Risk and Harm Issues in Social Science Research

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I. Introduction

For the past several years members of the social science community have been struggling to come to terms with the need to subject their work to human subjects review. As university IRB's become increasingly aggressive in their review of social science research, many organizations such as the AAUP and the various social science professional organizations have sought to defend social scientists from what are perceived as unfair, unnecessary and literally unlawful attempts to regulate their work. Much of this reaction might be called "social science exceptionalism," that is, an argument that the nature of social science research is very different from what the drafters of the Belmont report and the Common Rule had it mind. At the extreme, those who hold this point of view argue that for much of what social scientists do, IRB's have no business being involved at all.

As an experienced researcher, an active member of an IRB, and a member of a social science working group convened by the non-defunct National Human Research Protection Advisory Committee (NHRPAC) I can assure readers that there are horror stories on both sides. Disregarding the standard examples such as Millgram (about which there is a fair amount of controversy in any case) that are staples of "Human Subjects 101" courses, I have personally seen many examples of protocols submitted by social scientists that do indeed violate the rights of research subjects, and, of course, I have seen many examples of regulators run amok. Nothing is to be gained by re-hashing such stories – there is enough blame to go around.

The regulatory community, by which I mean the Office of Human Research Protection (OHRP) which is now lodged in the Department of Health and Human Services, and the professional associations that regulators belong to such as PRIMR (Public Responsibility in Medicine and Research) and ARENA (Applied Research Ethics National Association) tends to take the position that the Common Rule provides all the latitude that social scientists need. If one looks carefully at the Common Rule, the argument goes, one finds that much of what social scientists do is "exempt," and that for non-exempt research many of the more onerous requirements of informed consent can be waived in many cases.

In principle, this is true, but there are a number of reasons why social scientists are less than happy with how IRB's actually deal with their work. First, according to official guidance issued by OHRP, one does not declare an exemption, one asks for it, and the power to grant it lies in the IRB. But if one has to fill out forms and provide a detailed plan for research, the result is a *review* in most researchers' eyes, not an exemption. The official response is that being "exempt" means that one is free of informed consent and other requirements such as annual reports that non-exempt research must meet. What members of the social science community seem to want is a blanket exemption without the need to request it for broad classes of research. What the regulatory community seems to want is the ability to provide an imprimatur for all human subject research, however benign.

My own view is that social scientists have to come to terms with the fact that their research

will be regulated. The argument that "these rules don't apply to us," is not likely to work either globally in the sense of bringing about a revision of the Common Rule to exclude much of what we do or locally in the sense of getting local IRB's to ignore social science research. On the other hand, much of what social scientists do falls well below what the Common Rule defines as "minimal risk," and as such ought to be exempt. Indeed, for one broad class of what social scientists do, the analysis of secondary survey data using de-identified data, a strong argument can be made that the research does not even meet the definition of "human subject research."[1] There are two problems with trying to get regulators to take the concept of minimal risk seriously: (a) the definition of the term in the Common Rule is vague and (b) IRB's tend to insist on virtually a ful review of research that everyone agrees meets the minimal risk definition. The remainder of this paper focuses on the first issue. The following section discusses what the common rule says, shows how the definition of minimal risk is deficient and reviews a number of issues in the consideration of risk and harm. Section III considers two specific issues – confidentiality and psychological stress that together encompass much of what social scientists do. The last section of the paper presents a set of recommendations.

II. Minimal Risk in the Common Rule

The definition of minimal risk in the Common Rule is very brief and incomplete. Not only is the definition flawed but a number of issues surrounding the definition of the concept and its application in the regulation of research are ignored, both in the Common Rule itself and in subsequent attempts to clarify it.

The Common Rule and Minimal Risk

The Common Rule at §46.102(I) 45 CFR 46 defines minimal risk as follows

> *Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.*

On the surface, the common sense meaning of this definition is clear enough – if subjects are exposed to a degree of harm or discomfort roughly equivalent to what one would expect in the course of daily life or in the course of routine tests and examinations, then "minimal risk" applies. "Risk" here is being used to loosely to mean some combination of the degree of harm and the probability of experiencing it. In other words, "minimal risk" means that the worst harm that could occur in a study should not be very serious even if many subjects experience it, and if the harm is serious then the probability of any given subject experiencing it should be quite low.

[1] This issue is not the focus of the present paper and I will not expand on it here. However, there seems to be an emerging consensus that research on de-identified data files need not be reviewed once a competent IRB has determined that the data file does indeed not contain identifiable data.

However, IRB's and investigators seem to have some difficulty in understanding and applying this standard. One reason, perhaps the main reason, is that the formal definition is unclear in several respects. First, in attempting to define "risk" it conflates two concepts – the *probability* of harm and the *magnitude* of harm, and applies the word "minimal" to both. Second, it fails to make explicit that *by definition* "[harms] "ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests" are encountered by everyone with virtual certainty, that is, with a probability of 1.0. In order to deal with the ambiguities of the definition it is imperative to separate the concept of "risk" from the concept of "harm."

Defining Minimal Harm and Discomfort

The language of the Common Rule definition gives us one source of firm footing -- the discomfort of physical and psychological examinations -- and it is worth elaborating those discomforts a bit. Virtually everyone undergoes these kinds of examinations at one time or another. With regard to the former, in the course of a physical exam one is usually asked to remove one's clothing and there is usually penetration of various body orifices by instruments or fingers. One may also experience the pain and discomfort of a blood draw and be asked to leave samples of body fluids and excretions. Finally, a good "physical" involves questions about various intimate behaviors that most people find difficult to discuss. Although most of us submit to these indignities, we do not do it with enthusiasm. With regard to psychological examinations,, although academics of the sort who do research on humans typically do well on tests of academic aptitude and ability, most people find that sitting through a half day of tests such as the SAT is unpleasant, as is the subsequent psychological impact of receiving the score, since most people are forced to deal with the fact that they did not do as well as others.

What about harm and discomfort ordinarily encountered in daily life? Although the regulations are silent on this issue, one can make a list of the kinds of negative experiences that most of us encounter at one time or another as part of our daily routines. Here are some examples:

Getting a traffic ticket	Being involved in a minor "fender bender"
Having a tooth filled	Dealing with a child's routine illness
Having a minor argument at work	Losing something important e. g. keys

There are, of course, many other kinds of discomfort and harm that some of us experience at one time or another – the loss of a parent, an accident with injuries, termination of employment – that go will beyond what is meant by the "magnitude of discomfort" delineated in the Common Rule But with regard to what might be called "routine harms and discomforts" the definition of minimal risk sets the bar fairly high while making it clear that for most people the probability of experiencing such harms within the space of a year or two is virtually one.

Defining Risk

As noted, to say that something is "risky" in ordinary discourse usually means that we expect that some serious harm may result from a particular behavior or from exposure to a particular substance or some other aspect of one's environment. Not uncommonly, the word "risk" is often used to mean both a negative outcome and that which brought it about. It is important to distinguish between these two. The outcome is some form of harm and the determinant is the cause of that harm. Epidemiologists typically refer to the determinants of risk as "risk factors." Thus smoking is "risky" because it raises the probability that one will contract various diseases.

A precise definition of risk refers to the rate at which some event occurs in the population. That is, in the numerator one has the number of times a specific event, say death, occurs and in the denominator one has the size of the population to which the event refers. Not uncommonly, rates are reported in terms of a common base such as 100,000. Sometimes risk is reported indirectly as in the statement that the risk of dying from heart disease for the U. S. population is 1 in 385 so that the numerator is common (1) and the denominator varies. All of these approaches allow one to compute a probability. Thus *risk refers to the "chances" or probability that a specific event will occur*. Often, there is a time component involved so that risks of heart attack, for example, are typically expressed on a yearly basis. Risk is also a function of the length of time or the degree to which one is exposed to a given risk factor. Thus, the longer one smokes the greater the risk of lung cancer and the more second hand smoke one is exposed to the greater the risk as well. Similarly, the risk of being involved in a fatal car accident increases with miles that one travels in a car.

A second, very different and less precise definition of risk involves the notion of "uncertainty." Suppose I invest $10,000 in the stock market. I know that there is some risk involved in the sense that my investment can lose value. I have various ways that I might invest the money, some of which are known to be riskier (have a higher probability of loss) than others. But can I calculate the probability that a given investment, say in IBM stock, will gain or lose value? No, and particularly not in the short run. Thus, investment counselors typically use the term "risk" to mean "uncertainty" and advise clients who want to be sure that there principal is intact in the short run to "minimize risk." In effect, the client is advised to minimize exposure to an unknown probability. In common parlance the distinction between the two meanings of risk is often blurred as exemplified in this footnote which appears in a standard text on health economics.

> *Sometimes economists distinguish between risk and uncertainty. Risk refers to a situation where we can list all of the outcomes and assign probabilities to them. Uncertainty refers to situations where were may neither be able to list the outcomes or assign the probabilities. Except where we make explicit distinctions, we will*

simplify our exposition by using the two terms interchangeably.
Folland et al., 2001, p. 143)

It is important to understand that risk *does not* refer to the magnitude of harm. It is true that we tend only to compute risks for rather serious events such as death due to lightening, but it is worth keeping the distinction between the probability of harm and the magnitude of harm clear. Probabilities, of course, range between 0 and 1 and we are probably willing to tolerate a higher probability or risk of harm when the magnitude of harm is low than when it is high. These ideas can be expressed in Table 1.

The table makes clear that one can classify a given study in terms of the risk or probability of various kinds of harm. For example, a standard survey, with proper safeguards for confidentiality (see below) should involve a very low, near zero, risk of moderate or high magnitude harm, but, depending on content, might have low to high probability or even a certainty of causing low levels of psychological discomfort to one or more subjects

Table 1: Probability of Harm and Magnitude of Harm[2]

		Magnitude of Harm			
Probability of Harm Resulting from Study		None	Low	Moderate	High
	Examples	No harm of any kind	Daily life hassles, routine physical and psychological tests	Strong emotional reaction to survey questions, stressful medical tests	Severe social or psychological consequences such as loss of job or reputation
	Zero				
	Low				
	High				
	Certain				

Inter Individual Variability in Risk

"Risk" then refers to the probability of a particular level of harm which would be experienced by individuals in a particular study. We can think of this as a single number but in many studies the, the probability of harm may be greater for some subjects than for others. Thus, many studies routinely exclude pregnant women because of the risk of harm to them or their unborn child. Sometimes in behavioral research one can anticipate the degree to which the probability of some

[2] This table was kindly made available by Joan Sieber

harm is unequally distributed in the population in question. For example, in a study of widowhood, an investigator might decide that very recently widowed women have a much higher probability of a depressive episode as a result of an interview than other widows and therefore exclude them from the study. Conversely, an IRB might insist that an investigator must have immediate counseling available for some populations but not others.

Absolute versus Relative Risk

If minimal risk refers to the what might be called the background noise of daily life, whose life are we considering? Earlier, I provided a brief list of harms and discomforts which most of us can expect to experience on a fairly routine basis. But some populations are forced to deal with much higher probabilities of much more serious harms in the course of daily life than others. Low income populations are exposed to the risk of violence at much higher levels than those with higher income, for example. Researchers who deal with marginalized populations – injection drug users, prostitutes, gang members – can tell you that the probability of harm in the course of daily life is much higher than average. In evaluating minimal risk for such populations, what standard should apply – the middle class standard that the Common Rule implies or the "street standard," of the population in question?

Voluntary and Involuntary Risks

In the course of daily life we face two kinds of risks; those over which we have no control and those we willingly assume. In some cases, the distinction is clear. Each of us has some probability of dying as a result of a catastrophic illness, the origins of which we can not control. As we walk down the street each of us runs some risk of being run over by an out of control car. Other risks are more voluntary. Each time we actually get in a car we accept some degree of risk of being in an accident through our own fault or someone else's. Each time we enter a crowded night club we accept some risk of being involved in a fatal fire. When we ask research subjects to participate in a study we are asking them to *voluntarily* accept such degree of risk. In defining "minimal risk," do we only consider the risk of harm from involuntary sources or do we consider voluntary aspects as well? For example, if we know that our research subjects **need to finish this**

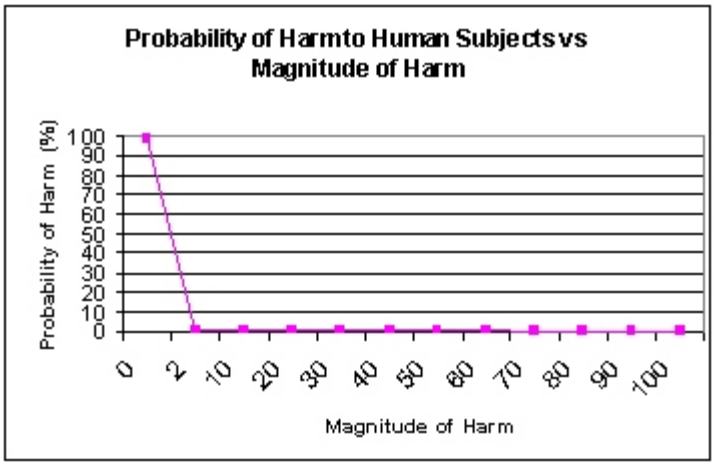
Table 2: Probability of Adverse Event Occuring for Variable Levels of Risk and Various Sample Sizes

Samp. Size	p (harm)	P (0 events)	P (>0 events)
50	0.01	0.60653	0.39347
50	0.001	0.95123	0.04877
50	0.0001	0.99501	0.00499
100	0.01	0.36788	0.63212
100	0.001	0.90484	0.09516
100	0.0001	0.99005	0.00995
300	0.01	0.04979	0.95021
300	0.001	0.74082	0.25918
300	0.0001	0.97045	0.02955
1000	0.01	0.00005	0.99995
1000	0.001	0.36788	0.63212
1000	0.0001	0.90484	0.09516
5000	0.01	0.00000	1.00000
5000	0.001	0.00674	0.99326
5000	0.0001	0.60653	0.39347

Harm to Any One Individual versus Harm to at Least One Individual

Finally, there is a difference between the probability *a given individual* will be harmed in the course of a study and the probability *that one or more individuals* will be harmed. The first probability

refers to *each individual* in the study, and the second refers to *the set of* individuals. Table 2 shows probabilities that no subjects will be harmed and the probability that at least one subject will be harmed for various levels of risk and sample sizes. The distinction can be confusing. For example, suppose the risk of some harm to subjects exposed to some intervention is 1/1000. Suppose a given study has 1000 subjects. What is the probability that at least one subject will experience the harm in question? The answer is not .001 (1 in a thousand) it is .63!



To summarize, one might use the graph at below to display a risk and harm profile for a given study. The graph can refer to either the probability of harm to a given subject or to the probability of harm to at least one subject. Note, however that to do so we have to be able to (a) state probabilities and (b) quantify harms. These are not easy tasks. In any case, the graph shows the fundamental relationship that is likely to obtain in most social science studies– the probability that subjects are likely to experience some low level "harm" such as minor embarrassment is high but the probability that they will experience serious, particularly permanent, harm is very low and in many cases zero.

III. Minimal Risk Issues Regarding Confidentiality and Psychological Stress

Two issues arise continually in IRB discussions of social science research. The first is the need to preserve confidentially and the second involves the possibility that subjects may be harmed in the process of answering questions about sensitive issues, particularly about their own past behavior. Of course, the two issues are not independent; a woman being asked if she ever had an abortion may well experience some psychological stress and if the fact that she had one were to become known publicly she might well be harmed. Most social scientists would argue that neither outcome is very likely, but there has not been a thorough discussion of either issue. Although the remainder of this paper will not provide one, it can at least provide a basis for thinking about the issues in light of the more complete definition of minimal risk which we now have.

Confidentiality Issues

No one would deny that investigators are obligated to protect the data they collect. Promises of confidentiality made to respondents need to be kept. And, to the profession's credit, there have been very few reported cases of violation of that trust. The few that I know about have been

"inside jobs" involving the use of data by project staff members. Most IRB proposals contain standard language about confidentiality and data protection ("the data will be kept in locked file drawer..."), but there is little serious attention paid to the issue. In the computer age, data live forever and careful attention needs to be paid to who has access to files both during the course of a project and after the project is completed. On the other hand, if adequate means of data protection are in place, the probability that unauthorized persons will gain access to data is very low. Thus, although the harm to an individual that might result from disclosure of confidential information might be very high, the probability that such information would actually be released is very low and the minimal risk standard is easily met. The Common Rule recognizes this issue, however it imposes a review standard which is too high in my opinion. The Rule exempts research which meets the following criteria:

> *(2) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless:*
>
> > *(I) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and*
> > *(ii) any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.* 45 CFR §46.101(b)

If a given research project does not meet these criteria the protocol can still be reviewed on an "expedited" basis, but at many institutions this is tantamount to full review. At the very least, IRB's need to recognize that surveys which collect "sensitive" information (and what most social scientists would consider relatively innocuous is considered sensitive under the Common Rule) need not be subjected to full scale review if a reasonable confidentiality-data protection plan is in place. Thus, the social science community would do well to formulate a set of suggested standards to accomplish that.

Psychological Harms

A former member of the OHRP staff with responsibilities for education was prone to remind researchers that "social and psychological harms are real harms." Of course that statement is true. Researchers who ask subjects about sensitive issues have to realize that many of their subjects might find the questions embarrassing, unpleasant, stressful or otherwise upsetting. To put the matter in perspective, consider the use of a standard depression inventory of the kind that appears in literally hundreds of studies every year. Might those questions themselves cause some respondents to experience periods of sadness and dysphoria? Perhaps. Is it possible that a very few respondents might experience most distressful outcomes that last longer than just a few hours? Yes, its possible. Finally, can one imagine a situation in which a respondent might actually attempt suicide as a result of the interview? While most researchers would agree that such an

outcome is possible, most would argue that it is highly unlikely. Asked to provide an actual estimate of probability, I suspect that most of us could not do so. At best we would argue that although the event is obvious at the high end of the harm dimension the probability is extremely low and thus an IRB should be confident that negative outcomes are unlikely.

Here we have, of course, a classic case of uncertainty, and in the face of uncertainty regulators are inclined to ask for maximum protection which might include exclusion criteria for persons known to be at risk for depression, the provision of follow up and psychological services for those who might need them and the actual re-wording and perhaps elimination of potentially harmful items in a survey or interview protocol. Experienced researchers react very negatively to such suggestions, pointing out that the likelihood of negative outcomes is very low. But without a clear understanding of the definition of risk and the distinction between risk as probability and risk as uncertainty both sides are unable to phrase questions clearly or communicate with each other.

Summary

Two of the most frequent issues arising in IRB review of social science research fall at opposite ends of the probability-magnitude spectrum. Confidentiality violations, at least for some kinds of data, can be very harmful to research participants. They are rare but IRB's have every right to ask that the probability be minimized. Researchers tend to be somewhat cavalier about data protection and a set of standard originating in the social science community would be of great value. Psychological harms, on the other hand can be quite common. Any experienced interviewer can point to examples of researcher subjects finding some interview content to be stressful. On the other hand, instances of extreme harm are very unlikely, Thus the probability of harm is high, but the magnitude of harm is low and in line with the minimal risk standard which appears in the Common Rule.

IV. Recommendations

The NHRPAC working group on social science issues prepared a set of recommendations for its parent body. That body is now defunct, replaced by a new advisory group with almost no overlapping membership. Thus the status of these recommendations is very unclear.

Draft Recommendations Regarding Risk and Harm
NHRPAC Social and Behavioral Science Working Group
July 2001

Recommendation 1

OHRP should clarify that much of the research in the social and behavioral sciences is minimal risk and needs to be examined from the vantage of that definition; that is, whether the potential harm and its risk of occurrence is no more than would be encountered in daily life or during the performance of routine medical tests or psychological examinations. Further, OHRP should clarify that much of social and behavioral science research falls within the list of categories set forth in the addendum referenced in 46.110(a). Because this list more heavily relies on biomedical examples, OHRP should issue additional guidance as to how different types of social and behavioral science research fit within these categories. Also, as allowed for in 46.110(a) and according to the procedures set forth therein, OHRP should recommend amendments to the list that more explicitly take into account minimal risk research in the social and behavioral science.

Analysis: At least with respect to social and behavioral research, practices of IRBs in recent years indicate insufficient understanding of the nature of this research, the benefits as well as the minimal nature of risk to human subjects of much of this work, what qualifies for expedited review, and standards of timeliness for expedited review. Training of IRB members is encouraged as well as more placement of social and behavioral science experts on IRBs or, when that is not possible, use of consultants.

Recommendation 2

OHRP should issue guidance to IRBs, to others associated with the human subjects protection system, and to the research community regarding the definition of minimal risk. The document should clarify the distinction between risk as a probability of harm and risk as a magnitude of harm. Investigators should be encouraged to clearly state the various kinds of harms that subjects might incur, the probability of subjects actually incurring such harm, and the available methods of ameliorating the harm. Educational materials elaborating the kinds of harms that can occur in social and behavioral research should be developed.

Rationale: As noted above, the definition of minimal risk as set forth in the Code captures the essence of minimal risk but would be informed by further elaboration regarding implied dimensions. A memorandum of guidance issued by OHRP would help IRBs orient their review, would help "designated" IRB persons undertaking expedited review (which can now take considerable time), and would help researchers know what

needs to be addressed in research protocols to inform the review process. If investigators are asked to be explicit about the kinds of harms that might occur and the actual likelihood of harm occurring, it will be easier for IRBs to make decisions.

Recommendation 3
OHRP should emphasize the "daily life" standard for minimal risk and note that the standard refers to the level of harm and not to the probability of harm since, by definition, everyone experiences the harms of "daily life"—which is why the Regulations use that minimal standard. Guidance should also make clear that the "daily life" standard refers to low-level harms which are transient in nature and easily ameliorated either by the passage of time, by adequate debriefing, or both. Studies in which the level of potential harm falls at or below this standard should meet the criteria for expedited review, and in many cases should be exempt from review.

Rationale: The stress, discomfort, or embarrassment experienced in routine medical and psychological examinations are things that virtually all of us have experienced routinely. A very low proportion of persons, probably less than one in a million, experience any thing other than transitory effects from these examinations. There are many other aspects of daily life which might be described as "hassles" which we almost all encounter such as getting a traffic ticket, having an argument at work, dealing with a child's routine illness or losing something important such as keys or documents. Most social and behavioral research falls at or well below this standard and thus should qualify for an exemption or expedited review, where it does not already (see also Recommendation 1 above).

Recommendation 4
Not all subjects incur the same risk of harm either in terms of probability or magnitude. Investigators should be encouraged to determine whether some human subjects might have higher probabilities of experiencing harm above the "daily life" standard and, if so, whether they need either to exclude such subjects from a study or provide them with special protection or support. Where relevant, protocols submitted to IRBs should be cognizant of this issue and how it was considered.

Rationale: One can imagine many situations in which relatively innocuous studies might be harmful on either a transient or permanent basis to very small numbers of potential subjects. Some potential subjects or subject populations might be anticipated to be more sensitive to being questioned or questioned about the topic of the research. In some instances, investigators might weigh or be encouraged to use various screening mechanisms to rule out such subjects. Where certain subject populations are included because of the nature of the research (e.g., an in-depth study of dietary patterns of homeless persons who do or do not use shelters), procedures should be considered for ameliorating or preventing harm (e.g., offering counseling).

Recommendation 5
In many cases, the most serious harm that could occur to subjects would result from a breach of confidentiality. Investigators should be encouraged to be specific about methods for preserving confidentiality and, where necessary, be provided with models for doing so. OHRP should take the lead in producing educational materials on this issue. A catalog of best practices would be useful.

Rationale: There are at least two areas in which investigators could use guidance on this topic. Investigators who collect survey data on sensitive topics need instruction on how to properly safeguard raw data and computerized files. Investigators who gather ethnographic data need guidance on how to report results in such a way as to conceal the identity of organizations, groups, or individual subjects where appropriate. Also, certain subject populations may be more vulnerable to harm from even a minimal risk of being identified or having information they provided be linked to them (e.g., undercover law enforcement officials, HIV-positive employees, illegal immigrants, professionals engaged in white collar crime, victims of spouse abuse). Under such circumstances, procedures for ensuring privacy (e.g., no signed consent forms or recording of identifiers) and the confidentiality of the data need to be fully and completed addressed.

Recommendation 6
Investigators are often unsure about the probability of harm or about just how harmful a study might be. While such instances are rare in social and behavioral science research, investigators should be encouraged to gather data from "surrogate subjects" regarding perceptions of harm and risk from the population to be studied. Such studies might consist of focus group interviews or "dry runs" of the experimental procedures. While such studies are potentially useful, it is recognized that naive subjects may not be the best judges of risk and that results from such studies need to be balanced against the judgments and guidance of IRBs composed of members or consultants with relevant expertise.

Rationale: Potential subjects can tell us a lot about risk, benefit, and harm, and they ought to be encouraged to do so. Investigators ought to be able to conduct such studies with minimal review and oversight. Indeed, these pretests should be encouraged as part of helping to assess harm and risk.