The author discusses the experimenter's responsibility for the protection of human subjects (such as the handicapped) in research and the impact of this responsibility on methods of doing research. Considered are the types of human rights that are most frequently in need of protection within a research setting (such as the right to privacy); the most common threats to these rights that are posed by research (such as when deception is used for experimental purposes); and the criteria for determining when a subject is 'at risk'. Seven actions the experimenter can take to minimize risks to the subject are proposed (such as maintaining the confidentiality of data), and conditions and procedures for the acceptance of risk by both a subject and an experimenter are outlined (including the mechanism of voluntary informed consent). (LS)
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This paper was presented at the annual meeting of the Council on Exceptional Children, April 26, 1973, in Dallas, Texas.

WORKING PAPER No. 70

THE IMPACT OF THE PROTECTION OF HUMAN SUBJECTS ON RESEARCH

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April, 1973
The Impact of the Protection of Human Subjects on Research

Responsibility for the protection of human subjects in research seems to fall largely on the shoulders of the experimenter. The primary purpose of this paper is to discuss the impact of this responsibility on methods of doing research. The issues will be unraveled under five general topics: (1) the types of human rights that are most frequently in need of protection within a research setting; (2) the most common threats to those rights that are posed by research; (3) the criteria for determining when a human subject is "at risk"; (4) ways of reducing research related risk; and (5) conditions and procedures for the acceptance of risk by both a subject and an experimenter.

Types of Human Rights

After reviewing many papers and positions on the protection of human subjects in research, it strikes me that there are three basic human rights that may be threatened by the research enterprise: (1) the right to privacy; (Conrad, 1967; Clark, et al., 1967; Kosa, 1968; Ruebhausen, et al., 1966; Smith, 1967) (2) the right to autonomy; (Wolfensberger, 1967; Kelman, 1972) and (3) the right to personal safety. (Schultz, 1969; Kelman, 1972; Baumrind, 1964; Rutstein, 1969)

Privacy can be defined as the right of an individual to keep some aspects of his personality and behavior hidden from public scrutiny. Counterbalancing this right is the public's need for information about individuals in order to build viable systems of social interaction, as well as to acquire knowledge that transcends individual self-awareness.

Since research is allied with the knowledge building end of this continuum,
it constitutes a threat to privacy by definition alone. The resolution of this conflict cannot be the abolition of all research, so that the problem becomes one of defining, first, the acceptable limits of privacy and second, those activities that constitute an invasion of privacy vis-a-vis the defined limits. This, of course, is no easy task.

Autonomy is the right of an individual to behave in accordance with his own inclinations, free from external force. As is the case with privacy, the right to autonomy is not absolute, but is counterbalanced by the need for societal controls over individual freedom. I am free to shop for my food at a large supermarket or in the neighborhood grocery store, but I am not free to decide whether the taxes I pay shall be used for the purchase of guns or butter. Whether or not I can order a drink with dinner depends upon whether I am dining at a restaurant in Dallas or in East Texas. The limits of autonomy vary with both time and place so that, like privacy, it is not always easy to determine whether or not an individual's autonomy has been violated.

The least ambiguous of these basic human rights is that of personal safety. In the context of research, this simply means that any procedure that may induce a potentially harmful physical or psychological state in a subject constitutes a threat to that individual's right to personal safety.

Having examined briefly the three primary human rights that are frequently threatened by the research enterprise, I shall elaborate next on the nature and extent of these threats.
Threats Posed By Research

In a general sense, human rights can be threatened by both the processes and the products of research. The processes - that is, the experimental procedures themselves - can have a short or long term impact on research subjects. The products - that is, the research data - may be used in ways that influence the life of a subject.

Historically, invasion of privacy has occurred with respect to both the processes and the products of research. If, during the course of conducting research, a person is induced to reveal more information about himself than he really wants to, or if he becomes embarrassed or humiliated as a result of the research procedures, the claim might be made that his privacy has been invaded. If data gathered during research, such as answers to sensitive questions on an interview schedule or personality test, are made public without the knowledge or consent of a research subject, this too would constitute an invasion of his privacy.

With respect to a research subject's autonomy, Kelman (1972) dramatically points out that the very nature of the research situation renders the subject relatively powerless in his relationship with the experimenter. Due to the experimenter's professional prestige and presumed competence, most subjects are quite willing to relinquish their autonomy and behave according to the instructions of the experimenter, even if such behavior is not consistent with how they would normally choose to act.

A subject's autonomy can also be threatened by the products of research insofar as data can be used to circumscribe both his freedom and that of the social group to which he belongs. As Kelman (1972) points
out, much of social research has been done on disadvantaged groups - children, minorities, the handicapped, antisocial persons, and college sophomores. The results of research on riot control, placement of handicapped children in special classes, and so forth, all tend, for better or for worse, to restrict the autonomy of the research subjects and their social groups. The social groups of the experimenters, on the other hand, are rarely themselves the subjects of research, thereby creating an additional power imbalance between experimenters and subjects.

Deception for experimental purposes, which is one of the most widely discussed threats against human rights, affects both privacy and autonomy. A subject is not free to act in his own best interests if he is not aware of the experimenter's intentions; moreover, a subject may inadvertently reveal aspects of his private self as a result of the deception. In spite of these threats to individual rights, deception has become a key component of many methodological approaches within the social sciences. (Beckman and Barbara, 1970; Kalman, 1967; Seeman, 1969)

The third right of personal safety is threatened whenever experimental procedures may result in physical or psychological harm to the participating subjects. Wolfensberger (1967) classifies such threats into two levels: (1) "exposure to procedures entailing mental or physical pain, but no risk of injury or lasting harm; and (2) exposure to procedures that may entail risk of physical or emotional injury" (p. 49).

When Is A Subject "At Risk?"

Having examined the kinds of human rights that may be threatened within the context of research and the nature of some of these threats, we must
next determine those conditions under which a human subject may be placed "at risk" or losing one or more of his rights. A recent publication of the Department of Health, Education, and Welfare (1971) dealing with the protection of human subjects in research offers the following definition of risk: "An individual is considered to be "at risk" if he may be exposed to the possibility of harm—physical, psychological, sociological, or other—as a consequence of any activity which goes beyond the application of those established and accepted methods necessary to meet his needs." (p. 2)

Not all risks, obviously, are related to research, and the HEW policy goes on to specifically exclude certain types of risk from consideration; namely, the ordinary risks of public or private living, and risks associated with the delivery of professional services to clients.

Two aspects of the HEW definition require additions and comment. According to that definition, the risk associated procedures applied to an individual concern the research community only insofar as they go beyond the application of established and accepted methods. The point when a procedure becomes established and accepted, however, is obviously a matter of judgment. Since the line of demarcation between experimental and established methods is not clear, experimenters should probably consider most procedures to be unestablished and thereby assume responsibility for any risks that may be experienced by the subjects. An exception to this liability might occur when a researcher is asked to perform a third-party evaluation of existing agency practices, and he obtains data primarily to fulfill the agency's needs rather than his own. In such instances it would seem appropriate for
the agency to assume responsibility for any risks to its clients.

The second criterion of the HFLW definition needing comment is the requirement that experimenters bear responsibility for risks to subjects from any procedures that are not geared specifically toward meeting their needs. Since most research is not focused on the needs of the subjects involved, this criterion also seems to imply that the experimenter is responsible for nearly all risks encountered by research subjects.

Ways Of Reducing Risk

Having established that basic human rights are frequently threatened in research involving human subjects and that experimenters are partially responsible for these risks, the question arises as to what precautions experimenters can take to either reduce or eliminate the risks to their subjects.

A general distinction must first be drawn between risks for which the experimenter is not responsible, risks intrinsic to the research situation, and risks extrinsic but related to the research situation. As I have mentioned, the experimenter is not responsible for the risks of ordinary daily living that his subjects may encounter. On the other hand, he does have some responsibility for risks that are intrinsic to the research situation. Such risks are the threats to human rights that have already been discussed. As Wolfensberger (1967) points out, however, there are also risks which are related, though extrinsic, to the research situation. As an example he cites the case of a mildly retarded teenager who nearly went to pieces prior to participating in a simple and harmless task because a "friend" told him that the psychologist might cut his head open. Obviously,
this kind of situation cannot be prevented by any specifiable efforts of the researcher.

The threat to a subject's privacy, within the research process, is also partially unavoidable. Since the subject must come into contact with the experimenter or his representative in order to provide data for the study, it is possible that one result of this contact will be embarrassment, humiliation, or greater self-revelation than he would normally have desired. Although the likelihood of such occurrences cannot always be predicted, Conrad (1967) has suggested eight questions to be asked of a study which, if answered in the affirmative, increase the likelihood that a subject's privacy may be invaded: (1) Does it deal with highly personal or private areas? (2) Does it seem to have likely adverse psychological effects in a significant number of respondents? (3) Does it call for self-incriminating or self-demeaning admissions? (4) Is it excessively "psychiatric" in that it refers to extremely abnormal or discreditable behavior or attitudes? (5) Does it seem to countenance undesirable or illegal behavior or views? (6) Does it request highly personal information about someone else whose permission is not sought? (7) Is it involved in propaganda? (8) Does it enter into politically sensitive areas? By sensitizing himself to these questions, the experimenter should at least become aware of the extent to which his procedures may result in an invasion of his subjects' privacy.

With respect to the products of research, it may be possible to safeguard a subject's privacy by taking appropriate precautions to maintain confidentiality of the data collected and thereby create anonymity for the subject. Such precautions include encoding names, locking up the
codebook, and destroying the data when they are no longer needed. (Zoruth, 1971) Although efforts of this sort will clearly reduce risk to the subject, Huebhausen and Brim (1966) point out that only by destroying the data can a subject be protected against a valid subpoena.

A few procedures have also been suggested for reducing threats to a subject's autonomy, within the context of both the process and the products of research. If research methods could involve more participation by human subjects, then a subject's autonomy would be less threatened, since he would be aware of and involved in the research problem being investigated and the research processes in which he was participating. This approach would make the research participant a collaborator with the experimenter rather than a subject to be manipulated. Although such a philosophy has intuitive appeal to those of egalitarian temperament, not much has yet been done to translate this principle into valid scientific designs.

The threats to a subject's autonomy posed by the products of research can be partially reduced, as in the case of privacy, by taking steps to insure the confidentiality of data. To the extent, however, that the products of research also may restrict the autonomy of the social group to which a subject belongs, additional precautions should be taken to minimize the loss of freedom. The most commonly suggested precautions include providing members of the potentially affected social group with opportunities to influence both the nature of the research problems and the manner in which the results are utilized.

The use of deception in the research process, as mentioned before, constitutes a threat to both the privacy and autonomy of a research subject.
Within the constraints of currently available research methods, however, deception seems to be a necessary component for the investigation of certain kinds of phenomena. Before a decision is reached to use deception, however, Kelman (1972) suggests that the following points be carefully considered:

"(1) the importance of the study, which refers not only to its scientific significance (admittedly, a subjective judgment), but also the stage of research that it represents (e.g., exploratory vs. final);

(2) the availability of alternative (deception free) methods capable of producing at least comparable information;

(3) the noxiousness of the deception, which refers both to the degree of deception involved and to the probability of harmful consequences." (p. 997).

A careful consideration of these three factors, Kelman argues, should reduce the tendency of experimenters to use deception as a component of their research methodology.

The reduction of risk to personal safety is highly idiosyncratic and consequently somewhat difficult to discuss in terms of broad principles. If there is a principle to be invoked, it would be simply that the risks to a subject's personal safety should never exceed the minimum level required to accomplish the objectives of the research study.

**Conditions For The Acceptance Of Risk**

Our discussion concerning ways of reducing risk was meant to suggest that risks can indeed by reduced. It should also be obvious, however, that in most research situations, human subjects will experience some degree
of risks or threats to human subjects in some of any attempts to maximize these risks. Even that these risks are almost inevitable, under
what circumstances the research is performed at some of these risks. Two
studies have suggested that (and this position, neither of which translates
into operations) it was clear that would result unambiguous implementation
(Parsons, 1974; Gray, 1971).

The first solution suggests that the risks which subjects may encounter
are acceptable if they are "compared" to the potential benefits of the
study to either the research subjects themselves or to humanity in general.
Although this suggestion is not easy, in principle, its implementation
is severely both unambiguous and subjective. That is deemed beneficial by
the one person but not by another. Yet even if the potential benefits
are commonly accepted, the point at which risks become unacceptable cannot
be objectively determined. Since the balance between presumed risks and
presumed benefits individually requires a subjective judgment, a statement
by the experimenter it with a committee of experts of the effect that such
balance exists cannot in and of itself provide moral or legal permission
to an experimenter to engage in a particular study.

The second common offered solution to the problem of accepting risk
centers around the mechanism of voluntary informed consent. In essence
this device transfers the responsibility for accepting risk from the exper-
imenters and allocates it to the research subject himself. If a subject
is aware of the risks to be encountered and agrees to accept them then the
experimenters has fulfilled his responsibility to protect the subject's
rights. Although this solution seems simple and uncomplicated, an attempt
to implement mechanisms of informed consent quickly reveals its underlying complexity.

In the first place, there are certain situations in which voluntary informed consent is an impossibility. Consent, obviously, cannot be voluntary when the involved subjects constitute a captive audience. When research is conducted involving prisoners, residents of mental institutions, or even college sophomores, care must be taken to determine whether sanctions are imposed on potential subjects who refuse to participate.

Determining if consent is informed is even more difficult than determining whether it has been obtained voluntarily. There are certain obvious instances where consent cannot be informed, for example, when the subjects are children or mentally handicapped. If deception is involved in the research methodology, it is also obvious that consent cannot be informed. But even in the most ideal circumstances - when the research subjects are intelligent and cooperative adults - it can be argued that only the experimenter has the background and knowledge necessary to evaluate adequately the research related risks his subjects may encounter. The HEW Manual recognizes this problem when it states that "the informed consent of the subject, while often a legal necessity, is a goal toward which we must strive, but hardly ever achieve except in the simplest cases."

Besides the concern that the very possibility of achieving informed consent is frequently in doubt, there is also current debate on the content of such consent. The HEW Manual mandates that informed consent must contain the following six components: (1) an explanation of the research procedures, (2) a description of risks to the subjects, (3) a description
of expected benefits, (4) alternate procedures available to the subject, (5) an offer to answer any questions the subject might have, and (6) an assurance that the subject may withdraw from the study at any time he desires. Others, such as Wolfensberger (1967), take issue with this list, especially with the requirement that the research procedures be explained. Subjects need not understand the minute details of a study, Wolfensberger argues, but should simply be informed of the rights they are yielding, the risks that are involved, and the good or bad consequences of the study that might affect them.

In addition to these conceptual and definitional dilemmas, there are also some practical problems which interfere with obtaining informed consent. The most serious is the amount of additional personnel that may be required to obtain informed consent in studies that require a large number of subjects. In the future, it may be necessary to include the protection of human subjects as a specific budget item within research proposals.

Summary And Conclusions

The main thrust of this presentation has been to suggest that the protection of human subjects, although largely the responsibility of the experimenter, is fraught with complexities which make it difficult for him to meet his responsibility. In spite of the fact that many of these complexities are ultimately insoluble, there are concrete actions that an experimenter can take which will minimize the risks encountered by his subjects. Seven such actions have been identified during this presentation: (1) Becoming sensitized to the issues so that blunders are not committed simply out of ignorance; (2) Maintaining the confidentiality of
data; (3) Avoiding deception whenever possible; (4) Exploring research designs that treat subjects as collaborators; (5) Using representatives of subject groups to help determine the research questions and interpret the results of studies; (6) Attempting to ascertain that the benefits of a given study outweigh the anticipated risks; and (7) attempting to obtain informed consent. The implementation of these seven actions will require time, money, and ingenuity, and still will frequently fall short of the mark, for the elimination of risk and the securing of informed consent are both ideals which can be approached but are rarely fully attained.
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