Courses and tutorials on human research protections emphasize the ethical principles behind the system and provide instructions for completing the required forms (sometimes available in a fill-in the blank format) and a list of research protocols to be included in the appendices. But the human subjects review process often places unforeseen obstacles in the path of researchers with no straightforward suggestions on how to meet the new conditions or constraints on their research activities. This tends to frustrate researchers. One reason may be that the courses and tutorials do not fully explain (1) the system of exemptions and waivers from documented informed consent and (2) how to assess the probability of risk and magnitude of potential harm to subjects when the study has more than minimal risk or deals with vulnerable populations such as children, the elderly, and minorities. The purpose of this paper is to help researchers make their case with Institutional Review Boards (IRBs) that they are conducting their research in an ethically responsible manner.

I begin this paper by sharing my experience in requesting a waiver from documented informed consent. I then present the dilemma of how to balance the interests of human subjects and those of the researcher and my brief history of human subjects protections. The main part of the paper examines the exemptions to IRB review, the assessment of risk, and the waivers to documented informed consent in the
federal regulations. Finally I discuss issues of protecting the rights and welfare of children, individuals in existing data bases, and third parties named by participants. Along the way I point out areas in need of empirical studies to better inform both researchers and IRBs.

**Background Experience**

My father was a tax attorney. He would often spend evenings reading case law as part of his work. One evening he read me a line from a judge’s opinion that Congress had built waivers and exceptions in the tax law to provide judges discretion under certain circumstances. It was my father’s job to find those waivers and exceptions and to make the best possible case for his client within the boundaries of the law. Although I was often told as a child, “Don’t make a federal case out of it,” this suggested something quite different: “If it’s a federal rule, there’s a federal waiver.”

A few years ago I was working as the local evaluator for a school district which had received a large federal grant. Our evaluation plan called for surveying students in 7th, 9th, and 11th grades over a three year period to measure the impact and outcomes of the district wide program. We submitted the application and a copy of the survey to our Institutional Review Board (IRB). Federal and University regulations required that all research projects involving human subjects and materials of human origin be reviewed and approved by an IRB before initiation. We pointed out that the surveys would be anonymous, that is, we would not collect the names of students. We would, however, be able to identify grade level, gender, and race.

We further proposed that the parents or guardians of all students in the 7th, 9th, and 11th grades would receive a mailed letter describing the purpose and nature of the survey and indicating that if they did not want their child to participate in the survey, they should fill out the enclosed form and send it back to the school principal. Their child would then be excused from class when the survey was given. This is a common practice in school districts and is known as implied or passive consent. The IRB wrote back that there is no such thing as implied or passive consent anywhere in the federal regulations known as the Common Rule (45 CFR 46) for 17 Federal agencies. The regulations speak only to general requirements for informed consent (46.116) and documented informed consent (46.117). The IRB concluded that we
could only administer the survey to those students whose parents or guardians had positively agreed to let their children take the survey by signing and sending back an informed consent form.

My survey research manager told me that this would make our response rate infinitesimal and that we could do little to get around it. At that point I remembered the judge’s opinion and my conclusion that there must be a waiver. I took up the challenge and within 24 hours had located the waivers in the Common Rule. After some consultation with colleagues, I drafted my case for a waiver and submitted it to the IRB. Some additional negotiation and refinements followed, and the request was approved.

I have subsequently learned more about the federal rules and regulations governing research involving human subjects, the workings and review procedures of Institutional Review Boards, the Office for Human Research Protections (OHRP) in the Department of Health and Human Services, and standards governing the release of individually identifiable health information. In that process I went to a number of presentations for researchers and evaluators on the topic of human subjects. I was hoping for a problem solving approach. Instead, I found almost all of them focused on why one should be ethical in the conduct of research and emphasized the mandatory nature of the rules and regulations.

Research, Evaluation and a Dilemma

Researchers and evaluators working on federally funded projects are required to follow human participant/subject protocols. The federal regulations at 45 CFR 46.102(d) state:

Research means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Activities which meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program, which is considered research for other purposes. For example, some demonstration and service programs may include research activities.

Evaluation is explicitly given as an example of a systematic investigation designed to contribute to generalizable knowledge. However, evaluators in university and research based settings perceive themselves as caught in the middle between their efforts to meet client demands and their desires to apply
their findings to other situations and share their results with fellow professionals. They may consider themselves to be at a disadvantage compared with unaffiliated investigators such as independent evaluators, market researchers and journalists. Henry and Wright (2001) explore the case of an evaluation of a medical school curriculum. If the evaluation is solely for the purpose of improving the curriculum, it would not require any IRB review. But if an evaluation activity initially conducted or supported for the purposes of assessing or improving a curriculum will be presented as a model for undertaking curriculum reform or a standard for curriculum content or will be used in a paper submitted for publication, then it has crossed a threshold. The evaluation now becomes the basis for generalizable knowledge and would be subject to IRB review. Henry and Wright conclude that evaluation research serving these dual purposes should be submitted for IRB approval in order to disseminate the report beyond the confines of the curriculum committee and medical school administration.

This presents a dilemma: how to protect the rights of human subjects while permitting researchers and evaluators to improve the human condition through dissemination of findings. One solution involves reforming what medical ethicist Howard Brody (2000) has termed the research-ethics bureaucracy. I would describe this as a fragmented and confusing system in which small groups of selected academic/professional peers and community lay people interpret and enforce federal law without much guidance and oversight. Many decisions are made on a case by case basis, often without regard to precedent or consistency across cases. The system lacks an appeals process to a neutral authority external to the IRB. Bureaucratic conformity to the letter of the rules and regulations is stressed over complying with their spirit and has led to closing down the research activities at major universities such as Johns-Hopkins and Duke.

Recent initiatives and enforcement actions have resulted in more closely scrutinized reviews by Institutional Review Boards, training certification for principle investigators, and requiring unaffiliated investigators to obtain human subjects approval from commercial review entities. New rules on protected health information and the establishment of privacy boards have been promulgated to go into effect by April 2003. All of these have changed the way in which researchers and evaluators operate and gain
access to subjects and data. The political solution is to develop a Researcher’s Bill of Rights and then work with various academic and professional associations to petition Congress to change the regulations which tend to increase the time and costs of conducting federally funded research. But this is a topic for another paper.

A second solution is to view the dilemma as a professional challenge. Ideally, an IRB should work with investigators “to find the most effective ways for a researcher to conduct productive research and contribute to the general knowledge pool” (Dressel, 2000). In order to achieve a working relationship, both researchers and IRB members must share a common understanding of the rise of human subjects protections and the intricacies of the federal rules governing exemptions and waivers. This paper, then, attempts to contribute to this understanding and enable researchers to better work within the rules.

A Brief History of Human Subjects Protections

Starting in the 1960's, a series of incidents and reports increased public consciousness concerning the protection of human subjects in research. These included the use of the experimental drug Thalidomide to treat nausea in pregnancy that resulted in birth defects, the 1966 article in the *New England Journal of Medicine* by Henry K. Beecher reporting twenty-two clinical studies in which the health or life of the subjects was at risk, the disclosure of the Tuskegee Syphilis Project in which poor Black disadvantaged males were not treated even after treatment was available, and the Milgram Experiments on Obedience in which subjects, under the direction to do what was in the best interests of the experiment, continued to administer what they thought were high and potentially fatal levels of electroshock to an unseen learner when a wrong answer was given (Swazey, 1978; Wright and Beach, 2000).

The National Research Act of 1974 (PL 93-348) established the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research to create a framework for legislation and rules governing research involving human subjects. The Commission was to identify ethical principles that would justify such rules and regulations, to distinguish between biomedical and
behavioral research on the one hand and accepted medical practice on the other, to propose criteria for assessing the degree of risk to human subjects, and to generate standards for informed consent in various research settings. The eleven member Commission consisted of three physicians, three attorneys, a bio-ethicist, a Christian ethicist, a behavioral-biologist, a physiological-psychologist and the president of the National Council of Negro Women, Inc. Conspicuously missing were any representatives from the main line social science research disciplines: anthropology, economics, geography, political science, psychology, and sociology, or related professional schools that conduct research: social work, criminal justice, and education.

In April, 1979 the Commission published Ethical Principles and Guidelines for the Protection of Human Subjects of Research, known as the Belmont Report. The document distinguished between research and practice, identified basic ethical principles applicable to research on human subjects, and called for the application of these principles as requirements for informed consent, assessment of risks and benefits, and selection of subjects.

The Belmont Report defined practice as interventions that are designed solely to enhance the well being of an individual patient or client and that have a reasonable expectation of success. The Commission held that although some forms of practice may benefit some other person, it was designed to enhance the well-being of a particular individual or groups of individuals and need not be reviewed as research. Research was an activity designed to test a hypothesis, permit conclusions to be drawn and thereby to develop or contribute to generalizable knowledge. It noted that research usually involved the scientific method, that is, a set of procedures designed to reach that objective. The conclusion was that if an activity contained any elements of research, then that activity should undergo review for the protection of human subjects.

This was an all encompassing definition of research and, given the make-up of the Commission, reflected their interest in differentiating clinical practice from research and lumping together all systematic efforts that involved using individuals to gain information regardless of whether the resulting generalizable knowledge would appear in academic publications, marketing reports, or public opinion
polls. While noting that social experimentations may differ substantially from those of biomedical and behavioral research, the Commission specifically declined to make any policy determination regarding such research which would include needs assessments, quality improvement studies, and program evaluation among others. They also did not consider epidemiological research or the use of vital statistics in public health. In fact, the Commission declined to make any specific recommendations for administrative action but rather wanted the report to be adopted in its entirety as a policy statement.

The *Belmont Report* was issued in April, 1979 and before the end of the year, the National Research Act was amended to include the report’s blunt practice/research distinction. Furthermore, the report’s failure to deal with the specifics meant that all research efforts—biomedical, behavioral, and social—were essentially treated alike when it came to writing the legislation and the regulations. The Act was amended in 1985 and again in 1991 when the Health and Human Services core regulations concerning IRBs and protection of human subjects found at 45 CFR 46 became the Common Rule covering 17 Federal agencies.

**Exemptions**

The Common Code at 46.101(b) exempts six types of research. The current climate, however, calls for removing discretion to decide on whether a project is exempt under the federal regulations from the individual researcher to the IRB.

The first exempts research involving normal educational practices such as educational strategies and research on the effectiveness of or comparison of instructional techniques, curricula or classroom management methods. But according to Henry and Wright (2001) the intended use of such research for generalizable findings to other educational programs and institutions is no longer exempt and requires IRB approval.

The second and third exempt educational testing, survey procedures, interview procedures or observation of public behavior with conditions. The second grants an exemption unless both of the following conditions are met: the information is recorded such that individuals can be identified, and any disclosure outside the research could place the subjects at risk for criminal or civil liability or damage
their financial standing, employability or reputation. The third then states that if both conditions are met, the research is still exempt if the human subjects are elected or appointed public officials or candidates for public office, or an existing federal statute requires without exception that confidentiality be maintained during the research and thereafter.

The fourth exempts the collection or study of existing data, document, records, pathological specimens or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified.

The media collects and uses the data exempted under two, three and four above without prior review under the First Amendment to the U.S. Constitution on the one hand, and then often refuses to reveal sources even under contempt of court citations on the other. Logic would suggest that if research is verified to be exempt, then that research should not have to meet the procedures required for non exempt research. But research institutions are requiring their IRBs not only to verify that individuals will not be identifiable in the research data base and that confidentiality will be assured, but to impose further conditions on exempt research such as having the IRB listed as a contact in case of questions or interrupting the flow of the interview to remind participants that they can quit at any time.

The fifth exempts research and demonstration projects conducted by or subject to the approval of federal department or agency heads and which are designed to study, evaluate or otherwise examine public benefit or service programs and possible alternative and changes in those programs. Although almost all research activity supported by the Health Resources and Services Administration (HRSA) could be technically exempt, HRSA requires that a claim of exemption be approved by either the HRSA Human Subjects Committee or and IRB (IOM Report, 2000, chapter 1 footnote 46). If HRSA would do such a review for its projects and issue a letter of exemption, researchers would be able to document their exemption and not have to satisfy their own IRB or even multiple IRBs when several institutions or sites are involved in a large demonstration or national program.
The sixth exempts the consumption of food for taste, food quality and consumer acceptance studies if the product contains no food additives, or contains food ingredients, or chemical or environmental contaminants at or below federally determined safe levels.

Assessing Risk

If almost all research proposals will be reviewed by an IRB, then researchers must clearly address the issue of risk to subjects. IRBs will generally want a reasonable and balanced discussion of risk. Unfortunately, the focus on minimal risk in the regulations, and in tutorials and training workshops has resulted in a lack of clarity about what constitutes more than minimal risk and how to conduct research under such conditions.

The concept of risk for human subjects involves the probability and magnitude of potential harm. Both probability and magnitude can be thought of as dimensions running from low to high. High probability of harm would mean the near certainty of experiencing an uncomfortable or undesirable process or outcome. High magnitude of potential harm would include but not be limited to death, physical injury, severe psychological distress, contracting a disease, criminal or civil liability, loss of job or income, cancellation of insurance. It is often difficult for both researchers and IRBs to assess the seriousness or significance of risk since only minimal risk is very broadly defined at 46.102(i).

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.

To help researchers, the University of Oregon (www.uoregon.edu/~humansub/manual.html#RISKS TO SUBJECTS) lists what it considers to be the specific criteria for minimal risk:

- the participant experiences no pain or physical danger;
- the participant experiences no emotional arousal or psychological stress beyond the levels normally to be expected in everyday life;
the project neither induces nor attempts to induce long-term significant change in the participant's behaviors (including attitudes toward self and others);
the data would not embarrass or socially disadvantage the participant were confidentiality to be violated; and
any concealment on the part of, or misinformation provided by, the investigator with regard to the specific purpose of the project is such that there is no basis for believing the participant would choose not to participate in the research had the true state of affairs been made known to him or her.

In most instances the case for minimal risk is easily made if the research topic and procedures are well known and standardized. Occasionally an IRB may request a researcher to alter or eliminate a procedure or item from an instrument. It may be well for the researcher to first assume that the IRB is not familiar with successful use of the procedure or item in previous research or the provisions to allow the subject to voluntarily end participation before acceding to the IRB request.

Otherwise, the principle investigator must make the case that risks are minimized by using procedures which are consistent with sound research design and do not unnecessarily expose the subjects to risk [46.11(a)(1)]. If research involves greater than minimal risk, such risks must be reasonable in relation to the anticipated benefits [46.11(a)(2) and 46.405, 406 and 407]. If risk is defined as the probability and magnitude of potential harm, this suggests that four categories can be created to assist researchers and IRBs. I have devised the following table to help clarify these aspects of risk.

**Human Subjects Risk Assessment Table**

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<th>low magnitude harm</th>
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<tr>
<td>low probability of harm</td>
<td>minimal risk</td>
<td>excessive risk</td>
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<tr>
<td>high probability of harm</td>
<td>questionable risk</td>
<td>hazardous risk</td>
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The risk of harm increases in order from minimal to questionable, which represents a minor increase over minimal risk, to excessive and hazardous, both of which involve a high magnitude of...
potential harm. Researchers should fully discuss not only the risks of harm, but whether the subjects would directly benefit from the project and, if not, how likely the project is to yield generalizable knowledge and a better understanding, amelioration, or prevention of their disorder, condition or circumstances. Proposals in the excessive or hazardous categories should document how subject safety, privacy, and confidentiality are maximized given the high magnitude of harm. Although I will provide both medical and social science examples for questionable, excessive and hazardous risks, the list of basic elements of informed consent at 46.116(a)6 indicates that for research involving more than minimal risk, potential subjects should be told whether or not any compensation and/or medical treatments would be available if injury occurs. The focus was clearly on medically related and treatable risks.

*Questionable Risk* has a high probability of experiencing harm but the magnitude of potential harm is relatively low. The appropriateness of the benefits to the likelihood of experiencing a small amount of harm is arguable. The researcher should be able to make a case that administering electroshock, placing subjects in stress inducing situations such as sensory or sleep deprivation, or asking questions about illegal activities or immoral behaviors are acceptable if the subject is willing to participate after being thoroughly briefed about any topics and procedures that could increase physical, emotional or psychological stress as well as measures to assure safety, privacy and confidentiality including the ability to end participation at any point during the research.

*Excessive Risk* has a low probability of experiencing harm but the magnitude of potential harm is high. The risk to subjects may be unreasonable in relation to the anticipated benefits they might receive. The researcher would have to make a case against risks such as an adverse reaction to an investigational drug, denying necessary treatment if part of a control group, blocking access to resources or opportunities if part of the treatment group, or using overpayment to entice initial or continuing participation by assuring adequate methodological and procedural safeguards. Given the low probability of great harm, the
researcher would have to indicate the direct benefits to individual subjects and how their safety will be monitored as well as how the generalizable knowledge would contribute to a better understanding, amelioration, or prevention of their disorder, condition or circumstances.

*Hazardous Risk* has a high probability of experiencing harm and the magnitude of potential harm is high. The chances of the subject directly receiving a benefit are extremely small. This would be a difficult case to make. The researcher would need to convince both the IRB and potential subjects that although the project involves little or no benefit to the individual participants, it may yield important generalizable knowledge about the subject’s disorder, condition, or circumstances. An altruistic argument could be made that terminal cancer patients can voluntarily choose to undergo highly experimental procedures that have a low recovery or cure rate. Most problematic would be a participant observation study of illegal activities or immoral behaviors in which subjects are very likely to suffer public condemnation or face legal liabilities if a breach of anonymity or confidentiality occurred and the generalizable findings are likely to contribute to restricting their private behavior or civil rights.

Having identified and defined the four categories created by probability of risk and magnitude of potential harm, researchers must then assess the risks for and their impacts on subjects. It appears that very little empirical research has been done on such risk assessment and risk impact. One excellent study was conducted by Disch and Avery (2001) as part of their research on survivors of sexual abuse by professionals such as therapists and clergy. Disch and Avery report that their IRB made helpful suggestions on informed consent and providing detailed information to the respondents. This included a three-page letter mentioning the painful feelings that might emerge as survivors recalled past events and advised that if a person was in therapy, participation should be discussed with their counselor. Further,
since anonymous questionnaires might be subpoenaed, participants already in or anticipating litigation were encouraged to contact their attorney about participating in the study.

After the data was collected and analyzed, Disch (2001) did a follow-up debriefing questionnaire to participants to learn about the impact of the study. Of 101 respondents, 96% reported a positive outcome including helpful review of events (41%), increased self awareness (37%), felt validated/ less alone (33%) and felt empowered (27%). On the other hand, 80% reported a negative effect including painful reliving of the abuse (48%), interfered with daily life/ had to put questionnaire away to break from intensity (23%), pain related to other issues (19%), facing reality/ impact was painful (19%) and troublesome symptoms/ nightmares and crying (17%). Several were concerned about how data might be used in negative ways. One participant who discarded the questionnaire because she found it too painful to complete, called and asked for another copy so that she could work through it with her therapist.

I would place this study under questionable risk since the probability of experiencing harm is high but the magnitude for potential long term harm was low to moderate. I did not place this under excessive risk because I would claim that the risk to subjects was not low and the magnitude for potential harm was reasonable in relation to the anticipated benefits. But regardless of the risk category, the researchers worked with their IRB, made adjustments to their protocols, and were successfully able to carry out research that involves more than minimal risk.

Waivers

The IRB Protocol Review Standards (www.ohsr.od.nih.gov/info/checklist_IRB_protocol.html) contains a list of suggested questions for IRB discussions. The last question under informed consent is “Is the IRB requested to waive or alter any informed consent requirement?” This is a reminder to the IRB that it must discuss and decide upon requests for waivers.

The criteria for waiving informed consent or altering informed consent elements at 45 CFR 46.116(d) are:

(1) the research involves no more than minimal risk to the subjects;

(2) the research could not practicably be carried out without the waiver or alteration,
(3) the waiver or alteration will not adversely affect the rights and welfare of the subjects, and
(4) whenever appropriate the subjects will be provided with additional pertinent information after participation.

In addition, the requirement to obtain a documented signed consent form may be waived under section 46.117(c) under one of two conditions. One is if the only link between the subject and the research would be the consent document and the principal risk is breach of confidentiality. The other is if 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.

A request for waiver or alteration should address each of these criteria in turn and present arguments for and against the granting of the waiver. The “pro” arguments could include the use of similar methods and instruments by the media, sales and marketing firms, or political campaigns. The “con” arguments should include at least one horrible hypothetical scenario that helps draw the line between responsible and irresponsible research activities or consent procedures under the proposed waiver. Let us consider each of the criteria in turn.

(1) the research involves no more than minimal risk to the subjects

The current requirement that IRBs verify claims for exemption has led them to conduct a more thorough review of proposals. IRBs may deny the claim and impose conditions of documented informed consent for their approval. The researcher may then respond with a request for a waiver on the basis that the research involves no more than minimal risk to the subjects and that documented signed informed consent may be waived under one of two conditions specified at 45 CFR 46.117(c). One is if the only link between the subject and the researcher would be the consent document itself. The regulations state that each subject will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern. In some treatment situations, state law may permit oral consent in the presence of a witness. Patients or clients may then be asked to sign a short form indicating the information was presented orally and agreed to. The researcher must convince the IRB that such consent was given and that releasing any signed consent form to the researcher or requiring the researcher
to obtain a new signed consent form from each patient or client would risk harm from a breach of confidentiality.

The other is if the research involves no procedure for which written consent is normally required outside the research context. The most typical case is an anonymous telephone or mail survey with no recorded identifiers. Such surveys are carried on outside the university research context by the media, marketing firms and political campaigns. Most inform the respondent that their answers will be kept confidential but do not require written confirmation or detailed presentation of the elements of informed consent.

(2) the research could not practicably be carried out without the waiver or alteration

The National Research Act (PL 93-348) which established the Belmont Commission directed the Commission to consider appropriate guidelines for the selection of human subjects for participation in such research. The Commission focused on applying principles of social justice in the selection of research subjects. The *Belmont Report* sought to protect vulnerable classes such as welfare patients or persons confined to institutions from being selected because of their easily availability and compromised position. Similarly minors, racial or ethnic minorities and the economically disadvantaged could be coerced into participation and manipulated in the course of treatment.

But social justice in subject selection has another side that the Commission did not consider. An Institute of Medicine Report (2001) noted that selecting participants equitably means (1) not unfairly excluding certain subgroups of the population from research and (2) working to ensure that the knowledge gained in research applies as appropriate across all groups in society. To this can be added (3) that if research is to create generalizable knowledge, then the Common Rules and IRBs should not impose barriers to the selection of human subjects that deliberately generate inordinate sampling bias or systematic sampling error. All population members must have a calculable probability of being included in the sample. Bias occurs if the sampling procedure is not random or certain population members are more likely to be included than others. Even if subjects are randomly selected from a sample frame or pool of eligible individuals, bias will exist if the sample frame is incomplete or limited.
One possible justification for a waiver from informed consent is that in certain instances documented informed consent creates sample bias and thereby reduces the generalizability of the findings. A needs assessment or program evaluation is different in scope from a basic research project or intervention in which a relatively small number of consenting participants from a larger pool of patients or students can be randomly assigned to a treatment or control/placebo group. The focus of some needs assessment or program evaluation may involve attitudes and behaviors that are relatively rare and it is therefore essential to obtain a random or probabilistic sample of sufficient size to permit valid generalizations and appropriate tests of statistical significance.

A researcher would have to make a case for waiving documented informed consent. For example, an evaluation of a project on preventing student violence would not be generalizable if the survey instrument were administered to only those students whose parents or guardians submitted a signed informed consent. Such a requirement would most likely result in a sample that is relatively small and certainly biased. One could argue that parents who do not sign report cards or call in absences may be highly unlikely to return research consent forms. More specifically, suppose 50 percent of the parents sign and return the informed consent form and all of their children answer the question “How often do you feel unsafe when you are at school?” If 25 percent of the students answered that they felt unsafe either most days or every day, without any information about the non-responders, the true rate could be as low as 12.5 percent (if none of the non-responders were to answer most or every day) or as high as 62.5 percent (if all the non-responders were to answer most or every day). This large range for possible answers exceeds the usual sampling confidence interval and would make the findings essentially meaningless.

The researcher might note that one method for increasing the informed consent rate from parents is to send a series of mailings to the parents or guardians over a two or three week period encouraging them to complete and return in the informed consent document. This might increase the informed consent rate a bit, but it is unlikely to approach an adequate consent rate of at least 75 percent. However, more than two or three reminders would border on harassment and compulsion. Therefore it is impractical to
conduct the research unless some waiver or alteration is granted for the required documented informed consent.

(3) the waiver or alteration will not adversely affect the rights and welfare of the subjects

Protecting the rights and welfare of children

The Common Code (45 CFR 46 subpart D) specifically protects the rights and welfare of children who are subjects of research through requirements for obtaining permission of parents or guardians and for assent from children between the ages of 7 and 17. For research involving minimal risks or involving greater than minimal risk but presenting the prospect of direct benefit to the children, the documented informed consent of one parent may be sufficient. But if the research involves more than minimal risk and presents no prospect of direct benefit to the children but is likely to yield generalizable knowledge and a better understanding, amelioration, or prevention of their disorder, condition or circumstances, then documented informed consent from both parents must be obtained unless one parent is deceased, unknown, incompetent, etc or if one parent has sole legal responsibility for the child. In addition the assent of children capable of providing it must also be obtained.

This is an extremely rigorous requirement. It may be easier for a 16 year old female to obtain a legal abortion in some states than to answer a questionnaire for a federally funded youth risk behavior survey. The waiver and alteration provisions are still available but such requests will be very closely scrutinized. Researchers should be aware that schools have used what is termed implied or passive consent to excuse students from sex education classes, school assemblies etc. Implied or passive consent involves sending the parent or guardian a notice about the class or assembly and excusing the student only if the school receives a signed document indicating the parent does not want their child to participate. I was told during a visit to the Centers for Disease Control that CDC was authorized to use passive consent for its Youth Behavior Risk Surveys. However, implied or passive consent is not informed consent under the Common Code and will not satisfy the requirements of informed documented consent in the judgment of most university based IRBs.
In one of the few methodological studies done comparing active and passive consent, Ellickson and Hawes (1989) followed up people who did not return either active or passive consent forms. They found that non-response to passive consent forms typically reflected a conscious decision by the parent to allow their child to participate, implying that those who did not want their child to participate responded and checked ‘no.’ On the other side, a non-response to an active consent form did not indicate a deliberate refusal but rather a latent or unexpressed consent. They noted that vigorous methods could be used to increase “active” consent but at a high cost in both time and money. More such studies are needed since a single study may not be sufficient to persuade an IRB to grant the waiver and permit an alternative procedure.

Therefore if the research with children cannot practicably be carried out with such documented informed consent, a waiver or alteration may be requested. Researchers proposing some form of implied or passive consent should obtain written approval from the school district’s research review entity. The proposed permission and assent provisions should be mailed to the parents or guardian containing all the required elements of informed consent and explain the procedure to notify the researchers that they would wish to exclude their child from the research. It must be explicitly clear that the parent or guardian is able to refuse participation by their child. This might include a last minute phone call by a parent to the school or researcher on the day of the survey. The procedure should also obtain the assent of the students if they are between 7 and 17 years old. The welfare and safety of the students could be promoted by offering them the name and number of a school based therapist, counselor or administrator they could contact if the research raises emotional or other issues they would like to deal with.

Protecting the rights and welfare of individuals in existing data bases

Some IRBs have become concerned about the rights and welfare of subjects who are included in existing databases, data files or records. A distinction can be made between public use data and protected individually identifiable health information. Public Use Data means data made available to researchers, the media, and/or the public by other investigators, data suppliers, repositories, or consortia or a government agency in which a data user cannot identify individual respondents. Protected Individually
Identifiable Health Information means (45 CFR 160.103) any information created or received by a health care provider, health plan, public health authority, employer, life insurer, school or university, or health care clearinghouse concerning an individual’s past, present, or future health status, utilization of health care, or payment for health care that identifies or can be used to identify the individual, and which the individual can reasonably expect will not be made public.

If the source of the data is public (e.g., published or broadcast media accounts, available in libraries or from unrestricted websites, is a public record or obtainable under the freedom of information act), then IRB review and approval is not needed. But data made available from public entities such as a state family services agency or a school system have generally required special permission to access. In some cases state and federal law prescribe informed consent procedures and conditions for release of data in aggregate form that are at variance with an IRB’s standards. The researcher may have to show that the rights of children are in fact protected by existing legal standards and that the data could not otherwise be practically obtained if documented informed consent was required of every client or student.

Previously collected data from suppliers, repositories, consortia, or other suppliers that has not received IRB approval may now require some level of IRB review. In many cases, the researcher could request verification of exempt status if the information is available in a format in which subjects cannot be identified directly or through identifiers linked to the subjects. It would be very convenient if, for example, the University of Michigan IRB would certify that data available from the Inter-university Consortium for Political and Social Research (ICPSR), (www.icpsr.umich.edu) such as the General Social Survey (GSS) and the National Election Survey (NES) are provided with anonymity of respondents.

Anonymous means no identifiers were collected or that researchers do not have access to the identifiers and receive data without identifiers. An interesting situation arises if merging two or more public data files will result in the ability to identify individuals or enhance a public data file with identifiable or potentially identifiable data. For example, the combination of data sources will enable researchers to identify individuals in a four block radius who have been convicted of a crime or utilize
mental health services. Although marketing firms exchange and combine data bases for business purposes, IRBs usually require researchers to submit an application for review. Depending on the source and nature of the data and the purpose of the analysis, this may mean an exempt review, an expedited review or a request for waivers.

The collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens from a school, health care organization, business or non-profit agency will undoubtedly involve receiving permission to access the data. Such organizations should be able to document that the data they are transmitting is already stripped of individual identifiers and therefore anonymity exists from the perspective of the data user. If information is only available as case records with identifiers, the data will need to be recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects. Sometimes the investigator can pay school, organization or agency personnel who are authorized to access confidential records and files to enter it into a form that is transmissible. Otherwise the investigator will have to assure that research assistants will observe confidentiality of the records they are transcribing or working with.

In order to protect the rights and welfare of individuals, a waiver request should specifically include (1) a statement from the data provider granting permission to access the data and indicating that the provider will not release data with identifiers, and (2) an adequate plan to protect the identifiers from improper use and disclosure, to destroy the identifiers at the earliest opportunity consistent with conduct of the research, and to ensure that the protected health or personal information will not be reused or disclosed to any other person or entity, except as required by law or for authorized oversight of the research project. (45 CFR 165.508(f) 2( ii) F, G, H).

Protecting the Rights and Welfare of Third Parties

The ability to conduct research in which third parties are identified by name could be seriously compromised if either the identity of the third party or the identity of the respondent/participant were to be known. Information about third parties means information provided by human subjects about feelings, perceptions, experiences, knowledge, or interactions with specifically identified others by name,
organization, or socio-demographic category. This would apply to a variety of studies dealing with leadership, social networks, disease transmission, or spouse abuse. The existing Code of Federal Regulations, 45CFR46, is silent on the issue of third parties, but some ethicists and IRBs are beginning to ask if informed consent should be required of third parties. If this were the case, then certain types of research could not practicably be carried out without a waiver or alteration, for it would mean breaking a confidence and possibly placing the informant at risk. Researchers are obligated to protect the privacy and confidentiality of information obtained about third parties (as with all information provided by actual study participants). These concerns should be addressed in the proposal under protecting the privacy of the actual study participants and under risks to subjects if the confidentiality is breached. Until a federal rule is promulgated concerning the rights of third parties, no waiver is necessary and the emphasis should be on protecting the rights of the actual study participants.

(4) whenever appropriate the subjects will be provided with additional pertinent information after participation.

Meeting these criteria would appear fairly straightforward. Subjects should be told the results of tests whether medical, knowledge, attitudinal etc. They should be debriefed if participating in an experimental or control situation and advised accordingly. They should have some reasonable way to access reports and papers produced by the research.

Conclusion

Human research protections began with ethical concerns over medical treatments but shifted from clinical treatments to any research involving human subjects. A research-ethics bureaucracy has emerged that has not dealt with issues of exemptions and waivers in a consistent and straightforward manner. In particular, the focus on minimal risk has resulted in a lack of clarity about what constitutes more than minimal risk and how to conduct research under such conditions. This paper proposed a typology of risks to human subjects. It also examined the various waivers that are currently available under the federal regulations and suggested ways to obtain data while protecting the rights of children, individuals with information in existing data bases and third parties. Outright exemptions from review appear to be very
limited. The ability to obtain a waiver for research involving more than minimal risk is possible if the proper justifications are presented and reasonable safeguards and assurances are in place. Hopefully these will enable researchers to work with their Institutional Review Boards without the current level of frustration.

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