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One Project and Twenty-Two Reviews

Are some Human Subjects Review Committees overprotecting research subjects and, in doing so, violating the right of the subjects to participate in research projects?

The task of carrying out an academic research project is both frustrating and exhilarating. The exhilaration comes when an investigator effectively collects data, while at the same time respecting the dignity and privacy of his research participants, reports on the results, and finally witnesses the results become part of the public policy agenda debate. On the other hand, one of many sources of frustration for the investigator occurs while grappling with federal guidelines for the protection of human subjects. There are two major sources of this frustration that an investigator experiences. First, the strict application of biomedical ethical guidelines to *behavioral* research, and second, the ambiguity of human subjects guidelines which allow everything and anything—for example, organizational factors having nothing to do with human subjects—to be considered as human subjects concerns. Critics of human subjects guidelines argue that while safeguards are necessary to insure the protection of human subjects in potentially high-risk research situations, in the case of low risks the conventional and inflexible protection review may not justify the costs, thereby running the risk of discouraging the conduct of significant applied research with potentially high social benefits.^{2,4,5} University-based review boards have recognized that the risks participants may experience as a direct

or indirect result of experimental biomedical manipulation are not applicable to survey-type behavioral inquiry, and have adopted a more flexible assessment of risks and benefits which advances the interests of the behavioral scientific community and the concerns of society at-large.

This paper is (1) an endorsement of a flexible interpretation of human subjects guidelines regarding projects that are potentially low individual risk and high social benefit, and (2) a documentation of possible problems arising from a lack of clear guidelines.

Research Experience

Our project, which provided us with the human subjects review experience and which prompted this paper, is entitled "Reintegrating the Mentally Ill in the Community." It focuses on understanding the long-term adjustment of the chronically mentally ill to community life and documents intrapsychic and contextual variables associated with community integration. The population being studied comprises a sample of all former mental patients in California ($N = 427$) who in 1973 were

The opinions and conclusions expressed herein are those of the authors, and do not necessarily reflect the views of the Robert Wood Johnson Foundation or the National Institute of Mental Health.

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residing in supervised living arrangements. This is the highest risk group from the perspective of the deinstitutionalization policy. The human subjects review experiences we are reporting relate to our 12-year follow-up study of individuals we interviewed in 1973. We are trying to document the health, mental health, and social services experiences of this cohort and determine how they have fared, both socially and psychologically.

At the level of social policy, a number of important practical implications emerge from our longitudinal research. First, we will have a much better picture of the factors which contribute to the adaptation of a high-risk group to community life. Second, our research findings will provide a comprehensive and meaningful core of theory and research from which mental health professionals and policy makers can draw in order to more effectively plan and develop supportive environments for this handicapped population.

The Review Process

The most difficult question in our human subjects review evolved from our efforts in 1983 to locate those individuals interviewed in 1973. The primary human subjects issue involved *access* to locational information possessed by health, mental health, and social service organizations. Confidentiality of agency contacts was brought into question as well as the ability to obtain informed consent from a disabled population.

To date, 22 human subjects reviews have been made of our study. These reviews were made during the course of approaching 36 agencies for help in locating sample members. One of the reviews, in fact the very first, was carried out by the University of California at Berkeley. It set the framework for our approach to other agencies. This process involved the preparation of 20 protocols. Following the third protocol, the whole protocol was computerized so that modifications could be made to the front matter and the concluding parts, thus adapting it to the unique requirements of each individual review. The latter procedure resulted in the need for only three protocol addenda to answer

additional questions posed by review committees. In addition to the preparation of the addenda, the principal investigator personally attended meetings with three of the twenty-two human subjects review committees which entailed five long-distance, intrastate trips. We also became involved in four court cases, not in any way involved with complaints about the project, but simply involving the request to the Lanterman-Petris-Short (LPS) Conservatorship Court to allow us to interview four conservatees. This emanated from one county agency's desire to have the LPS Conservatorship judge make such a decision rather than making it itself. All of the twenty-two foregoing reviews have ultimately resulted in successful access to locational data. Only two have severe limitations on the nature of this access due to legal restrictions on these agencies' ability to share information.

A Flexible Approach

As will become evident, the human subjects review process has worked well for our research endeavors, as well as for protecting the rights of individuals and helping the development of our knowledge base in the area of mental health services for the mentally ill. Further, the ethical issues deriving from the experiences of our research with this vulnerable population illustrated that human subjects committees' protective criteria, if inflexibly enforced, can be overly paternalistic and thus allow the violation of freedom of choice rights, or so over-libertarian that they lose sight of society's responsibilities to the disabled. Let us now turn to our experiences which demonstrate how the ethical issues raised were satisfactorily resolved within the context of the aforementioned Institutional Review Board (IRB) flexibility.

The Autonomy of the Participant. The first issue concerns individuals living in supervised environments—that is, a facility or institution where they are under the supervision, often control, of caretakers, some of whom are mental health professionals, health professionals, facility managers, or owners who operate their own residential care facilities. Our research group has

now faced several situations where access to the 1973 interviewee has been denied us by the manager/owner of the interviewee's 1983 facility. In these instances we know the resident is living at the facility, but we cannot interview him or her. This is an extremely difficult situation since the resident is currently under the supervision and care of the manager. We have not been able to ask the resident personally for an interview, and thus, to

up an interview with them because the facility manager was objecting to the interview. The resident whom we were then interviewing suggested that he would be happy to try to arrange a meeting with them at his own apartment. This he did, and two additional interviews were completed with very cooperative individuals who were quite concerned about the fact that they had not been approached in their residential care facility — that is,

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a large extent *the resident's right to decide whether or not he or she wishes to participate in our study is being denied.* There may be reasons for this denial: a legitimate concern on the part of the manager to protect against outside intruders or a manager who does not wish us to view his or her residential care facility for some other reason. Regardless of the reason, the individual is being deprived of the right to decide whether or not he or she wants to participate in our study. In one such situation, we obtained evidence of this and of the reaction of some residents when we interviewed a former resident

concerned that they had not been given the right to make a decision regarding their participation in this follow-up study. Thus, the irony is that "vulnerability" becomes the rationale for denying people the right to make their own decisions regarding participation in the study. In some situations, one wonders who is being protected.

Participant Remuneration. Another ethical issue revolved around the *profit motive* for participation in the study. It must be emphasized that we are talking about an interview. We are not talking about any internal treatments, drugs, physical manipu-

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who was now living in the community. He wondered whether or not we had interviewed the other residents of his former facility who were still living in that facility and referred to several of them by name. We indicated that in fact we had interviewed them 11 years ago (a possible breach of confidentiality), but that currently we were unable to set

lations, or even mental manipulations which may have long-term negative effects. The probability of such negative effects approaches zero with this interview. Yet there is significant concern among human subjects committees about the encouragement of profit to the former resident as a motive to participate — in other words, offering the resident

a token cash payment for his or her participation in the study. There is concern that these individuals will be coerced into participation because of their poverty and thus are not making a voluntary decision to participate. This is an interesting issue since, in the same sense, we are all making less than voluntary decisions when we go to work each day and participate in our jobs so that we have money to survive. Our experience with offering money on a selective basis has been most interesting. We have generally offered money as an inducement to people who have been *ambivalent about cooperating*. We have been forced into this selective stance since we do not have enough money to offer everyone (ethics of unequal treatment). In offering ten dollars per interview as an inducement, we have had varying responses. Some individuals would only do the interview for the money, some individuals did not want money but preferred doughnuts or some other type of small gift as an inducement, and some individuals have completed the interview and refused to take the money. When we inquired about the reasons for rejecting the money, we were told that they felt it tended to devalue their participation. Our observation on this was that the money was so little that it was inconsequential in changing an individual's life significantly, but that their participation was a highly valued accomplishment — that is, they so valued their ability to participate that the money tended only to devalue their sense of participation or their sense of the worth of the participation they offered in the interview (c.f., cognitive dissonance theory). In the two situations where individuals found out that their friend had been paid, they were paid as well. In any event, small inducements to participate, while not effective with some, were effective with others, and for this reason should be available to the researcher as a means of encouraging people to participate in research which will not be detrimental to them but can be helpful to others.

Other Incentives. We had an interesting example of an *additional* form of profit-motive participation. This profit motive came from one of the residents who had been hospitalized on a charge of assault and had been transferred to a medical facility from the jails since he was claiming to be mentally dis-

turbed. The ongoing purge of records in California to protect the rights of individuals and their privacy left this individual more vulnerable to the charge that he was *not* mentally ill because he had no documented history of mental illness. As time would have it, our follow-up coincided perfectly with his need to document his history of a mental disorder and we were the history-carriers because we were the only people who had long-term documentation of his disturbance. Through his lawyer he agreed to participate in the interview, and also asked if we would allow him to have a copy of his interview from 11 years ago. It was ultimately agreed upon with the Human Subjects Committee at UC-Berkeley that the materials he supplied us with 11 years ago would be appropriate to give back to him and his lawyer. This apparently was sufficient for his needs because the case went no further in terms of seeking information. The question did come up whether information related to the resident's involvements with other agencies, supplied by other agencies, should also be given to the attorney. The issues, however, never had to be faced since the information from the resident himself was sufficient for their purposes.

Impaired Capacity. A fourth issue was raised when *individuals were too ill to respond to our interviews*. We often were in places where it was possible to obtain information about these individuals from their mental health practitioners, physicians, or helpers. Where a person was totally isolated in the community — that is, where there were no individuals who could act for the person who was so ill — we were able to obtain at least some information about their health care and their current mental health care with the consent of a relative.

In these situations we were also faced with the ethical dilemma of making referrals for the care and treatment of these individuals. In several situations it was extremely difficult to avoid making such referrals. For example, two paranoid individuals, who lived in counties a hundred miles apart, led very similar lives of total confinement in small trailers, locked in against the world, seeing very few people and living extremely frightened lives. It is unfortunate for these people that they are so isolated, and their fright is problematic for us. In this

type of situation we chose to avoid offering or making any referral without the knowledge of a relative. On the other hand, we did come across one case where an interviewer found a woman living in a hotel room, lying in her own defecation. This woman had been in the midst of a major depression for approximately two weeks. The hotel manager was aware of her situation but had done nothing about it. The matter had deteriorated to such a low level that our interviewer chose to convince this individual to seek hospitalization. (All our interviewers have had at least a year's experience in working with the chronically mentally ill). Fortunately, the woman was convinced to hospitalize herself, which probably saved her life; she had developed a kidney infection that, untreated, might have killed her. This case has been useful as an example for interview trainees, teaching them when it might be necessary to take an active role as a helper in addition to being an interviewer.

Contacting Participants. A fifth issue relates to the use of a letter in trying to reach this vulnerable population. Many agencies have offered to send out a letter for us to former interviewees who are now their clients to encourage the clients to participate in our research. While this is gracious on the part of the agency, their letters are perhaps much more frightening to many of our former sample members than would be a telephone contact from someone actually involved in the study. The agency letters mentioned our initial contact with the individual and, as we all know, it is difficult to remember a single contact from eleven years ago (though many of our residents made independent allusions to such contacts, which led us to believe that they did remember it). Moreover, it is difficult for people who do not regularly send letters to return a letter to us to say they will participate, even when a stamped, self-addressed envelope is enclosed. Further, people often have no phone available to telephone us to say they are willing to participate, even though they are told in the letter they can call collect. The letter places the burden of contact on these individuals, and that is a lot to ask of a vulnerable group. We think it is important to encourage people in a personal way to par-

ticipate in important studies, and the impersonal letter requiring them to take an independent action before they have any real relationship with anyone related to the study is inappropriate. While this action is geared to protect their identity, it actually may ethically deprive them of their right to participate since responding to an impersonal letter is generally outside of their normal behavior.

Protecting Privacy. The sixth and final issue is actually more of a pet peeve. It is the inability to use the terms "mental health" and "mental illness" in our communications with people. We have deleted all reference to "mental" in our letters and our contacts. In fact, rather than answer our phones properly as the Mental Health and Social Welfare Research Group, we now have shortened our answer to "Social Welfare Research Group." This is in response to concerns of human subjects committees and, to some extent, our own observations that the word "mental" tends to raise a red flag and should not be used in initial correspondence or conversations. This is especially so with people not related to the former resident who might not have any knowledge of their history of mental illness. While we agree with this tactic, we are concerned about feeding the myth that "the mark of Cain" is on one's head once one had been labelled "mentally ill," thereby making the label even more significant than it is. We do not know the answer to this particular problem; we give it to you for your consideration. When we do speak to individuals alone who are involved in the study we definitely speak to them about our concerns both with health and mental health; not to do so would mislead them about the content of our interview with them. However, we do this only in private.

Extraneous Materials

One of the most interesting and unique characteristics of this study, particularly concerning the research participants' rights and welfare, is the *organizational scope*. This project involved efforts to access the files of many human service agencies at the local, state, and federal levels. Its multi-organizational character allowed us to observe the nature

of what we identify as the intra- and interorganizational component of the human subjects review committees' deliberations. This phenomenon is akin to the notion of "overinclusivity"—that is, certain organizations have unduly included extraneous factors in the deliberations concerning the rights of their clientele.⁴ We have found that the introduction of these factors (and some are quite dubious) runs the risk of confounding the legitimate issue of safeguarding the rights and welfare of research participants. We contend that this issue deserves attention because the extraneous considerations may inappropriately lead to denials of requests simi-

lar to our own, thereby obstructing important low-risk research projects. the human subjects review process; it is an administrative decision. Despite this observation, the organizational effort involved is a definite part of the deliberation of many review committees. When committees did take organizational effort into account, they often tended to be either willing to make unreasonable demands upon the organization to facilitate human subjects goals or to be overprotective of the organization. In the former situation, one committee chairman noted that he "didn't care what it cost for the organization to help with this research project." His committee recommended an extensive organizational commitment to meet its in-

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These encroachments are significant at the organizational level in the sense that what appears as purely an ethical question—namely, the protection of the research participants' rights and welfare—reflects possible broader organizational and management problems, particularly "organizational politics," "political maneuvering," and "territorial encroachments."¹ Moreover, the presence of these obstacles is not purely incidental, but is a classical symptom of organizational ineffectiveness.³ And perhaps most important for our present purposes, is that under the guise of protecting rights and confidentiality, some of these agencies could deny their clients the right to exercise their freedom of choice. To illustrate the foregoing arguments, let us turn to six aspects of the organizational component which we contend have become part of the review process.

Organization Effort. The amount of effort expended by organizations to facilitate this research study has been truly gratifying, yet the contemplation of how much effort an organization should be asked to expend or, equally importantly, *not* asked to expend, does not belong in the deliberations of

interpretation of the strict confidentiality standard. Consequently, his committee recommended the delegation of search responsibilities for sample members who may have been served by his organization to a member of the staff of the organization. He suggested that since we did not have the current information on whether or not a person was served, the organization should not tell us whether or not they were currently being served and, therefore, that the organization should take it upon itself to contact each of the people in our sample who they did serve and try to enlist their help or participation in the study. In placing the organization in the direct role of research staff on the project, the committee forced the organization into a situation of appointing a person to carry out these responsibilities who already had another full-time job. This staff member had none of the linkages necessary to actually complete the search successfully. Thus, this procedure was programmed to fail from the outset; while the committee was informed of this they tended to go, at least initially, with the suggestion of their chairman.

The opposite tactic, however, has also been observed. The principal investigator found himself facing a committee chairman who directly noted

in his introduction of the project that it was the researcher's role to tell his committee "how [he] was going to protect an overworked staff from the additional burdens of helping out on another research project." This latter type of comment had no place in the human subjects deliberations. It is something for the administration to handle and, as part of the human subjects review process, becomes a means of "bootlegging" administrative goals.

Organization Autonomy. The assertion of organizational autonomy is often included in the human subjects review process. While it was clearly stated in the procedures of one super-agency's review process that approval by that agency and one of its direct line agencies would be sufficient for general approval in *all* direct line agencies, independent reviews were still required in at least half of the direct line agencies approached. One rather vituperative letter asserting the independence of the direct line agency was forwarded to the head of the super-agency's human subjects committee indicating that the procedure should have been one of individual approach to the direct line agency.

While the assertion of organizational autonomy may happen in an interorganizational context, it also occurs within units of the same organization. Different administrative committees, representing government or problem areas such as mental health and the health department, conducted independent reviews of the study within the same organizational context. It was not an infrequent occurrence where two review committees were reviewing the human subjects protocol within the same organization! Although all the reviews we experienced in this manner were conducted quite appropriately, it was clear that they reflected administrative concerns over the autonomous actions of the organization.

Organization Turf. Closely related to the notion of organizational autonomy is the notion of *organizational turf*. This, however, is not administrative autonomy so much as it is the organization's statement of "ownership" of its clients. The most blatant statement of this action is illustrated in one letter we received from an organization initially withholding its cooperation. The writer expressed concern that "individuals involved [in your study] may become less willing to cooperate in any statistical or

research study including those which [our organization] itself carries out."

Ironically, this quote comes from a "Freedom of Information officer," yet it represents a statement of ownership of a client population by a service organization embedded in the context of a committee that is supposed to be considering the ethics of protecting human subjects.

Organization Protection. In issues of organizational turf, the organization treats its staff and its clientele as a commodity in the human subjects deliberation process. In organization protection the organization seeks to cover itself through the use of the human subjects committee, either to cover abuses or to protect itself from the risks of legal action. The latter initial response is quite common in the seeking of a "legal opinion." Since lawyers are there to advise on the likelihood of a suit, and there is always a possibility of a suit, no matter how small, it takes a risk-taking administrator to move beyond this small risk and to reach out and help. It has been our good fortune to have dealt with several courageous administrators who have supported the importance of research and have been willing to take this small legal risk. Further, lawyers involved have been quite supportive of the research. Yet the wish to adhere to confidentiality standards, or to protect the organization, has led to situations where we have actually gone through four court cases to obtain consent to interview people we had already located so that the decision could be moved from the organization to the conservator court judge. These cases involved the appointment of a public defender for each of the four individuals involved and the placement of the cases on the court calender. Further, the principal investigator was required to be available during the time period of the hearings. There was even a possibility that he might have to make a long-distance trip to attend a hearing on the issue.

In protecting itself against abuses, the organization may deny access to clients. In one situation, noted above, an organization had denied us access to their clients—that is, we were unable to even ask them to participate in our research. A former client, however, contacted current clients of the organization, told them about the study, and arranged

for the interviews to be conducted at his own home. It is extremely difficult to know, without direct contact with each sample member, whether or not an organization is fulfilling the respect-for-individual-autonomy mandate inherent in the human subjects review process, overprotecting the client, or trying to protect itself.

Organization Prestige. Human subjects procedures become involved with the prestige of an organization. Several organizations thought it necessary to set up independent human subjects review committees and independent human subjects procedures where none had previously existed because the or-

project several weekends of work. This happened despite the fact that every effort was made by the researchers to meet with all involved staff and a specific request made for notification of everyone on staff of our human subjects protocol and procedures. In another situation, despite letters attesting to "partial committee approval" — that is, where a quorum was not possible — by a human subjects committee, and statements in one of the letters that (1) "complete committee approval" would be forthcoming, and (2) that the study should be allowed to proceed, release of information was held up for over a month until formal notification in writing of "com-

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ganization had not been involved in such a research effort before. The formal submission of a protocol to an administrator precipitated the development of human subjects review committees so as to document the official status of the organization. There is no doubt that there was legitimate concern for the protection of the rights of human subjects by these organizations. Still, whether that concern required an independent human subjects review, given previous reviews already conducted, is questionable.

Organization Procedures. Up to this point we have been discussing factors involved in the deliberations of the human subjects committee. It is extremely important, however, that the decisions emanating from the committee be well integrated with organization procedures and that a channel for apprising staff members of the results of human subjects reviews be open and clear-cut. There seems to be almost an avenging spirit among some staff who discover researchers working in a "grey" area associated with human subjects activity. Weekend staff, not apprised of record access procedures for human subjects materials, have cost our research

plete committee approval" was received. All these latter facts do not apply specifically to the review process, but they do unduly expand and emphasize impact of the timing of the review process. They take a toll not only on the organizational staff but also on the research staff, and create an atmosphere of suspicion regarding the motives of researchers.

Conclusion

This paper has presented material which outlines what we perceive to be the current inflexibility of some human subjects committees regarding projects that are potentially low-risk and high-benefit. Specifically, we are referring to projects where the primary contact between the researcher and the research subject involves a questionnaire, interview, or observational assessment of a behavioral type.

Our argument is for greater IRB flexibility and a heightened awareness of the imprecision involved in determining risks to research participants, es-

pecially when those risks are psychological in nature or involve rights violations. In the latter situations, the definition of risk is nowhere as clear as it is in research involving hands-on activity, particularly those involving experimental biomedical procedures.

The mandated review process has been flexible enough in the past to allow us to settle questions and problems that arose beyond the Institutional Review Boards. But the situation we have today with human subjects committees is something of a mixed blessing. On one hand, our experiences bode well for the current, relatively flexible stance of most committees toward investigators involved in behavioral-type research endeavors. On the other hand, a sign of trouble ahead concerns the very real problem of allowing extraneous considerations into the committees' deliberations. Many questions that surfaced while our human subjects protocols were under review fell outside the purview of legitimate human rights and human welfare considerations. This is a source of frustration for the researcher and may actually discourage some valuable projects. Still, we are sure that maintaining flexibility is a continued high priority for human subjects review committee members. Perhaps it is only constant vigilance regarding these issues that

will make the system work more efficiently. It is with this in mind that we have shared our experiences.

References

1. DuBrin, Andrew J., *Fundamentals of Organizational Behavior—An Applied Perspective*, New York, Pergamon Press, 1978.
2. Levine, Robert J., "The Role of Assessment of Risk Benefit Criteria in the Determination of the Appropriateness of Research Involving Human Subjects," in National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research (eds.), *The Belmont Report—Ethical Principles and Guidelines for the Protection of Human Subjects of Research*, Appendix, Vol. 1, DHEW Publication No. (OS)78-0013, Washington, D.C., Government Printing Office, 1978, pp. (2-1)-(2-59).
3. Mohr, Lawrence B., *Explaining Organizational Behavior*. San Francisco, Jossey-Bass, 1982.
4. Robertson, John A., "The Social Scientist's Right to Research and the IRB System," Beauchamp, T. L. et al. (eds.), *Ethical Issues Social Science Research*. Baltimore: Johns Hopkins University Press, 1982. pp. 356-372.
5. Tropp, Richard, "What Problems Are Raised when the Current DHEW Regulation on Protection of Human Subjects Is Applied to Social Science Research?" in National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research (eds.), *The Belmont Report—Ethical Principles and Guidelines for the Protection of Human Subjects of Research*, Appendix, Vol. 2, DHEW Publication no. (OS)78-0014, Washington, D.C., Government Printing Office, 1978, pp. (18-1)-(18-17).