Session 11

Ensuring Citizen Privacy

Data Privacy and Confidentiality Issues and the Role of the IRB

Lawrence A. Greenfeld, Director
Bureau of Justice Statistics

The collection of data on crime and the administration of justice nationwide, particularly data from individuals on their victimization experiences, is often sensitive and controversial because of the fear of disclosure. A sheriff may fear that disclosure of data will reflect poorly on the operations of his/her jail or that the information may be used by DOJ's Civil Rights Division to challenge the conditions within the jail. Knowing that about 45% of the violent victimization of males and 68% of the violent victimizations of women occur between offenders and victims with a prior relationship, victims may fear disclosure of information about the victimizer but they also may fear the release of what they consider to be intimate, personal information. Many victims, for example, tell us that they did not conceive of the violence they experienced as a criminal act.

BJS data series entail more than 200,000 interviews with the public annually and the collection of administrative data from some 50,000 agencies, offices, and institutions that do something called criminal justice. In addition, every few years we interview tens of thousands of prisoners and jail inmates to learn about their backgrounds and the contingencies of their offense. The most obvious problem we face at BJS is insuring that respondents feel free to share with us their experiences and information without fear of exposure to legal process or authorities. This expectation must never be violated though DOJ litigating branches often express interest in what we collect. This tension between operating agencies who want to use detailed data to make decisions and statistics agencies who want to protect data from disclosure so as to insure the continued ability to obtain the data is, I think, the core of what this session is about. The IRB is thought to represent the best vehicle for insuring that respondents are protected as this drama plays out between stats agencies and operating agencies.

Perhaps the most important element of statistical collections is the maintenance of stable ways to collect information and stability in what is collected over time and across geographic locations so that time series are possible—everyone wants to know whether domestic violence is increasing or decreasing and whether prisons are more crowded this year compared to last year. In my experience, the IRB generally does not demonstrate a strong commitment to this core principle of stability. Rather, the potential discomfort of the respondent may be exaggerated by IRB members in what I have seen as undisciplined meandering through data collection instruments, often instruments which have a long track-record of successful use without complaint. In addition, many instruments reflect a consensus as to what is actually collectible from literally thousands of agencies within a framework of common counting rules and units.

Much of our thinking about privacy and confidentiality comes from various protections afforded respondents who cooperate in Federal statistical programs. The Federal guidelines for the protection of human subjects have been incorporated into the regulatory structure of many Federal agencies. 45 CFR 46, Subpart A, which is now known as the Common Rule defines the criteria for IRB review, the elements of research protocols which are relevant for concern such as informed consent, and it describes the role and operation of the IRB. The DOJ regulation is found at 28 CFR Part 46.

The Common Rule states that "When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data."

For most of what we do as Federal statistics agencies, risks to privacy and confidentiality are the primary risks associated with our work. However there are other risks as well for respondents for which we may or may not be concerned---inconvenience, emotional upset or worry, legal risk if illegal activities are disclosed, etc. Most of us do not prepare a detailed list of every conceivable risk a respondent could face as a result of participation in a self-report survey, for example, since we consider privacy and confidentiality the main concerns for risk of our intrusion into the life of the respondent. But we should always be mindful that a sensitive and private matter is often a troubling matter for the respondent. In addition, a victim-respondent's disclosure to data collectors about certain behaviors by others---such as domestic violence committed by a husband or boyfriend---also raises privacy and confidentiality issues relative to the offender. I think we always need to carefully review our procedures to insure that respondents fully understand the nature of the consent they give---especially children, vulnerable populations, non-English speaking respondents, and even proxy respondents.

The Common Rule really does not clearly tell us objectively what to do to minimize the risk of privacy or confidentiality problems. Essentially, the Common Rule advises us only to use procedures "which are consistent with sound research design and which do not unnecessarily expose subjects to risk." At BJS we often spend a great deal of time, often together with the Census Bureau's Disclosure Review Board, thinking through what anonymity really means---birthdates, occupations, race, geographic locations, gender, type of offense, etc.---may make someone identifiable even when no name or address is given.

Recently, for example, I was utilizing the FBI's Supplementary Homicide Report file covering the years 1976-99; this file contains over a half million descriptions of individual homicides provided by investigating officers occurring over that reference period without names or addresses for any of the victims or offenders. I wanted to see if I could find the actual statistical information filed on the OJ Simpson case. First, I selected cases with multiple victims; among these I selected cases in cities over 1 million population; among these I selected cases where the victims were white and the offender was black. I then selected cases where the offense had been cleared by the arrest of a black male. I then selected cases where the offender and at least one of the victims had a prior relationship as spouse or ex-spouse. I came up with one case which met all the criteria and it occurred in June 1994 the same month as the murders in the Simpson case. The police had coded the circumstance of the case as a "lover's triangle" which was new information to me. The point is to illustrate that even with a very large, "anonymous' dataset, knowing only a few pieces of information can reveal identities.

Often at BJS and at other agencies as well, I am sure, we use privacy and confidentiality as interchangeable terms. Privacy generally refers to how we wish to control what access we give others to ourselves. Confidentiality refers to procedures we use to keep identifiable data from being disclosed and what agreements we make with a data supplier, such as a respondent, about the handling of the information they give us. Privacy is more of a conceptual concern while confidentiality is a procedural concern. It is assumed that if we have the proper confidentiality procedures, privacy will be protected. As the Simpson case illustrates, I think, even the best

confidentiality procedures may not fully protect privacy, if the contingencies or characteristics of an event are sufficiently rare.

At BJS, there are really 6 key confidentiality actions we take to try to make privacy a primary goal:

1) Eliminate linkage of data to unique identifiers---our surveys are conducted with an assurance of anonymity. Different procedures may be needed depending upon whether the survey is being conducted cross-sectionally or longitudinally.

2) Minimize identifiable information from linked datasets---oftentimes we may try to match individuals from one dataset to another---a frequent practice of ours to study recidivism, for example, where we match correctional discharges with criminal records. Scrambling of identifying numbers or other information or their elimination from public use datasets is essential.

3) Utilize statistical methods to protect privacy---a very frequent practice at BJS is to group or aggregate data likely to result in identifiability, such as age, employment, education, income, number of offenders (i.e. 2 or more), etc.

4) Collect data under legal authority guaranteeing confidentiality---we have a statute governing the operation of BJS which provides for protection against disclosure and we often utilize Census Bureau's statute as well. We also have grantees and others who use our data enter into confidentiality agreements (privacy certificates) with us. Such certificates create the kind of intermediate data that are not really fully public but are made available for limited, specified research purposes.

5) Test the dataset to see if small cells can be produced---as a part of the process for preparing a dataset for public release, we try to run numerous cross-tabulations to see if cells can reasonably be generated containing only 1 respondent. If such is the case, we will impose greater aggregation to eliminate the likelihood of creating identifiable cases. A good example, which often occurs, is the use of "other race" to cover persons who may have identified themselves as Asian, Pacific Islander, American Indian, Alaska Native, etc.

For statisticians, aggregation is a very tough problem as we are always curious about subgroup differences and fear that aggregation will introduce bias into an analysis. The problem of aggregation bias is a very real one as revealed in the following example: Suppose I was studying racial bias in the implementation of the death penalty in a State which has only two counties---County A and County B. Suppose County A sentences 10/20 black murderers to death and 50/100 white murderers to death. In each case the probability for white and black murderers is identical . In County B, 1/5 black murderers is sentenced to death and 100 of 500 white murderers is sentenced to death---again, within this county the probability of a death sentence by race is exactly the same. When we aggregate to produce "Statewide" statistics we find that for blacks the probability was 11/25 or 44% while for white murderers the probability was 150/600 or 25%. We might erroneously conclude that there is a huge racial disparity yet in no

jurisdiction within the State was that the case. While aggregation is an obvious solution to problems of confidentiality, it may also introduce other problems.

> 6) Use IRB review as a last resort after seeking exemption—BJS has consistently sought exemption from IRB review for our major statistical series, a strategy which has been based upon our view that the review procedures within BJS and Census Bureau are sufficient and that our governing legislation is clear with respect to confidentiality. In some cases, exemptions have not been granted because juveniles are respondents. However, in these cases, the IRB found minimal to no risk involved and the collections cleared review.

Based on our experience, BJS believes that for IRBs to effectively work with statistical agencies, they must:

> (1) recognize the need to measure the same thing over time and consider the past success of data collections in protecting human subjects (for instance, we have been collecting data from jail inmates for 25 years and have never received a complaint related to the survey);
>
> (2) keep panel discussions focused on human subject protection issues and not stray into areas which go beyond their purview, such as survey administration;
>
> (3) give adequate regard for the procedures already in place to protect human subjects, such as data confidentiality statutes and procedures; and
>
> (4) ensure that the IRB members possesses certain relevant knowledges, particularly in the area of survey methodology.

When IRBs fail to instill these elements, the result is much more paperwork for the statistical agency in responding to questions that oftentimes has already been provided (and not clearly understood by the IRB) and at times, irrelevant to the matter at hand. The result is a poor relationship between the agency and the IRB.

BJS does however, acknowledge that the IRB process impels us to think through our procedures to make certain that interviewers and others who come into contact with respondents are adequately prepared to handle upsetting or troubling matters about which we want to know—i.e. domestic violence, sexual assault, child abuse, etc.

Another related issue that BJS, and possibly other research agencies, is experiencing is how to handle situations in which the respondent reveals information that they are being abused or in some way endangered -- particularly if they are under 18 years old. One of our most important surveys at BJS is the National Crime Victimization Survey or NCVS. The NCVS utilizes a nationally representative sample of 50,000 households who participate under a rotating panel design---each household is in sample for 3 years before rotating out. The first interview from the 7 which take place during the 3-year period is a bounding interview used only for cueing respondents temporally. Respondents can be as young as 12 years old and are asked very

sensitive questions about assaults, sexual assaults, and other crimes they may be experiencing, sometimes on a serial basis. Oftentimes, the offender described by the victim is another household member, neighbor, or family acquaintance. I have struggled with the issue of what to do when young or other vulnerable respondents tell our interviewers about a continuing pattern of abuse and victimization which has never been reported to police or other agencies. Obviously "doing something" about the continuing victimization will be rate-affecting given the longitudinal nature of the design and our promise of strict confidentiality. Various suggestions have included replacing the household in the sample with another similar household and providing social service information to the victim. I would certainly appreciate any thoughts on this.

Basically, each agency needs to consider a set of procedures which may be tailored to the individual series but which follows a general set of principles with respect to both respondent concerns and disclosure concerns. In my mind, methods for addressing the respondent concerns are far less developed than the methods for protecting against disclosure of data. In our case, providing assistance or intervention to a vulnerable respondent who is experiencing emotional upset as a consequence of our questions could affect what we are trying to measure over time and I suspect among many of you this is also a great concern. But the single most important challenge, both statistically and morally, is that once we know the respondent is experiencing a continuing exposure to victimization, what should we do about it?

Another matter of growing concern with respect to privacy among statistical agencies has nothing to do with IRB's. One of the principal challenges to the protection of privacy is the loss of control over computer networks and the increasing centralization of information management in the hands of a CIO. That is, CIO's for the departments in which stats agencies are often housed are assuming increasing oversight for all computer functions. This has the effect of potentially reducing the firewall between policy-making and policy-advocating branches and the statistical agencies. For example, BJS has been aggressively moving toward the collection of administrative data through web-based collection protocols. The CIO is also asserting control over our software purchases and maintenance contracts as our administrative funds are given to the CIO to manage these computer-related functions. There is obviously much that we will need to negotiate with the CIO about the architecture of our computing facilities to insure the protection of respondent privacy and the security of our statistical data—but it is a challenge which will probably be similarly experienced by many in the Federal statistical community.

To conclude, I guess my bottom line is that while I understand the need for IRB's, social science surveys and data collection conducted by Federal statistical agencies require a very different perspective than other types of statistical activity which involves intrusive methods for collecting data or research conducted for the government by outside entities. For the most part, respondent risks associated with Federal social science surveys primarily involve the risk of disclosure, a concern which has always been of paramount concern to Federal statistical agencies and one for which we have all put in place procedures and statutes to protect against such breaches of standards and practice.

In the most recent IRB in which we participated, the review of the our Survey of Inmates in Local Jails, a survey which we have conducted since 1972, the IRB requested that we prepare

some hundreds of pages of material including about 40 pages responding to their questions about why we ask certain questions. The need to maintain stability over time in what is collected should not be subject to the whims of an IRB made up of persons with little or no familiarity with the long-term need for particular data; for many of our statistical series it creates a paperwork burden to simply, in the final analysis, receive approval for the things we have been doing successfully for 30 years without ever having received a single respondent complaint.

Oval Pegs in Round Holes: Health Surveys and the Common Rule

Jennifer Madans, PhD
National Center for Health Statistics

The application of the Common Rule to the federal statistical system is not done uniformly and has not been without some challenges where it has been implemented. NCHS is a good case study of how these regulations have been applied because its data collection systems bridge social, behavioral and health sciences and even encroach into the fringes of biomedical research (eg. NHANES).

My comments are based on my personal experiences as the NCHS Human Subjects Contact, as an observer and presenter at IRB meetings, and as a reader of multiple IRB submissions and reports. Others are more expert in the regulations themselves; the perspective I hope to bring is how these regulations have been applied in one federal statistical system. Primarily, I will talk about survey research and mostly, but not exclusively, from the perspective of using questionnaires to collect data.

History of NCHS's Experience With IRBs:

The manner in which human subject's protection activities and IRB operations have been conducted at NCHS has matured over time and is reflective of changes in the agency's organizational location, in the type of data being collected and in the IRB environment itself. NCHS has a long history of conducting human subjects review (starting in xxx) and currently, the IRB is monitoring about 45 active protocols. Since January 2002, the IRB has reviewed and processed 16 new protocols (9 full Board, 7 expedited), 27 continuations (6 full board, 21 expedited), and 52 amendments (14 full board, 38 expedited).

The NCHS IRB may be unique in that it reviews a relatively small number of protocols but the protocols are for relatively large, repeating studies--the basic data collection systems of the agency. This would likely be the case for other statistical agencies. Some of our data systems submit a single protocol and undergo a series of continuations and amendments; one study has submitted 71 amendments and is still in operation. The oldest protocol still running was initiated 12/06/96. Other data systems submit a new protocol for each data collection cycle, usually a year. However, all NCHS protocols will require at least one continuation as data collection and processing go beyond the 12 months from when the protocol is first approved. So, in any given year, a data collection system would submit a new protocol, a continuation of the protocol submitted the year before and a termination for a protocol submitted in a year prior to that.

Application of 45 CFR 46:

To determine if NCHS surveys fall under 45 CFR 46, it would be necessary to review the requirements for inclusion (do the surveys meet the definition of research involving human subjects as used in the regulation) and exemption. Of note is that most data collections that are done by statistical and other agencies do not obtain IRB approval. One could argue that the Common Rule does not apply or that all protocols would be exempt given NCHS's authorizing legislation and requirements for confidentiality. However, even if this argument could be upheld there would still be the need to assure that the rights of subjects were being protected. If NCHS did not review protocols under 45 CFR 46, we would need to develop another process for review but that process would have no external validity and would not be held in as high a regard as the IRB process. As a result, we have chosen not to make the argument that 45 CFR 46 does not apply. While this had lead to implementation problems, there have also been benefits from under going review under 45 CFR 46 including improved protocols and documentation of survey procedures and more careful consideration of human subjects issues, specifically informed consent.

Although intended to apply more broadly, 45 CFR 46 was modeled for use in biomedical research involving some risk and this model doesn't always fit the survey situation. If research isn't exempt, it follows the same rules as clinical trials sometimes making it difficult to implement the regulations in a reasonable way. This causes problems for investigators and for the IRB. The unintended consequence is that there is an appearance that regulations are not meaningful but just a bureaucratic hurdle to be met.

What Makes For Oval Pegs:

There are several characteristics of survey research that can make applying the regulations challenging.

The evaluation of risks and benefits--If one considers the entire risk/benefit continuum, NCHS surveys are definitely at the low risk end with the main risk being a breech of confidentiality that would lead to the damage to the subject's reputation, financial standing or employability not an adverse effect of a medical intervention. Other risks are difficult to evaluate. For example, how can one evaluate hypothetical risks such as the possible psychological discomfort of asking people about illnesses they may have. Who can determine how likely such a risk is or how severe it would be? It is also more difficult to evaluate the benefits, as they tend to be indirect and non-specific. How should the IRB deal with these potential risks? NCHS surveys are generally national in scope but IRBs are meant to reflect community attitudes and adhere to state law. There is a general lack of guidance in how to adjudicate local vs. national requirements.

Meaning of informed consent in the survey situation-- A major component of IRB review is the evaluation of the informed consent process. The nature of the survey process raises some unique

questions about critical aspects of the process. For example, the identity of the subject is not always clear at the onset of the survey process. This raises the question of who needs to be informed and to consent to the research and when does the consent process start. The consent process for surveys also takes different forms. Advance letters are often sent prior to actual contact. Many subjects don't receive or read these letters. Are the letters considered part of the process and must they include all required items? The primary risk associated with participating in most surveys is the adverse effects of disclosure and many statistical agencies have the legal ability to protect confidentiality. However, this is different than being able to protect against all disclosure risk either during data collection or after release especially in an evolving IT environment. What must respondents be told about the possibility of risks to confidentiality that are either very small or that might occur in the future?

Informed consent makes most sense in situations where the components of the research can be clearly described, as is the case for most clinical research. This is harder in the survey situation where it is difficult to convey comprehensive information about the information that will be collected. In cases where the data collection is multi-purpose both the nature of commitment (generally in terms of time) and the exact content of the survey varies significantly across subjects. Can respondents truly consent to participation before hearing all that will be asked of them but how can this be done prior to actually asking the questions? Is has be suggested that it makes more sense to obtain consent after an interview than before it and that only some aspects of consent need to be mentioned prior to beginning the data collection.

Nature of the information obtained—The notion of private information is used to determine whether an individual is in fact a "human subject" but the distinction between private and public information is not always clear. Many times, the information obtained in surveys might be considered shared information or quasi-public information. For example, if a family member can report information about another family member or if an informant can provide information about the observable characteristics of another person, is the information private? These gradations of "private" are not dealt with in the IRB regulations but they can be important in survey research.

Recognition of investigator expertise— Questionnaires are designed to be understandable to respondents and since it is easy for IRB members to think of themselves as potential respondents (they would be more likely to be survey respondents of some kind than the subjects of a clinical trial), it is not unusual for IRB members to devote considerable attention to question wording and to make the leap from respondent to survey designer. However, potential respondents (including IRB members) are not qualified by virtue of their IRB membership to require changes in research instruments. Identifying the appropriate responsibility of the IRB in the area of scientific quality is always difficult but it is more difficult in survey as opposed to clinical research where IRB members are more likely to erroneously believe that they have more technical/scientific expertise than the investigators. IRBs that are over zealous in their requirements regarding technical issues can have the effect of reducing rather than enhancing quality and this is more likely to occur in the case of survey research. It is important to find a

way to obtain appropriate outside scientific review of the technical aspects of protocols so that IRBs can be comfortable with the scientific validity.

Results of putting oval pegs in round holes:

In trying to apply the requirements of 45 CFR 46 without acknowledging basic differences in research characteristics can have unintended consequences that serve neither to protect subjects nor to improve the science. Often, informed consent processes can overstate the risks of the research thus making it difficult for the respondent to appropriately way the risks and benefits. Perhaps more problematic is that overly strict requirements can give the appearance that the agency sponsoring the research is trying to avoid liability by transferring the burden to the respondent. For example, some IRBs have required signed informed consent prior to participation in survey research. Studies have shown that some respondents find this inappropriate given the nature of the research and question why a signature is needed.

A lack of flexibility can lead to large workloads for the IRB as they have to work very hard to figure out how to make the pegs fit. This can also lead to different standards being used across IRBs, which diminishes credibility of the system especially when data collection is national in scope.

Do we change the pegs or the holes?

To maximize the protection of survey subjects as well as scientific quality we need procedures that will provide human subjects protection appropriate to the level and nature of the risk and that respect the rights of the subject without unnecessary and seemingly irrelevant requirements. One option is to create regulations that apply to survey research. Such regulations might focus on the following aspects of the research activity: providing a general description of survey (rather than mentioning research which is less meaningful in this context); stressing that participation is voluntary and can that the subject can cease participation at any time; identifying who will see the data and perhaps allowing for the final consent to be obtained at the end of the survey rather than at the beginning. However, is this option really viable and would such regulation carry the same weight as the Common Rule. While the current regulations were not written primarily for the survey situation, they do contain enough flexibility so that they can be successfully applied to the work of statistical agencies, as they have been at NCHS. The use of waivers as well as the ability of the IRB to interpret the regulations provides this flexibility.

It is often suggested that the use of the expedited review can solve some of the problems listed above. However, this really is not the case. The use of an expedited review process does not alter any of the stated, potentially problematic requirements in the regulations and does not always result in a quicker review. The regulations do provide for waivers. However, IRBs do not necessarily grant waivers when the requirements for a waiver are met. In some cases, IRBs also require that investigators demonstrate a positive argument for granting the waiver.

Confusion about how to evaluate waiver requests introduces inconsistencies into the system and can actually decrease scientific value without increasing subject protection.

The IRB is itself a social group that responds to the social context within which it exits and its behavior is, to some extent, conditioned by its environment. Recent events in the biomedical/clinical areas are putting more pressure on IRBs to be more conservative and to use literal interpretations of the regulations. Since this can have adverse consequences in some settings, it is important to also provide mechanisms for discussion of all aspects of the review process and to support research that can shed light on how to best achieve the dual objectives of human subjects protection and quality research. These activities could be directed to providing more guidance to IRBs in how to applying 45 CFR 46 to survey research particularly regarding the granting of waivers. Given that survey research involves no more than minimal risk, IRB might benefit from guidance in what standards to use in determining whether the rights and welfare of subjects would be adversely affected by the waiver and whether the research could not be practicably carried out without the waiver particularly in determining what is practicable. Such guidance would have to come from a respected source with standing in the IRB community and should be the result of serious deliberations. If such further exploration of the issue related to the protection of human subjects in survey research could be conducted, we could likely make oval pegs fit nicely in round holes.

Ensuring Citizen Privacy Discussion

Wendy Visscher
RTI International

I'm pleased to be here from Research Triangle Institute. I enjoyed both presentations and will comment on the issues raised by Larry Greenfield and Jennifer Madans, particularly those related to the role of the IRB in ensuring citizen privacy.

Our collective goal is to be able to do important social research while protecting the people who provide the information we need. This means we need to consider how to protect privacy and confidentiality, how to assess risks, and how to design studies that are compliant with the human subjects regulations and acceptable to the IRB. This is a lot to think about and often very creative procedures are needed to accomplish the scientific goal while assuring the welfare of the participants. And the system for protecting human subjects in social research could be improved.

As Larry Greenfield reminded us, privacy and confidentiality are two closely related, but different things. Privacy is how a person protects his or her personal information, while confidentiality refers to how we – as researchers – protect this information once we have been granted access to it. In research studies, we are concerned about both privacy and confidentiality.

Both speakers pointed out that violations of privacy and confidentiality are generally considered to be the major risks associated with social research. People decide to participate in research studies for a variety of reasons. We make a promise to them to keep their information confidential as part of the informed consent process. Different people consider different types of information to be personal and private. This judgment will affect whether they decide to accept our promise and the associated risk of an inadvertent breach. I think that if we could maximize our ability to protect confidentiality - and the public's confidence in this ability - we might also be able to increase our survey response rates. Larry Greenfield also noted that this could affect data quality if respondents are not convinced that their data will be confidential.

A researcher's plan for protecting privacy and confidentiality is one element that must be considered by an IRB. Unfortunately, the human subjects regulations give very little guidance about what constitutes adequate protection. In fact, all the regulations say is that the provisions for this must be adequate. Thus the IRB must evaluate the proposed procedures for protecting study data, in conjunction with the promises made to respondents in the consent form. Evaluating data security plans is becoming increasingly difficult for IRBs as information technology advances. At RTI, we have done a lot of web-based data collection. Some of the data collected using this technology are quite sensitive. For example, we just completed a study of post-traumatic stress in New York and DC following the September 11 attacks. When our IRB initially reviewed this data collection method, it had to assess very complicated computer systems to determine if the study data would be well protected.

Another issue mentioned by Larry Greenfield is that study respondents must be told if there are exceptions to confidentiality. For example, if minor respondents report abuse, the researchers and the IRB must develop procedures for the mandatory reporting of this information to the proper authorities. RTI is currently conducting a very sensitive study on child welfare that requires elaborate reporting procedures for this.

In addition to the human subjects regulations, the new medical privacy law HIPAA (the Health Insurance Portability and Accountability Act), will afford additional protections to personal health information. This law will restrict how clinics and hospitals can release identifiable medical information to persons outside their institution, including researchers. Fortunately, HIPAA gives slightly more guidance than the human subject regulations regarding what is needed to protect this personal information. In order for a researcher to receive this type of information from a health provider, he or she must satisfy the three criteria: (1) an adequate plan for protecting identifiers, (2) a plan for destroying identifiers at the earliest possible time, and (3) an assurance that they will not release the information to anyone else.

If we acknowledge that potential breaches of privacy or confidentiality are the major risks of social research, what type of risks are they? As the speakers said, risks are hard to assess and the IRB may make a different assessment than do the researchers. Two components of risks must be considered – the probability of harm and the magnitude of harm. We can think of these in a 2 by 2 table, high and low probability by large and small harm. Hopefully, neither a social study nor a medical study falls into the quadrant of high probability of a large harm. It would be nice if all studies were low probability of small harms, but in reality either type of study can fall into any of the other three quadrants. Another thing to keep in mind, from an ethical standpoint, is that a person can be wronged even if he or she is not actually harmed.

So what are the risks that are possible from participation in a social research study. As mentioned, most are related to breach of confidentiality. If private information is released inappropriately, it could adversely affect a person's legal status, financial standing, reputation, job, or insurability. Larry Greenfield noted that these risks would vary for vulnerable populations such as inmates. Another risk to be considered for social studies is the emotional risk associated with recalling, in the course of an interview, past or present events that are upsetting. These are very real risks. Note that the types of information that could be damaging if released – even in a social research study – are not limited to social, demographic, or behavioral data. A definite trend is that these studies are starting to collect biospecimens so that genetic indicators can be studied. DNA information is some of the most identifiable and most personal data and its release could damage not only the study respondent but also his or her family. Jennifer Madans discussed this issue of shared information and third parties in her remarks.

How does the IRB consider risks during its review? The regulations define a risk level called "minimal risk". This definition takes into account both the probability and magnitude of harm, and compares these to those that a person would experience in his or her everyday life. Some

types of social research - that impose no more than minimal risk - may qualify as exempt from IRB review, or can undergo expedited IRB review. Both speakers mentioned IRB exemptions. It appears that exemptions are not applied in a standard fashion across institutions. Jennifer Madans also noted that if a study is exempted, there are often no standard procedures for assuring protections for respondents. She also reiterated that the level of risk should determine what types of protections, and what level of review, the IRB should require for a given study.

Who is responsible for protecting the information our respondents entrust us with and making sure the risks we subject them to are as low as possible? This responsibility falls on all of us who do research with human subjects. As we've all described, assessing possible risks and appropriate protections are not straightforward and are not clearly defined in any regulation. Thus, the client, the research team, and the IRB must work together to protect research participants. And all of us have a vested interest in doing this right. Not only is it the right thing to do, but it increases the public's confidence in research, which increases the chance that they will participate in our studies. The IRB at RTI tries very hard to be collaborative, and not adversarial, with our researchers. Many of our IRB members are researchers themselves so really can help the researchers think through these issues. Larry Greenfield mentioned that some IRB members may not fully understand the needs of longitudinal research. It may be that adding social researchers to the IRB membership could help alleviate this problem.

Both speakers mentioned their experiences with IRB review and the focus of some of these reviews. IRBs are tasked with reviewing all studies which involve human subjects (or data from human subjects) for compliance with human subjects regulations -- either the "Common Rule", or the corresponding FDA regulations. These regulations are based on three ethical principles that were delineated in Belmont Report -- beneficence, justice, and respect for persons. If they focus on these principles, the IRB can best achieve its main purpose of safeguarding the rights and welfare of the participants. As such, the IRB can be more objective than the researchers about the true level of risks possible and what are reasonable protections. Larry Greenfield acknowledged that one area in which researchers can benefit from the IRB's perspective is in developing effective ways for interviewers to handle upset respondents.

I'd like to take a closer look at the DHHS human subjects regulations – or the "Common Rule". It is often said that this regulation was written with only biomedical studies in mind. This is not entirely true. The Common Rule does not distinguish between social, behavioral, and biomedical research and it was problems in both medical and behavioral research that prompted the regulations in the first place. In fact, the regulations were written to be intentionally vague – for two reasons. First, they allow the IRB to be flexible and to make judgments based on the specifics of an individual study. An example of flexibility is that an IRB can waive some elements of informed consent for some studies. Second, they allow the IRB to apply the Common Rule to any study, whether it is clinical trial or a household survey about health habits. Jennifer Madans noted that CDC does both types of studies, which further supports the need for a single set of regulations and system of protections. As she said, it is possible to fit oval pegs

into round holes, but more guidance is needed to help the IRBs apply the Common Rule to social and behavioral research.

The speakers have pointed to deficiencies in our system for ensuring citizen privacy in research. I recognize these issues and have also heard them from RTI researchers. How can we improve it? First, we must affirm our shared commitment to do ethical research and to protect our respondents. We need to design good studies and assess the risks and threats to data security imposed by increasingly sophisticated computerized data collection and management. But most importantly, we need to find ways to encourage more collaboration and openness between IRBs and researchers. I think that researchers can realize real value from IRB review of their studies. An IRB review does not need to be mysterious and it should not be arbitrary. But the review of a study by people with different perspectives really can strengthen the protections that are given to respondents. There are regulations that need to be followed by the IRB, and although they leave some room for interpretation, their purpose is clear. I agree that, although the IRB system is not perfect, if does offer some structure and validity to the review of studies that involve human subjects. Since the IRB and the researchers have the same overriding goal of doing good research that respects the rights of participants; it makes sense for them to work collaboratively towards this goal.