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# Ethical Issues in AIDS Research

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*There is a need for carefully controlled and scientifically rigorous research studies of the acquired immunodeficiency syndrome (AIDS). The morbidity and mortality associated with AIDS patients and the public health concerns for control of this epidemic have distorted the usual process of research. The Institutional Review Board at Boston City Hospital is suggested as an appropriate mechanism for clarifying the distinctions between research and innovative therapies and for assuring the protection of this vulnerable population of research subjects. This article addresses ethical concerns relating to the time frame of research, drug and antibody testing, vaccine trials, and questions of justice in micro- or macro-allocation. The unique problems in AIDS research with informed consent and confidentiality are discussed. Finally, the need is outlined for careful balancing of individual welfare and rights and those of society.*

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**P**erhaps the least controversial point in all discussions about AIDS and AIDS-related complex (ARC) is the need for research. The need to discover the etiology, natural history, epidemiology, and treatment of AIDS is indisputable. However, ethical dilemmas surrounding the priorities, methodologies, and timing of research strategies pose unique problems for patients, researchers, clinicians, hospitals, institutional review boards (IRBs), public health workers, health care policymakers, and society at large.<sup>1</sup>

From the earliest case reports in late 1979 of male homosexuals with Kaposi's sarcoma, immunosuppression, and opportunistic infections, through May 1984, when the human immunodeficiency virus (HIV, formerly known as HTLV-III/LAV) was accepted as the etiologic agent of AIDS, to the present, medical scientists have been and continue to be involved in clinical, epidemiological, and basic science research into AIDS.<sup>2</sup> The Centers for Disease Control (CDC) has been involved in surveillance and epidemiological re-

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search, while other federal agencies, such as the National Institutes of Health and the National Cancer Institute, have sponsored and carried out other investigations. Privately funded commercial, pharmaceutical, and hospital-based research has also been initiated. The rapid mobilization of the medical research community in the face of this deadly, immensely complex, and emotionally charged public health problem has caused some wobbles in the balance that is carefully maintained between individual patient welfare and the public welfare — a balance that has always been an integral part of the ethical principles of medical research.

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### **The Nature of AIDS Research**

The primary goal of medical research is to contribute to the development of general knowledge about a particular disease or condition; the primary goal of clinical therapy, on the other hand, is to benefit the individual patient. When medical research enters the clinical therapy setting in the form of testing new drugs, vaccines, or diagnostic procedures, a blurring between these two objectives often occurs. The goal of participating in the testing of a new drug or an innovative therapy may be one thing for the patient and the clinician team, another for the research scientist, and quite another for the sponsoring agency.

The potentially competing interests of the various parties involved in human experimentation present a crucial issue in AIDS research. Additional surveillance is needed because of the wide array of unvalidated and innovative therapies being tested on AIDS patients — members of a special population with a fatal disease who may be willing to incur greater risk to themselves for the good of others. This surveillance must be undertaken by a group that represents the interests not only of the researchers and sponsoring agencies but also of the patients and the public at large.

### ***Institutional Review Boards***

IRBs are the intra-institutional committees established under regulations promulgated by the U.S. Department of Health and Human Services.<sup>3</sup> They are mandated to review research involving humans and to monitor the protection of human subjects in order to ensure that socially accepted ethical norms are met.<sup>4</sup> IRBs require that research protocols involve sound scientific design; competent methods of investigation; favorable balance of risks and benefits; adequate informed-consent mechanisms; equitable selection of subjects; justification for research on special populations; and consideration of compensation for research-induced injury. Those who comprise IRBs fall into one of two groups, broadly speaking: individuals who are affiliated with the institution or hospital, such as physicians, nurses, scientists, pharmacists, and public health workers; and unaffiliated lay members, such as philosophers, theologians, lawyers, and other community representatives. Such broad representation and mandated authority place IRBs in the pivotal position necessary to provide additional surveillance of AIDS research.

### ***Time Frame for Research***

The high morbidity and mortality of AIDS patients and the serious public health concerns regarding the etiology, natural history, and transmission of HIV have accelerated the standard medical research time frame for AIDS research. Although the pressure to speed up AIDS research is understandable, perhaps even desirable, such distortion of standard research practice implies potential dangers. Moreover, the publicity concerning AIDS re-

search has created a public image of medical research that is quite different from reality.

Standard medical research is a slow, meticulous process. Once the safety and efficacy of proposed therapies have been established, controlled clinical tests are performed. To minimize human risk, animal studies are used when possible before human studies; competent adult patients are studied before incompetent patients; and, when applicable, healthy volunteers are studied before sick or exposed volunteers. Special protections are needed for the study of populations who are at special risk of possible coercion or duress. As a rule, indiscriminate or premature use of therapies that have not been vigorously tested and verified is discouraged.

In AIDS research, however, there has been a rapid movement from basic-science studies to clinical trials. Researchers have been quick to report the results of their work, and the publication of these results has been almost immediate through the news media. Data from such research may be quickly transferred to the clinical setting, where they are often applied without controlled clinical testing. This is understandable. Physicians want to be able to treat their AIDS patients as effectively as possible, and they also want to be able to educate their patients and the public appropriately in order to prevent the spread of AIDS. AIDS patients, searching for hope of survival, scan the medical literature and news reports for access to new drugs or therapies. Premature media coverage of research results has often been accompanied by unwarranted claims of success, thereby raising the public's expectations unfairly. When the initial studies of interferon and interleukins were released by the press, AIDS patients from all over the country flooded researchers with requests for treatment.

Public health concerns about the prevention and spread of AIDS have caused the early introduction of research data into public policy debates. Epidemiological studies are sought as a means of dealing with disease risk management. Such data are used in arguments for and against policies regarding persons with AIDS and their school attendance; the safety and appropriateness of their employment; acceptance for health and life insurance; and possible large-scale screening and quarantine.

Through the rapid publication of their data, many investigators have gained professional and personal renown as well as guarantees of future research funding. The race to cure AIDS has even spurred one research team in France to bring a legal suit against a U.S.-based research team in an argument over who really discovered the AIDS virus.<sup>5</sup>

The rather unorthodox methodology of AIDS research has led to several problems. Data are presented which have not been adequately tested or controlled. Reports of conflicts in data or errors in data cause alarm among clinicians and patients alike. Premature claims of certainty about results which prove to be inaccurate and the continual updating and reclarifying of results of epidemiological studies and clinical tests have confused the public and shaken its confidence in AIDS research.

Because of the urgency of AIDS research, IRBs have felt increased pressure from both researchers and the public to approve AIDS research protocols rapidly. Since it is both the function and responsibility of IRBs to protect human subjects in medical research, they must assume the crucial tasks of helping to maintain ethical and standard research procedures and of helping to develop responsible modifications in those procedures. However, IRBs cannot and should not be the sole gatekeepers safeguarding the integrity of AIDS research.

### ***AIDS Drug Testing***

The discovery of experimental antibiotics and antiviral agents that may help fight AIDS

and the complicating opportunistic infections found in AIDS patients has spurred the early clinical testing of such drugs. Research protocols involving these drugs represent some of the most ethically complex situations that come before IRBs. Researchers ask IRBs for approval to bypass standard research procedures and to grant compassionate use of drugs they believe will be of particular benefit to AIDS patients. Private pharmaceutical companies are eager to introduce their new antiviral products, because sometimes the mere suggestion of the possible success of an experimental antiviral agent has caused stock in the companies producing such drugs to rise rapidly. Requests are also made for special, expedited approval for new uses of approved drugs without controlled trials or standardized testing.

An excellent example of the dilemmas associated with drug testing in AIDS patients is the case of Azidothymidine (AZT).<sup>6</sup> From the moment this antiviral agent was shown to have some efficacy with the AIDS virus, an emotionally charged and ethically complex series of questions arose. Should the drug go through the standard three-phase, slow medical research protocol of exhaustive testing of safety and efficacy in animals and humans? What patients should be used in human experimentation, and how should they be selected? Should a standard controlled clinical trial of the experimental agent matched against a placebo-control group be undertaken to prove clinical efficacy scientifically? How much of a role should AIDS patients, ARC patients, physicians, scientists, drug companies, and the public play in determining the research trials of AZT? If a randomized clinical trial of placebo versus AZT were undertaken, at what point should the code be broken, identifying which patients received AZT and which received placebo in such a blind study? Once a trend toward efficacy has been established in the course of clinical experimentation, when should the trials be terminated and the drug made available? Is a desperately ill, dying patient with AIDS the appropriate subject for study, or are patients with ARC or HIV-antibody-positive patients with no symptoms a more justifiable group in which to conduct clinical trials? How should one assess the relative risks and benefits in these populations? Should dying patients be included in the randomization, or should they be treated with drugs outside of clinical trials as a last glimmer of hope? Can patients who are dying give an informed consent? Even if they are competent to do so, should they be approached with new, untested drugs with no clear evidence of safety or efficacy? Who should bear the cost of the research project and of the drugs themselves? If a drug appears to be effective late in a clinical trial, can the research subject be asked to pay for the drug? After the research trials are over, can a patient who appears to have responded continue to have access to the experimental agent? As newer drugs become available, should they be tested against placebo controls or against other existing drugs, such as AZT? What control should IRBs have in the resolution of these dilemmas? And, finally, what role should such regulatory bodies as the Department of Health and Human Services or the Food and Drug Administration (FDA) play in monitoring and granting final approval for AIDS drugs?

The history of AZT, from its early synthesis as an anticancer drug through animal and human testing and then to FDA approval and marketing, represents a fair balance between the expediency of drug development and the protection of human subjects at risk. AZT was first tested for *in vitro* activity against HIV. When the drug's efficacy with HIV had been demonstrated, animal trials were undertaken. The first human experiments were conducted at the National Cancer Institute as an open, nonrandomized trial. Once AZT showed promise as an agent *in vivo* against HIV, a randomized, placebo-controlled clinical trial was carried out at several medical institutions caring for AIDS patients. Early in

the controlled trials, researchers broke the code to identify patients receiving the drug when it became apparent that some patients benefited from the trial more than others.

On the basis of accumulated data from these trials, the FDA approved AZT for clinical use on March 19, 1987. After AZT was approved, the manufacturer began to charge for its use. Initially the cost of AZT was approximately \$10,000 per year, but the increasing market and efficiency of production have already led the manufacturer to begin lowering this figure. However, the cost may still present an economic hardship for some. Increased production of the drug seems to have alleviated the problems of access that accompanied its emergence. Insurance coverage may vary, though it appears that access has not been limited nationally by inability to pay. In Massachusetts, all third-party payers, including Medicaid, have covered the cost of AZT. Massachusetts has also recently established a program to cover the cost of the drug for patients who have no other means to pay. AZT has thus proven to be a paradigm for a reasonable approach to drug testing in AIDS.

In June 1987, partly in response to AIDS drug testing, the FDA issued final regulations outlining procedures under which “promising, investigational new drugs could be made available to desperately ill patients before general marketing begins.”<sup>7</sup> The regulation applies to “patients with serious and immediately life-threatening diagnoses for which no comparable or satisfactory alternative drug or other therapies exist.” The FDA also defined “conditions under which drug manufacturers may charge for investigational new drug products.” It remains to be seen whether such FDA regulatory changes will accomplish the goal of releasing new drugs to patients prior to marketing while at the same time protecting the scientific clinical-trials process for testing safety and efficacy and protecting the human subjects participating in research.

### *HIV Antibody Testing*

Perhaps the clearest example of the quick transition of AIDS research from the laboratory to the clinic is the HIV antibody test. Because of the need to identify subjects carrying the HIV antibody in order to protect the blood supply from contaminated donor units, antibody testing was one of the first priorities of AIDS research. The test was also necessary for quantifying epidemiological data and for therapeutic trials and screens. Once developed, the HIV antibody test was rapidly introduced into research protocols and clinical practice, but problems of sensitivity and specificity resulted because experience with the significance and variances of the test was not complete. Beyond test reproducibility, questions about the reliability of HIV antibody positivity and the significant false-positive and false-negative rates caused concern about how quickly this test was being used for clinical screening and public policy guidelines. Extending the use of the HIV antibody test to patient care is complicated by the questions of where, when, how, and why it should be used. In using antibody testing, the distinctions between purposes of epidemiology, diagnosis, and public policy have not always been clear.

### *HIV Vaccine*

As more is learned about the structure and function of the AIDS virus, several research groups have begun work on the development of an HIV vaccine. If and when such a vaccine becomes available, how should it be tested? Do safety and efficacy studies in animals warrant the move to human studies? Who should be used for human studies — patients who are already infected with the virus, or normal subjects with no evidence of viral infection? Is it appropriate to test the vaccine on at-risk populations when education and change in lifestyle are known to be effective preventive measures? Once the vaccine is

administered, how will immunity be tested? Should such subjects be challenged with the virus or allowed or even encouraged to continue their high-risk behavior? The laboratory development of an HIV vaccine may raise the hope of universal protection through immunization, but there will be significant ethical debate about research trials and subsequent recommendations for widespread clinical use.

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### **Justice in Micro-Allocation**

The main concern of persons with AIDS is the possible avoidance of what appears to be an inevitable early death. This fact brings into focus the problem of population selection for AIDS research. It is reasonable to assume that some experimental drugs will eventually be effective in combating AIDS. Are chances of survival increased when an AIDS patient participates in many research protocols involving different experimental drugs? How are participants to be selected? Who serves as the control group for these drug trials? Should selection be based on the ability to pay, on special needs, or on special merit? Since participation in AIDS research may be viewed as a public good that may also be helpful to the individual AIDS patient, questions about distributive justice must be addressed. How should promising experimental therapies be distributed among all too many claimants in a research setting?

Distributive justice also enters into the problem of disseminating knowledge about AIDS research. Who should know about it? How should such knowledge be provided? Who should pay for it? Should the public as a whole bear the burden of learning and teaching all there is to know about AIDS? Should all the media outlets devote time to AIDS-related issues? Should all public schools devote regular sessions to AIDS-related issues? Should the public be alerted as soon as possible to all new stages of AIDS research?

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### **Justice in Macro-Allocation**

Most medical research in the United States is funded either by government agencies or by private foundations and corporations. More specifically, when the research pertains to national epidemics or to medical ailments that are of concern to a wide portion of the population, funding has been provided largely by government agencies. Because AIDS was not viewed at first as an epidemic of national concern, however, AIDS research was initially given little attention and little funding.

Several explanations can be given for this early public policy decision. First, AIDS was thought to afflict only a small minority and thus was not a national concern. Second, some viewed AIDS in theological terms and claimed that this disease was divine punishment against the immoral acts of homosexuals. Third, political pressure to do anything about AIDS was lacking. This is understandable, given the politically conservative stance of the current administration, especially toward the population at risk for developing AIDS.

Political compromises regarding AIDS became quite evident to the growing population of potential AIDS patients. The male homosexual populations of cities like Boston, New York, and San Francisco flexed their political muscles and demanded that their city governments do something about AIDS. These powerful grassroots efforts provided the popular support that city mayors needed to pressure their state legislators for funds to help with AIDS research and education programs. Finally, through pressure from local and

state governments and the public at large, the federal administration began to provide funds for AIDS research through the office of the secretary of health and human services.

If only a marginal segment of the population is afflicted with a certain disease, it seems reasonable and just that only a small proportion of public funds earmarked for medical research be allocated for the study of that disease. This was the original proposition advocated in the case of AIDS on both logical and ethical grounds. But this reasoning cannot hold. Now that cases of heterosexual partners and children with AIDS have been confirmed, it remains unclear how small or large the at-risk population is. Because the potential risk to the public at large is uncertain, it is not obvious how to proceed. Should funds be provided only according to the proven proportion of the population which has already contracted the disease? Or should the potential spread of AIDS be taken into account?

Questions also arise concerning the priority of other ongoing medical research. Should federal funding for the less urgent areas of medical research be halted and those funds channeled to AIDS research? Such a suggestion could be defended if one were able to show that unless the government did just that, millions of lives would be endangered. Arguments of this sort presuppose that it is possible to establish a medical research agenda with an agreed-upon set of priorities determined by society as a whole. There are, of course, practical problems with setting such an agenda. How could all of society participate in such a discussion? Can any procedure guarantee democratic control of the setting of these priorities?

A discussion of the macro-allocation of resources for AIDS research would not be complete without considering what it is that private foundations and corporations have at stake in funding AIDS research. Are these organizations concerned with the well-being of those afflicted with AIDS? Or are they hoping to discover the cure in order to capitalize on their discovery and make huge profits? It is possible to claim that the motives for research are unimportant as long as the results are beneficial to patients and society. Moreover, whether or not profits will be secured remains an open question that has little bearing on the ability of the private sector to supplement the federal funds allocated for AIDS research. There are always potential conflicts of interest on the part of those involved in research, in terms of compromises that might be made to maximize profits.

Although IRBs should be cognizant of these issues, their concern about funding sources is limited to the ways in which financing may affect the well-being of human subjects. Is there adequate funding to assure the completion of the proposed research, so that the claimed benefits will indeed outweigh the risks the subjects are asked to incur? It should also be noted that the role of the IRBs is not to set up or implement any specified research agenda but merely to ensure the protection of the subjects who are enrolled in medical research projects.

It is impossible and would be presumptuous to provide any answers or even rules for action regarding the many questions raised so far. The main purpose of this discussion and that which follows is to illustrate the complexity of the ethical issues surrounding AIDS, both for society as a whole and for the individuals involved, and to show that these issues are intimately connected to other social and political concerns.

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## **Informed Consent**

Obtaining informed consent in any type of research is a demonstration of respect for an individual's autonomy. Informed consent has three primary components:



- the individual giving consent is mentally competent;
- the individual giving consent is presented with enough information to make rational decisions; and
- the consent is uncoerced — freely given by a nonvulnerable, autonomous individual.

AIDS research raises ethical questions about each of these components. First, when research involves a new vaccine or treatment, both the scientific community and the subjects are faced with more unknowns than knowns. Because AIDS research is so new, the range and magnitude of the unknowns are great. Researchers may believe that their ethical obligations are fulfilled by advising the subjects of the range of unknowns and asking them to weigh the potential risk/benefit ratio on that basis. However, at some point, particularly where new ideas are being rushed through the research system and virtually no information may be available, potential subjects may be placed at too great a risk. IRBs need to make this kind of assessment and, if necessary, restrict participation in such a study.

Second, some persons with AIDS show clinical signs of a central nervous system dysfunction associated with the AIDS virus. To the extent that such symptoms render them mentally incompetent, they will be unable to give informed consent. A question that arises when research is directed at central nervous system AIDS is, Who, if anyone, can or should give consent for the patient? This question arises in both clinical and research settings. Generally, substitute decision makers (for example, parent, spouse) are approached.<sup>8</sup> But what happens when an individual with AIDS is alienated from his or her family and has no legally recognized spouse? The individual who is closest to and who best knows the patient may not be legally recognized as such and may know of difficulties between the patient and other family members.

Third, and finally, when research involves a dying patient whose body has been ravaged by a continuous series of recurring infections and the patient is given a glimmer of relief, the consent can hardly be considered freely given by a nonvulnerable person. Or, how about the symptomatic or asymptomatic individual who feels a sense of guilt from the possibility of having infected a loved one and who is willing to undergo unusual risks to make amends? How about the intravenous (IV) drug user who may link the research with access to methadone?

What obligations do researchers have to look beyond the surface of consent and protect the individual? How paternalistic may the researcher be? Or, conversely, are members of a group uniquely infected by a virus under some obligation to society and the other members of their group to sacrifice their individuality in order to help avert further infection? IRBs are in a position to protect the rights of individuals to make autonomous and informed decisions and not be pressured either by researchers or by the population of persons with AIDS. In this sense, then, IRBs may be considered paternalistic when attempting to maintain the rights and welfare of potential research subjects.

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## **Confidentiality**

Preservation of the confidentiality of individuals with AIDS or of other participants in AIDS research is a major concern of clinicians, researchers, lawyers, ethicists, and com-

munity groups.<sup>9</sup> The right to privacy, as associated with individual liberty and autonomy, is an important ideal in our society. All medical clinicians and researchers are obligated to maintain confidential information acquired in the clinical and research settings. In the therapeutic environment, such ethical obligations are supported by legal rights in order to permit a free exchange of information between patient and clinician so that possible benefits of treatment will be maximized. The federal guidelines for federally funded research require that researchers provide for confidentiality of records and subject information and that IRBs consider this issue when reviewing research protocols.<sup>10</sup>

The complexity of AIDS research makes difficult demands on researchers with regard to confidentiality. First, in a society in which homophobia exists and AIDS phobia runs rampant, the risk of information leaks is quite high. Individuals may be stigmatized generally for being gay or drug users, or specifically for having a fatal, contagious disease. There are cases in which people either with AIDS, ARC, or HIV antibody positivity have been denied insurance benefits or have suffered the loss of their jobs. Medical providers, acting on their unsubstantiated fears of treating individuals with AIDS, may inappropriately gown or glove before entering the patient's room, may over-isolate AIDS patients, or may even refuse to treat AIDS patients altogether. Another repercussion of AIDS is a family's discovery that a family member is a homosexual or an IV drug user. Further, certain activities that contribute to the spread of AIDS, such as prostitution and IV drug use, are illegal. Knowledge of the individual's status may be followed by legal prosecution. However, in a fear-driven society, failure to release information about particular individuals with AIDS may subject all members of high-risk groups to being ostracized, denied benefits, and treated in a discriminatory fashion. Should such a societal response justify invasion of an individual's privacy and liberty?

Recognizing the importance of medical research, both the federal government and the Massachusetts legislature provide mechanisms for protecting confidentiality by limiting access to research records in certain cases. Under federal law, a researcher can apply for a confidentiality certificate when engaged in mental health research, including research on the use and effect of alcohol and psychoactive drugs, to prohibit access to information by compulsory process.<sup>11</sup> The Massachusetts statute similarly protects certain information from release under subpoena.<sup>12</sup> Laws regarding the protection of confidentiality and access to research records may vary among states.

One major dilemma for researchers who learn that an individual has AIDS, ARC, or HIV antibody positivity and may therefore be infectious is how to preserve the patient's confidentiality while at the same time protecting medical personnel from exposure to AIDS. An example from Boston City Hospital will illustrate this point. When the HIV antibody test was first developed, it was available only for research and blood bank use, not for clinical purposes. At that time, the Centers for Disease Control and the Massachusetts state health agencies felt that, in the absence of treatment for the AIDS antibody, the information would be of little clinical value and would result only in negative consequences for the patient. Since that time, the CDC has become more interested in tracing the course of the virus at earlier stages and has encouraged antibody testing in clinical settings where the information would assist clinical management.

Seroepidemiological studies of HIV with IV drug users, including a substantial number of pregnant addicts, were conducted at a drug treatment clinic operated by Boston City Hospital. The researchers in this instance had information about the clients which they could not disclose to other clinicians without proper consent. These other clinicians believed such information would be invaluable in the clients' treatment plans. The problem

was further complicated for pregnant addicts, because a particular physician could be both a researcher and a clinician for them. How could the clinician advise the obstetric and pediatric staffs at the hospital where the clinician practiced, and where the clients would deliver their babies, to take precautions against blood exposure from mother and infant without disclosing the mother's HIV antibody status, learned only through research? Should all high-risk mothers and infants be considered infectious?

In AIDS research, it may be important to distinguish between confidentiality and anonymity. If the only concern is an epidemiological analysis of prevalence, then anonymity may be preferred. However, if there are good reasons — such as the ability to trace a person with AIDS in order to provide therapeutically relevant data or to alert a victim that a new therapy is available — then keeping patients' names in confidential files may be preferred. IRBs have emphasized this distinction and have challenged researchers to decide whether anonymity or confidentiality is preferable and for what reasons.

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## Conclusion

The ethical and societal concerns about AIDS research which are raised by the relationship between research findings, available clinical treatments, and public health policy actions call for a national assessment of medical research priorities and intermediate goals for AIDS research.<sup>13</sup> Assessments must then lead to directing research funds in accordance with the national research agenda in the most cost-efficient manner. Such a public policy could be cooperatively addressed by private researchers and institutions and public agencies and officials. To some extent, such forums have already been established in various states. For example, in Massachusetts the Governor's Task Force on AIDS is composed of researchers, public health officials, and community representatives. All of the New England states have established similar investigational bodies. State plans should be consistent with broader, more comprehensive national agendas.

Many ethical, legal, and public policy considerations are involved in addressing the problems associated with AIDS research. Professionals in all aspects of health care need to recognize and understand the possible alternative approaches to resolution of these practical and moral quandaries. IRBs can serve as locally based forums for the initiation of debate. Such boards have had ample experience in dealing with the substantive issues of consent, confidentiality, the balancing of risks and benefits, and the proper selection of populations for research. This experience is complemented by federally mandated guidelines that assure proper procedures for the protection of human subjects in research. Since the procedures are open to public scrutiny and since these boards have public representation, IRBs are particularly appropriate forums for public participation in addressing AIDS research.

Although the principles of biomedical ethics, such as beneficence, justice, and respect for persons, are not unique to AIDS research, the enormity and gravity of AIDS necessitate a careful application of these principles. The continuous balancing of the rights and welfare of individuals and the rights and welfare of the public is a crucial element in resolving the complex ethical issues involved in AIDS research. 🍷

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## Notes

1. See generally Hastings Center (Hastings-on-Hudson, N.Y.), "AIDS: The Emerging Ethical Dilemmas," *Hastings Center Report* (special supplement) 15, no. 4 (August 1985):1-32.
2. See Anthony S. Fauci (moderator), "Acquired Immunodeficiency Syndrome: Epidemiology, Clinical, Immunologic and Therapeutic Considerations," *Annals of Internal Medicine* 100 (January 1984):92-106; Samuel Broder, Robert C. Gallo, "A Pathogenic Retrovirus (HTLV-III) Linked to AIDS," *New England Journal of Medicine* 311, no. 20 (November 15, 1984):1292-1297; Sirkka-Liisa Valle, Carl Saxinger, Annamari Ranki, Jaako Antonen, Jukka Suni, Juhan Lahdevirta, Kai Krohn, "Diversity of Clinical Spectrum of HTLV-III Infection," *Lancet* 1 (February 9, 1985):301-304; James W. Curran, W. Meade Morgan, Ann M. Harding, Harold Jaffe, William Darrow, Walter Dowdle, "The Epidemiology of AIDS: Current Status and Future Prospects," *Science* 229 (September 27, 1985):1352-1357; and Sheldon H. Landesman, Harold M. Ginzberg, Stanley H. Weiss, "The AIDS Epidemic," *New England Journal of Medicine* 312, no. 8 (February 21, 1985):521-525.
3. See Code of Federal Regulations, 45 C.F.R., 46 (1974, rev. 1981, rev. 1983).
4. See generally Tom L. Beauchamp and James F. Childress, *Principles of Biomedical Ethics* (New York: Oxford University Press, 1983) and Robert J. Levine, *Ethics and Regulation of Clinical Research* (Baltimore and Munich: Urban and Schwarzenberg, 1986).
5. See Colin Norman, "News and Comments," *Science* 231 (January 3, 1986):11-12.
6. See Ruth Macklin and Gerald Friedland, "AIDS Research: The Ethics of Clinical Trials," *Law, Medicine and Health Care* 14, no. 5-6 (December 1986):273-286.
7. See Code of Federal Regulations 21 C.F.R., 312.
8. See Robert Steinbrook, Bernard Lo, Jill Tirpack, James Dilley, Paul Volberding, "Ethical Dilemmas in Caring for Patients with the Acquired Immunodeficiency Syndrome," *Annals of Internal Medicine* 103 (November 1985):787-790; and Kevin Kelly, "AIDS and Ethics: An Overview," *General Hospital Psychiatry* 9, no. 5 (September 1987):331-340.
9. See Charles Marwick, "Confidentiality Issues May Cloud Epidemiologic Studies of AIDS," *Journal of the American Medical Association* 250, no. 15 (October 21, 1983):1945-1946.
10. See Code of Federal Regulations 45 C.F.R., 46.111, and 45 C.F.R., 46.116.
11. See *ibid.*, 42 C.F.R., 2a; 42 U.S.C., 242(a).
12. Massachusetts General Laws Ch. 3, 2.4A.
13. American Medical Association, "Task Force Formed to Coordinate Study, Testing of AIDS Therapies," *Journal of the American Medical Association* 255, no. 10 (March 14, 1986):1233-1242; and Edward N. Brandt, "Implications of the Acquired Immunodeficiency Syndrome for Health Policy," *Annals of Internal Medicine* 103 (November 1985):771-793.

**"S**omeone once described AIDS like being in a canoe in the middle of a hurricane. It's pretty lonely and it's pretty terrifying. But when someone is in that canoe with you it's not nearly so frightening. So it is with our coalition of PWAs. We even believe that we can bring that canoe into a safe harbor."**"**