NATIONAL ACADEMY OF SCIENCES

OFFICE OF THE PRESIDENT
2101 CONSTITUTION AVENUE
WASHINGTON, D. C. 20418

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Mr. Charles U. Lowe
Executive Director
National Commission for the Protection
of Human Subjects in Biomedical and
Behavioral Research
5333 Westbard Avenue
Room 125
Bethesda, Maryland 20016

Dear Mr. Lowe:

Rather belatedly I have been informed of the notice in the Federal Register for Monday, December 27, and of what is now an immediate deadline for receipt of the communications invited by that notice. I am aware that the Commission has been taking testimony for some time and has had opportunity for its own discussions. And I am also aware that the Commission will have had access to the various materials assembled with respect to the case of Washington Research Project, Inc. vs. The Department of Health, Education, and Welfare and Caspar W. Weinberger. Under these circumstances it seems rather unlikely that I can add any information or point of view to which the Commission has not already been exposed. Nevertheless, I would be remiss were I to fail to indicate, however briefly and superficially, my own views in these matters, views which, I believe, reflect those of many of the relevant scientific community.

If I properly appreciate the significance of the questions posed in the notice of the Federal Register, within the context of the charge to the Commission, a two-sided question is at issue: (a) To what extent is it necessary to make publicly available the information within applications for research support in order to assure that maximum protection would be afforded the potential subjects of the research proposed therein, insofar as the information in such applications may contribute to that process; (b) To what extent would such disclosure be detrimental to the public interest from other standpoints?

I shall speak only briefly to the first question. It seems unlikely that extending the "Freedom of Information Act" and the "Government in the Sunshine Act" to research grant applications and the comments of those who review such applications would indeed afford a significant measure of protection except in instances which involve the most gross violation of ethical practice. Detailed research protocols are seldom found in research grant applications, largely because actual research requirements develop as the research itself develops and are rarely adequately foreseeable. Indeed, the specific populations to be examined are frequently uncertain in the mind of the investigator at the time of making application. And it would surely be an immense hindrance and a monstrous bureaucratic snare to expect each individual research protocol to find approval at the supporting federal agency before an experiment can be undertaken. A significant fraction of all such clinical research is conducted under nonfederal auspices in any case and the subjects of such studies also warrant our protection.

The burden of responsibility for the protection of human subjects must be placed back on the institution within which the research is conducted. Appropriate and increasingly effective local mechanisms for such monitoring now exist in most such institutions and means exist to assure that every institution must put an appropriate mechanism into place and utilize it faithfully. The details of such mechanisms are well known to the Commission and need not be recounted here. Transgressions can only be prevented at the local institutional level. External regulations with sufficient force can assure that monitoring at the local level will be continuous and consistent. A principal challenge to the Commission is the formulation of an appropriate and definitive code or set of guidelines for such local use.

If one accepts the argument above, then it becomes apparent that relatively little is to be gained, in fact, by way of additional protection by opening the research grant application to public scrutiny. On the other hand, considerable security is achievable by formally placing upon each "study section" that examines applications for clinical research a requirement for specific comment with respect to each application for which it recommends approval concerning any possible breaches of ethical practice which it might sense to be explicit or implicit in the research proposed. Whenever a problem is thus detected and noted, the burden is then transferred to the administering agency to

satisfy itself by direct communication with the investigator or the officials of the investigator's institution concerning the procedures that will be followed to avoid the problem that has been detected. Formal award should await satisfactory resolution of the problem.

As one who was for more than two dozen years recipient of research grants awarded by the competitive process and peer review and who himself served as chairman of two study sections at NIH, on one panel at the National Science Foundation, on two Advisory Councils at NIH and as chairman of the National Science Board at the National Science Foundation, I have developed a firm belief in and deep respect for the mechanisms which have been evolved for the operation of the competitive peer review process.

Every examination that has been made of that process has concluded that it is equitable, consistent and highly successful in identifying those projects and investigators of greatest research promise. No alternative has been offered which might comparably serve the public interest. That same interest demands that applications to be reviewed provide sufficient detail to permit adequate examination by the reviewers with respect to the historical background of the problem, the guiding hypothesis of the research, the general experimental approach to be followed, the scientific significance of the findings which are sought and their potential for application. From the standpoint of the prospective investigator, assurance is required that his "intellectual property rights" will be respected throughout this process.

Were the confidentiality of research grant applications and their review to be surrendered, there must surely follow a steady deterioration in the efficacy and value of the entire process. Inevitably, investigators, concerned for those intellectual property rights, will come to practice artful evasion; applications will be less than fully forthcoming and candid. When informed that their comments are no longer to be held confidential, scientists who have heretofore welcomed the opportunity to serve on study sections and review panels will either practice a comparable form of evasive generality or decline to serve in the first instance. It is difficult for me to consider that such deterioration is in the public interest, particularly when no remotely comparable public good is served other than "freedom of information" as a fetish rather than as a device for protection of the public interest. Repeated examination has failed to confirm the allegations which have occasionally been brought against the peer review process, e.g., favoring of an

"Old Boys Club," favoring of applicants from the institutions represented by members of the study section, failure to support untried young investigators, etc. And the diverse members of a given study section are sufficient in number and stature to assure that none of their own group can successfully appropriate, as his own, the ideas in a research grant application.

To be sure, it is desirable that there be a public record of the basic fact of the award of a research grant or contract together with a sufficient amount of information to indicate the subject of the research and the most general description of the nature thereof. This has long been afforded in the form of a publicly available abstract prepared by the applicant investigator himself. When such an abstract is insufficiently informative, the agency can request its improvement.

It is unlikely that any of the thoughts recorded above are new to the Commission. But there is a point of view with respect to what I have, above, called "intellectual property rights" to which I would like to give a special emphasis. It is not unlike that which appeared, in part, in the paper entitled "Confidentiality of Research Grant Proposals" by T. E. Morgan, J. A. Keyes, and J. F. Sherman in CLINICAL RESEARCH, 24, 5 (1976).

The social utility of promoting the arts and sciences by extraordinary measures directed toward this end was made explicit in the Constitution. Article I, section 8, directs the Congress to "promote the progress of science and useful arts; by securing for limited times to authors and inventors the exclusive right to their respective writings and discoveries." The patent and copyright systems that derive therefrom exist not for the enrichment of a privileged few but for the stimulus they give to innovation and the public benefits which result therefrom. Implicit in the patent system is detailed disclosure of each invention in a prescribed form and by a prescribed process. Premature disclosure or prior publication of the ideas involved preclude forever award of patent protection under this system.

The patent policy of the Department of Health, Education, and Welfare has taken cognizance of the role that the granting of exclusive rights and inventions must play in the prospective transfer of technology "from the laboratory bench to the patient beds." The NIH system for awarding research grants has deliberately operated in such fashion as not to adversely affect the patentability of any inventions which may result from federally funded projects. This productive articulation of governmental policy would be seriously

undermined by a measure that would require unrestricted public access to research grant applications. Surely, it is as serious to deny to a scientist his right to hold and exploit his own original ideas as it is to deny him the right to patent their subsequent culmination in a mature "invention."

Relevant also is the Fifth Amendment of the Constitution: "No person shall be deprived of life, liberty or property without due process of law nor shall private property be taken for public use without just compensation." I believe it to be accepted in the law that the term "property," in this context, embraces "intellectual property" of the type accorded special treatment under Article I, section 8, i.e., a citizen has a right to his own ideas and may not be deprived of their fruits without "due process" or "just compensation." It seems to me that it might well be argued that the conditions of disclosure which some have contemplated would destroy the prospective property rights of the applicant without just compensation or due process. Were a research grant application to be judged to be, effectively, a waiver of property rights, surely the wisdom of such a policy would be subject to question. The reality of our circumstances is inherent in the fact that the government controls the preponderance of the financial resources now devoted to biomedical research and, thus, is in position to exercise effective coercion. But, were the government to exact such a price, would it not erode other rights and jeopardize policies which have served our society well?

Conceivably, there may be specific instances in which it may prove necessary that such property rights be subordinated in order that sufficient protection be afforded to persons who stand to be adversely affected as the subjects of research. But such instances should be identified and appraised on their individual merits; the Commission might find it useful to consider recommending the procedures to be utilized in such instances. For research, in general, too much will be lost and little gained by wholesale disclosure. The loss is certain and predictable; the gain is at best uncertain and highly speculative. It is not evident that a formula can be developed for the classification of projects, in advance, on some *a priori* basis, which would permit automatic decision as to when disclosure would result in minimal loss and maximal gain.

Perhaps the deliberations of the Commission will be illuminated by a passage which has recently been called to my attention. They are the words of James Madison in a letter to Thomas Jefferson,

dated 17 October 1788 in support of Article 1, section 8 of the then proposed Constitution,

> "With regard to monopolies, they are justly classed among the greatest nuisances in government, but is it clear that, as encouragements to literary works and ingenious discoveries, they are not too valuable to be wholly renounced? Would it not suffice to reserve in all cases a right to the public to abolish the privilege at a price to be specified in the grant of it? Monopolies are sacrifices of the many to the few. Where the power is in the few, it is natural for them to sacrifice the many to their own partialities and corruptions. Where the power, as with us, is in the many, not in the few, the danger cannot be very great that the few will be thus favored. It is much more to be dreaded that the few will be unnecessarily sacrificed to the many."

The Commission has accepted the considerable burden of helping to steer the Nation on a course which will maximize the protection that our society owes to those who are the subjects of research while at the same time assuring that the research enterprise can go forward with a minimum of impediment so that its benefits may be brought to our people as soon as possible. Accordingly, may I respectfully urge the Commission to seek means for the protection of human subjects which will not so erode the rights and satisfactions of the individual investigator as seriously to weaken his motivation and thereby markedly impair the entire research process upon which progress depends.

Sincerely yours,

P Handler

Philip Handler
President