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Ethics Review of Social, Behavioral, and Economic Research: Where Should We Go From Here?

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It is not unusual for researchers to complain about institutional review board (IRB) oversight, but social scientists have a unique set of objections to the work of ethics committees. In an effort to better understand the problems associated with ethics review of social, behavioral, and economic sciences (SBES) research, this article examines 3 different aspects of research ethics committees: (a) the *composition* of review boards; (b) the *guidelines* used by these boards to review SBES—and in particular, behavioral health—research; and (c) the *actual deliberations* of IRBs. The article concludes with recommendations for changes in the review process and with suggestions for filling the gaps in knowledge about the way IRBs work.

Keywords: behavioral health research, institutional review boards, research ethics, informed consent.

Although researchers of all types complain about mandatory review of research protocols involving human participants, those who work in the social, behavioral, and economic sciences (SBES) are especially vexed by research ethics committees. In the United States, the code of federal regulations (Federal Policy for the Protection of Human Subjects, 2001; also known as the "Common Rule")

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and institutional review boards (IRBs)—committees charged with implementing the guidelines—are the source of much frustration on the part of SBES researchers. Social scientists often argue that the federal guidelines for the protection of human participants are better suited to medical research than to SBES research, and that members of IRBs are often unfamiliar with social science research methods and data files. IRBs are faulted for being overprotective, unreasonable in their demands for consent, impractical in their directives for the protection of confidentiality, and excessive in the time required for review. In his testimony before the National Bioethics Advisory Commission (NBAC), Murray Wax (2001), an anthropologist, complained that the regulations actually *heightened* the risk to the participants of research: "The gravest ethical problem facing the people studied by anthropological research is posed by unknowing and overzealous IRBs and by governmental regulators attempting to force qualitative ethnographic studies into a biomedical mold" (p. 95).

Wax's (2001) statement was not hyperbolic: Standard applications of the Federal Policy (2001) can create serious problems for SBES researchers and their participants. For example, the regulations governing consent state that "informed consent shall be documented by the use of a written consent form approved by the IRB and signed by the subject or the subject's legally authorized representative" (Federal Policy, 2001, § 46.117a). Exceptions are made for cases where "the only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality" (Federal Policy, 2001, § 46.117c1). This is a wise and useful exception; yet, in reality, IRBs are hesitant to allow research to proceed without the legal cover of written consent, insisting that researchers collect consent forms even when the participants are illiterate or where the consent form would jeopardize participants. Definitions of *risk* are also a point of contention between social scientists and IRBs. SBES researchers complain that their protocols—limited to observations, interviews, or surveys—are scrutinized more thoroughly and seen as potentially more harmful than medical protocols involving the ingestion of untested chemicals and the collection of bodily fluids (Sieber, 2003).[1]

Frustration with IRB review of SBES research protocols surfaces regularly in the newsletters of the professional associations of social science. Dissatisfaction with the process is expressed in many ways: There are calls for careful study of the effectiveness of IRB review (Mueller & Furedy, 2001), guidelines for navigating the IRB process (Oakes, 2002; Spellman, 2001), and proposals for a "Researcher's Bill of Rights" (Perlstadt, 2002). For their part, professional associations have weighed in with reports (American Association of University Professors [AAUP],

[1]See also the National Science Foundation Web site for a review of the assessment of risk in the social and behavioral sciences (http://www.nsf.gov/bfa/dga/policy/hsfaqs.htm).

2001), letters (American Sociological Association, 2001), and articles (Azar, 2002; Spellman, 2001) offering criticism and advice for improving IRB review of SBES research.

Dissatisfaction with the system for protecting human participants on the part of social scientists is not new. A survey done in the 1980s showed higher percentage of SBES researchers (53%) than biomedical researchers (43%) agreeing that the IRB system impeded the progress of research at their institution (Gray, 1982). Furthermore, the complaints now being leveled against the system are nearly identical to those made in the mid-1970s. Testimony provided in 1974 to the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research included the following concerns—among others (Citro, Ilgen, & Marrett, 2003):

- Problems with written consent
- Need for social science expertise on IRBs
- The lack of appeal procedures
- Problems with risk–benefit analysis
- Lack of fit between the regulations and certain social science methods
- Vagueness of the regulations (e.g., What is a "human participant?")

These same concerns remain today. Notice the similarity of this list with the six issues addressed in the 2001 report of the AAUP:

> This section of the report addresses six issues: the Common Rule's definitions of research and of human subjects; the rule's statements concerning the risks and benefits of research involving human subjects; the rule's provisions regarding informed consent and research that is exempt from this requirement; research that is subject to an expedited review procedure; the composition of IRBs; and, lastly, the appeal of IRB decisions.

The 2003 National Research Council report (Citro et al., 2003) and the ongoing work of the National Institutes of Health (NIH)-funded Social and Behavioral Sciences Working Group on Human Research Protections (2004) also address these problems in IRB review of SBES research.

Given this continued and high level of displeasure with IRBs, we would expect SBES researchers—of all people—to be developing research-based policy guidelines for consideration by regulatory bodies. In fact, plenty of policy recommendations have been made, but surprisingly few are based on research. When it comes to IRBs, social scientists are cobbler's children. Like the hapless waifs whose feet remain unshod while their parent makes shoes for others, social scientists complain about the many shortcomings of IRBs while using their skills to describe and analyze nearly every *other* sphere of human activity. The AAUP

(2001) report is based on anecdote, an informal, nonscientific survey of SBES researchers, and testimony given to government committees. The report of the National Research Council (Citro et al., 2003) lists only eight studies in an appendix: "Selected Studies of IRB Operations: Summary Descriptions." One might assume this small number is the result of careful selection; but as the authors of the study noted, "there is little regularly available systematic information about the functioning of the U.S. human research participant protection system" (Citro et al., 2003, p. 5).

The relatively few attempts to understand the way IRBs work fall into two categories: descriptions of the characteristics of IRBs and studies of IRB decision making. The best known and most thorough example of the first category is a survey study done by Bell, Whiton, and Connelly (1998). The Bell report includes information gathered from 491 IRBs located at several different types of institutions. Bell et al. collected data on IRB workloads and personnel, the actions of IRBs, and the opinions of board members and chairs on the adequacy of protection afforded by IRBs. These data are now well over 5 years old, and no nationally based studies describing IRBs have been published since. Other efforts to examine IRBs are concerned with decisions made by the boards. This has been done by either (a) analyzing the responses of several IRBs to a single protocol (in some cases a "mock" protocol and in other cases a real one) or (b) by doing content analyses of IRB documents.

Why have so few studies been done? Three reasons come to mind. First, IRBs are seen as a step toward getting research done, not as a subject of research itself. For similar reasons there are few studies of the funding of research, although every social scientist has complaints (and untested theories) about the way the system works. Second, studies of IRBs take social science into the muddy waters of ethics and values; waters that social scientists would rather avoid. This tendency of ours to stick with the "is" and avoid the "ought" is plainly visible in the lack of interest in ethics and bioethics on the part of social scientists. Finally, IRBs are not easy to study. Raymond De Vries has labored to get the cooperation of IRBs for both survey and ethnographic research and has found that IRB members are reluctant to become the subjects of research. This story is not unique: Other social scientists have described the delays and stonewalling they faced in their attempts to get IRB approval of research on IRBs (Casper, 1998).

In an effort to better understand the problems associated with human participant review of SBES research, we examine three different aspects of research ethics committees: (a) the *composition* of review boards; (b) the *guidelines* used by these boards to review SBES—and, in particular, behavioral health—research; and (c) the *actual deliberations* of IRBs. We conclude with recommendations for changes in the review process and with suggestions for filling the gaps in our knowledge about the way IRBs work.

WHO DECIDES? THE COMPOSITION OF IRBS

We cannot understand the fate of SBES protocols in IRB deliberations without knowing something about the IRB members who make the decisions. Responding to the paucity of information on IRBs described earlier, De Vries and Forsberg (2002) conducted a survey of a stratified random sample of 89 IRBs selected from the list of the 892 IRBs registered with the United States Office of Human Research Protection (OHRP) on February 9, 2001. In June and July of 2001, the administrator at each IRB was contacted by telephone and asked questions about demographic characteristics of the members of the IRB and the workload of the committee. Eighty-seven of the 89 administrators responded (a response rate of 98%). These 87 administrators—some of whom were also IRB chairs—were responsible for a total 206 IRBs; 54 administrators (59%) managed only 1 IRB, whereas 21 (24%) managed 3 or more boards. The 87 IRBs in the survey included 1,161 members.

This study is unique in that the unit of analysis is *not* the individual member, but the boards themselves; the data reflect the characteristics of boards. Earlier surveys often reported their findings as if individuals *were* the unit of analysis: This is an easier way to organize and present data—it gets cumbersome to report the percentage of boards with percentages of members in certain categories. However, aggregates based on total members in the sample are misleading because they do not give us a picture of how local boards are constituted. The overall findings on IRBs are presented in De Vries and Forsberg (2002). Here we look only at questions related to IRBs and social science.

Figure 1 shows the breakdown of IRBs by the type of research reviewed. Note that 14% of IRBs are dedicated to behavioral science research, whereas another 58% review both social science and medical protocols (“general”). These data suggest that a majority of social science research is reviewed by boards lacking *specific* expertise in SBES research.

Data on the number and, more important, the *distribution* of social and behavioral scientists on IRBs confirm a lack of SBES expertise on these boards. Figure 2 shows the breakdown of occupations of the 1,161 IRB members included in the study. It might come as a surprise to some that social scientists are the second largest category. This suggests ample presence of an SBES voice on IRBs; however, when we look at how social scientists are distributed across IRBs (Figure 3), we see that nearly 40% of boards have 10% or fewer social science members. By way of contrast, nearly 70% of boards have 30% or more of their members drawn from biology and medicine; approximately 45% of boards have a majority of members from these fields (Figure 4). Together, these data lend credence to the complaints of SBES researchers. The relatively few IRBs dedicated to social science research, coupled with the thin distribution of social scientists on IRBs, shows a preference for biomedical protocols—in terms of experience and expertise—over SBES protocols.

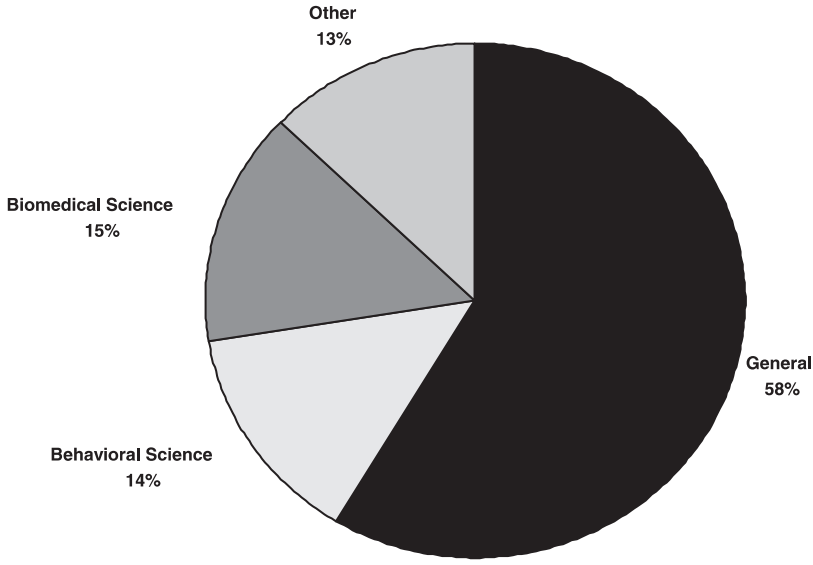

FIGURE 1 Types of protocols reviewed

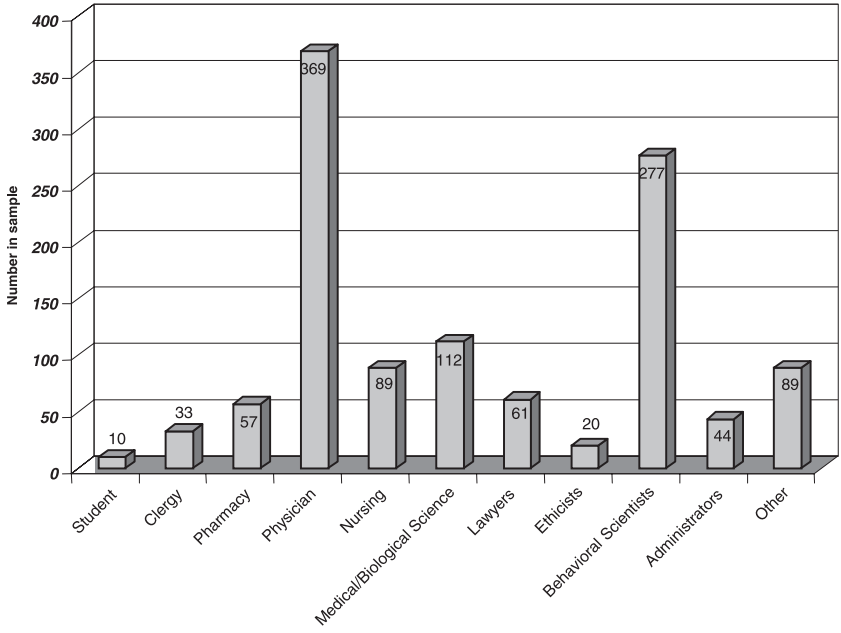

FIGURE 2 Occupations of members

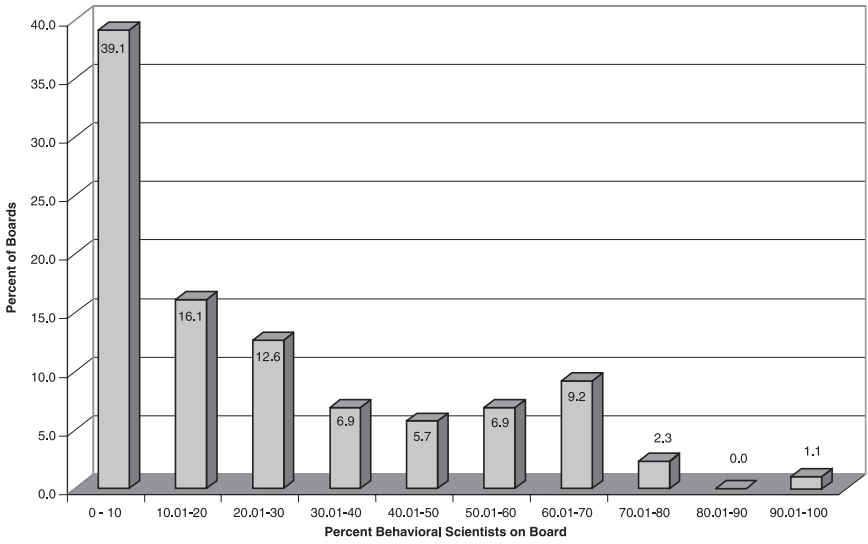

FIGURE 3 Behaviorial scientists on institutional review boards

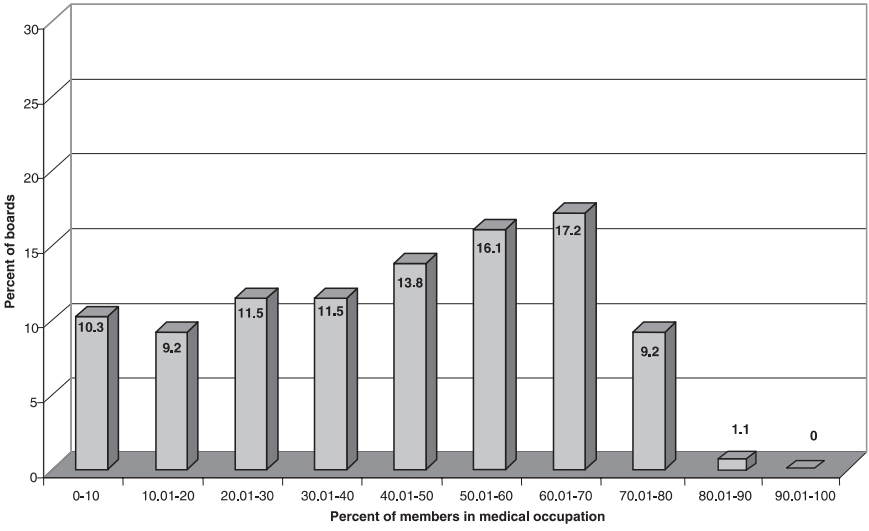

FIGURE 4 Percentage of institutional review board members in medical occupations

APPLYING FEDERAL GUIDELINES TO SBES RESEARCH

The litany of complaints we have summarized and the data we have reviewed speak to the broad range of social and behavioral research. Included here is everything from historical research using data archives or oral histories to research looking at therapeutic interventions for psychological problems. IRBs must apply the Common Rule to this diverse array of fields of study, as well as to all other varieties of human participants research. SBES researchers often protest that these federal guidelines were designed with biomedical research in mind, and so cannot appropriately guide the review of other types of research. Revisions of the regulations may indeed be necessary. However, we must also recognize that the Common Rule leaves much room for judgment on the part of IRBs, and so may allow them the flexibility to tailor their review to the distinctive characteristics of various types of research.

Consider the following example, typical of SBES researchers' complaints about the demand for written documentation of informed consent:

> When [the researcher reported her interests] to the administrators of her program and they, in turn, to the IRB, she was instructed she must secure from the *curanderos* [native healers who provide Hispanic communities with medical advice, prescriptions, and treatments] signed papers of informed consent. To her credit, this action was one she would not do. The *curanderos* have very good reasons to keep their identities concealed from figures of authority. Some are illegal immigrants. Depending on local law, they could be charged with practicing medicine without a license. Most are illiterate. Most have poor command of the English language, [and a] limited understanding of what might be implied in signing any sort of legal form. (AAUP, 2001, p. 11).

As we noted earlier, the Common Rule does require signed consent forms in most cases, but it also allows IRBs to waive this requirement in certain cases. A morally sensitive review of this study could have required that consent be secured from prospective participants without requiring that it be documented in writing.

Consider, too, complaints about IRBs' analyses of the risks and benefits involved in SBES research. The Common Rule requires IRBs to ascertain that "risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result" (Federal Policy, 2001, § 46.111a2). This regulatory language applies equally well to biomedical and SBES research. However, IRBs may not review both types of research equally well. As the NBAC (2001) noted: "Determinations concerning the probability of physical harms are often easier to make than those involving the probability of nonphysical harms" (p. 72). Further, as the AAUP (2001) recognized, "For members of an IRB who are not familiar with

social science research, the task [of judging the importance of proposed research] can be daunting" (p. 9).

Even SBES research that is squarely clinical in nature—as is much behavioral health research—cannot be appropriately reviewed unless IRBs exercise appropriate discretion in their application of guidelines. Within the broad range of SBES research, behavioral health research attracts special scrutiny, in large part because of the participants enrolled and the risks involved. Therefore, we frequently illustrate our discussion by appealing to such research, although many of the points we raise about it also apply to other types of SBES research.

Because much behavioral health research involves "vulnerable participants"—for example, persons suffering from dementia or mental illnesses such as schizophrenia or bipolar disorder—researchers and IRBs are forced to struggle with appropriate definitions of vulnerability. Regulations are not always helpful here; when IRBs look to the Federal Policy (2001) for guidance on this issue, they are left with many unanswered questions.

The Common Rule provides no definition of vulnerability; it simply provides examples. It lists "children, prisoners, pregnant women, mentally disabled persons, [and] economically or educationally disadvantaged persons" as vulnerable (Federal Policy, 2001, § 46.111a3 and § 46.111b). In the Belmont Report, the National Commission (1979) added, "racial minorities … the very sick, and the institutionalized" to the list (part C, § 3). In an effort to protect vulnerable participants, the Common Rule requires IRBs to "be particularly cognizant of the special problems of research involving vulnerable populations" when considering issues of participant selection (Federal Policy, 2001, § 46.111a3), and to ensure that "additional safeguards have been included in the study to protect the rights and welfare of these subjects" when considering dangers of "coercion or undue influence" (Federal Policy, 2001, § 46.111b). However, IRBs are largely left to determine for themselves what special problems the vulnerable face in research and what additional safeguards are advisable.

Subparts B, C, and D of the Federal Policy (2001) regulations provide more detailed guidance about specific vulnerable groups—pregnant women and fetuses, prisoners, and children, respectively. These protections imply that we ought to adopt a model of "protective guardianship" (Weijer & Emanuel, 2000) when we contemplate the inclusion of vulnerable populations in research. In this model, persons are considered to be vulnerable in research if they cannot provide informed consent, either because they lack capacity (like fetuses and small children) or because their situation impedes free, informed choice (like prisoners). Because they cannot adequately protect themselves, we must shield them from the risks of research.

Protective guardianship may seem to be an especially appropriate stance to take toward participants in behavioral health research, many of whom suffer with conditions that may impair their decision-making capacity. However, behavioral

health researchers and IRBs need to remember that an individual's decision-making capacity is not fixed. The NBAC (1998) explained:

> First, some individuals might have fluctuating capacity, what is often called waxing and waning ability to make decisions, as in schizophrenia, bipolar disorders, depressive disorders, and some dementias. Second, decision-making deficits can be predicted in some individuals due to the course of their disease or the nature of their treatment. Although these individuals may be decisionally capable in the early stages of disease progression, such as in Alzheimer's disease, they have prospective incapacity. Third, most persons with limited capacity are in some way still able to object or assent to research, as in the case of more advanced Alzheimer's disease. (p. 10)

Furthermore, IRBs and researchers cannot simply assume that persons afflicted with certain conditions lack the ability to provide informed consent. However surprising, evidence demonstrates the fallacy of drawing conclusions about a person's decision-making abilities from information about the severity of their symptoms (Charland, 1998; Moser et al., 2002; Roberts, Warner, & Brody, 2000).

The problems of informed consent and decisional capacity are further complicated by study designs used by behavioral health researchers. For example, some research is designed to intentionally provoke the symptoms of the disease being studied. As the NBAC (1998) noted, "In these studies, the goal is to generate disease manifestations in a controlled setting so that they can be more fully understood and so that appropriate interventions can be designed, attempted, and evaluated" (p. 13). Other types of research, called *washout studies,* withdraw a participant's medications so that behavior can be assessed or experimental drugs evaluated without the confounding effects of those medications. Placebo-controlled trials, which are often controversial, raise special issues for study populations who may not only have limited capacity for understanding this sort of study design, but may also be desperate for treatment for their conditions (NBAC, 1998). In these cases, IRBs must develop a calculus of risk and benefit that incorporates the problem of vulnerability.

Most discussions of vulnerability are limited to the topics we have explored thus far: decision-making capacity and the risks involved in particular study designs. However, it is increasingly clear that these are not the only sources of vulnerability for research participants. In its report, *Ethical and Policy Issues in Research Involving Human Participants,* the NBAC (2001) argued that the understanding of vulnerability offered by the protective guardianship model is too narrow (Kipnis, 2001). In the case of behavioral health research, participants may exhibit any of a number of types of vulnerability, including institutional or deferential vulnerability, medical vulnerability, economic vulnerability, and social vulnerability.

Although some have attempted to distinguish between institutional and deferential vulnerability, we think these categories can be collapsed. Both involve indi-

viduals who have the capacity to consent, but who may feel the need to defer to the wishes of "others who may have independent interests in whether the prospective participant agrees to enroll in the research study" (NBAC, 2001, pp. 88–89). Any number of power relationships common to participants in behavioral health research may give rise to a felt need to defer to others. For example, a participant may be formally institutionalized (in a health care or penal setting) or—outside of those settings—a participant may feel dependent on health care professionals or family members. Subordinate status in these social situations renders a participant vulnerable to failures of informed consent or exploitation (NBAC, 2001).

In addition, persons suffering from serious behavioral health conditions may feel desperate for relief, and so be medically vulnerable. Such an emotional state may prompt participants to focus on an overly hopeful picture of the potential benefits of research, and to underappreciate its risks. It may also render them vulnerable to exploitation (NBAC, 2001).

Socioeconomic disadvantage is also a critical concern in the context of behavioral health research. "Participants might have an economic vulnerability when they have the cognitive capacity to consent but are disadvantaged in the distribution of social goods and services such as income, housing, or health care" (NBAC, 2001, p. 90). The President's New Freedom Commission on Mental Health (2003) stated,

> Insurance plans that place greater restrictions on treating mental illnesses than on other illnesses prevent some individuals from getting the care that would dramatically improve their lives. Mental health benefits have traditionally been more limited than other medical benefits. (p. 21)

Financing for care is often restrictive and fragmented (President's New Freedom Commission on Mental Health, 2003):

> Each program has its own complex, sometimes contradictory, set of rules. Many mainstream social welfare programs are not designed to serve people with serious mental illnesses, although this group has become one of the largest and most severely disabled groups of beneficiaries. (p. 28)

People with mental illnesses have startlingly high rates of unemployment and homelessness (President's New Freedom Commission on Mental Health, 2003). Such extreme socioeconomic disadvantage may render one dependent on enrollment in research for access to care and heighten one's vulnerability to exploitation. Because relief from illness can significantly improve one's socioeconomic condition, such disadvantage may serve to further complicate one's medical vulnerability.

Finally, participants in behavioral health research are often socially vulnerable; that is, they may have the capacity to consent, but belong to socially undervalued groups, and so be at greater risk of discrimination and exploitation (NBAC, 2001). We cannot ignore the stigma that continues to be a significant problem for persons suffering from behavioral health conditions. For certain groups of patients (e.g., racial and ethnic minorities), this stigma may be further complicated by other stereotypes and forms of bias. Such biases infect the care provided to members of these groups (President's New Freedom Commission on Mental Health, 2003; U.S. Department of Health and Human Services, 2001), and have created a legacy of egregious research abuses.

Although behavioral health research often raises concerns about the vulnerability of participants, such concerns are not limited to this sort of research. To adequately protect research participants, researchers and research ethics committees must take *all* types of vulnerability into account in their deliberations, not just concerns about ability to consent. At first blush, this may seem a further complication in the ethics review process, but it need not be. Indeed, discussions of vulnerability become *more* complicated when—as is often the case now—these various types of vulnerabilities are lumped into the single issue of decisional capacity. Separating out the different types of vulnerability will make for clearer, more efficient discussions of vulnerability and more humane selection and treatment of research participants.

WHAT REALLY HAPPENS? OBSERVING IRBS

We now have an understanding of the composition of IRBs and the rules that guide their deliberations about SBES—and in particular, behavioral health—research, but neither allows us to see what occurs when these committees meet and review protocols. In fact, we know very little about how IRB meetings proceed. We must watch IRBs deliberate if we are to understand the "real rules" of human participant review—that is, how the rules are actually used—as opposed to the "paper rules" found in the regulations (Llewellyn, 1930). This is not easy to do. As we noted earlier, IRBs are not eager to be watched, especially in an environment where research institutions are facing lawsuits from research participants and are being scrutinized by government agencies, in particular, the OHRP, an agency that has suspended federal funds for human participant violations (Citro et al., 2003).

After a protracted approval process, one of us (Raymond De Vries) succeeding in getting IRB approval to observe the deliberations of an IRB. It took additional time to find an IRB where all members agreed to be watched; but after experimenting with various recruitment strategies, this was arranged. Observations of a "gen-

eral IRB" (i.e., an IRB that reviews both medical and SBES protocols) were made over the period of June 2002 to August 2003.

The work of this IRB leaned heavily toward the medical but, on occasion, SBES protocols were considered. In most cases these protocols were given much *more* scrutiny than medical protocols. To an unschooled observer, this seems odd. Often, SBES research poses much less risk to participants than medical research—much of which involves new drugs and unproven therapies—and yet, SBES researchers were questioned more intensely and their protocols reviewed more thoroughly than research involving medical interventions.

Consider a typical case. This study involved a comparison of two different techniques for debriefing victims of rape. One model involved a single interview of the victim by a team that included medical staff, a law enforcement officer, and prosecutors; the second model involved successive interviews by these same team members. Both models are currently used, and the researchers knew of no studies comparing the two, but they cited literature that suggested that post traumatic stress disorder may be lessened by repeated recounting and processing of the traumatic event (thus favoring the second model).

This seems a rather straightforward protocol, as long as issues of confidentiality and informed consent are handled properly. And indeed, these two issues were discussed and suggestions for improvement were made and accepted by the researchers. However, after dealing with these issues there was a long discussion and several questions about details of the research; details that were often left unaddressed in reviews of medical protocols. Included here were questions about study design, sample selection, study location, the extent of stress caused by having to answer questions for researchers, the expected effect of each method on the likelihood of successful prosecution of the perpetrator, and the statistical analysis to be used. These are all important questions, but why are they more likely to come up in the case of a behavioral health protocol?

It could be the novelty of SBES protocols for this particular IRB; being slightly out of the ordinary, these protocols pique the attention of committee members. There is a sense, too, that social and behavioral sciences are soft sciences, allowing all to comment. Whereas in medical protocols members defer to the specialties of their colleagues—the emergency room doctor is relied on to give advice about protocols in emergency medicine—in the case of SBES research there is the sense that everyone is an expert. Field notes suggest that SBES protocols do generate comments from a larger percentage of members than medical protocols. Again, we see different understandings of risk at play here. The majority of IRB members are drawn from medical occupations where clear and established understandings of the physical, bodily risks of medical research exist. These members are less well acquainted with the risks posed by SBES research and are likely to overestimate the risks involved, thus generating more comments and questions.

WHERE TO GO FROM HERE? IMPROVING THE REVIEW PROCESS

SBES research protocols present IRBs with a variety of challenges. Based on what we know about IRBs as a result of research, anecdote, and personal experience, we believe that several steps should be taken to enable IRBs to best promote the rights and welfare of participants in this type of research while allowing this important work to be done. Most important, the makeup of review panels should change. There is a need for more IRBs dedicated to reviewing SBES research protocols, and general IRBs must include more members with SBES credentials. In addition, prospective participants of such research should be given a greater voice in the review process, especially when they are vulnerable. For example, IRBs should appoint persons with behavioral health conditions, or persons qualified to serve as advocates for them, to IRBs that regularly review such research. The Common Rule requires that:

> The IRB shall be sufficiently qualified through the experience and expertise of its members, and the diversity of the members, including consideration of race, gender, and cultural backgrounds and sensitivity to such issues as community attitudes, to promote respect for its advice and counsel in safeguarding the rights and welfare of human subjects. (Federal Policy, 2001, § 46.107a)

Given the spirit of this requirement, the NBAC's (1998) recommendation that these IRBs should include at least one advocate for participants seems woefully inadequate because the concerns of a token advocate (with little or no power within the institution) can be easily ignored or overruled by the views of the majority. If the perspective of the participants of research is to be well represented, IRBs need a more substantial proportion of participant advocates.

In addition, committee members reviewing SBES research must educate themselves about the attitudes and concerns of persons in study populations. The need for such education intensifies when IRBs lack substantial representation of participant advocates. For example, published research offers IRBs invaluable information about methods for assessing decision-making capacity and for improving the ability of prospective participants to give valid consent, as well as perspectives of particular patient populations on risky research designs, vulnerability, and conditions that imperil the voluntariness of choice (Moser et al., 2002; Roberts et al., 2000; Roberts et al., 2003). The government should place priority on funding such research, given its importance in protecting the rights and welfare of research participants. Of course, IRBs must be given sufficient resources to allow them to implement such educational initiatives.

IRBs also need to exercise the discretionary power the regulations give them to tailor their review to different varieties of research. In some instances, they may re-

quire additional guidance to foster this. For example, IRBs would likely benefit from improved guidance for responding to concerns about vulnerability. As we have shown, behavioral health research often involves a dizzying array of interacting vulnerabilities—but so may other types of research. IRBs must attend to all forms of vulnerability, not just decisional incapacity. The ethical treatment of vulnerable participants in research is not a "one size fits all" endeavor. Protective guardianship is not always the appropriate response to vulnerability. Persons who are truly unable to provide informed consent should be shielded from research risks. However, persons or groups at risk of stigma, exploitation, and discrimination ought to be safeguarded against these harms by being empowered in the research process. Consider, for example, members of undervalued groups in our society—persons who, because of their race, ethnicity, gender, age, socioeconomic status, and so on, are stereotyped, marginalized, exploited, and subordinated. To insinuate that such persons are incapable of making informed decisions for themselves and so in need of our protection is to compound the injustices they face by further insulting and stigmatizing them. In addition, routinely excluding them from research in an effort to protect them from risk deprives them of whatever benefits research may bestow.

Researchers must also assume responsibility for the appropriate treatment of vulnerable participants. "Participatory research" is a good strategy in this regard. The participatory model empowers vulnerable persons and groups by giving them a voice in setting research agendas, designing and conducting studies, and reviewing and disseminating the results (Centers for Disease Control, 1998; NBAC, 2001). Therefore, it provides an alternative to the protective guardianship model when vulnerabilities of participants require strategies other than (or in addition to) such paternalistic protectionism. The participatory model may be used in any type of research involving these types of vulnerability from, for example, genomics research involving particular racial or ethnic groups, to survey research about HIV risk factors in communities where transmission rates are high, to ethnographic research of the legal system's treatment of victims of domestic violence.

The difficult task ethics committees face in their review of SBES research is made more pressing by the need for this research. Behavioral health problems are the leading cause of disability in Western industrialized societies (see Figure 5). We must conduct research that can help alleviate the enormous harms—physical, psychological, social, economic—caused by these conditions. At the same time we must not allow this research to proceed without the proper safeguards for vulnerable participants. We must, as a society, strike a balance between promoting valuable research and protecting research participants. Research ethics committees play an important role in securing that balance. They must be structured appropriately, given workable guidelines, and provided with the support they need to do their work.

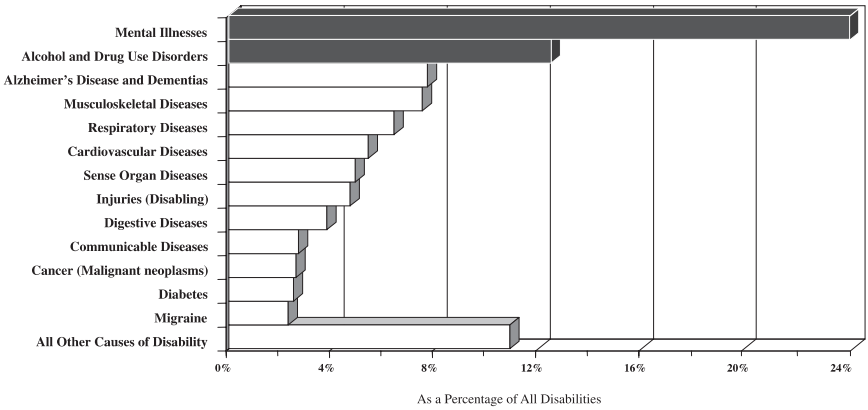

FIGURE 5 Cause of Disability; United States, Canada, and Western Europe, 2000. *Note.* Causes of disability for all ages combined. Measures of disability are based on the number of years of "healthy" life lost with less than full health (i.e., years lost due to disability) for each incidence of disease, illness, or condition. All data shown add up to 100%. Although the President's New Freedom Commission (2003, p. 20) focused on the categories of mental illness and alcohol and drug use disorders, our concern in this article extends to Alzheimer's disease and dementias as well.

Effective reform of IRBs, including the reforms we suggest here, cannot be accomplished without more and better research on the way IRBs work. Our plea for more research is not new; calls for more research on the operation and effectiveness of IRBs are becoming commonplace (Citro et al., 2003), but these calls seldom specify the type of research that is needed. Our review points to the need for more information about the way IRBs actually work, including information about the degree to which researchers abide by IRB-approved protocols. This information cannot be gathered by means of surveys, mock protocols, or the review of documents generated by IRBs. The only way to see the real rules that govern IRB deliberations, and the behavior of researchers, is to watch IRBs deliberate and to talk to researchers about their work (De Vries, Anderson, & Martinson, 2002). It is one thing to know the nature of the expertise that IRB members bring into their board meetings, it is quite another (and a more important) thing to know how that expertise is marshaled and responded to in the course of the meeting.

Observational studies of IRBs, and of scientists, are—as we have noted—difficult to implement; IRB members are hesitant to subject themselves to the ethnographic gaze, and scientists are unwilling to discuss behaviors that violate regulations. However, if we are serious about improving the effectiveness of IRBs, we must find ways to overcome these barriers to research. The necessary balance between protecting participants and promoting research will not be found if we con-

tinue to ground our proposals for IRB reform on anecdote and hearsay rather than on systematic research.

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