cilitate CO_2 transport between cell interior and exterior by the process demonstrated in Fig. 4; such transport would be particularly effective at CO_2 pressures of about 0.01 atmosphere. Bicarbonate ions, in the absence of carbonic anhydrase, also enhance CO_2 transport. While this enhancement does not approach the transport rates made possible by the enzyme, it is still quite significant.

The presence of carbonic anhydrase in animal and plant tissues has been reported by many investigators. Almost unavoidably it will be decisive in determining rates of CO_2 transport wherever it is located; for this reason the enzyme can be expected to play an important role in metabolic processes ranging from pulmonary and kidney function in vertebrates to photosynthesis in plants.

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Ethical Issues in Research with Human Subjects

A rationale is formulated for a code of conduct in the recruitment of subjects for research.

Wolf Wolfensberger

A number of disciplines engaging in clinical practice with humans have been concerned with questions of ethics for some time, and their considerable experience provides a basis for the evolution of widely accepted codes of professional conduct. Ethics in research, however, is still rather virgin territory. What little there is in the way of codification is very inadequate. Cranberg (*1*) pointed out that the 1953 code of ethics of the American Psychological Association (*2*) was apparently the only one existent in 1963 that had been officially adopted by a scientific organization. Another code, applicable mainly to medical research with human subjects but not (as far as I know) officially embraced by any professional or scientific group, was promulgated at the Nuremberg war-crime trials (*3*). More recently, the World Medical Association (*4*) in 1964 passed a statement on human experimentation known as the Declaration of Helsinki. Britain's Medical Research Council, also in 1964, published a "Statement . . . intended to serve as a guide . . ." on "Responsibility in investigation on human subjects" (*5*). Other organizations also have taken steps toward codification of ethics in research but no code, statement, guide, or other set of widely adopted principles yet has the degree of clarity and adequacy that appears feasible and necessary to guide researchers through certain problem areas.

In the past, when lack or inadequacy of rules in research had not been perceived as a major problem, researchers muddled along in the belief or hope that procedures and conventions either in common use or approved by their peers were proper and ethical. At times it was even assumed that a novel procedure entailing unknown degrees of risk, or a procedure requiring definite risks, could be made respectable by having the experimenter share the risk with the subject, or by using volunteers. We have now arrived at a point in the evolution of science at which both scientists and the intelligent lay public consider universality of procedure, approval by peers, sharing of risks, and even use of volunteers questionable or even unacceptable and unethical in some research situations.

A number of recent events have thrust the question of ethics in research into sharp focus. The censuring by the regents of the University of the State of New York (*6*) of a respected hospital and of respected physicians will probably constitute a landmark in the development of codification of ethics in research. This decision censured research procedures that are believed by many scientists in the field to be rather conventional. Then there were the uproar over Project Camelot (*7*); the widespread concern with the psychological test movement, culminating in the recent congressional hearings (*8*); and even the battle over animal-research legislation, and the wave of recent publicity regarding instances of cruelty to research dogs. Indeed, the concern with research practices is probably only one expression of broader-current reexamination and formulation of the rights of the individual. Related expressions may be widespread interest in draft laws, civil rights, the rights of an accused, the right to privacy, compensation to victims of crime, and the concern expressed by both the public and various professional and scientific bodies about the need to update or establish professional codes of ethics in general (*9*).

The degree to which concern about conduct of research has grown among the intelligent lay public is of interest. Controversial news items about recent conduct of research were carried in many and diverse news media: The *Wall Street Journal* ran several articles on problems of ethics in research (*10*), and the *Saturday Review* (*11*) devoted 10 pages to the subject, covering some

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aspects of the New York decision in even greater detail than did *Science*. It is also of note that no one discipline has been singled out by public criticism. Thus medical researchers were most affected by the New York regents' decision; social scientists, by the Camelot affair; and behavioral scientists, by the "anti-test" movement (*12*).

There is a danger that, if scientists do not respond to the public's concern about research conduct, research rules will be imposed on science from without. Such rules may be formulated in an emotional atmosphere; may be selective, inconsistent, and inadequate; and may be enacted into law in such a fashion as to be unnecessarily burdensome, restrictive, and rigid—or even absurd, as in the spoof example conjured up by Burnham (*13*). Again, we have a recent illustration of how awkward regulations may develop. Presumably the New York regents' decision is now binding on medical researchers under their jurisdiction, yet it falls far short of providing adequate guidance. It contains ambivalent-appearing statements such as the following:

> No consent is valid unless it is made by a person with legal and mental capacity to make it, and is based on a disclosure of all material facts. . . . We do not say that it is necessary in all cases of human experimentation to obtain consents from relatives. . . ." (*6*).

How close some scientists are to being governed by outrightly unserviceable research rules was also revealed in a nationwide survey conducted by myself and colleagues (*14*). One object of this survey was to ascertain the limits that superintendents of state institutions for the mentally retarded would place on behavioral research, and to identify in turn what limits and administrative obstacles behavioral researchers in retardation had encountered or anticipated encountering.

Both groups of respondents expressed strong concern for the need to safeguard the rights and integrity of retarded subjects of research and of their families. However, we were surprised to find that, when "experiment" was mentioned in connection with a handicapped individual, responses from both groups were not only strong and emotional but at times absolutely irrational. Consistently with such irrationality, some institutions reported working under sets of rules that were meaningless or which, if they were applied literally, would exclude virtually all activity identified as research. The irrationality of this situation is underlined by the fact that one of the major arguments advanced in favor of the continued existence of large institutions for the retarded is their potential contribution to research.

Another "semanticism," which is somewhat of an argument-stopper, has to do with the sacredness or inviolability of the individual. The argument that research must not violate a person's integrity is very powerful and tends to elicit wholehearted agreement. However, the fact is that society constantly encroaches upon individual lives and freedoms for the sake of the community or mankind as a whole. We do not give driving licenses to 12-year-olds—no matter how competently an individual youngster may drive. Traffic and labor laws, the draft for the armed forces, and many other conventions, designed and tolerated for what is believed to be the welfare of society, may detrimentally affect an individual. In some instances we may infringe the rights of an individual not in order to benefit or punish him, prevent him from harming others, or keep him from harming himself, but to benefit others—as when we levy taxes (without individual consent) or ask a man to risk his life (perhaps with his consent) to save women and children during a shipwreck. The crucial point is not that conventions be fair and just in each instance, but that they be administered in a fashion characterized as constituting "due process."

The controversy regarding conduct of research has served to increase the tension between the long-range interests of society, science, and progress, on the one hand, and the rights of the individual, on the other. It is important that this tension should be a creative one resulting in a higher order of problem-solving that safeguards both interests, rather than a solution that gravely impedes the progress of science. Society must preserve the delicate balance between these interests, realizing that the cost of excessive restriction of research can come very dear.

If a code of due process or research ethics is ever to be formulated, it must be based on clearly stated principles. In order to identify these principles, the issues must be sharply defined and disentangled from the irrationalities and clichés in which they are currently enmeshed. I shall now attempt such disentanglement and sharpening, and refinement of principle (*15*).

Types of Consent

The cornerstone of all considerations of the welfare and protection of subjects appears to be what has been called informed consent. This term refers to a person's ability to consent freely to serve in an experiment in which he adequately understands both what is required of him and the "cost" or risk to him.

What ethical guidelines now exist have usually been promulgated primarily relative to adult subjects of adequate mentality and communication skills. Ethical problems can greatly increase in complexity when a human subject's ability to absorb information or to consent is inadequate. One or both inadequacies may exist in the mentally retarded, the emotionally disturbed, children, those suffering from impairment of consciousness by disease or age, or those who perceive themselves under threat or duress if they refuse to participate—such as prisoners or college students. Obviously, the capacity to become informed or to consent freely is a continuous and not a categorical variable.

One problem has been disagreement as to the extent of information required to make a consent valid. Some individuals have taken a very narrow view, insisting that even the most minute aspect of an experiment (*16*) should be disclosed to the subject; such interpretation of the term "informed" would negate the conduct of many important projects for which it is mandatory that the subject be ignorant of certain aspects of the research. For instance, a recent psychosocial research project, having potential implications for the very survival of our democratic way of life (*17*), could not have been conducted with fully informed subjects.

I propose that consent be considered "informed" when all essential aspects are understood by the subject. Essential aspects consist primarily of information regarding the "rights" (see following section) yielded to an experimenter by a subject; the types and degrees of risk involved; and the detrimental or beneficial consequences, if any, that may directly affect the subject. Explanation of the purpose of a study should probably be considered a desirable but not essential element unless the results could affect the subject directly. Some experiments are so technical as to be unintelligible even to scientific peers from outside a specialty area; they could not be mean-

ingfully explained to many or any lay subjects. It is particularly important that the potentially endless detailing of minutiae of an experiment, per se, does not come to be considered the only adequate method of informing.

Contents of the Consent Agreement

Surprisingly, it appears that no clear distinctions have yet been drawn regarding the type of content of consent agreements. Such distinctions, however, appear to be very helpful in sharpening the issues.

Generally it appears that in the consent agreement the subject may yield one or more of five "rights" to the experimenter: (i) Invasion of privacy; (ii) donation or sacrifice of personal resources such as time, attention, dignity, and physical, mental, or emotional energy; (iii) surrender of autonomy, as in hypnotic, drug, or brain-stimulation studies, or in studies entailing restriction of movement and action; (iv) exposure to procedures entailing mental or physical pain or discomfort, but no risk of injury or lasting harm; and (v) exposure to procedures that may entail risk of physical or emotional injury.

Although the experimenter is asking in each instance that the subject surrender what is ordinarily considered to be a legal or moral right, it becomes apparent that the rigor of requirements for consent may conceivably be permitted to vary, and that codes of research conduct should perhaps take into account what is being asked of a subject. Ordinarily, it would appear to be much more objectionable to risk infliction of bodily injury without a valid consent than to inflict a 5-minute loss of time upon a person. The criteria for invasion of privacy appear especially apt to vary: For instance, it is conceivable that a researcher is working in a setting that invades privacy as part of routine and sanctioned operation; a marriage-guidance clinic is a good example. In such situations privacy during research is protected by preservation of confidentiality or anonymity, or of both, rather than by nonuse of the already available highly personal information.

In some situations, such as with infants or with institutionalized lower-functioning retardates, there may be very little for which a researcher can ask in a request for consent because whatever a subject ordinarily has to give has never been possessed, or has already been given—or taken. Such a subject may have little if any autonomy and privacy, his threshold for pain or unpleasantness may be very high, and his consciousness may be so impaired that emotional trauma is unlikely to occur. Some personal resources, such as time, he may still possess, but such a resource may not be deemed valuable to him because he has large and unutilized amounts of it. Unpleasant as it sounds and is, the one thing that such a person usually still has that a researcher may want is part of his bodily functioning.

Types of Research

Since the very question of experimental risk, especially for handicapped subjects, appears so apt to arouse emotions that can becloud reason, conceptualization of the relation between certain types of research and experimental risks may be helpful. I propose that there are roughly three levels of research, and even though there is an underlying continuum most experiments with human subjects can probably be assigned to one of these levels.

In level-1 research, experimental activities and procedures are employed but are not consciously recognized or formally labeled as research. A considerable amount of the clinical management of human beings falls into this category. Many techniques of diagnosis and treatment, widely practiced in medicine, psychiatry, clinical psychology, social work, education, rehabilitation, and other human-management professions, lack adequate empirical validation and must be considered tentative and experimental. Indeed, innumerable human-management and administrative practices are no more than ill-controlled experiments. Examples are the current fad of introducing crawling exercises in some schools in order to accelerate progress in reading, use of drugs in medical practice on an intuitive basis, and manipulation of the social milieus of institutions or hospital wards. In the field of mental retardation, such ordinary events as a mixed dance, a trial-and-error work assignment, or even a trip to the toilet can become an experimental act.

There appear to be three reasons why such activities are not recognized or labeled as research: (i) a certain hyperclinical type of practitioner finds it difficult to think of himself as being a researcher, and may even attach negative values to research activities; (ii) some experimentation loses its research identification because of its sloppiness; and (iii) some experimental and ultimately nonvalidated procedures have been adopted so universally that they have lost their research identification.

There is no doubt that level-1 research can be risky to the subject. An invalidated medical treatment, like bloodletting as practiced in the 18th century, can be worse than no treatment at all. Is it really so inconceivable that some widely current but insufficiently validated human-management practices (psychotherapy, for example) may constitute the bloodletting of the 20th century?

Research at level 1 may also consist of the utilization of impersonal and grouped data collected in the course of routine and accepted operations of agencies. Thus school-enrollment, traffic-accident, and armed forces selection and rejection studies use information pertaining to individuals, group such information, and make it the substance of research. Such data are often collected without the knowledge or consent of the subjects and may or may not affect them.

Research at level 2 is clearly identified and conceptualized as research. Usually, but not necessarily, a distinct manipulation of subjects, individually or in groups, is entailed; at times it may be identified as research more by its "unnaturalness" than by anything else. A situation in which for several hours a subject has to push a button whenever a light appears on a screen (in a vigilance experiment, for instance) is perceived quite differently from assignment to a dishwashing task as perhaps in a study of vocational-training practices. Regardless of the oddity of the task, a crucial characteristic of level-2 research is that it stays close to the mainstream of knowledge; the procedures employed are well tried, tend to be familiar at least to specialists, and are known to be harmless; the new knowledge sought is usually modest; and possible outcomes of the research can be fairly well described in advance. Most importantly, risk to the subject is very small, perhaps even smaller than in the often poorly conceptualized and planned and chaotically conducted level-1 research.

It is research at level 3 that tends to give rise to most of the ethical concern. Level-3 research is risky to the subject; either previous work has shown

it to be risky or the procedures are novel and untried, and outcomes are less predictable. The fact that this kind of research may occasionally promise more substantial increments in knowledge is likely to lead to dilemmas.

Types of Risk

Risk to the subject may exist at any level of research, but there is a very useful distinction between risk that is *intrinsic* to the experimental task and risk *extrinsic* to it. Intrinsic risk arises from the very nature of the task. For instance, a drug may trigger convulsions or allergic reactions; a spinal tap carries a low but definite risk of damage to the central nervous system; and sensory deprivation can result in disturbed behavior.

Extrinsic risk might be viewed as being little or not at all under the control of the experimenter, and not being ordinarily foreseeable; it might be subdivided into types *a* and *b*. Thus type-*a* extrinsic risk may refer to consequences for which the experimenter or his agency is legally liable, even though they comply most meticulously with ethical demands. For example, a subject may slip on the waxed floor of the experimental room, break his leg, and sue for compensation. Type-*b* extrinsic risk may refer to consequences for which the experimenter or his agency is not legally liable: a subject may be struck by a car as he leaves home on his way to the experiment.

Some extrinsic risks are difficult to classify, especially those arising from psychic processes within the subject, of which the experimenter has little or no knowledge. For instance, even the most innocuous research task may seem threatening to some subject; such a perceived threat can cause psychological stress, which in turn can result in physical harm. It is unlikely but conceivable that the mere request to serve as a subject in an "experiment" might lead to heart failure. I have in fact witnessed a breakdown in functioning in a mildly retarded teenager who was asked to leave class and spend a few minutes on an undemanding, simple, and utterly harmless task; it appeared that a "friend" had told him something to the effect that the psychologist was going to cut his head open.

Except in instances in which research involves only record data, the researcher can never state with certainty that a subject will not experience some kind of trauma. At best, he can estimate the level of probability of trauma if intrinsic research risks exist, or state that, if trauma occurs, it will occur because of the extrinsic risks.

The distinction I have drawn may appear labored, but it becomes more meaningful when applied to factual problem situations. For example, several respondents in the obstacles survey cited (*14*) proclaimed strong opposition to inclusion of mentally retarded subjects in any experiment entailing even the slightest risk. Unless the distinction between intrinsic and extrinsic risks were clearly conceptualized, such a rule, if consequentially applied, would prohibit *all* research with retarded subjects except analysis of case-file data.

Guidelines

Guidelines for ethical conduct of research should be based on clearly identifiable and internally consistent principles. It is important that issues be stated with maximum clarity, so that problems for which no specific solutions have been previously formulated can be handled in the light of the broader principles. I shall state some principles and guidelines that can be derived, at least in part, from the considerations discussed above.

1) The more deleterious an experimental effect may be to a subject, the more precautions the researcher should take.

2) "Risk-sharing" between experimenter and subject in no way releases the experimenter from any obligation toward his subject.

3) The more serious or extensive the right that the researcher wants a subject to surrender, the more consideration and effort should be devoted to the problem of consent or release.

4) No consent for level-1 research should be required at this time to use a procedure which, although it may be experimental and nonvalidated in nature, is used primarily for treating a person therapeutically, *if* (i) the procedure is considered justifiable and appropriate by qualified peers, and (ii) a consent (to treatment) appropriate to the occasion and to the risk inherent in the procedure has been obtained.

5) No consent appears necessary if the right needed by the experimenter is already possessed by him or by the legal body that he represents; then consent by that legal body, rather than by the subject, must be obtained. For example, a member of the armed forces loses certain rights of autonomy, which in turn might be delegated by the proper authorities to an experimenter without the subject's consent or knowledge. However, it would appear to be desirable to obtain the personal consent of each subject if this is at all feasible; furthermore, if there is uncertainty as to whether the legal body in question possesses the rights required by the experimenter, then, in proportion to the extent of the rights involved, the experimenter should exert efforts to obtain opinions on this question from a group of impartial referees who could be considered qualified to judge.

6) I propose that except under extraordinary circumstances no consent is required where (level-1) research is conducted on record-file data if (i) such data are grouped, or their anonymity is otherwise assured, so that no subject is identified and no definite statement can be made about any specific subject; and (ii) the manipulation of the research data does not lead to consequences detrimental to a subject.

7) Where level-2 research is involved (that is, risks are extrinsic), and where only modest and reasonable amounts of rights i and ii (privacy and personal resources) are concerned, consent may be obtained by means of a routine release form. Thus agencies such as institutions, public clinics, and university hospitals might explain to their clients, during the intake process, the research orientation of the agency and the type of research that might be typically involved, and ask for the clients' cooperation and signature. Much would depend on the manner in which this approach was handled. My personal experience is that it may be best to inform the subject or his agents as early as possible, both orally and in writing, of four things: (i) there is little likelihood that the research will benefit the subject; (ii) the subject's participation may benefit many others like him in the future, and research is the only way to improve certain services, conditions, and treatments; (iii) the research will entail no undue (that is, considered unreasonable by most people) discomfort, consumption of time, or loss of privacy; and there is no direct risk; and (iv) participation is voluntary.

Such a routine release may not be legal in all states, but it can be very important in certain agencies, such as

institutions for the retarded. If a broad release were not obtained, even the most harmless and minor participation in research would require a specific release. In some research-oriented institutions, a resident may be called upon several times a year to serve as a subject, and obtaining a specific release each time would be prohibitively cumbersome. Moreover, after placing residents many parents are no longer accessible, do not visit or answer mail, and may live many hundreds of miles distant. In short, unless either the superintendent were the guardian—and the trend is away from this practice—or a general release were obtained upon admission, little or no research on mental retardation could be conducted in such institutions. The implications of such a situation would be vast and horrendous.

Hyman (*18*) makes the point that an issue must be drawn on the question of when an experimenter may use a person as a subject. However, I believe that the type of risk involved, though a separate issue, affects the drawing of the first issue since it bears upon the type of consent required. I must point out that my proposal may not be entirely consistent with the Medical Research Council statement (*5*), which can be interpreted to advocate that a specific rather than general consent should be obtained when a research procedure is not intended directly to benefit a subject.

8) When level-2 research calls for right iv, a borderline case exists. Then a decision to obtain a specific release may be based on the degree of discomfort or pain involved and on purely psychosocial considerations such as a subject's familiarity with the procedures and the public emotion that the research could generate.

9) A specific and relatively detailed release for research either on level 3 or entailing right iii appears to be mandatory.

10) The more reason there is to question a subject's ability to give a free, informed consent, the more care should be taken to assure that consent is free and informed, or that the responsible agent's release is appropriate; here the advice of the Medical Research Council (*5*) appears sound: one should obtain consent not only in written form but also in the presence of witnesses who can provide consensual agreement regarding the subject's understanding and freedom of choice.

It is not sufficient for the researcher to exercise restraint in eliciting consent; he must also ascertain to a reasonable degree that a subject, even a volunteer, does not *perceive* himself coerced when he is not. For instance, no matter what a prisoner is told, he is likely to believe that by not volunteering to serve in a cancer-cell-injection experiment he may delay his parole; thus he may be under a subtle form of coercion. College students are particularly apt to believe that refusal to volunteer as subjects in an instructor's experiment will jeopardize their progress—and they are often right. The researcher should go out of his way to create an atmosphere and structure that permit a truly free choice.

Finally, not ethics but wisdom dictates that, when emotionally charged situations and issues are involved (such as research with "live cancer," and handicapped children), the researcher should consider raising his safeguards to a level above that required by ethical considerations alone.

Let us reflect for a moment how the above guidelines and considerations would have applied to the researchers censured by the New York regents. Within the framework that I propose, one crucial question would have hinged on whether the injection of live cancer cells was definitely known to be harmless (risk thus being extrinsic) or was merely likely to be so (risk being small but definite and intrinsic). If it were clearly established that the risk was extrinsic (*19*), we would ascertain that the researchers were not asking for surrender of privacy, autonomy, or health, but only for very modest amounts of rights ii and iv: that is, a little time and bother and a little discomfort. With subjects of sound mind, a routine research release obtained on the subject's admission to hospital should then have sufficed, but, with aged individuals with questionable clarity of mind, the situation would appear to be borderline between choice of a routine or of a specific release. The choice would definitely be tipped in favor of a specific release by the presence of an emotionally charged element such as use of "live cancer cells."

Conclusion

It is obvious that many disciplines confront ethical problems in research in which situational details may vary, but in which the same ethical principles may prevail. I write not in order to propose a definitive set of rules but to demonstrate how situations posing ethical problems can be reduced and more readily resolved by rational analysis of underlying issues and principles; I hope to stimulate further analysis and dialogue. It might be particularly helpful if researchers in a wide range of disciplines contributed experiences permitting a sharpening of guidelines. Finally, it is conceivable that a code of ethics might eventually be promulgated by a supradisciplinary body such as the AAAS, and that such a code could then be adapted and adopted by other scientific bodies and professional organizations—even by specific agencies such as research institutes, clinics, institutions, and schools.

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7. Much of an entire issue of *Amer. Psychologist* (21 May 1966) is devoted to the Camelot affair.
8. See the entire November 1965 issue of *Amer. Psychologist*, as well as parts of the May 1966 issue.
9. *Time* reported (19 August 1966) that the Amer. Bar Assoc. is studying modernization of its 60-year-old canon of ethics; and (15 July 1966) a government suit to prescribe revision of the code of ethics of the College of American Pathologists. The supradisciplinary Amer. Assoc. on Mental Deficiency [*Amer. J. Mental. Deficiency* **71**, 340 (1966)] appears to be moving toward establishment of a standing committee on ethics and practices.
10. For example: *Wall St. J.* 31 Aug. 1964, 21 Jan. 1966.
11. *Saturday Rev.* 5 Feb. 1966.
12. In early 1966 PHS notified its research grantees that in future each grantee agency must establish a formal review procedure aimed at safeguarding the rights and welfare of research subjects. This step almost certainly resulted from recent events.
13. P. J. Burnham, *Science* **152**, 448 (1966).
14. W. Wolfensberger *et al.*, *Mental Retardation* 3(6), 7 (1965).
15. A similar attempt was recently undertaken by O. M. Ruebhausen and O. G. Brim, Jr., who addressed themselves most thoughtfully to the specific topic of privacy and behavioral research; see *Amer. Psychologist* **21**, 423 (1966).
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17. S. Milgram, *J. Abnormal Psychol.* **67**, 371 (1963); *Human Relations* **18**, 57 (1965).
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20. Supported by PHS grant HD 00370. I thank George Ebling of Plymouth State Home and Training School, Northville, Mich., R. A. Kurtz of Notre Dame Univ., and Charles Fishell for suggestions and criticism.