INSTITUTE OF SOCIETY, ETHICS AND THE LIFE SCIENCES
THE HASTINGS CENTER
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Copies to
AIDS Med Adv Comm

TO: Participants in the December 1, 1983, meeting on Confidentiality and AIDS Research
FROM: Ronald Bayer, Carol Levine, Thomas Murray

Enclosed you will find a copy of our draft guidelines on confidentiality and the conduct of AIDS research. We hope that you will have a chance to consider this draft carefully before the meeting on Thursday.

Our discussion on that date will serve to provide the Hastings Center staff with the observations and insights nececessary to strengthen the recommendations. After the December 1 meeting we will produce a final document, which we will distribute early in 1984.

Since these guidelines are not final or official in any way, publicizing them would be premature and unwarranted. Therefore while we urge you to speak with your colleagues about this draft, please do not discuss it with or release it to the press.

MEETING PLACE: New York Academy of Medicine, 2 East 103rd Street (at Fifth Avenue)
TIME: 9 A.M. to 5 P.M.
Lunch will be serve at the Academy.

DRAFT GUIDELINES

AIDS CONFIDENTIALITY PROJECT

December 1, 1983

NOT FOR QUOTATION OR PUBLIC RELEASE

The identification of Acquired Immune Deficiency Syndrome (AIDS) two years ago has created a significant ethical dilemma for patients, physicians, public health officials, researchers, and society. Any scientific investigation into the incidence, causes, modes of transmission, and treatment of a presumably communicable disease poses a tension between an individual's right to control personal information and a researcher's need for access to portions of that information. The tension is not unique to AIDS, but it is particularly sharply drawn because those groups that have been identified as at high risk are also highly vulnerable socially, economically, and politically.

AIDS patients are understandably concerned about the confidentiality of information they might divulge for purposes of scientific research. Researchers are similarly concerned that, without accurate and comprehensive data from AIDS patients, they will not be able to conduct the studies essential to understanding the disease. Society has interests both in protecting the privacy and dignity of AIDS patients and in encouraging the research that may lead to the treatment and ultimately the prevention of the disease.

At this stage--when major research efforts are being undertaken to tackle the many puzzling aspects of AIDS--it is essential to address all these concerns. While in part a technical problem, it is one that has important ethical, legal, and symbolic aspects as well. Ethically, a balance must be struck between the principle of respect for persons (which requires that individuals should be treated as autonomous agents who have the right to control their own destinies), and the principle of beneficence (which requires maximizing possible benefits and minimizing possible harms, to society as well as to individuals). Legally--by statute and regulation--patients, researchers, and institutions must be protected from involuntary disclosure of information to other parties. Symbolically we must express our commitment to the principle that all persons are due a full measure of compassion and respect.

These guidelines are concerned, then, with the protection of the privacy interests of patients with AIDS and their families and friends, with the confidentiality of data collected about them, and with the security of data systems in which this information is stored. The guidelines are intended to supplement, not to supplant, existing protections and procedures. For example, we believe that every AIDS research protocol should be reviewed by an institutional review board (IRB) and that at a minimum the IRB should follow the federal regulations governing research involving human subjects.[1] At present such review is mandated only for federally funded research. Furthermore, IRBs reviewing AIDS research protocols should consult with representatives of the subject population on all relevant aspects of subject protection.

The guidelines should be applied broadly, that is, not only to activities that involve a systematic testing of hypotheses ("research") but also to activities that involve systematic monitoring of the disease ("surveillance"). Furthermore the guidelines should be applied not only to activities involving patients who meet the Center for Disease Control's criteria for AIDS but also to activities involving patients who have some suggestive but not conclusive symptoms of AIDS and who may or may not develop the more serious symptoms (prodromal cases). They should also be applied to activities involving patients' families and friends, to members of those groups that have been or may be identified as at risk, and to research subjects who are enrolled as controls in a study.

I. What kinds of information are researchers likely to need?

Information relevant to AIDS research may be of many kinds and may come from numerous sources. Researchers may, for example, need information about an individual's medical condition, medical history, sexual practices, and drug use. Such information may be obtained from, for example, interviews with patients, physicians' records, hospital records, administrative records (for example, insurance claims), records gathered by other researchers, records gathered by public health agencies, and interviews with friends and relatives.

II. For what purposes will researchers need this information?

Researchers need this information to understand the nature of AIDS, its effects, the way it is transmitted, and its prevention. Their research may take the form of clinical investigations, laboratory studies, epidemiological studies, or those surveillance

activities that include the systematic collection and analysis of data about the disease. Epidemiological studies in particular are likely to create potential difficulties for consent and confidentiality. Yet these studies are essential for understanding the disease.

III. For what purposes might nonresearchers seek this information?

We believe that it is crucial to distinguish between research (including health surveillance) and nonresearch activities. We must further distinguish between one very specialized kind of nonresearch activity--public health interventions--and all other forms of nonresearch activities. Information gathered in the course of research or mandatory public health reporting should under no circumstances be disclosed to federal agencies such as the Departments of Justice or Defense, the Internal Revenue Service or the Immigration and Naturalization Service; to local law-enforcement agencies; or to employers, landlords, or other private individuals or institutions. No individual or agency should have access to any information gathered in research on AIDS for any nonresearch purpose without the explicit consent of the participants in that research.

We can conceive of one possible exception to this blanket prohibition on nonresearch uses of data gathered for research on AIDS: when research confirms that specific individuals are at preventable risk for the disease, and that information contained in research records is uniquely necessary to protect those endangered persons. Even in this case, we believe it is possible to protect the identities of research participants through one of a variety of methods which have been invented to protect confidentiality. We

further recommend that if and when such a use is contemplated, the continuing review board suggested later in this document be given authority to judge whether the information is genuinely needed, and if the protection for confidentiality is adequate.

IV. The need for identifiers

Identifiers are not necessary in all research. For example, a study that involves only a single patient interview or a single compilation of statistical data does not need identifiers. Identifiers are necessary when: (a) the researcher wants to check on the reliability of the data; (b) the researcher wants to link one set of data with other sets; (c) the researcher wants to link information gathered at different times. The most common identifier is a person's name or Social Security number, but many other identification schemes are available. The need for identifiers may create a conflict with individuals' interests in protecting their privacy. This conflict can be minimized in several ways.

First, researchers should make sure that identifiers are really needed to carry out the research and are not simply a convenience or a habit.

Second, researchers should examine various options and select the form of identifier that provides maximum protection of individuals' identities commensurate with responsible research.

Third, researchers should explain to research participants why identifiers are needed in that particular instance and how that system works. For example, the Soundex system currently in use by the CDC codes only the consonants of a person's last name, is combined with the individual's birth date to provide a code that is almost, though not completely, unique for that person.

Fourth, research data should be stripped of personal identifying material and be assigned coded identifiers immediately so that there is no lag between the receipt of the information and the initiation of protections.

Fifth, along with a coding scheme to protect identities, any institution or agency that conducts research should have a clearly stated and enforced policy, addressing the security of records, how identifiers will be handled, and their eventual disposition. Even with conscientious and well-intentioned guardians of records and identifiers, the possibilities of inadvertent or malicious misuse of this information must be considered, and precautions taken.

Finally, we urge that explicit consideration be given to the problem of deductive disclosure--the possibility that someone might be able to deduce the identity of a particular individual from the combination of a coded identifier and other information. We know of no scheme that provides complete immunity from the possibility of deductive disclosure. However, careful attention to limiting the information given out in connection with coded identifiers can make deductive disclosure so technically difficult, or so cumbersome and costly as to make it practically unfeasible.

✓ ~~5~~. Consent

Informed consent, derived from the principle of respect for persons, is a cornerstone of the ethical conduct of human subjects research. These guidelines reaffirm the importance of obtaining informed consent from prospective research subjects but they also recognize that for research involving only medical records, notification, combined with stringent confidentiality protections, may be an appropriate substitute for full informed consent.

IRBs that review research protocols involving interviews with patients or family, friends, or sexual contacts; clinical interventions; laboratory procedures; or any collection of data that results in identifiable information should see that, as a minimum, the basic elements of informed consent outlined in 45 CFR 46.116 are present. These include a statement that the study involves research and an explanation of its purposes, procedures, and expected duration; a description of any reasonably foreseeable risks or discomforts; a description of any reasonably foreseeable benefits; a disclosure of appropriate alternative procedures or courses of treatment; a statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained; an explanation of the institution's policy regarding compensation for injury; an explanation of whom to contact if the subject has questions; and a statement that participation is voluntary and that refusal to participate or a decision to withdraw from the protocol will not result in the loss of benefits to which the subject is otherwise entitled.

The IRB should pay special attention to the explanation about confidentiality given to the subjects so that they will understand just what protections, legal and technical, are in place; under what circumstances, if any, the information about them may be released to other parties; and in particular, whether any information identifying them may be released. Subjects involved in research subject to FDA regulations should be informed that as part of its oversight of new drug applications the FDA has the right to inspect patient records, as stated in 21 CFR 50.25(a)(5), and that protection against the release of identifiable data is governed by

laws regarding public disclosure of information (the Freedom of Information Act and the Privacy Act).

Research that involves only the use of medical records (defined by the U.S. Privacy Protection Study Commission as a "record, file, or other written material relating to an individual's diagnosis, condition, treatment, or evaluation created or maintained by a medical-care provider") should also be reviewed by an IRB. The IRB may approve biomedical or epidemiological research without requiring that investigators obtain informed consent from each subject as long as the person was notified at the time of admission to the hospital or the initiation of the patient-physician relationship that medical records may be used for research purposes. In such cases the patient must be protected from any inadvertent or malicious release of information from the medical record, and no identifiers should be used in any publication from the research. In the case of already existing medical records, patients should be informed that these records may be used for research purposes. Consent must be obtained from the subject for any further use or redisclosure of the record in individually identifiable form.[2]

VII. Legal protections

Researchers and patients share a concern that data will be disclosed involuntarily by subpoena, a Freedom of Information Act request, or other legal procedure. While to some extent their fears are justified--that is, anyone can attempt through these means to obtain data--the legal process offers various protections for the confidentiality of medical research records. Researchers, institutions, and IRBs should investigate the laws about confidentiality that pertain in their local and state jurisdictions before undertaking any research on AIDS.

At the federal level, the Freedom of Information Act (5 U.S.C. 552 (1967)), as amended in 1974 by the Privacy Act (5 U.S.C. Section 552a (1974)), mandates disclosure of data held in government files, but exempts "personnel and medical files and similar files the disclosure of which would constitute a clearly unwarranted invasion of personal privacy." If a request were made for research data under the FOIA, the agency can resist disclosure through an administrative process.

Similarly, researchers should resist subpoenas that seek the compulsory disclosure of information that might prove detrimental to subjects' interests. Courts are likely to look more favorably on a researcher's arguments against disclosure if the researcher has from the beginning of the project placed a high value on the confidentiality of the material, set up stringent measures for its protection, and assured subjects that their data will be kept confidential. This concern is not limited to AIDS research, and a model from the fields of alcohol and drug abuse and law enforcement may be applicable. Confidentiality certificates that offer some, albeit limited, protections against the subpoena of research data are available under certain circumstances to researchers conducting projects funded by the Alcohol, Drug Abuse and Mental Health Administration within the Department of Health and Human Services and the Drug Enforcement Administration and the Law Enforcement Assistance Administration within the Department of Justice. Some research projects that involve AIDS patients who are intravenous drug users may already fall into these categories, but the majority of subjects will not be covered. We recommend that legislation be introduced to create a similar confidentiality certificate

specifically for AIDS research funded by federal agencies or carried out in institutions receiving federal support.

However, confidentiality certificates and other legal mechanisms come into play only when the researcher or agency wishes to prevent the disclosure of information; they do not prevent voluntary disclosure or protect from inadvertent disclosure. We recommend that the unwarranted voluntary disclosure of identifiable data be prohibited by statute and administrative regulation.

VIII. The need for consistency.

Legal protections and policies governing confidentiality of research data should be as consistent as possible across various legal jurisdictions, research institutions, and public health bodies. That is, the protection of research data should not depend on vagaries of geography, inclination, or individual conscience. To some extent the protections afforded research subjects by the federal regulations governing human subjects research are a helpful step toward consistency. But even these regulations are, for good reasons, worded in a general way and are subject to different interpretation by local IRBs.

To encourage consistency, as well as to improve communication, we urge all relevant policy-making bodies to develop a statement about confidentiality, using these guidelines as well as other relevant documents, and to circulate or publish them so that others will be able to compare their own policies. A model statute governing the confidentiality of research data might be developed, as well as a model policy statement for a research institute, a public health department, and so on. It would be advisable as well for all public health agencies to agree on a single coding system.

IX. A continuing review board.

We hope that these guidelines will cover the majority of cases, but both to monitor the ongoing research and to provide a mechanism to adjudicate instances not covered or not foreseen by the guidelines, we recommend that a continuing ethics review board be constituted. This board would be made up of representatives of the subject populations, researchers, public health officials, ethicists, and others. Such a broad-based group, on the model of the now-defunct Ethics Advisory Board within the former Department of Health, Education, and Welfare, could provide a forum for the ongoing mediation of conflicts and could represent the interests of all the involved parties. The composition, funding, authority, and accountability of such a group are beyond the scope of the guidelines, but we suggest at a minimum that it not be located within a government agency (but that it should have government representation), that it have a national representation, and that it should meet regularly as well as on an ad hoc basis, that it deal not only with individual research protocols but develop policy guidelines as necessary.

X. Communication and education

We hope that these guidelines will be distributed as widely as possible among the research, public health, and subject communities. Moreover, we hope that they will form the basis for a continuing discussion of confidentiality.

But more must be done. All those who do research on AIDS must make a commitment to communicate, as fully and frankly as possible, their policies on confidentiality. They must be ready to explain why certain kinds of information are needed and what protections

exist--and perhaps most difficult, what risks about disclosure of data the subject undertakes in entering the study. These risks must be minimized as much as possible, but where they exist, they should be disclosed.

If AIDS is to be understood and controlled, trust between researcher and subject is essential. We hope that these guidelines will serve to reinforce that trust where it already exists and to create it where it has not existed before.

REFERENCES

[1]45 CFR 46 for the Department of Health and Human Services, 21 CFR Parts 50, 56, et. al. for the Food and Drug Administration.

[2]An example of a hospital policy for the use of medical records for research that follows these principles is described in "The Use of Medical Records for Research at Georgetown University," IRB: A Review of Human Subjects Research 3:3 (March 1981), 1-3.