PROTECTION OF HUMAN PARTICIPANTS IN SURVEY RESEARCH: A SOURCE DOCUMENT FOR INSTITUTIONAL REVIEW BOARDS

American Association *for* Public Opinion Research, May 2003 (Updated November 2005)

Executive Summary

This statement is intended to provide information and guidance regarding survey methods and the human participant protections review process. The goal is to provide guidelines with a sound basis in the federal regulations, acknowledging the importance of protecting survey participants while maintaining the integrity of the survey research process. This information is provided with the hope that more IRBs will use this information in their review processes and to help investigators better understand how these processes apply to survey research. It is intended specifically as an aid for persons serving on or chairing IRBs. It deals with such issues as survey participation and risk, anonymity and confidentiality, benefits of surveys, and issues of informed consent. This statement is prepared as an aid to you in your deliberations about whether appropriate consideration has been given to the protection of human research participants when a study involving survey interviews or questionnaires is proposed. It is based on extensive experience with surveys by the members of our association and is intended to address a wide range of situations. Key summary points are presented below.

- Participation in surveys rarely puts respondents at more than the minimal risks of everyday of life. This fact is recognized explicitly in the Federal regulations which list surveys as examples of research that can be exempted or handled with an expedited review process.

- Most surveys offer benefits to advancing knowledge and to society broadly. The survey is the only method capable of providing generalizable information on a variety of aspects of the human condition. Survey data are essential to advancing our understanding of health and disease, explanations of social, psychological, and political processes, and evaluation and improvement of public policy.

- Documentation of consent is often not feasible in a survey and may be potentially damaging to participation. However, in virtually all survey-based studies, the key elements of consent can be provided to respondents in a concise way at the beginning of a survey in the brief introductory statements of a telephone interview, in a cover letter for a self-administered survey or in the introductory screen in a web survey. This is true regardless of level of risk, and is consistent with the contemporary view of consent as an ongoing process rather than a document.

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Introduction

This statement is prepared as an aid to you in your deliberations about whether appropriate consideration has been given to the protection of human subjects when a study involving survey interviews or questionnaires is proposed. Consistent with the recommendations of the National Research Council (2003), we encourage IRBs to provide a review process that is commensurate with the level of risk associated with the specific research design proposed. The statement is based on extensive experience with surveys by the members of our association and is intended to address a wide range of situations. Since it cannot address the particulars of every case, AAPOR, through its Standards Committee, would be glad to assist you if asked about a specific research proposal. We hope that the information presented below is helpful, and that you will contact us with questions and problems. Because the Federal regulations specifically require that IRB members possess expertise or consult with experts in the areas of research that they review, we invite you to contact us to assist with reviews if survey research expertise is not available on your local IRB or in your institution. Please contact the AAPOR Standards Chair, currently Roger Tourangeau (RTourangeau@Survey.UMD.Edu).

Survey Participation and Risk: Participation in surveys rarely puts respondents at more than the minimal risks of everyday of life. This fact is recognized explicitly in the Federal regulations which list surveys as examples of research that may be exempted by the IRB or handled with an expedited review process. Unless the intended participants are minors, in many cases, surveys meet the requirements for exemption provided in 45 CFR 46.101b and presented in the category description below.

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 participants can be identified, directly or through identifiers linked to the participants; **and**
(ii) any disclosure of the human participants' responses outside the research could reasonably place the participants at risk of criminal or civil liability or be damaging to the participants' financial standing, employability, or reputation. [Emphasis added]

Participation in certain surveys can, however, put respondents at significant risk when, for example, the inquiry concerns stigmatizing or illegal activity and inadequate attention is paid to ensuring respondent anonymity and the confidentiality of responses. We discuss various questions about surveys below to highlight this distinction.

1. **Does simply asking a question cause some respondents mental distress?** Our experience indicates that some questions may cause momentary unhappiness when asked. Unemployed persons may become upset in talking about being fired or out of work. People may become unhappy talking about their own illness or that of a friend or relative. However, this risk is well within the range of day-to-day experiences and activities. There is no known case, of any person sustaining any lasting physical or psychological harm from a survey interview. On the contrary, many people report that talking about themselves and their problems is therapeutic. Analysis of response rates across studies

indicate that people are more willing to be interviewed about their work or health, and to spend a longer time giving interviewers what might be considered "personal information" than they are to talk about public affairs or foreign policy.

2. **Does answering a question cause some respondents mental distress?** Respondents have significant defenses against becoming embarrassed by answering a survey question. They can refuse to answer if they wish to do so. There is substantial evidence that respondents do refuse to answer when questions that appear to be threatening to respondents are asked of them. Interviewers -- strangers to the respondent -- are trained to remain neutral and to treat each answer as legitimate no matter what is said. It is still possible, however, that some respondents who choose to answer a threatening question may feel temporary embarrassment. There is, again, no known case of any lasting physical of psychological harm from participating in a survey interview.

3. **Are there risks to respondents who admit to illegal or stigmatizing behavior?** On some occasions, researchers must ask about matters such as tax evasion, illegal drug use, or HIV-related behaviors. Such surveys can pose significant risks to respondents since they may suffer adverse consequences if individual identities and responses are disclosed. In all surveys, but particularly in these atypical cases, two issues need to be examined by the researcher and the IRB:
    1. Have sufficient steps been taken to protect the identity of respondents and the confidentiality of their answers?
    2. Do the anticipated benefits to society outweigh the risks?

Anonymity and Confidentiality: It is essential in all surveys that the researcher separate all identifier information (name, address, telephone number, if known) from the interview itself as soon as it is no longer needed, typically, immediately after the interview has been verified. Verification is a standard quality control procedure and is normally conducted soon after the initial interview is completed. The identifier information must be stored separately from the interview in secure files. The level of security needed should be determined according to the level of risk assumed by the respondent and the likelihood that efforts will be made (by, say, law enforcement personnel) to access the identifying information. In cases where data are linked over time, for example in panel studies, identifiers may need to remain with the data for longer periods. In these cases, data security and storage must be a priority.

Additional special measures should be considered to ensure confidentiality of responses in the rare cases where surveys pose significant risks to respondents. In these cases, the researcher should review alternative methods to see to it that respondents cannot be identified through analysis of the data file alone. The methods may involve adding random noise to the file, altering demographic information according to a coded system, or some other procedure. AAPOR can recommend consulting support for researchers and IRBs to decide on appropriate methods for treating data files in these special survey situations.

Electronic data collection via the internet and email has increased in recent years and also presents special challenges for data confidentiality. When disclosure of responses would place participants at risk, investigators and IRBs should make sure that appropriate security measures are in place to safeguard both the transmission and storage of survey responses. Such safeguards might include encryption during transmission, storage of data on secure servers, and provision of firewalls to protect data from unauthorized access.

Benefits of Surveys to Respondents and Others: Many survey participants report that they enjoy the survey process. This enjoyment and the sense of good feeling they get from helping the research enterprise makes surveys possible. The pleasure is probably temporary; no systematic evidence of long-term benefits from survey participation has been collected, though such benefits are possible. (We set aside, for purposes of this document, the tangible benefit of any payments made to respondents to compensate them for their participation.)

The most obvious benefits of surveys are those to the researcher and to society. The survey is the only method capable of providing generalizable information on a variety of aspects of the human condition. Survey data are essential to advancing our understanding of health and disease, explanations of social, psychological, and political processes, and evaluation and improvement of public policy. Even where the benefits of surveys are not immediately apparent, the potential benefits clearly outweigh the minimal risk of harm to respondents in the majority of surveys.

In the case of surveys that do pose substantial risks for respondents, the societal benefits are usually, if anything, more clear cut. Studies of HIV-related behavior, for example, are conducted so that better methods of disease tracking and prevention can be developed. These studies are conducted with appropriate safeguards for anonymity and confidentiality to minimize respondent risk, which is potentially very great. When the risks to respondents are not appropriately considered in a survey design, however, the study should not be conducted.

The Issue of Informed Consent

In virtually all survey-based studies, the key elements of consent can be provided to respondents in a concise way at the beginning of a survey in the brief introductory statements of a telephone interview, in a cover letter for a self-administered survey or in the introductory screen in a web survey. This is true regardless of level of risk, and is consistent with the contemporary view of consent as an ongoing process rather than a document. The main elements of consent are: an explanation of the purpose(s) of the study, the approximate amount of time it will take, a description of what the respondents will be asked to do, a description of any foreseeable risks or discomforts, a description of any benefits to the respondents or others, a statement describing the confidentiality of responses, and a statement of the voluntary nature of participation. In telephone surveys, contact information should also be available upon request for questions about the research and about respondent rights. In self-administered and electronic modes, this information can be included in the written introductory information.

It is useful to discuss informed consent in surveys using the questions: Who can give consent? How does a survey respondent indicate consent? How much information about the study must be provided to a survey respondent, and when?

Who can give consent to participate in a survey? As a general principle, consent can be obtained from adult respondents who can understand the benefits and risks of the survey. Except in the special cases where parental consent itself could pose risks (e.g., studies of child abuse), parental consent must be obtained prior to administration of a survey to a minor and assent (agreement to participate) should be obtained from the child or teen. The age of majority varies slightly from state to state. Investigators should be aware of the age of majority in the geographic region(s) where they are collecting data.

Special consideration must be given to studies being conducted by someone with authority over potential respondents (e.g., teachers, employers, physicians). In these cases, it is particularly important that the respondent recruitment procedures evidence no coercion, either explicit or implicit. Further, it is essential that the researcher make a clear demarcation between research questions and issues arising out of the authority relationship. As a general rule, we discourage persons with authority over potential respondents from administering surveys themselves if they will have knowledge about who did and did not participate or have access to individual responses.

How does a survey respondent indicate consent? In most surveys, respondents indicate their consent by agreeing to participate at the beginning of the interview, and/or by answering questions as they are asked or that appear on a paper or electronic questionnaire. Thus, people may consent to all of an interview, to part of it, or to none of it, depending on how they respond to requests from the interviewer. We should note that significant numbers of people who are approached to participate in surveys refuse to do so or refuse to answer individual questions. There is no evidence that people feel coerced to participate in survey research. Unlike much medical research, which requires "all or nothing" cooperation, surveys permit respondents to opt out easily of parts of the measurement process if they so desire.

Federal regulations (CFR 46.117c) on human subjects protections recognize that written consent forms are not necessary or desirable in every research setting. The regulations provide that, while written consent is the norm in much research involving humans, IRBs may waive requirements for signed consent if they find that the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context. These conditions describe the vast majority of surveys. As noted above, few surveys pose risks greater than those that the respondent would confront in everyday life. Further, in many contexts, written consent forms may threaten respondents (e.g., research on illegal behavior, health, immigrants, etc.) and reduce cooperation unnecessarily. For example, Singer (1978) conducted an experiment that showed the need for a signed consent form reduced response rates by six percent. More recently, Singer (in press) reported that 13 percent of respondents who say they would be willing to take part in a hypothetical survey would be unwilling to sign the consent form. Nonresponse is a primary source of error in surveys, and we attempt to keep it at a minimum so that our samples will be representative of the populations of interest. Written consent forms, in the case of the normal survey, can increase nonresponse error

and increase the burden on respondents without the gain of protecting respondents from significant risks.

Moreover, beyond the possible negative effects of requiring written consent, telephone surveys using random-digit dialing -- a very common approach in survey research -- cannot incorporate signed consent in the protocol prior to the initial contact since respondents' names and addresses are unknown to the researcher. Requiring signed consent prior to the beginning of an interview would, for all practical purposes, make many telephone surveys impossible. Thus, a waiver of documentation of consent is typically the most desirable approach for survey protocols – especially those utilizing telephone and electronic modes.

Even in the case of that small percentage of surveys that do pose more than minimal risks for respondents, the Federal regulations (CFR 46.117c) allow IRBs to waive requirements for signed consent if they find that the proposed research cannot practicably be carried out without the waiver. These types of surveys require a more extensive discussion of risks and benefits with the respondents than do the usual minimal risk surveys. We encourage IRBs to work with the researcher and with the AAPOR Standards Committee to identify means of providing an adequate informed consent process other than the signed consent form when that method would threaten the viability of the research.

How much should survey respondents be told, and when? We firmly believe that potential respondents should understand the risks and benefits of surveys, particularly in those rare cases where surveys do, in fact, pose more than minimal risks. In order that the goal of informing respondents not interfere with sound research practice, we must use information methods that do not unduly exacerbate nonresponse bias, jeopardize the measures of knowledge, opinion and behavior in the survey, or induce unnecessary anxiety in respondents.

IRBs should consider, in other words, the impact of an informed consent procedure on the data collection objectives of the research. In the normal survey that presents minimal risk, lengthy and detailed information about the objectives of the survey and the questions to be asked is apt to bias respondent participation and responses without safeguarding respondent rights. In these surveys, the usual practice of a short introduction about the purpose of the study, the approximate amount of time it will take, the sponsor and/or responsible survey organization, and the general topics to be covered is typically deemed sufficient. This statement should also include the instruction that responses will be held in confidence.

More detailed methods of informing respondents may be considered when survey participation does pose substantial risk. The key here is to provide necessary information for informed choice without dramatic increases in nonresponse or response error, which can render survey efforts useless. Each case will have its own unique problems, and so it is difficult to suggest a standard approach. In broad terms, respondents should be informed in an introduction to the survey that the instrument will cover some sensitive topics, but they should not be told so much as to bias their answers (e.g., they should not be informed of the study hypothesis). This is consistent with much other social science research performed in lab settings where explanations of the hypotheses at the outset would render the study useless. They should be told that questions that cause them discomfort, or those they do not want to answer can be skipped.

The purpose of the introductory statement and the reminders on the voluntary nature of response is to help ensure respondent autonomy without affecting substantive responses. If appropriate, at the end of the interview, respondents can be debriefed to see if any of the matters covered were upsetting, to give further information on study purposes, or to see if respondents have any further questions. This treatment of informed consent in surveys that are more than minimal risk is necessarily brief. Thus, it is important for IRBs to work with the researcher and with the AAPOR Standards Committee in such cases to craft a procedure that meets the demands of respondent protection, maximum survey participation, and low response bias.

Conclusion

Surveys comprise a large portion of research involving human subjects. We in AAPOR believe that it is essential to protect the autonomy of potential respondents and to handle with utmost care the personal information they provide to us. The very existence of the survey as a research tool depends upon a firm foundation of public support. We endorse the aims of human subjects protection regulations and the efforts of institutional review boards to apply them. We want to work with IRBs and investigators to see to it that human subjects protections are applied in a manner that serves the ends for which they were intended. This goal requires distinguishing between surveys and other types of research involving humans, and between the vast majority of surveys that pose little risk and those that pose some risk to respondents. The survey profession has developed methods for ensuring respondent anonymity and confidentiality, and for allowing respondents to express a thoughtful decision to participate or not participate. These procedures differ from those employed in some other forms of research with humans, but they are effective. We urge you to judge how well the survey designs you review embody the principles we have presented here—principles that embrace the fundamental protection process as set forth in the Federal regulations. Finally, AAPOR stands ready to serve as a resource when questions arise about the particulars of any survey design. We can supply advice or consulting support to work out the particulars of difficult survey problems that occasionally arise when balancing good research design and human participants protections.

References

Citro, C., Ilgen, D. & Marrett, C. Eds. (2003). *"Protecting Participants and Facilitating Social and Behavioral Sciences Research,"* Panel on Institutional Review Boards, Surveys, and Social Science Research, National Research Council. Available at www.nap.edu/books/0309088526/html/, May, 2003.

Singer, E. (1978). *"Informed Consent: Consequences for Response Rate and Response Quality in Social Surveys."* American Sociological Review 43: 144-162.

Singer, E. (In press). *"Exploring the Meaning of Consent: Participation in Research and Beliefs about Risks and Benefits."* Journal of Official Statistics.