific merit of the proposed study and to ensure that human participants, the study "subjects" of older days, are adequately informed and protected. The IRB follows the federal mandate to ensure that all protocols involving forensic patients are given additional scrutiny on par with those afforded prisoners.[3] At this point in the review process, the researcher fills out the DMHAS IRB application and submits it to the IRB. This application is considerably more detailed than the hospital Research Committee application. A pri-

Dr. Hillbrand is Chair of Psychology, Connecticut Valley Hospital, Middletown, CT, and Assistant Clinical Professor of Psychiatry, Yale University School of Medicine, New Haven, CT. Address correspondence to: Marc Hillbrand, PhD, Connecticut Valley Hospital, 70 O'Brien Drive, Middletown, CT 06457. E-mail: marc.hillbrand@po.state.ct.us

mary IRB reviewer must examine the submission. Each review usually results in numerous recommendations for changes, such as the need to describe the study in a considerably more elaborate fashion, or to add various levels of protection for the human participant. These protections typically consist of various mechanisms to ensure: 1) the absence of coercion or appearance of coercion; 2) the knowledgeable and competent assent or consent of the patient, and of a conservator if applicable; and 3) the patient's knowledge that he/she may quit the study at any time, among many others. Several revisions of the application are generally required to obtain the primary reviewer's approval to forward the protocol to the full IRB. At its next monthly meeting, the IRB then reviews the protocol, and usually adds additional conditions for approval (see examples below), resulting in additional modifications to the protocol until it can be resubmitted and re-examined by the primary reviewer, who must approve it for resubmission to the full IRB. Several months may elapse until the IRB approves the protocol. In the case of federally-funded projects, the IRB offers "conditional" approval only. It forwards the conditionally approved protocol to the U.S. Department of Health & Human Services–Office of Human Research Protections in Washington, DC. This additional level of review is required by federal human participant protection rules that grant greater scrutiny in studies involving human participants residing in environments that could be considered judicial alternatives to prisons.[3] The IRB approval is finally forwarded to the Commissioner of DMHAS, who ultimately approves or disapproves the study based on three criteria: scientific merit (verified by the IRB), consistency with the DMHAS mission, and cost.

Many researchers are put off by this review process. Three categorical examples illustrate this. University faculty advisors have become reluctant to encourage their students to choose a clinical sample for their thesis or dissertation, for fear that the lengthy IRB approval process may unduly prolong their students' course of studies. At our facility, the five theses and three dissertations completed in the 1987–1996 span stand in stark contrast to the single thesis proposal reviewed since 1996, which did not result in approval. Similarly, many of the hospital-based clinicians who are also experienced researchers have become hesitant to encourage their supervisees (psychiatry and law or psychology fellows, psychiatry residents, psychology interns, and others) to initiate research projects that they may not be able to complete by the end of their training year.

Even university-based scholars who do not depend on the labor of students or clinical trainees for their research are discouraged by the review process. One prominent scholar decided to abandon a most worthy, well-funded project, despairing of getting the IRB to approve the protocol, which entailed only clinical interviews with forensic patients and no intervention. Reports of such misfortunes spread quickly in the hospital. As a consequence, talented clinicians who have limited research experience have come to view the idea of turning their clinical insights into systematic research as a lofty, unattainable goal.

The current challenges of obtaining IRB approval have exerted adverse effects on forensic research and on forensic practice. Although obtaining IRB approval in any branch of medicine has become more difficult,[2,4] few have experienced the squelching that forensic psychiatric research has seen. The field risks stagnation because it may come to lack the benefits of novel research findings as the IRB approval process becomes lengthier, more cumbersome, and more exacting. Everyone loses in the process. Patients lose the potential benefits of innovation and of improved methods of assessment and treatment, as do clinicians, who also lose the professional and intellectual benefit of scholarly work. Departments of Mental Health throughout the country also suffer from this loss. In the end, citizens receive a smaller return on their taxes in the form of less effective forensic services.

Fortunately, the situation is not hopeless. A number of strategies exist to resolve the current problems. Firstly, advocacy is needed. A dialogue to devise solutions must be initiated among the various stakeholders, including clinicians, local and central administrators, academics, IRB members and overseers, and forensic patients. Our patients could play a prominent advocacy role in the future, just as individuals with severe mental illnesses and their families rallied under umbrellas like the National Alliance for the Mentally Ill (NAMI), an advocacy group that has forcefully supported research.[5]

Secondly, IRBs must begin to consider realistically the consequences of not conducting forensic psychiatric research. When reviewing a protocol for a novel cancer treatment intervention, IRB members may be acutely aware of the importance of making it possible

for cancer sufferers to gain access, first to an experimental treatment protocol and, in due time, to a new, empirically-validated treatment. IRB members may have friends and relatives suffering from cancer, and may have developed compassion for cancer victims. They may feel a sense of personal accomplishment when completing the review of a cancer research protocol, a sense of contributing to a worthy public health goal. However, they may not approach the review of a forensic research protocol in the same spirit. Rather, they may primarily be motivated by the goal of protecting the rights of forensic patients, fearing that such patients may be exploited and abused, as were prisoners in a dark chapter of our history.[6] In fact, making it more difficult to conduct forensic research has the unwanted effect of depriving patients of the potential benefits of research-based therapeutic innovations and improvements.

Colleagues in other agencies have found it slightly easier to obtain IRB approval for archival studies. This greater ease is a mixed blessing. The typical archival study is an examination of a variable of interest to the investigator, drawn from the fairly large universe of variables documented in a medical chart (e.g., presence versus absence of command hallucinations) and its relationship to one of a few of the dependent variables of greatest interest to forensic practitioners. These include physical aggression, verbal aggression, use of restraints, etc. In other words, archival forensic studies tend to focus on psychopathology and on aggression. Thus they contribute to the enormous imbalance in the literature in forensic psychiatry and psychology, the imbalance between what could be called "problems" (i.e., psychopathology and its many manifestations) and what could be called "solutions" (treatment, in the largest sense of the term). There are probably 100 studies on what is wrong with forensic patients for each study on how to fix it.

Research committees and IRBs must adopt a more proactive role in promoting research and in ensuring that their review mechanisms do not prevent research from taking place. These efforts must be supported by local and central forensic service administrators. Research should be an intrinsic part of the mission of any state forensic services and any state mental health services, one promoted at every level of the forensic system. There should be accountability to forensic patients and to the citizenry. In other words, sufficient funding should be devoted to research to improve the effectiveness of the treatment of forensic patients and to promote their recovery. Forensic research probably should not be centralized but result from the collaborative efforts of all stakeholders including clinicians, administrators, patients, advocates, and the representatives of the public.

A high priority should be placed on systematic investigations that examine the actual risk that forensic research poses to patients. These risks are low in our experience. Not a single adverse event was reported in the studies conducted during the aforementioned 1987–1996 period, which covered one drug efficacy study and 44 paper-and-pencil studies. Deception was involved in none of the studies. There were no reports of breaches of confidentiality. Despite our patients' highly resourceful use of various mechanisms for the expression of their grievances (e.g., complaints to local and statewide advocates, to local and central administrations, civil and criminal litigation in State and Federal courts), patients did not express a single complaint related to research through any of these grievance-resolution mechanisms in the 1987–1996 period.

In our experience, forensic patients value research and respond positively to it. When asked about it, many articulate various reasons they value research. These include the following points: Research conducted at the hospital communicates to them that there are people who are motivated to help them, that patients matter and are valuable human beings, like the cancer patients of the previous example. Research provides not only relief from boredom, but also an opportunity to make a contribution to the welfare of others, not unlike the recent news story reporting on death row inmates who raised money to support a college student whose relative was murdered. Patients value the opportunity to meet new faces and to reflect on their experiences as forensic patients. Many feel a sense of pride when they contribute to the education of a trainee, regardless of his or her discipline.

There should be tangible reinforcers for research, to complement the intangible ones on which most researchers rely. Examples include granting administrative time for research (i.e., without clinical responsibilities), funding research-related travel, and supervision. There can be no good reason that the following goal could not be added to the annual performance objectives of every forensic clinician and administrator: "contribute to forensic research."

Steps toward the goal of a scholarly publication should be rewarded: participating in a study group, joining a research group, reviewing a body of literature, volunteering to help a colleague collect data, etc.

Finally, forensic patients and their advocates should be enlisted to support forensic research. It is time to abandon the paternalistic stance ("clinicians and administrators know what is best for forensic patients") in favor of a collaborative one.[7,8] A collaborative approach entails working together with patients toward mutually agreed upon goals that include quality of life, autonomy, self-control, relative freedom from incapacitating symptoms, while remaining mindful of societal expectations, including judicial mandates. This collaborative philosophy of forensic practice is as relevant to clinical practice as it is to research. Patients have a stake in whether research is conducted, which research is conducted, how it is conducted, and how its results are disseminated and used. Similar arguments have been made in other branches of medicine.[9]

In that spirit, we described to our patient steering committee a study on spirituality and hope. That committee consists of patient representatives from each of the maximum-security service wards and representatives from the clinical staff and the hospital administration. It meets weekly to address patient concerns and aims to improve patients' quality of life and promote their recovery. Two topics in the lengthy discussion about the spirituality study illustrate the benefit of holding such discussions with patients. Despite our statements that patients would be invited to fill out questionnaires anonymously, patient representatives expressed strong fears. They asked how personal information about them would be used. This discussion generated a practical plan to collect study questionnaires that eased their fears: the anonymous questionnaires would be placed by the participants in sealed envelopes and dropped in a large cardboard box, making it impossible to match participants and responses. Once that plan was worked out, all representatives expressed their willingness to participate, and even their willingness to encourage their peers to participate. They also expressed the need for rewards, a very delicate issue in institutional research because of the issue of undue influence.[6] Here again the group developed a plan entailing non-contingent rewards for the entire unit in the form of "smoothies" (frozen fruit beverages). The participants would thus be reinforced, and non-participants would be extended a gesture of good will. These modifications to the initial research protocol are likely to increase the enrollment rate, which is so crucial in forensic research.

We need to be advocates for our patients on all fronts, and move toward a less paternalistic, more recovery-oriented philosophy of care, one closer to what our European forensic colleagues consider the best risk management strategy for patients: good quality treatment.[10]

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