Report and Recommendations

# DISCLOSURE OF RESEARCH INFORMATION UNDER THE FREEDOM OF INFORMATION ACT

The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research

1977

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National Commission for the Protection of Human Subjects
of Biomedical and Behavioral Research

Westwood Building, Room 125
5333 Westbard Avenue
Bethesda, Maryland 20016

April 8, 1977

Honorable Edward M. Kennedy
Chairman, Subcommittee on
Health
United States Senate
Washington, D.C. 20510

Dear Senator Kennedy:

On behalf of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, I am pleased to transmit our Report and Recommendations on Disclosure of Research Information. Title III of the Health Research and Health Services Amendments of 1976 (Public Law 94-278) directed the Commission to study the implications of public disclosure of certain research information, and to submit to Congress a report on this topic not later than December 31, 1976. In previous correspondence, the Commision requested an extention of the deadline until March 31, 1977. This report is being transmitted also to the Secretary of Health, Education, and Welfare, because certain of our recommendations are for administrative action within his discretion.

It is our hope that you will find the Commission's recommendations for legislative action to be reasonable and appropriate.

Respectfully,

Kenneth J. Ryan, M.D.
Chairman

National Commission for the Protection of Human Subjects
of Biomedical and Behavioral Research

Westwood Building, Room 125
5333 Westbard Avenue
Bethesda, Maryland 20016

April 8, 1977

Honorable Paul G. Rogers
Chairman, Subcommittee on
Health and Environment
U.S. House of Representatives
Washington, D.C. 20515

Dear Mr. Rogers:

On behalf of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, I am pleased to transmit our Report and Recommendations on Disclosure of Research Information. Title III of the Health Research and Health Services Amendments of 1976 (Public Law 94-278) directed the Commission to study the implications of public disclosure of certain research information, and to submit to Congress a report on this topic not later than December 31, 1976. In previous correspondence, the Commission requested an extention of the deadline until March 31, 1977. This report is being transmitted also to the Secretary of Health, Education, and Welfare, because certain of our recommendations are for administrative action within his discretion.

It is our hope that you will find the Commission's recommendations for legislative action to be reasonable and appropriate.

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Westwood Building, Room 125
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Bethesda, Maryland 20016

April 8, 1977

Honorable Joseph A. Califano, Jr.
Secretary of Health, Education, and Welfare
Washington, D.C. 20201

Dear Mr. Secretary:

On behalf of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, I am pleased to transmit our Report and Recommendations on Disclosure of Research Information. Title III of the Health Research and Health Services Amendments of 1976 (Public Law 94-278) directed the Commission to study the implications of public disclosure of certain information, and to submit to Congress a report on this topic. We are also transmitting this report to you, because the department has interest in the matters under discussion and certain of our recommendations are for administrative action within your discretion. These recommendations are not made pursuant to the Commission's basic mandate under the National Research Act (Public Law 93-348), and consequently do not invoke the departmental response that is required under that Act. It is our hope, however, that you will find the recommendations for administrative action to be reasonable and appropriate to implement.

Respectfully,

Kenneth J. Ryan, M.D.
Chairman

# NATIONAL COMMISSION FOR THE PROTECTION OF HUMAN SUBJECTS OF BIOMEDICAL AND BEHAVIORAL RESEARCH

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# INTRODUCTION

The National Commission for the Protection of Human Subjects was directed (under title III of the Health Research and Health Services Amendments of 1976, P.L. 94-278) to investigate and study the implications of public disclosure of information contained in research protocols, hypotheses and designs submitted to the Secretary of Health, Education, and Welfare in connection with applications or proposals for grants, fellowships or contracts under the Public Health Service Act.

This mandate to the Commission followed a court decision (Washington Research Project, Inc. v. DHEW, 504 F. 2d 238, cert. denied, 421 U.S. 963 (1975)) which held such information generally to be disclosable pursuant to the Freedom of Information Act (FOIA) (5 USC § 552). The decision has caused concern to many members of the research community, who take the position that an investigator's ideas and methodology are his or her "stock-in-trade" and thus deserving of protection from disclosure. Some have argued that plagiarism and loss of potential patent rights may result from premature disclosure, while others have expressed fear that premature disclosure of hypotheses and data from clinical trials might have detrimental consequences to the public. Several organizations which represent investigators have urged that legislation exempting certain research information from disclosure under the FOIA be enacted. Public interest groups, however, have opposed such legislative proposals on the grounds that disclosure serves the public interest in open government and, more particularly, provides additional protection for human research subjects.

The Commission and the President's Biomedical Research Panel were directed to investigate and study the implications of disclosure of research information and to report to Congress their findings, including such recommendations for legislation as deemed appropriate. In the course of their investigation and study, the Commission and Panel were required to determine the following:

> (A) The number of requests made to the Secretary [DHEW] for the disclosure of information contained in such research protocols, hypotheses, and designs and the interests represented by the persons for whom such requests were made.
>
> (B) The purposes for which information disclosed by the Secretary pursuant to such requests was used.
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> (C) The effect of the disclosure of such information on --
>
> (i) proprietary interests in the research protocol, hypothesis, or design from which such information was disclosed and on patent rights;
>
> (ii) the ability of peer review systems to insure high quality federally funded research; and
>
> (iii) the (I) protection of the public against research which presents an unreasonable risk to human subjects of such research and (II) the adequacy of informed consent procedures.

The mandate was drafted originally to direct an investigation and study by the Panel.* Congress first evidenced a desire that the Commission study this problem in the course of discussions concerning the disclosure of protocols which involve human subjects.** Although the mandate assigned the

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* H.R. Conf. Rep. No. 94-1005, 94th Cong., 2d Sess. 22 (1976).

** Hearings on S. 988 Before the Subcommittee on Health of the Senate Committee on Labor and Public Welfare, 94th Cong., 1st Sess. 120-21 (1975); Hearings on H.R. 7039 *et al.* Before the Subcommittee on Health and the Environment of the House Committee on Interstate and Foreign Commerce, 94th Cong., 1st Sess. 159 (1975).

same issues to the Commission and the Panel, the Commission concluded that its special expertise as an advisory body would best be utilized by focusing primarily on paragraph (C)(iii) of the section of the mandate quoted above, i.e., the impact of disclosure on the protection of human subjects and the adequacy of the informed consent process. The Commission recognized, however, that the rationale underlying such recommendations as would be made with respect to research involving human subjects has broader applicability; accordingly, the final recommendations of the Commission relate to research protocols generally.

The Commission construed its mandate to include study of the implications of the Government in the Sunshine Act (Public Law 94-409) (enacted after the passage of the mandate) for the protection of human subjects. Some peer review meetings may be opened pursuant to the Sunshine Act, and the Commission considered the possible effects of such opening.

The Commission's investigation included a review of the following information: the survey conducted by the President's Biomedical Research Panel of those requesting research information under the FOIA; a legal and policy analysis of public disclosure requirements and their implications for the review process at DHEW;* testimony presented at a Commission meeting on December 11, 1976, by representatives of diverse viewpoints;

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* Prepared by James H. Wallace, Jr., and Thomas C. Arthur, members of the District of Columbia Bar.

and approximately 240 written comments submitted to the Commission in response to a public solicitation. In addition, most Commission members have observed or participated in meetings of peer review study sections. Finally, the Commission conducted public deliberations and adopted recommendations to be considered by Congress and the Secretary of Health, Education, and Welfare. The deliberations are summarized and the recommendations set forth in the final chapter of this report.

# Table of Contents

# CHAPTER I. BACKGROUND

DHEW regulations (42 CFR 52) require that initial grant applications for biomedical and behavioral research describe the nature, duration, purpose and plan of any proposed project, *i.e.*, the hypothesis, design and protocol of the researcher. Also required to be described are the qualifications of the principal investigator and primary staff members, the total facilities and resources available, and a justification of the amount of grant funds requested. Grants may not be awarded to profit-making institutions.

DHEW has established a peer review system to evaluate the often highly specialized grant applications (and subsequent renewal or supplemental applications). Panels of outside consultants are organized around various areas of research. These panels, termed "initial review groups" (IRGs), consist usually of eight to twenty members, of whom not more than 25% are full-time federal employees. Each IRG is administered by an executive secretary, who is a DHEW employee. Usually the IRGs are standing committees, called "study sections," although ad hoc committees are sometimes formed for reviewing particular applications.

Most study sections review 50 to 100 applications at each of three meetings annually (lasting from two to three days). The scientific merit of the proposals and the appropriateness of the requested budgets are discussed, as are the suitability of the research facilities and the training, experience and research competence or promise of the investigator. Recom-

mendations are made as to whether proposals should be supported, the level and duration of funding, and the priority for funding. The executive secretary prepares a summary statement ("pink sheet") for each application, describing the proposal and the considerations that led the IRG to its recommendations.

The application and summary statement are transmitted to the appropriate national advisory council -- a body composed of leading figures in relevant science and health fields and prominent lay people. The advisory council does not usually pass upon the scientific merits of each application, but gives primary attention to policy direction and emphasis, generally acting on proposals in subject matter groups. The IRGs and advisory councils also review applications for fellowship grants.

Contracts, unlike grants, may be awarded to profit-making entities. The initial review of solicited proposals (or modification and renewal proposals incident to awarded contracts) is either by standing committees or ad hoc groups, which may include both federal employees and outside consultants. The final review is done by a "source selection panel," usually composed of senior DHEW officials.

The effect of the Washington Research Project case was to make it more difficult for nonprofit institutions, as opposed to commercial firms, to protect submitted applications and proposals from public disclosure under the FOIA. The court rejected the argument that an investigator's ideas, or "stock-in-trade," were analogous to trade secrets and commercial information

and thereby exempt from disclosure under Exemption (4) of the FOIA. The research information contained in funded grant applications (and any subsequent continuation, renewal or supplemental applications) was held to be disclosable, absent a showing that conventionally defined proprietary interests (*e.g.*, patent rights) were present. The court did, however, find Exemption (5) (intra-agency memoranda) applicable to the requests for the summary statements; only reasonably segregable, purely factual matter is disclosable. The summary statements, absent the priority rating, are presently disclosed to principal investigators pursuant to the Privacy Act (5 USC 552a).

DHEW evaluates FOIA requests for funded grant applications on a case-by-case basis in order to determine whether an application contains trade secrets or commercial information. The principal investigator and the responsible official at the grantee institution are immediately notified by telephone or telegram of any request and of the identity of the requester. They must precisely identify to DHEW, within 72 hours, any material the disclosure of which would adversely affect future patent or other valuable commercial rights. Such material may include descriptions of inventions in conceptual form at a time when there are not yet data to demonstrate utility or efficacy and support a patent application.* DHEW then reviews the identified material and other parts of the application to

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* See Washington Research Project, Inc. v. DHEW (Civ. No. 75-0743, D.C.C. 1975) (such material successfully denied where suit was dismissed with prejudice).

ensure that only material exempt under the FOIA is deleted. Material intended to be copyrighted is not deleted but is released with an appropriate notice of copyright to the requester.

Bowen Hosford (Office of NIH Associate Director for Communications) has reported that in 1976 only 15 out of 537 FOIA requests to NIH for disclosure of research information were denied by DHEW. Responding to FOIA requests often involves negotiation among the parties on acceptable levels of disclosure; investigators are not always successful in having materials deleted at their request. Major portions of awarded contract proposals are also disclosed upon request, although it is much easier for profit-making contractors to demonstrate proprietary interests and therefore the applicability of Exemption (4).

The Washington Research Project case did not involve the disclosability of pending or unsuccessful grant applications or contract proposals, collectively referred to as "unfunded" applications or proposals. DHEW policy with respect to pending initial grant applications is to deny FOIA requests, citing Exemption (4) and also Exemption (6), which applies to "personnel and medical files and similar files the disclosure of which would constitute a clearly unwarranted invasion of personal privacy." Pending contract proposals appear to be exempt under Exemption (4) in order to protect the competitive contract bidding process.

As a general practice, unsuccessful grant applications are destroyed within a year after the funding decision, and unawarded contract proposals

are disposed of within three months after the date of the award decision. Exemptions (4) and (6) are also relied upon in preventing the disclosure of unsuccessful grant applications and contract proposals before their destruction.* Thus, all "unfunded" initial grant applications and proposals presently are not disclosed by DHEW. Pursuant to DHEW's interpretation of the Washington Research Project case, however, pending and unsuccessful continuation, renewal and supplemental applications incident to funded initial applications, as well as progress reports, are disclosable.

DHEW is relying upon Exemptions (4) and (6) of the Sunshine Act to justify closing those portions of the peer review meetings regulated by the Federal Advisory Committee Act (FACA) (5 USC app. I) in which applications and proposals are reviewed.** Peer review meetings not covered by the FACA are also closed.

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* This practice is currently being challenged in a court suit.

** But see H.R. Conf. Rep. No. 94-1441, 94th Cong., 2d Sess. 26-27 (1976) (legislative intent can reasonably be construed as generally requiring meetings to be opened, with subsequent review of the unique problems of NIH under the Act by the appropriate House and Senate committees).

## Chapter II. Interests For and Against Disclosure of Research Information and Opening of Meetings

Review of the data presented to the Commission (including testimony by representatives of NIH, the Association of American Medical Colleges (AAMC), the Department of Commerce, DHEW, the National Association of College and University Business Officers (NACUBO), and public interest groups) reveals the following values at stake in balancing the interests for and against disclosure of research information.

### A. Interests in Preserving Confidentiality of Information

Protection of Researcher's "Stock-in-Trade." The principal argument advanced in the testimony of Drs. Thomas Malone (Associate NIH Director for Extramural Research and Training) and Thomas Morgan (representing AAMC) was that the research ideas of an investigator are his or her intellectual property, or "stock-in-trade," and thus should be accorded the same exemption from disclosure as are trade secrets and commercial information. By controlling the timing of disclosure of the ideas, the investigator can prevent both intentional and inadvertent copying by other investigators, as well as release of unfounded hypotheses or possibly misleading preliminary data. Preventing disclosure of unfunded applications may also serve to avoid prejudicing an investigator's chances of receiving funding from another source. It was argued that existing incentives for early publication of results adequately assure the timely release of research information.

Protection of Patent and Other Proprietary Interests. Testimony by Dr. Betsy Ancker-Johnson (Assistant Secretary of Commerce for Science and

Technology), Norman Latker (DHEW Patent Counsel), Howard Bremer (representing NACUBO), and Neils Reimers (Stanford University) concern the effect of disclosure of research information upon the transfer of technology from the laboratory to the health care consumer. Disclosure, it was argued, jeopardizes the ability of research institutions to attract private risk capital for the development of health care innovations through patent licensing.* Ancker-Johnson illustrated how patients in need of health care innovations suffer when patentable interests are not protected. She pointed out that disclosure of such information (sometimes even orally) prior to filing of a patent application by a grantee or contractor immediately extinguishes patent rights in over 50 countries, and in the United States if the application is not made within one year after "printed publication." Reimers gave an example of the attempt of a foreign firm to obtain information on a valuable computerized axial tomography (CAT) system under the FOIA.

Bremer noted that at the time of the grant application most researchers are not aware of patentable potential. Latker gave the example of the laser, which was briefly described in a footnote in a grant proposal, without any indication of its value. Reimers added that even where the patentable potential is recognized, it may be necessary first to obtain data from the conduct of research before the grantee institution is persuaded to invest re-

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* A grantee has the option to claim the patent rights if it is one of the 69 universities which presently have Institutional Patent Agreements with DHEW; otherwise, DHEW has the option to retain patent rights pursuant to a deferred determination clause. Contractors operate under a system which utilizes deferred determination clauses.

sources in the patent application process. Clinical evidence may at times be required by law to support assertions of usefulness and safety in humans that appear in a patent application.

From 1969 to 1974, an estimated 329 inventions generated or corroborated by DHEW funded grants and awarded contracts were under the control of university patent-management offices. The patents attracted about $100 million in private risk capital via 78 exclusive and 44 nonexclusive licenses. While recent years have witnessed a higher frequency of patent applications, the total of 329 inventions should be viewed in the context of the roughly 100,000 applications and proposals submitted to DHEW during that time frame.

Privacy of Investigator. It was argued also that the investigator has a privacy interest in controlling the dissemination of information contained in an application or proposal. Such information is generally either biographical or otherwise personal (*e.g.*, requested salary) or is indirect information about a person (*e.g.*, his or her research hypotheses and designs). While the investigator is often in attendance when an Institutional Review Board (IRB) reviews a protocol that involves risks to human subjects, the investigator is unable personally to explain or defend information contained in an application or proposal once it is submitted to DHEW. The inability to regulate the disclosure of personal information may impair the investigator's capacity for projecting a self-selected professional image to his peers and others.

Integrity of Peer Review System. Drs. Ruth Kirschstein (Chairman of NIH Grants Review Study Team) and Thomas Morgan (AAMC) both argued that one of the detrimental results of the fear of plagiarism through public disclosure might be a tendency to draft less detailed research proposals. It was further argued that the quality of DHEW funded research would decline if grant applications became less detailed, possibly exposing human research subjects to greater risks. A corollary argument advanced was that some qualified researchers would fail to submit their proposals at all.

The Biomedical Research Panel conducted a survey of the members and executive secretaries of 68 study section and review committees at NIH and ADAMHA to determine whether the Washington Research Project case was perceived as having such a deleterious effect on grant applications. The Panel reported that those surveyed

> perceived no change in the quality or quantity of information provided in research grant applications since [the Washington Research Project case. But many] recognized that it was too soon for any significant indications of impact on content of applications because the scientific community was not then fully aware of the recent change in policy.

Dangers to the Public from Premature Disclosure of Hypotheses or Data. Dr. Jerome Green (Division of Extramural Affairs, National Heart, Lung, and Blood Institute, NIH) testified that release of preliminary data from clinical trials would result in premature conclusions as to study results, wasteful development of unvalidated hypotheses, and pressure upon doctors

to try untested therapies. The release of such data might also induce the subjects of such research to disregard their protocol duties in order to avoid or have access to unvalidated therapies utilized in the research. It was argued also that similar results might flow from the premature disclosure of hypotheses in applications, particularly because applications are often drafted in a very optimistic tone in order to attract funding support.

Preliminary research data may be presented in initial applications or proposals, as well as in competitive renewal and supplemental applications, and progress reports. Continuation applications, required annually, are noncompetitive and rarely contain preliminary data.

B. Interests in Disclosure of Information

Protection of Human Subjects. Michael Trister (representing the Children's Defense Fund) and Lois Schiffer (representing the Women's Rights Project of the Center for Law and Social Policy) testified that disclosure of information can play an important role in the protection of human subjects. They argued that monitoring of applications and proposals by the press and the public at the earliest possible stage of the review process would safeguard human subjects from any errors that review committees might make in evaluating risks to human subjects or the adequacy of consent forms. It was further alleged that research not involving human subjects must be reviewed in order to determine whether extensions of inquiries to human subjects are safe and ethical.

Open Government. Trister and Schiffer also emphasized that the First Amendment, FOIA and related "sunshine" laws all express the same fundamental value -- that of the public interest in obtaining information on the operation of governmental processes, including the DHEW grant review system. Schiffer contended that access to both funded and unfunded protocols is necessary in order to determine, for example, why relatively few women researchers receive grant support.* This interest in public awareness of, and participation in, the review process was argued to be greatest when DHEW actually expends public monies in support of a project.

Free Exchange of Scientific Ideas. The free exchange of scientific ideas was contended by Wallace and Arthur (contractors to the Commission) to be a basic method of facilitating progress in science. Exchange of ideas enables scientists to build upon the discoveries of others, and as a consequence reduces the cost of duplicative research efforts.

C. Interests For and Against the Closing of Meetings

The interests outlined above for preserving confidentiality are also present in the argument for closing of peer review meetings, especially the interest in preserving the integrity of the peer review system. Malone and Morgan strongly emphasized the need for keeping the meetings closed in order to maintain the level of full and frank discussion of the competence of peers and the merits of their proposals. Such discussion, they argued,

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* NIH has indicated that the difference between men and women in funding success has been decreasing and may no longer exist.

is an important reason for the success of the peer review system in funding high quality research. The presence of grant applicants, the press and interested public, it was contended, is likely to have a number of detrimental impacts: loss of participation of peer reviewers who may be exposed to lobbying, harassment or recrimination; disruption of meetings, thereby increasing the administrative costs on the system; a chilling of critical review that would result in low quality research being funded, thereby increasing the risk to human subjects; driving the actual decision-making process underground, resulting in pro forma ratifications at open meetings of previously made decisions; and discrimination against grant applicants who are unable to attend meetings in Washington because of geographic distance.

Kirschstein cited the results of a comprehensive survey of IRG and advisory council members: 90% thought that the opening up of IRG meetings to applicant investigators or the public would have either unfavorable or very unfavorable consequences, while 85% expressed the same opinion with respect to the opening up of advisory council meetings.

The investigator's interest in privacy is also jeopardized in the context of open meetings. The investigator, even if present, has no right to influence or participate in the deliberations. Thus, the investigator is unable to defend his or her reputation or explain information provided to the reviewers. To the extent that the press or public is present, the investigator's privacy is seriously eroded.

The interests favoring disclosure of information are likewise applicable to the argument for opening IRG and advisory council meetings. Transfer of scientific ideas and public review of governmental processes would be furthered, as might the protection of human subjects in certain instances. The interest in free and frank discussion, identified as a reason for closing of meetings, was also relied upon by advocates of openness. They contended that truly free and frank discussion would be enhanced, not deterred, pointing to the experience of other governmental bodies under the "sunshine" laws.

# Chapter III. Investigation of Requests for Disclosure of Information

The mandate from Congress directed the Commission and the President's Biomedical Research Panel to determine the number of requests for disclosure of research information contained in applications and proposals submitted during 1975, the interests represented by those making requests, and the purposes for which the requested information was used. Records of the stipulated requests for research information were provided to the Panel by the agencies within DHEW that award grants, fellowships and contracts: NIH, ADAMHA, the Health Services Administration, and the Center for Disease Control.* As of May 1, 1976, these agencies had received a total of 160 requests from 124 individuals. The requests were for a total of 586 separate informational items. Most of these requests were to NIH.

These requests were often silent with regard to the interests represented by the requesters and the purposes for which the information was used. Answers to these questions were sought by the Panel in a brief, two-item questionnaire that was sent to the 124 individuals who had made requests for research information. The Commission decided that it would not be productive to attempt to gain further information from the same individuals who were surveyed by the Panel.

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* Two other agencies, the Food and Drug Administration and the Health Resources Administration, reported receiving no requests which met the conditions stipulated in the mandate.

The Panel described the interests represented by those who had made requests for research information as follows:

> The 76 respondents to the Panel's questionnaire represented interests that could be classified into six identifiable groups: private citizens (10 respondents), commercial and nonprofit research and development organizations (33 respondents), academic institutions (21 respondents), public interest groups and the press (9 respondents), professional associations (2 respondents), and federal agencies (3 respondents). (Two individuals returned the questionnaire unanswered.)

Respondents were asked to state the purposes for which the disclosed information was used. The Panel found eight types of requesters. Seven requesters wanted to examine winning contract proposals; 19 respondents sought information to improve their own applications or proposals; 14 requests were part of attempts to learn of other research in particular fields; five requests were concerned with avoiding duplication of research efforts; 10 requests were seeking collection of material for publication; three requests were concerned with research involving human or animal subjects; two requesters were interested in patent and license applications; and 10 requests were for other, miscellaneous purposes.

From this survey data the Panel drew two conclusions -- first, that the data "confirm the validity of congressional concerns about proprietary rights and about the effect of disclosure on the peer review system," and second, that the "results indicated only slight interest in use of the provisions of the Freedom of Information Act for assuring the protection of human subjects or for monitoring consent procedures; only three of the seventy-six replies concerned human subjects."

The data, however, are consonant with a different set of conclusions -- first, that there is a legitimate public interest served by applying the Freedom of Information Act to the type of research information under consideration, and second, that the Freedom of Information Act has been used by people with serious concerns for protection of human subjects as a method of monitoring the activities of federal agencies providing major support for biomedical and behavioral research.

The survey does not show whether proprietary interests or the peer review system have in fact been harmed by the application of the Freedom of Information Act to materials contained in research proposals. Evidence of such harms could not reasonably be expected in a survey of persons who have made FOIA requests for research proposals, because such persons have little or no direct knowledge of the effects of disclosure on investigators or the peer review system. Furthermore, during the period in which the requests were made, the Freedom of Information Act's Exemption (4), which covers patentable material, was being applied with care so that patent rights would not be jeopardized by disclosure. In sum, there is little to support the Panel's conclusion that the survey "validates congressional concerns about proprietary rights and ... the peer review system." The purposes offered by individuals who responded to the questionnaire can be viewed as consistent with the purpose of, and the public policy goals represented by, the Freedom of Information Act.

The Panel's conclusion that there has been only slight interest in the use of the Freedom of Information Act to assure that human subjects

are protected, since "only three of seventy-six replies concerned human subjects," is in large measure an artifact of the presentation of the data in terms of numbers of requesters. Of equal relevance (or lack of relevance) is the number or proportion of proposals requested by persons concerned with issues of protection of human subjects. From that standpoint, the intention to protect human subjects can be said to have been an important purpose for use of the Freedom of Information Act; of the 586 proposals sought by the 124 requesters during the period, more than one-third were requested by the Children's Defense Fund in connection with a specific study of the adequacy of protection of children who are subjects in federally funded biomedical research. Little evidence is available to show the degree to which information disclosed under FOIA has contributed to the actual protection of human subjects.

In summary, the data from the survey of persons who have requested research information under the FOIA shed little light on the issues of patent rights, proprietary interests, and the integrity of the peer review process. Requests for research information under the FOIA reflect several different purposes, including protection of human subjects. While the primary locus of the existing system of protection of human subjects is at the local level and such FOIA requests may add only minimally to the protection provided by this system, the FOIA does provide a way for concerned members of the public to obtain information about federally supported research. Public confidence and trust in the research enterprise may be enhanced by this use of the FOIA.

## Chapter IV. Comments Solicited by Commission

To further the investigation and assure that interested parties had an opportunity to present their views to the Commission, a solicitation of written statements was published in the Federal Register (42 Fed. Reg. 56239 (Dec. 27, 1976)) and distributed to over 36,000 individuals listed on certain NIH and ADAMHA rolls, and public interest groups. The announcement elicited approximately 240 responses, virtually all of which (98%) were from persons associated with research institutions or societies. These responses consisted of 11 from officials of national scientific, medical and academic societies; 190 from private individuals (excluding co-signers); and 33 from federal officials or employees.

The solicitation invited comments on several issues. One issue concerned reasons for protecting confidentiality (protection of the investigator's stock-in-trade and of patent and proprietary interests, the integrity of peer review systems, and premature disclosure of preliminary clinical trial data) and reasons for disclosure (protection of human subjects and open government). Another issue was the feasibility of separating out the basic idea of an application or proposal for the purpose of exempting it from disclosure for a period of time. The last issue concerned the possibility of predicting which categories of applications or proposals have potential patent implications. Although the announcement did not specifically request comments on the opening of peer review meetings during review of applications, a number of respondents did address themselves to this issue.

The large number of very thoughtful and detailed responses indicates that the issues at stake in the disclosure of research information are of great concern to a substantial number of people. Copies of all materials received were distributed to the members of the Commission, and the concerns expressed therein were reflected in the Commission's deliberations. While it is not possible within the confines of this report to review all of the points brought to the Commission's attention in these letters and to acknowledge separately the time and effort of persons whose views enriched the Commission's deliberations, the summary presented in this section is intended to convey a sense of the concerns expressed.

All of the national society officials and 77 individuals (41%) stressed the interest in protecting the investigator's ideas, or stock-in-trade. Protection of applications from disclosure was thought necessary to diminish the opportunities for plagiarism, especially by large laboratories. For example, AAMC, the American Heart Association, and the Board of Scientific Affairs of the American Psychological Association (APA) were particularly concerned with the potential for plagiarism of the ideas of young investigators, with APA arguing that because "particular techniques or theoretical viewpoints will not be recognized as uniquely theirs, or growing logically out of their earlier work," it would be difficult to prove plagiarism. Dr. Philip Handler (National Academy of Sciences), Mr. Ray Woodrow (Society of University Patent Administrators) and Dean D.C. Spriestersbach (University of Iowa) argued that disclosure of unfunded applications might be an unconstitutional

taking of property for public use without just compensation. Two respondents also alleged that they had hearsay evidence of plagiarism which resulted from use of the FOIA.

Six national society officials and 49 individuals (26%) expressed concern over the effect of disclosure on the integrity of the peer review system as a mechanism for promoting high quality research. The threat of disclosure was argued to have an effect on the amount of detail provided in applications, thereby complicating the task of IRGs in reviewing for scientific merit. For example, Dr. Henry C. Pitot (University of Wisconsin) predicted that applications will devolve into requests for support of obvious experiments confirming or slightly extending previous work. In a similar vein, Dr. Stanley M. Parsons (University of California, Santa Barbara) contended that the threat of disclosure would have a chilling effect on the diversity of research ideas because the "thinking of less original but competent workers would center on published ideas before they were shown to have special merit."

There appeared to be a difference in opinion as to the effect that less-detailed applications would have on the distribution of funds. Dr. Edward Reich (Rockefeller University) thought that standards of review might be lowered, and a tendency to "spread the available funds around" might arise. On the other hand, Dr. S. Robert Snodgrass (Harvard) was concerned that increased reliance by reviewers upon personal qualifications, rather than scientific merits, might lead to "elite" schools acquiring a disproportionate sum of research funds. Several other possible

effects were noted. President Edward J. Boling (University of Tennessee), Dr. R. L. Harrington (Permanente Group, San Jose) and Messrs. Clive Liston and Neils Reimers (Stanford) all indicated concern that responses to FOIA requests could increase institutions' costs of complying with federal regulations in the administration and performance of research. Dr. Carl G. Becker (New York Hospital - Cornell) noted the increasing difficulty that medical school faculties have in recruiting young physicians into research careers, and argued that the situation will worsen if the fear of plagiarism is increased through the use of the FOIA. Drs. Lowell A. Goldsmith (Duke) and Ernest B. Hook (New York Department of Health) suggested that the threat of indiscriminate disclosure might lead investigators to introduce untested procedures into clinical practice, thereby evading all the usual reviews for protecting research subjects. Dr. John P. Flynn (Yale) indicated that investigators may resort to submitting applications for research already done, so that publication can occur quickly after approval.

The next most cited reason for preserving confidentiality of research information was the desire to protect patent and other proprietary interests. Six national society officials and 31 individuals (16%) mentioned the need to facilitate the transfer of technology from the "bench" to the needy health consumer by preserving marketable rights. However, President Boling submitted a statement, by Drs. Carl Thomas and Charles Brown (University of Tennessee), that minimized the patent issue. The statement argued that if an investigator has a potentially patentable concept and desires to perfect rights, it is unlikely federal funding will be sought in many instances because of the uncertainty in determining whether the government will seek to

retain the patent rights. Dr. Jonathan A. King (MIT), in a similar vein, noted that "taxpayers do not support research to provide for private gain." Drs. B. Raymond Fink (University of Washington), Charles L. Fox (Columbia) and C. Chester Stock (Sloan-Kettering Institute) all implied that most patentable interests will materialize by the time preliminary animal trials have been performed. Several other commenters thought that the patent issue was extraneous to the disclosure problem.

Seven of the national society officials and 27 individual respondents (14%) emphasized the need to protect the public from the premature disclosure of research information, especially preliminary clinical trial data. Dean Byron Backlar (University of California, Los Angeles) pointed out that applications may be written in an optimistic tone regarding the outlook for success, and thus may be misinterpreted by the layperson. It was argued that premature disclosure would lead to pressures upon health professionals to utilize untested therapies incautiously. A few respondents disagreed with the solution of nondisclosure, however; Drs. Martin J. Kushmerick (Harvard) and Donald E. Mackenzie (Marquette) argued that a more appropriate way to avoid deleterious effects would be to encourage mature and critical reporting by the scientific news media.

Professor Robert Wyer (University of Illinois, Urbana-Champaign) stated his concern for the privacy of the investigator by drawing an analogy between the submission of proposals to DHEW and the submission of manuscripts for publication. He concluded that the author of a research proposal should retain control of his or her work until it is

funded by the public treasury, just as the author of a rejected manuscript retains the right to submit it to another journal.

Few of the responding investigators found protection of human subjects to be a significant reason for disclosure. Most respondents did not think human subjects would receive significant additional protection from disclosure and random monitoring, and argued that existing mechanisms for review of consent and risk are sufficient. Some respondents stated that the interest in public disclosure as a means of protecting human subjects was misplaced. Dean J. R. Sokatch (University of Oklahoma) contended that the greatest threats to human subjects are presented by unfunded studies or in institutions that are too small to have a properly functioning IRB. Dr. Frederick C. Battaglia (University of Colorado) suggested that the Commission could achieve more protection if it considered improving review mechanisms for nonfederally funded research; Dr. Irving I. Kessler (Johns Hopkins) made a similar recommendation with respect to improving supervision of research. Dr. Donald L. Klein (New York Department of Mental Hygiene) thought that public input would make more sense in the selection of peer reviewers than in the random monitoring for abuses.

Open government was mentioned infrequently by the responding investigators as a reason for disclosure, and was not valued highly in this context. It was felt that a general policy of disclosure in order to promote public awareness need not dictate that all governmental processes be opened to public review. On the other hand, Dr. King maintained that it will be difficult to have public input over the direction of science policy if proposals are not disclosed prior to the initiation of research projects.

A few writers addressed the issue of exchange of scientific ideas. Dr. William A. Douglass (University of Nevada, Reno) stated that disclosure after funding would be helpful to investigators who needed to be aware of similar research in progress, and would also provide investigators, particularly young and minority scholars, with examples of well-structured and successful applications. Dr. R. I. Leininger (Battelle) also stressed the value of stimulation by disclosure, noting that studies of biomedical advances had found the presence of multiple parallel efforts to be an accelerating factor. On the other hand, Dr. Kushmerick pointed out the danger that well-organized imitators ("data factories") will spend lots of time and money testing ideas, with little comprehension of theories and methods. Drs. Robert A. Gordon (Johns Hopkins) and Barbara H. Starfield (Johns Hopkins) argued that "enforced idea-sharing" will result in shoddy duplication by persons with limited understanding of the idea, and that this will multiply the task of replication in the traditional sense, because conflicting data from apparently the same design are bound to appear.

Responses were also analyzed to determine satisfaction with the present state of the law and whether more or less disclosure was desired. The present state of the law was presumed to be that funded applications or proposals as well as progress reports are disclosed in their entirety, with the exception of materials covered by Exemption (4) (trade secrets) or (6) (invasion of privacy), and that unfunded applications are exempt from disclosure (the current DHEW interpretation).

Each of the national society officials suggested that more protection for the ideas of investigators be afforded than is currently pro-

vided by law. Nearly all stated that the existing mechanisms for protecting human subjects offer adequate protection, and that improvements, if needed, should focus on the existing system rather than attempting to protect subjects through indiscriminate disclosure, at a great cost to the research community. Of the individual responses, 19 (10%) could be construed as indicating acceptance of the present compromise worked out in the law. Three respondents desired more disclosure, while five would be satisfied with delayed disclosure of unsuccessful applications. The largest group of respondents, however, was composed of the 118 (62%) who could be interpreted as desiring more protection for applications and proposals than is currently afforded by the law. About one-fourth of this group suggested that the publication of abstracts of funded applications in the Smithsonian Scientific Information Exchange is sufficient disclosure. About one-fifth recommended postponement of disclosure of the entire application (for periods ranging from one to six years after funding). Leaving the decision on disclosure in the hands of the investigator (e.g., by allowing release of all or portions of the application at his or her discretion, or awaiting publication of results or the final report) was mentioned by about one in eight members of this group.

Some examples of proposed solutions to the problem follow. The American Heart Association recommended that preliminary clinical trial data be exempt from disclosure and funded applications be exempt for a fixed period of time or until funding ceases. The American Nurses' Association, Inc., the American Psychological Association, the Inter-

Society Council for Biology and Medicine (ISCBM), Dr. C. D. Cox (American Society for Microbiology) and Dr. Handler all suggested that the publication of abstracts of funded applications be considered sufficient disclosure until funding ceases or results are published. The APA proposed that the IRB or IRG determine the sufficiency of the content of the abstract.

ISCBM, pointing to the precedent set by Congress in the 1975 amendment (P.L. 94-187, § 312) of section 17 of the Federal Nonnuclear Energy Research and Development Act of 1974 (42 USC § 5901), recommended that the Public Health Service Act be amended to grant the Secretary of DHEW similar discretionary authority to exempt from disclosure (pursuant to FOIA Exemption (3)) technical and proprietary information without regard to the judicial interpretations of Exemption (4). (Subsequent to the vesting of this authority in the Administrator of ERDA, however, section 5(b) of the Sunshine Act amended FOIA Exemption (3) so that an exemption afforded by another statute (e.g., PHSA) is valid only if such statute "(A) requires that the matters be withheld from the public in such a manner as to leave no discretion on the issues or (B) establishes particular criteria for withholding or refers to particular types of matters to be withheld.")

Individual respondents also proposed various solutions that differed from those of the national societies and NIH. For example, Mr. R. K. Dismukes (Institute for Society, Ethics, and the Life Sciences) suggested that misuse of disclosed information might be prevented by precluding

requesters from obtaining patents in areas in which they have made requests, and Dr. Thomas W. Conway (University of Iowa) proposed that the federal government should represent any individual in patent litigation whose rights have been infringed through FOIA disclosure. Ms. Ann H. Greenberg and Mr. Victor Medina (New York University) and Dr. B. Connor Johnson (University of Oklahoma) suggested the creation of public representatives to participate in the peer review system as an alternative to indiscriminate disclosure.

Drs. Nazir Ahmad (University of Southern California) and Ronald Breslow (Columbia) each urged the Commission to focus on the level of disclosure needed for protocols which involve human subjects and, conversely, to recommend protecting from disclosure all research that does not involve human subjects. Dr. Samuel Charache (Johns Hopkins) would include proposals containing a potential hazard to public health in the category of proposals that merit special disclosure requirements. Professor Wyer added that whatever disclosure policies are adopted should be stated explicitly in the instructions given to the applicant, and that in cases of partial funding, only those portions of the application which are funded should be disclosable.

With respect to the proposal that the basic idea might be separated from the remainder of an application for the purpose of exempting it from disclosure for a period of time, four of the national society officials viewed such a process as unfeasible; only one official supported this proposal. Twenty-three individual respondents expressed the view that

it is not possible to separate the basic idea, because it often permeates an entire application. Dr. Dennis M. Maloney (Boys Town, Nebraska) and others pointed out that the primary aim of some research protocols is the development of new procedures, not the proof of a new idea. A few respondents thought it would be futile to separate the basic idea and release the rest in order to protect subjects, because adequate risk/benefit assessment requires knowledge of the basic idea and purpose. Nine respondents thought that separation would be possible but too time consuming; only one writer perceived separation as a reasonable approach.

NACUBO, ISCBM and 39 individual respondents argued that it is not possible to identify categories of applications that have potential patent implications. A common argument was that many discoveries have been stumbled upon accidentally in the course of research projects, often because the discoveries were tangential to the primary research designs. Ten respondents did think it reasonable to identify a few categories of applications that have patent potential, mostly projects involving drug and device testing.

Some respondents also addressed the issue of whether the balance of interests should be struck differently in human and nonhuman research. Thirteen respondents found the interest in protecting human subjects of clinical trials significant enough to require more disclosure of clinical protocols, while 23 respondents appeared to find the stock-in-trade interest weighty enough to favor equal treatment of all applications, whether or not human subjects are involved. Dean Backlar argued that

it "may be impossible or even artificial to separate clinical from non-clinical research, [and] the latter from the clinical application of basic research," particularly during the formative period of a project.

Of the respondents employed by the federal government, twenty-six were officials of DHEW, while six were officials of the Veterans Administration. Five of the six VA respondents addressed the FOIA issue and indicated a need for more protection of applications from disclosure, as did one respondent from the Department of Agriculture. Twenty-two of the 26 responses submitted by DHEW personnel focused on the opening of advisory committee meetings. Twenty of these responses were from executive secretaries of study sections. Eighteen of the 20 executive secretaries, and both of the other officials, opposed the opening of meetings. They emphasized the need for full and frank discussion and described the dangers to efficient peer review if confidentiality is compromised (these arguments were summarized by Drs. S. Stephen Schiaffino and Ann A. Kaufman). One executive secretary stated that the case for closing advisory council meetings is not as strong as that for closing IRG meetings.

Of those who do not oppose opening of meetings, one argued that even if a reduction in frank discussion did occur, this would be only a short-term effect, and new procedures for insuring high quality review and adequate protection of the rights of all parties would soon evolve. The second respondent noted that part of a scientist's training is learning to criticize and accept criticism from colleagues, and to separate criticism of ideas from criticism of one's person. It was also contended that public observation would lead to greater appreciation of the complexity of the review process.

# Chapter V. Deliberations and Recommendations

The mandate to the Commission was to investigate and study the implications of public disclosure under the Freedom of Information Act (FOIA) of information contained in research protocols, hypotheses and designs submitted to the Secretary of Health, Education, and Welfare, in connection with applications or proposals for grants, fellowships or contracts under the Public Health Service Act. Specifically, the Commission was directed to consider the effects of such disclosure on proprietary interests and patent rights, the ability of the peer review system to insure high quality federally funded research, protection against unreasonable risk to human subjects, and the adequacy of informed consent procedures. Since the Washington Research Project case was decided in 1975, research protocols have been disclosable at the time of funding, with the exceptions provided under the FOIA to protect patentable ideas and proprietary interests. Some have argued for disclosure at an earlier point, during the review process; others have argued for exemption from disclosure even after funding. In formulating its recommendations, the Commission considered the arguments presented, along with the limited amount of available data regarding the number and nature of past requests for research proposals and the effects of disclosure of the requested information.

The Commission's deliberations on disclosure of research information focused primarily on the possible effects of such disclosure on the protection of human subjects. The broader applicability of the rationale underlying the recommendations that the Commission might make with respect

solely to research involving human subjects became apparent, however. Accordingly, the Commission's recommendations are not limited to research involving human subjects, although at places particular attention is paid to the subject protection issue.

In one respect the Commission broadened its inquiry and recommendations beyond the areas specifically mentioned in the legislative mandate. The implications of the Government in the Sunshine Act (P.L. 94-409) for the disclosure of research information and the ability of the peer review system to insure high quality federally funded research were considered, and the Commission has made recommendations in this area.

Some issues under consideration may be resolved by administrative action, and the Commission has accordingly made certain recommendations to the Secretary of Health, Education, and Welfare.

The arguments presented to the Commission regarding disclosure of research information may be summarized as follows. Arguments for full and prompt disclosure include appeals to the protection of human subjects, the enhancement of public trust, open government, and free exchange of scientific ideas. Arguments for limiting or delaying disclosure appeal to protection of the investigator's stock-in-trade, protection of patent and other proprietary interests, protection of the privacy of the investigator, preservation of the integrity of the peer review system, and prevention of harm to the public from premature disclosure of research hypotheses and preliminary data. As is often the

case, there are merits to both sides, and the Commission's task was to determine the proper balance among competing claims.

For the reasons set forth below, the Commission has concluded that the present DHEW policy of conducting peer review in closed session and disclosing research information only after funding strikes the proper balance between the need for critical and comprehensive review of proposed research, the protection of investigator's privacy and stock-in-trade, the public's right to know, and the protection of human subjects. The Commission has further concluded that this policy should apply to renewal and supplemental grant applications and to modification and renewal contract proposals, as well as to initial applications and proposals. To assist in the public review of funded research involving human subjects, the Commission has determined that informed consent statements should be made available along with the funded research protocols. Finally, acknowledging the paucity of data on the actual effects of relatively recent changes in disclosability of research information, the Commission has concluded that the Secretary of Health, Education, and Welfare should continue to monitor and study the effects of disclosure practices and report his findings to Congress within three years.

The Commission is sensitive to the concern of some members of the public regarding risks of research involving human subjects and the adequacy of consent procedures. The Commission believes that the public is entitled to information that would either substantiate or allay those concerns. In addition, it believes that if an error in the review pro-

cess does occur, public disclosure at the time of funding might identify the error and permit corrective action, including termination of the research. Even if such public monitoring is on a random basis and does not generally disclose errors, the possibility itself of public disclosure may serve to increase awareness of public accountability on the part of investigators and reviewers alike. The Commission believes that the public's interest in insuring the protection of human subjects comes into play at the point at which an investigator leaves the stage of negotiation and review of proposals and moves into the stage of potential interaction with such subjects.

Without doubt, public trust would be enhanced by openness on the part of the research community, evidenced by disclosure of research protocols. Because public concern has focused primarily, and logically, on research that is being or will be conducted, this concern can be addressed by releasing protocols, upon request, after funding. Little would be gained by disclosing proposals that are not approved or funded, and are therefore unlikely to be carried out.

The Commission emphasizes that the primary mechanism for assuring the protection of human subjects is the local review conduct by Institutional Review Boards (IRBs), and it believes that public disclosure of research protocols at the time of funding will have at most a minimal effect on such protection. Furthermore, informed consent forms are only one aspect of the interactive process for obtaining informed consent, and the disclosure of such forms (recommended by the Commission) will merely

provide an additional window on the system but will do little to insure the adequacy of the informed consent procedures. (The Commission will make recommendations regarding the IRB review process in a subsequent report, following completion of its review and analysis of the present system.) The Commission does not consider public disclosure of funded grants and awarded contracts or of consent forms to be a substitute for adequate IRB review mechanisms; it does believe, however, that disclosure may enhance the public's trust in the activities of the government and the research community.

It has been suggested that disclosure of research information would also enhance the exchange of scientific ideas and thus serve to reduce duplication of efforts and possible unnecessary exposure of research subjects to risk. To the extent that this argument has merit, the need is met by disclosing research information at the time of funding, as is now the rule. Little would be gained in this regard by disclosure during the review process.

All of the arguments in favor of full disclosure thus far appear to be met by the current practice of disclosing research information after funding. There is one argument, however, for which this does not hold; that is the appeal to open government and the suggestion that the public must have access to the operations of the review process in order to "keep it honest," e.g., to determine whether awards are made according to valid and relevant criteria. The Commission recognizes a legitimate

concern here, but suggests that alternative mechanisms for assessing the performance of the peer review system, rather than imposition of disclosure requirements, be explored.

Of all the arguments for limiting disclosure of research information, the most frequently expressed has been protection of the investigators' stock-in-trade. The Commission recognizes that while investigators at nonprofit institutions do not usually have proprietary interests (as that term has been construed by the courts) in applications or proposals, investigators do have a valid interest in protecting the ideas and methods uniquely their own and developed in pursuit of their profession. It is difficult to assess the validity of the concern of some investigators that their ideas may be plagiarized before they can bring them to fruition; insufficient time has elapsed since the Washington Research Project decision for such effects to become evident. Nevertheless, the possibility cannot be denied. Furthermore, the investigators' ownership of their research proposals and the need to protect that ownership should be recognized as a simple matter of fairness.

On the other hand, investigators who receive public funds in support of their research must be willing to compromise their individual interests at some point to meet legitimate public interests. In weighing the claims of the research community on this issue, the Commission believes that investigators' research ideas should be protected during the review process, especially since not all applications are approved, and not all approved applications are funded. To this extent, the situation is analogous to

an author's submission of a manuscript for publication or a competitive proposal for a contract. If an application does not receive an affirmative response, the applicant should be able to try to develop the ideas elsewhere or by other means. The ideas contained in research proposals should not be given to the public as a consequence merely of applying for funding. As stated earlier, however, the investigator's interest in protecting research ideas is less persuasive after a decision has been made to support that research with public funds. At this point, the protection of research ideas should yield to the public's right to know and the interest in protecting human subjects.

If patentable ideas are involved in a research project, however, they should be protected for the benefit of the public at large as well as the investigator. In this regard, the Commission agrees with current DHEW policy of reviewing protocols that have been requested under the FOIA and deleting material the disclosure of which would adversely affect future patent or other valuable commercial rights. The Commission urges, however, that only information that directly involves patentable ideas be deleted, and that as much of the protocol as can be revealed without jeopardizing patent rights be disclosed. The Commission realizes that the possibility remains that patent rights may be lost because of the investigator's or DHEW's inability to identify patent potentiality. However, no evidence has been presented to the Commission that an investigator has lost patent rights by application of the FOIA because of such inability to identify patentable material in a protocol. This may be due to the insufficient time that has elapsed since the Washington Research

Project case for such loss of patent rights to become evident. In any event, the Commission believes this to be a narrow problem area that is adequately being handled under the present policy of disclosure after funding and review for patentable information.

Suggestions that the peer review process be opened to the public are opposed by the arguments that the investigators' privacy (as well as stock-in-trade) must be protected, and that the integrity of the peer review system must be preserved. To the extent that the materials discussed at peer review meetings are the proposed research ideas, the previously discussed stock-in-trade argument applies. Beyond this argument, however, the Commission has concluded that both the privacy of investigators and the ability of the review system to insure high quality research require that peer review meetings be closed. Matters discussed during the process of review, which in some aspects is analogous to consideration of personnel actions, include the competence, reputation and promise of investigators and supporting personnel, their salaries, and the reputations of their institutions. In order to encourage full and frank discussion of such matters, as well as sharp criticism of research proposals, the Commission believes that peer review meetings should be conducted in closed session. Aside from protection of investigators' privacy, the public as well as potential research subjects benefit from the fostering of high quality research through strenuous review.

The Commission notes that some have suggested that the possibility of disclosure of protocols even after funding will adversely affect the

peer review process by resulting in the submission of less detailed proposals. Neither the Panel's survey of executive secretaries of initial review groups nor the more recent communications by the executive secretaries to the Commission, however, have provided data suggesting such a result. The Commission doubts that this will be a serious problem, because most investigators would not want to jeopardize their chances of receiving federal funds by submitting proposals of lower quality.

Finally, it has been suggested that disclosure of research information after funding would harm the public by creating misunderstandings and unrealistic hopes for cures based upon preliminary findings. The Commission is not persuaded that this possibility represents a sufficient threat to outweigh the public's right to know, and notes that reported instances of distorted interpretation of hypotheses and data appear to be generally attributable to material released to the press by investigators, on their own initiative.

The Commission suggests a modification in the current policy of disclosure of pending or unsuccessful renewal and supplemental grant applications and modification and renewal contract proposals. The policy of releasing such information, while withholding information on initial grant and contract proposals until funding, has resulted from a DHEW interpretation of the Washington Research Project case. The court, however, had before it only funded applications and gave no legal argument for treating competitive applications and proposals incident to funded applications and awarded proposals differently from initial applications and proposals.

Competitive renewal and supplemental grant applications and proposals may also contain new ideas and data and are given equal scrutiny in the peer review system. Accordingly, competitive applications and proposals should be kept confidential until funded.

The Commission also notes that consent forms are not uniformly required to be submitted to DHEW. The availability of consent forms associated with funded research would reinforce public trust in the research enterprise. Accordingly, consent forms to be utilized in DHEW funded research should be disclosable upon funding of the underlying protocols.

Finally, the Commission notes that there is little information available concerning the effects of disclosure under the current system, because only two years have elapsed since the decision of the Washington Research Project case. It further notes that Congress has indicated a willingness to review any evidence of plagiarism resulting from operation of the FOIA and to take appropriate action. The Commission suggests therefore that the Secretary of Health, Education, and Welfare conduct an ongoing study of the effects of public disclosure on all phases of the review of research proposals and on the protection of human subjects, in order to gather data that are currently lacking. A report of the findings of such a study should be submitted to the Congress when any such effects become clearly recognizable and, in any event, within three years.

## Recommendations

The Commission recommends to Congress that appropriate legislation be enacted to insure that (A) INITIAL, RENEWAL AND SUPPLEMENTAL GRANT APPLICATIONS AND INITIAL, MODIFICATION AND RENEWAL CONTRACT PROPOSALS UNDER THE PUBLIC HEALTH SERVICE ACT ARE DISCLOSABLE WHEN FUNDS HAVE BEEN AWARDED, SUBJECT TO EXISTING STATUTORY EXEMPTIONS AND REVIEW FOR PATENTABLE MATERIAL; (B) SUCH APPLICATIONS AND PROPOSALS ARE NOT DISCLOSABLE PRIOR TO THE AWARD OF FUNDS UNLESS THE INVESTIGATOR AND THE CONTRACTOR OR GRANTEE HAVE CONSENTED; AND (C) INITIAL REVIEW GROUP AND ADVISORY COUNCIL MEETINGS ARE CLOSABLE WHEN SUCH APPLICATIONS AND PROPOSALS ARE REVIEWED.

Comment: Present DHEW practice is to disclose, upon request, funded initial grant applications and contract proposals, after review for statutory exemptions from FOIA, and to conduct peer review in closed session. Renewal and supplemental grant applications and modification and renewal contract proposals are treated as disclosable prior to funding. None of these practices has been clearly affirmed, either judicially or by legislation. The Commission is accordingly recommending that appropriate legislation be enacted to insure continuance of the present practices with respect to initial grant applications and contract proposals, and the closing of peer review meetings. With respect to renewal and supplemental grant applications and modification and renewal contract proposals, the Commission has concluded that they should be treated in the same manner as initial applications and proposals, and is accordingly recommending that appropriate legislation be enacted to provide a clear legal justification for such treatment.

The Commission recommends to the Secretary of Health, Education, and Welfare that appropriate administrative action be taken to insure that (A) THE CONSENT FORMS TO BE USED IN RESEARCH INVOLVING HUMAN SUBJECTS ARE DISCLOSABLE WHEN FUNDS FOR SUCH RESEARCH HAVE BEEN AWARDED; AND (B) AN ONGOING STUDY OF THE EFFECTS OF DISCLOSURE OF FUNDED RESEARCH ON THE PEER REVIEW PROCESS AND THE PROTECTION OF HUMAN SUBJECTS BE CONDUCTED, AND A REPORT OF THE FINDINGS OF SUCH STUDY BE SUBMITTED TO CONGRESS WITHIN THREE YEARS.

# Philip Handler on recombinant DNA research

*In his annual report to the National Academy of Sciences, NAS president Philip Handler discusses, among other things, research with recombinant DNA. He says that with the greatest reluctance he has come to the conclusion that federal legislation to put some controls on such research is inevitable and perhaps desirable. But he goes on:*

I am reluctant for two reasons.

First, I view with great alarm the prospect of any law that would authorize government officials to determine what subject matter it is permissible to investigate as well as the manner in which such research is to be conducted. It would be a first step along a dimly perceived trail concerning which we can be certain only that each step will facilitate the next. As a minimum, one can foresee constraints that will swathe research with bureaucratic complexities, will increase costs, will extend the time required for the gathering of information, and generally frustrate a career in research. If pursued yet farther, science could be shattered.

Second, it is profoundly ironic that this extraordinarily serious step should be taken in order to avoid hazards which, as best I can ascertain, exist largely in the imaginations of a very small group of scientists. Let me explain. Gene exchange among microorganisms and viruses undoubtedly occurs spontaneously on a vast scale in nature. Incorporation of eukaryotic genes into bacteria must be much less frequent but there is highly suggestive evidence that it does occur. Yet appearance of a new pathogen is extraordinarily rare. Thousands of clinicians and microbiologists have daily contact with the virulent pathogens responsible for the classical infectious diseases. They are seldom infected themselves and no epidemic has been known to start in this way. Moreover, it seems inconceivable that a successful pathogen can be created by the insertion of only one or two genes into an innocuous organism. Yet that is what such experiments entail. To be sure, no absolute guarantee can be offered. Nevertheless, those who have inflamed the public imagination by their rhetoric have raised fears that rest on no factual basis but their own science fiction.

The NIH guidelines already govern the conduct of research by all those whose work is supported by federal funds. The purpose of federal legislation, then, is to give those guidelines the force of law and extend that force to laboratories whose work is not supported by federal funds. But the principal reasons that many scientists acquiesce to passage of such legislation are (1) to terminate the feckless debate which has offered outlets for anti-intellectualism and opportunity for political misbehavior while making dreadful inroads on the energies of the most productive scientists in the field, and (2) to assure that no state or local government will adopt yet more stringent legislation or, indeed, ban such research entirely. But those outcomes are not yet assured.

The bills directed at regulation of research with recombinant DNA that have been placed in the Senate hopper seem better designed to prevent the conduct of such research than to promote its progress while also protecting the public health. One must continually remind oneself that [the] subject [of these bills] is not some monstrous ugliness but, rather, the conduct of elegant and extraordinarily productive research.

Moreover, by the terms of [several of the] bills, the federal government would deliberately forgo its right to pre-empt regulation in this field. Instead, they convey to state and local authorities the right to consider and implement yet more restrictive regulation, thereby inviting an endless series of episodes such as that which occurred in Cambridge, and with their outcome uncertain. I am unaware of the reasons for this position but I sincerely trust that if there is any legislation in this area, Congress will have the federal government exercise its right of pre-emption.

However the specifics may turn out, our successors will rue the day this legislation was passed. □