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The Use of Human Subjects in Research at Adventist Colleges and Universities: Suggested Guidelines

by

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The term "human experimentation" often brings to mind horrifying abuses of human rights, such as experiments in Nazi concentration camps. Other, less famous examples include the following:

- In the late 1800s E. Franenkel inoculated the eyes of terminally ill infants with gonorrhea cultures.[1]

- Early in the 20th century Richard P. Strong (later professor of tropical medicine at Harvard) injected plague germs into death-row inmates in the Philippines.[2]

- In the Tuskegee (Alabama) syphilis experiment that stretched over 40 years, researchers withheld treatment from 399 poor black men so that they could study the physical effects of untreated venereal disease.[3]

- In 1966, Henry Beecher, a Harvard Medical School professor, exposed more recent abuses in human experimentation. His "roll of dishonor" included withholding of penicillin from uninformed servicemen with streptoccal infections, a number of whom contracted rheumatic fever; feeding of live hepatitis viruses to residents of a state institution for the retarded to study the disease and attempt to develop a vaccine; the injection of live cancer cells into elderly and senile hospitalized patients without telling them the nature of the cells; and a number of other shocking abuses. Beecher maintained that "unethical or questionably ethical procedures are not uncommon" among researchers, and that the rights of human subjects were widely disregarded.[4]

- In order to investigate whether side effects such as nervousness and depression could be caused by oral contraceptives, Goldzieher gave dummy pills to 76 women who sought treatment in a San Antonio, Texas, clinic to prevent further pregnancies. None of the women was told that she was participating in research or receiving placebos. Most of the experimental subjects were poor Mexican-Americans with several children.[5]

- In at least 31 separate experiments between the mid-1940s and the 1970s the U.S. Government exposed nearly 700 people to radioactive substances. These included an experiment in which Manhattan Project scientists, the designers of the first atomic bomb, injected 18 people with "relatively massive quantities of bomb-grade plutonium" to see how much of the toxic substance their bodies would retain.[6]

The above examples highlight abuses in medical experimentation. But some investigations by social scientists have been scarcely less questionable. For example:

- Zillman and Bryant randomly assigned 80 male and female undergraduates to watch various amounts of heterosexual pornography for a six-week period. The students were then asked to estimate the percentage of U.S. adults performing certain sexual acts, and to recommend a prison term for a rapist described in a newspaper article.[7]

- To evaluate a questionnaire that proported to test people's comprehension of moral principles, a team of social scientists proposed to administer it to teenagers at a male juvenile delinquency rehabilitation center, and then tempt them to lie or steal.[8]

- Posing as fellow believers, researchers covertly studied a small flying saucer cult whose members were waiting for the end of the world. The ratio of researcher-believers to true-believers was so high, however, that their participation wronged those studied not only by lying to them but also by providing false "evidence" to reinforce their beliefs (and at the same time, altering the phenomena under investigation).[9]

Other studies have attempted to find a genetic link to criminal behavior or intelligence,[10] or have exposed subjects to psychoactive drugs without their knowledge.

Professors and students at Seventh-day Adventist healthcare training institutions, as well as at our other colleges and universities sometimes conduct medical and social science experiments and studies using human subjects. In the United States, the federal government closely regulates medical experimentation on humans; therefore, that area will not be the primary focus of this paper, though some of the

policies established for healthcare institutions provide the basis of its suggestions for social science research. Administrators would be well advised to use these guidelines in developing policies for their institutions. A list of helpful sources is included at the end of the paper.

Reasons for Experimenting on Human Subjects

As abhorrent as the above experiments seem to us today, they appeared perfectly defensible and even urgently necessary to the people who performed them. So we are forced to look more closely at the reasons for using human beings in research.

In general, researchers argue that they are contributing to and extending human knowledge through research, and that their studies advance health, science, and human welfare (perhaps also providing the researchers with some renown in the annals of science). An ethicist commenting on such research said that these scientists seek to avoid the "menace of avoidable ignorance."[11] In times of national emergency, such as wartime, research seems a patriotic imperative, for it provides knowledge that may help subdue enemy aggression or save the lives of military personnel.

Researchers claim that they need to use human subjects in their studies because they cannot achieve the same results with simulations or animals. This is especially true in social science research. In resisting external controls on their research, they argue that freedom of inquiry is essential for healthy research.[12]

Despite researchers' commitment to the general good and to extending human knowledge, their "omnivorous appetite"[13] for scientific research, as ethicist Paul Ramsey puts it, can cause them to lose sight of the importance of each individual subject. As Henry Beecher pointed out:

"Any classification of human experimentation as 'for the good of society' is to be viewed with distaste, even alarm. Undoubtedly all sound work has this as its ultimate aim, but such high-flown expressions. . .have been used within recent memory as cover for outrageous acts. . . . There is no justification. . .for risking an injury for the benefit of other people. . . .Such a rule would open the door wide to perversions of practice, even such as were inflicted by Nazi doctors on concentration-camp prisoners. . . .The individual must not be subordinated to the community."[14]

Although progress depends heavily on science and technology, we no longer naively assume that this is the way to the good life. Nuclear weaponry, widespread pollution, and abuses of human beings in research like that cited above have sensitized us to the potential for evil--as well as good--that science and technology can achieve. Previously undreamed-of capabilities for human beings to control birth and death, to transplant human organs, even to manipulate genetic material, have highlighted the need for external controls over researchers and medical personnel.

Exposés in scientific journals and the popular press have revealed a stark conflict of interest between researchers' ambitions and subjects' well being. As a result, in the U.S., federal regulations have been passed requiring oversight and collective decision making.[15]

The areas that have generated the most serious ethical problems are the design of the experiment, choice of subjects, obtaining informed consent, balancing risk to the subject with benefits to the research-

er and society, and maintaining the participant's dignity and privacy. These topics will be dealt with in greater detail later in this paper.

Moral Implications

As Christians, we view the scientific method differently from those who hold a naturalistic philosophy about the origins of human beings. We believe that God designed the universe to operate in an orderly way, although He may occasionally step outside of natural processes to perform miracles. Therefore, since the universe is orderly, and God made human beings capable of rational thought, we can design experiments to explore the mechanisms of the physical universe and even to study human behavior through the social sciences. We can thereby discover some of the marvelous aspects of God's creation, extend the boundaries of knowledge, and alleviate human suffering.

However, our beliefs will put certain constraints on the kinds of scientific research that we do. For example, if we believe that human beings are created in the image of God, we will treat humanity at every stage of life with respect--even miscarried fetuses, human tissue, and frozen embryos--in contrast to how we would act if we believed that homo sapiens are essentially no different from other creatures in the natural world.

Human experimentation raises a number of religious and ethical dilemmas. Traditionally, such research occurred in the field of medicine, where the physician was expected to be committed to the good of the individual patient. The primary rule of medical morality was to do no harm--based on the Hippocratic Oath and guidelines for medical ethics drawn up by the General Assembly of the World Medical Association in 1949.[16] The timing of the latter guidelines was doubtless inspired in part by the Nuremberg trials, which revealed the flagrant abuses of Nazi researchers.

How do we balance the needs of the individual with those of society? Should researchers be allowed to induce or coerce individuals to subject themselves to certain risks for the good of others? To clarify this, let us look at two extreme positions: The first would subordinate the individual to the good of society. This would allow medical and psychological experimentation on human beings without their consent if the studies would benefit society. This represents the classical utilitarian theory of choosing the greatest good for the greatest number. Thus, anytime a researcher could claim that a procedure or experiment would benefit society, he or she could justify overriding the rights of the individuals involved, for each person counts for only one.

At the opposite extreme, absolute individualism acknowledges no significant relationship between the individual and society, and asserts the primacy of the individual over the group. Most ethicists acknowledge that at times the individual must be limited by the needs of society, and that each person has an obligation, as part of a community, to act in ways that benefit others.

> Human beings do not exist as isolated atoms. They are actually constituted by their relationships--to the world, to their family, to their fellow human beings, to the Church, and to God. It is important to stress that these relationships are not extrinsic or spatial but intrinsic; they belong to the very fabric of each person's being.[17]

Jesus' admonition to "love your neighbor as yourself" ties together both respect for persons and one's obligation to the larger community.

It may be helpful at this point to divide moral obligations into two categories--those that are required of all human beings, and others that are heroic--above and beyond the call of duty. Some people would want to volunteer for experiments to help others, despite the risk to themselves. But no one should be coerced into participating in such studies. In every case, we must evaluate the balance between the risks and potential benefits and give potential subjects enough information to allow them to make an informed choice.

In recent times, Western society has become more concerned about protecting the individual against possible invasions of dignity, privacy, and freedom. Christian ethics has always asserted that every person possesses certain inalienable rights, that individuals are ends in themselves. They are never to be used merely as a means to something else--no matter what their race or color, how well or poorly endowed with talents, or how primitive or developed. Therefore, the individual takes primacy over society. However much the good of the whole exceeds that of any of its parts, and whatever duties each person owes to society, individuals constitute the supreme value, and society exists only to promote the good of its members.

"In view of people's tendency to exploit their fellow human beings, the scriptural revelation of the innate, inalienable dignity and value of the individual provides an indispensable bulwark of freedom and growth."[18] Christ's example and teachings and the admonitions of Old Testament prophets provide a basic ethical framework for making decisions about how to treat people, both in daily life and in experimentation.

> Our Lord has taught us that the Decalogue is centrally a statement of what love demands. But since justice is one of the things that love enjoins, it is possible to distill from the Ten Commandments a list, even though it be a partial list, of the rights and liberties men can claim. . . .This. . .is only a partial list of the rights we tend to claim. . . .We can go to the Old Testament prophets and learn from, say, Hosea, that the powerless have a right to be protected against the strong.[19]

Each human being is unique, created in the image of God and redeemed at an infinite price. He or she possesses the power to think and to do, according to Ellen White.[20] This means that God places a high value on allowing each person to choose freely what actions he or she will take. This principle should influence researchers' choice of subjects and topics for investigation. They too are free to choose, but should keep in mind Paul's admonition: "Brethren, ye have been called unto liberty; only use not liberty for an occasion to the flesh, but by love serve one another" (Galatians 5:13).

Research, optimally, should consist of a "truly joint venture between two human beings working together for the increase of human knowledge and the ability of human beings to serve one another. From this perspective, the subject is a coparticipant in the human quest for progress."[21] This gives the subject a more active role, and requires the researcher to respect his or her humanity and rights as a freewill agent. Therefore, as Hans Jonas points out, the most highly motivated, the most highly educated, and the least captive members of our communities would make the best research subjects. Subjects with poorer knowledge, motivation, and decision-making freedoms (who are consequently more readily available in terms of numbers and possible manipulation) should be used more sparingly and reluctantly.[22] Curran suggests as a criterion whether one would subject his or her own children to the proposed experiments.[23]

Unfortunately, this has not been the usual method of choosing subjects for experimentation. Those from lower socioeconomic classes, minorities, prisoners, the gullible, and the mentally incompetent have borne an undue share of the burden as subjects of experimentation.

To treat individuals ethically means not only to respect their decisions and protect them from harm, but also to actively attempt to ensure their well-being. This is encompassed in the term *beneficence*, which implies the following principles for research on human beings: "(1) do not harm, and (2) maximize possible benefits and minimize possible harms."[24]

Although discovering what will in fact benefit people may require exposing them to risk, forethought and oversight are needed to assess when it is justified to seek certain benefits despite the risks involved, and when the experiment should be forgone because of the possible risks. Such risks may involve psychological, physical, legal, social, or economic harm.

For the Christian researcher, the principle of stewardship is also a relevant concern. "We do not possess anything in the world, absolutely, not even our own [or other people's] bodies; we hold things in trust for God, who created them, and are bound, therefore, to use them only as He intends that they should be used."[25]

Montemorelos University's "Philosophy and Role of Research" statement expresses well the concept of stewardship:

> A consciousness of our stewardship of God's creation prohibits the investment of time, ability, or economic resources in the search of knowledge that may result in adverse effects for human life, or that involve immoral elements or consequences. By the same token, this consciousness motivates us to the diligent research of all practical possibilities toward the common well-being of mankind.[26]

Christian principles should be applied at every stage of research--planning the study, choosing subjects, informing participants of the risks and benefits, performing the experiment, debriefing subjects, and guarding the privacy of subjects--as well as careful analysis of the data, reporting of the study, and ethical use of the data after the study has been completed.

Design of the Experiment or Study

David Rutstein points out that "Attention must be given to the ways an experiment can be designed to maintain its scientific validity, meet ethical requirements, and yet yield the necessary new knowledge."[27] The experiment's design goes straight to the basic questions asked by the investigator. What problem does he or she seek to solve? What information does he desire to obtain? Are the proposed methods and techniques consistent with Christian ethics?

In the medical area, a standard question is whether the experimentation is therapeutic, or conducted only for its research value. Research is clearly non-therapeutic when it is carried out solely to gain information that will benefit others, but which is of no use to the patient.

An analysis of the design of social science experiments should address the following questions:

- Is it ethical to ask people to perform the actions specified by the researcher?
- Will the procedures cause psychological injury or humiliation to the subjects?
- Could any part of the research cause irreversible changes in the subjects' personality or moral values?
- Do the researcher's actions mislead subjects by lending support to false ideas or prejudices?

Application of the principles underlying these questions would clearly eliminate any proposals that require participants to perform illegal or immoral acts, that expose them to pornography or depictions of violence, or ask them to participate in psychological experiments that would be demeaning to themselves or to others.

Potential conflicts of interest and threats to researcher integrity also present ethical dilemmas. Research sponsored by an organization that expects a particular result (a tobacco company, for example), whether or not it uses human subjects, should raise a red flag for researchers who seek to do pure science and arrive at truth, unencumbered by any type of coercion. Christian researchers will doubtless also want to engage in serious reflection and prayer, perhaps seeking pastoral and ethical guidance, before participating in research that may contribute to military weaponry or be used to destroy or harm human beings or the natural world.

Choosing Subjects for Research

Methods for choosing subjects may not be as obvious or ethically neutral as some researchers would have us believe. Participant selection raises ethical issues on two levels: social and individual. Researchers should not offer potentially beneficial research only to certain categories of persons, or select only "undesirable" persons for risky research. Social justice requires that distinctions be drawn between classes of subjects. Those who cannot give consent or who ought not to be further burdened, such as the indigent, children, the institutionalized or mentally infirm, and prisoners should be used only under certain carefully controlled conditions.

Conversely, a variety of groups should be included in research, particularly if the anticipated benefits of the studies might better their lives. This would mean, for example, not testing drugs only on men, or selecting only young, well-educated subjects for research on organ transplants.

Disclosure

Candor helps ensure the integrity of the encounter between researcher and subject, and prevents the researcher from exploiting and subordinating participants to the research process. It demeans the subject's humanity to see him or her simply as a case or a statistic, a mere representative of some class or category of persons.

As autonomous agents, human beings have the right to control their own lives and to receive enough information to make informed decisions; therefore, researchers should share adequate facts to enable the subjects to judge for themselves the balance between risk and benefit, and to decide whether to participate in the study.

In general, the law imposes a strict duty of disclosure, wherever an individual with a great deal to lose is exposed to a risk or is asked to relinquish rights by someone with considerably greater knowledge.[28]

Less than complete disclosure deprives the subject of the opportunity to consciously and deliberately render service in a crucial social enterprise, while greater candor enables him or her to become a partner in the thrill of scientific discovery and perhaps relief of human misery.

Therefore, each subject should receive an explanation of the procedures to be followed and their purposes, including (1) identification of any procedures that are experimental; (2) a description of the discomforts and risks, as well as benefits that may reasonably be expected; (3) disclosure of any appropriate alternative procedures that might be advantageous; (4) an offer to explain any questions about the procedures; (6) assurance that the subject is free to withdraw his or her consent and to stop participating in the project at any time.[29]

Coercion

Subjects should participate in research without coercion, after the risks and benefits of their participation have been fully explained. But there remains some question whether certain groups are capable of making truly free choices, either because of their circumstances or the nature of their relationship to the researchers.

If the explanations are geared to their level of comprehension, even poorly educated persons can be considered capable of participating freely in research. However, certain groups present ethical difficulties because they cannot give informed consent or are susceptible to coercion.

Payment for participation may raise concern, if care is promised to indigent persons in exchange for participating in experimentation, or if people "volunteer" for a study because of financial need or their desire for some benefit, such as a reduced prison sentence.

Other groups that may be susceptible to coercion include students and research assistants. Such persons may depend on the researchers for grades, recommendations for graduate study, or advancement in the institution.

Persons who cannot give consent, or who are incapable of understanding the nature of the proposed experiment, constitute a particularly vulnerable group. This would include children, the underclass, and the mentally incompetent.

Jesus' example is instructive in this area. According to Robert Mortimer, "The Son of God showed particular care and concern for the fallen, the outcast, the weak and the despised."[30] Likewise, researchers should treat with special regard those in vulnerable groups.

John Fletcher, a Christian ethicist who has devoted much study to the practical aspects of informed consent, suggests that several other factors can affect the autonomy of subjects: whether they are ill or dependent on the researcher for medical care, the circumstances surrounding the institution, and the desire to please the investigator.[31]

Psychological researchers generally have less power over their subjects than their biomedical counterparts. However, their experiments often occur within the context of a university or other large institution, and invoke the more generalized prestige of "science," which subjects may perceive as authorita-

tive. For example, Milgram's famous studies[32] testing the likelihood that people would obey the commands of authority figures, to the point of administering shocks to uncooperative subjects, took place at Yale University and a New Haven research laboratory. Subjects would doubtless hold even higher ethical expectations of a Christian institution. Consequently, the Christian researcher might have greater moral authority and more effective powers of persuasion with subjects from his or her own religious tradition.

Informed Consent

Respect for persons demands that, in most cases, subjects should enter into the research voluntarily and with adequate information. They should receive the following information: the research procedure; risks and anticipated benefits, if any; alternative procedures (where therapy is involved); a statement inviting the subject to ask questions; and an explicit statement allowing him or her to withdraw at any time from the research. The details should be given in a way that the subject can understand, allowing time for him or her to process the information and return with additional questions. On occasion, it may be helpful to give some sort of oral or written test of comprehension. (See the sample consent form in Appendix B.)

Deception

Many researchers argue that the only way to obtain accurate information about certain aspects of their subjects' behavior is not to inform them of the nature of the experiment or study. If the subject knew his or her actions were being studied, this would almost certainly result in the behavior being modified. Solutions to this problem have been difficult to find. Simulations have proved inadequate, both methodologically and ethically, since subjects who are asked to describe how they would react in a particular situation may not know, or don't want to tell. On the other hand, if the simulations are too realistic, they may cause stresses resembling those experienced by people participating in the actual experiment.[33]

Deception appears to be fairly widespread in various kinds of scientific research. In tests of medicines and treatments, patients--and even doctors--are not told which persons are in control groups or are receiving placebos. Likewise, deception occurs rather frequently in social science studies. In 1978, Diener and Crandall estimated that between 19 percent and 44 percent of social psychology and personality research involved direct lying, and one study of psychology experiments suggested that complete information was given in only 3 percent of the cases reviewed.[34]

The category of subjects being used may affect the prevalence of deceptive practices. Researchers may be tempted to treat more cavalierly a disadvantaged group, feeling that they cannot seriously disrupt the research, compared to more powerful or well-educated subjects.

Deception always poses the potential for harm to those being deceived, since they might have chosen to avoid participation if they had been fully and accurately informed. They may lose faith in the researchers and other authority figures, and even in the merits of science in general.

When researchers deceive subjects, their reputation for truthfulness may be harmed, as well as their character. Scientists in general may be less trusted if deceptive practices become widely known. And

society may be harmed, since deception could contribute to a general lack of trust and a willingness by nonprofessionals to act deceptively themselves.

As researchers trick, deceive, and manipulate their subjects, they thereby accustom themselves to denigrating other people's humanity. They may also develop delusions of grandeur and omnipotence, and become progressively more calloused and cynical, which could interfere with the integrity of their scientific work.

Researchers need to rethink the ethics, as well as the methodology, of some of the studies they propose, since there will always be a delicate balance between the need to obtain information that benefits humankind and the rights of individual subjects.[35] In a Christian institution, research participants, as well as the constituency and the general public, would doubtless expect a higher level of ethical behavior than at a public institution. Therefore, proposed research should be screened with care to ensure that its methods and aims are consistent with the mission of the institution and the moral principles of the denomination.

When planning an experiment, the researcher should consider carefully the nature of the study to determine whether deception is really necessary, and if so, then work out ways that informed consent and subsequent debriefing can ameliorate the negative effects of deception. Internal review boards should look carefully at this issue and provide quite specific guidance to help researchers resolve the problems through the application of ethical principles.

Privacy

Throughout the research process, subjects' privacy should be carefully guarded. Social scientists invade their subjects' privacy when they manipulate them into doing something embarrassing or by disclosing private facts that place the subjects in a false public light or intrude into their private domain. Having sensitive personal information about a person means gaining power over that person, power that can then be used to his or her detriment. As a result, the person may be subjected to ridicule and intolerance--or to legal or governmental action. His or her community and descendants might even be harmed if the studies are used to stereotype a particular ethnic group.

Personal interviews are especially problematic, as the researcher's records on identified subjects may be subpoenaed or used in legal proceedings against such persons, thereby breaching the researcher's promise of confidentiality, putting the subjects at risk, and possibly disrupting the researcher's work.[36] Therefore, invasion of privacy should be undertaken only with greatest caution and after careful consideration of the potential results.

The following questions are central to assessing potential violations of privacy:

1. For what purpose(s) is the undocumented personal knowledge sought?
2. Is this purpose a legitimate and important one?
3. Is the knowledge sought through invasion of privacy relevant to its justifying purpose?
4. Is invasion of privacy the only or the least offensive means of obtaining the information?
5. What restrictions or procedural restraints have been placed on the privacy-invading techniques?
6. What protection is to be afforded the personal knowledge once it has been acquired?[37]

With modern data processing equipment, it has become much easier to run sophisticated analyses of statistical information and identify the subjects of research, thereby potentially endangering their welfare and privacy. Therefore, safeguards should be taken to minimize any harm to subjects that might occur--either by not identifying them at all, or perhaps by using a number for each case, with the code being destroyed after the analysis has been completed.

Recommendations

To help sensitize students to the ethical and procedural dilemmas described above, Adventist colleges should require ethics courses in each discipline. In addition, by reading about current dilemmas in their fields of study, ethical issues involved in using human subjects in research, and the codes of professional responsibility for their professions,[38] teachers can prepare themselves to discuss with their students the ways in which Christian principles interact with real life.

Colleges should set up institutional review boards to screen proposed research by both professors and students. (See Appendix A.) These boards should develop guidelines defining the boundaries of acceptable research and describing the appropriate steps to implement such studies. These guidelines should be disseminated to students, staff, constituents, and other interested persons.

No one should be allowed to undertake any type of research that involves human subjects unless he or she has obtained prior clearance from the IRB and has signed a form indicating understanding of and assent to the principles governing such research. Some of the areas that should be addressed in the guidelines and consent form include the following:

- Ethical and scientific design of the experiment/study, including potential usefulness of the research versus drawbacks
- Methods of data collection and storage, including provisions for ensuring confidentiality of data
- Methods of choosing subjects
- Types of subjects to be used (special cautions should be included when children, the elderly, minorities, marginalized groups, persons engaged in illegal activities, or prisoners are included as subjects of research; or when the researcher-subject relationship might affect the ability to freely give consent)
- Promises and commitments made to subjects
- Informed consent, including debriefing of subjects and permission for them to withdraw at any time without repercussions
- Other ethical considerations (lying to subjects, asking subjects to engage in unethical behavior, conflicts of interest, etc.)
- Any laws or government guidelines that apply to the research being done
- Method of presenting the findings

By following the above suggestions, Adventist colleges and universities will be able to help their students discover the exciting mysteries of science, while respecting and benefiting God's crowning creation, humankind.

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33. Alan C. Elms, "Keeping Deception Honest: Justifying Conditions for Social Scientific Research Stratagems," in Beauchamp, et al, pp. 235, 236.

34. Edward Diener and Rick Crandall, *Ethics in Social and Behavioral Research* (Chicago: University of Chicago Press, 1978), cited in Beauchamp, et al, p. 169.

35. If deception is considered absolutely essential to the experiment, one researcher suggests using it only "when (1) there is no other feasible way to obtain the desired information, (2) the likely benefits substantially outweigh the likely harms, (3) subjects are given the option to withdraw from participation at any time without penalty, (4) any physical or psychological harm to subjects is temporary, (5) subjects are debriefed as to all substantial deceptions and the research procedures are made available for public review" (Elms, in Beauchamp, et al, pp. 233, 234). While gaining general assent from the subjects, the researcher might also tell them that the experiment may involve deception (Margaret Mead, "Research With Human Beings: Model Derived From Anthropological Field Practice," in Freund, p. 167).

36. R. Jay Wallace, Jr., "Privacy and the Use of Data in Epidemiology," in Beauchamp, p. 297.

37. W. A. Parent, "Privacy, Morality, and the Law," in Joan C. Callahan, ed., *Ethical Issues in Professional Life* (New York: Oxford University Press, 1988), p. 220.

38. See for example, Clifford G. Christians and Catherine L. Covert, *Teaching Ethics in Journalism Education* (Briarcliff Manor, N.Y.: The Hastings Center, 1980); and Rena A. Gorlin, ed. *Codes of Professional Responsibility* (Washington, D.C.: The Bureau of National Affairs, Inc., 1990).

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Appendix A

The Responsibilities and Composition of an Internal Review Board

"An IRB is a board, committee, or other group formally designated by an institution to review, to approve the initiation of, and to conduct continuing review of biomedical [or social science] research involving human subjects in accordance with FDA regulations [and the policies and principles of the institution]. An IRB has the authority to approve, require modifications in (to secure approval), or disapprove the research. The purpose of IRB review is to assure that:

"• Risks to subjects are minimized: (1) by using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk, and (2) whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes.

"• Risks are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may be expected to result.

"• Selection of subjects is equitable.

"• Informed consent will be sought from each prospective subject or the subject's legally authorized representative and will be documented in accordance with, and to the extent required, by FDA's informed consent regulations.

"• Where appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects.

"• There are adequate provisions to ensure the privacy of subjects and to maintain the confidentiality of data.

"• Appropriate additional safeguards have been included in the study to protect the rights and welfare of subjects who are members of a particularly vulnerable group."[1]

Guidelines issued by the U.S. Secretary of Health and Human Services in 1988 suggest the following criteria for membership in an IRB:

1. Each IRB should include at least five members from varying backgrounds; each member should be qualified through experience and expertise. Members should be chosen so as to achieve a balance in the areas of race, gender, and cultural background. They should also be selected for their sensitivity to such issues as community attitudes. This will help ensure respect for the IRB's work, particularly in terms of safeguarding the rights and welfare of human subjects. IRB members should be able to assess the acceptability of proposed research in terms of institutional commitments and regulations, applicable law, and standards of professional conduct and practice. If the IRB regularly reviews research that includes vulnerable groups such as children, prisoners, pregnant women, or mentally handicapped persons, it should consider including one or more persons who are knowledgeable about and experienced in working with these types of individuals. (One person might fill two or more of the above listed roles.)

Other sources suggest including a lawyer, a statistician, a layperson, or a ethicist who specializes in the field of the proposed research. It would be helpful for the institution's media specialist to attend meetings as an observer, so that he or she can answer questions from the administration or the press regarding the type of research being done at the institution.

2. Every effort should be made to ensure that both sexes and members of different professions are included in the IRB.

3. Each IRB should include at least one member whose primary concerns lie in scientific areas, and at least one member whose concerns are primarily in nonscientific areas.[2]

4. Members of the IRB should excuse themselves from voting on the acceptability of any project that gives the appearance of a conflict of interest with their work or that of their students.[3]

Further guidance in forming an IRB, identifying research studies that require oversight, determining frequency of meetings, reporting requirements, and other protocol involved in its operation may be found in the endnote sources, and by consulting the administration of one of the numerous universities where IRBs are currently operating.

REFERENCES

1. Department of Health and Human Services, "Answers to Frequently Asked Questions," FDA IRB Information Sheets (Rockville, Md.: Public Health Service, FDA, February 1989), pp. 23, 24; see also President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research, "Implementing Human Research Regulations, Second Biennial Report on the Adequacy and Uniformity of Federal Review Rules and Policies, and Their Implementation, for the Protection of Human Subjects" (March 1983).

2. "Institutional Review Boards," Proposed Rules, Part 56, Section 56.107, *Federal Register* 53:218 (November 10, 1988).

3. "Answers to Frequently Asked Questions," p. 25.

Appendix B

Prescott University
Advil, Oklahoma 78888

INSTITUTIONAL REVIEW BOARD APPLICATION FOR RESEARCH USING HUMAN SUBJECTS

Name of Principal Investigator _____ Tel. No. _____
(or Co-Investigator)
Address _____

Name of Student Investigator _____ Tel. No. _____

Student Identification Number _____

Department _____ Project Duration _____

Project Title _____

Funding Agency _____

Has this project been approved by a departmental Human Subjects Review Committee?

Yes (Date) _____ No _____

Please attach a copy of your responses to Questions I - XI of the instructions along with the proposal.

Please specify whether this research should be exempt or non-exempt for human subjects review and stipulate which of the exemptions justifies an exempt status:.

Exempt _____ Non-exempt _____

If exempt, indicate reason (see page _ for exemption reasons)

_____

_____ _____
Date Principal Investigator (or Co-Investigator)

_____ _____
Date Student Investigator

_____ _____
Date Department Chair's Signature or Departmental Human Subjects Committee Chair's Signature

"I accept responsibility for the factual content of this report and will be available for discussion if additional questions are raised."

Signature of Investigator(s) _____

_____

Prescott University
Advil, Oklahoma 78888

Instructions for Completing the Application for Review of Research Using Human Subjects

Please answer the following questions, taking care to make the answers intelligible to non-specialists.

I. Provide a brief description of the research you are proposing.

II. Subject selection:

a. Who will be the subjects? How will you enlist their participation? If you plan to advertise for subjects, include a copy of the ad.

b. Will the subjects be selected for any specific characteristics, e.g., age, sex, race, ethnic origin, religion, or any social or economic qualifications?

c. If the answer to "b" is Yes, state why the selection is made on this basis. (If children are used, be sure to include forms used to solicit the assent of the children as well as of their parents or guardians.)

III. What will be done to the subjects? Explain in detail your methods and procedures in this area. If you are using a mailed questionnaire or handout, please include a copy.

IV. Are there any risks to subjects? If so, what are these risks? Can the observations, if known outside the study, place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing or employability? What potential benefits will accrue to justify taking these risks?

V. Explain what you plan to do with the research findings.

VI. Explain how your procedures will protect the privacy of subjects and maintain confidentiality of identifiable information at all phases of the research, i.e., when collecting, coding, storing, analyzing, and disposing of the data.

VII. Does the research deal with sensitive issues such as illegal conduct, drug use, sexual behavior, or use of alcohol?

VIII. State specifically what information will be provided to the subjects about the investigation. Is any of this information deceptive? State how the subjects' informed consent will be obtained. Attach the form that will be used when written consent is required.

IX. Describe the debriefing and follow-up process you will use to explain the experiment and answer questions after the research is completed.

X. Will electrical or mechanical equipment be used? If yes, has it been checked for safety?

Please include 10 copies of this form if the application if the entire IRB will be reviewing your application. Be sure to include all relevant supporting documents. Typical supporting documents include consent forms, letters sent to recruit participants, questionnaires to be completed by participants, routing form for sponsored projects, and any other materials germane to human subjects review.

XI. Other obligations: (a) Report to the Institutional Review Board any unanticipated effects harmful to subjects that become apparent during the research. (b) Cooperate with the continuing review of this research project by submitting annual reports and a final report. (c) Maintain all documentation required by the institution and federal guidelines.

(This sample form merges guidelines from SDA and public institutions. In the U.S., certain types of research are exempt from more intense scrutiny. See federal statutes or local university regulations for category definitions.)

SAMPLE CONSENT FORM

Identification of Project	Project Title _____
Statement of Age of Subject (parental consent needed for minors)	I am over 18 years of age, in good physical health, and wish to participate in a program of research being conducted by _____ at the Graduate School, Prescott University, Advil, Oklahoma, Department of Psychology.
Purpose	The purpose of the research is to measure the effects of prolonged sleep loss on the response time tasks.
Procedures	The procedures involve three sessions, four weeks apart, during which I will be asked to go without sleep for periods of 24 to 48 hours. At various times during the sleepless period, I will be asked to perform simple tasks and to respond to sound by pushing a button.
Confidentiality	All information collected in the study is confidential, and my name will not be identified at any time.
Risks/Benefits:	I understand that as a result of sleeplessness, I may experience extreme tiredness and sleep disturbances over a short period of time. I understand that there are ordinarily no long-term effects associated with the periods of sleeplessness involved in this experiment. I understand that the experiment is not designed to help me personally, but that the investigator hopes to learn more about sleep loss and the ability of people to perform tasks for the safe operation of machinery and cars.
Freedom to Withdraw and to Ask Questions	I understand that I am free to ask questions or to withdraw from participation at any time without penalty.
Where Medical Care Is Available (as applicable)	In the event of physical injury resulting from participation in this study, I understand that immediate medical treatment is available nearby at Hope Community Hospital. However, I understand that Prescott University does not provide any medical or hospitalization coverage for participants in the research study nor will the university provide compensation for any injury sustained as a result of participation in this research study except as required by law.
Payment	I understand that I will receive a cash payment of $_____ when the experiment has been completed.
Name and Address, Phone Number--Principal Investigator	_____
Signature of Subject	_____
Date	_____