DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

OFFICE OF THE SECRETARY

WASHINGTON, D.C. 20201

July 8, 1976

OFFICE OF THE
GENERAL COUNSEL

TO: Holders of HEW Institutional Patent Agreements and Members of the Society of University Patent Administrators

SUBJECT: Information Item No. 43

Attached herewith is a report by the President's Biomedical Research Panel recommending to Congress that the Public Health Service Act be amended to provide adequate protection for intellectual property rights of investigators in their research proposals submitted to PHS, either prior to funding or after funding. As you will note, the Panel took strong notice of the relationship between successful technology transfer and the ability of investigators and their organizations to protect intellectual property rights.

Sincerely yours,

Norman J. Latker
Patent Counsel

Enclosure

Report of the
President's
Biomedical
Research Panel

DISCLOSURE OF RESEARCH INFORMATION

Report of the
President's
Biomedical
Research Panel

DISCLOSURE OF RESEARCH INFORMATION

submitted to the

Committee on Interstate and Foreign Commerce
of the House of Representatives

and the

Committee on Labor and Public Welfare
of the Senate

pursuant to

Title III of Public Law 94-278

June 30, 1976

U.S. DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
Public Health Service
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adequacy of informed consent procedures. The Panel was instructed to complete the investigation by May 31, 1976, and to submit its report by June 30, 1976, to the Committee on Interstate and Foreign Commerce of the House of Representatives and the Committee on Labor and Public Welfare of the Senate.

The Panel's investigation and study employed several methods in fulfilling its legislative charge. The Panel examined records of requests for disclosure of information as provided by the Secretary of Health, Education, and Welfare. These records of requests were supplemented by direct inquiry by means of a questionnaire (Appendix B) mailed to each individual or organization that had made such requests of the Secretary. The Panel also sought advice and testimony from the government officials most directly concerned with the disclosure of research information, as defined in Title III of Public Law 94-278, as well as from experts outside of government. This report of the Panel is based on the findings of this investigation.

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RECOMMENDATIONS AND CONCLUSIONS

The Panel's mandate under Public Law 93-352 called for review and assessment of biomedical and behavioral research supported by the National Institutes of Health and the Alcohol, Drug Abuse, and Mental Health Administration. The Panel's recommendations in its Report[1] to the President and the Congress outlined steps that should be taken to strengthen and improve the biomedical and behavioral research efforts of those agencies.

Several of the recommendations addressed specific issues regarding the effect of the Freedom of Information Act of 1967 (and as amended in 1974), the Federal Advisory Committee Act, and the Privacy Act of 1974, popularly known, as a group, as the "sunshine laws," and the recommendations are cited here because of their relevance to the present report.

> **The Panel recommends that the Public Health Service Act be amended to provide statutory assurance that the initial review for scientific and technical merit ("peer review") remain totally confidential.**
>
> **The Public Health Service Act also should be amended to provide a statutory exemption from disclosure in accordance with exemption (3) of the Freedom of Information Act for research designs and protocols contained in grant applications and contract proposals until the grant or contract funds have been received by the grantee institution or contractor. Unfunded grant applications and contract proposals should remain confidential.**
>
> **In the case of grant applications and contract proposals that contain clinical protocols, there must be a period of thirty days for public review of clinical protocols before research is commenced.**
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> **The Public Health Service Act should be amended to provide protection from premature disclosure of data that are (1) part of a larger data set and can only be reviewed within the greater context; (2) data that are incomplete, such as interim reports of clinical trials; and (3) data obtained by federally employed investigators and scientists, either as part of their own research or obtained in conjunction with nonfederal scientists, until such time as the study has been published in a professional periodical.**

In this present study and report, pursuant to Title III of Public Law 94-278, the Panel has addressed the issue of the effect of the disclosure to the public of information contained in research protocols, hypotheses, and designs. Specifically, the Panel has inquired as to whether there are aspects of the disclosure of such information that serve to strengthen or to interfere with the biomedical and behavioral research effort in this nation.

The present study provides additional evidence that leads the Panel to recommend further that the Public Health Service Act be amended (1) to provide adequate protection for intellectual property rights of investigators who submit applications or proposals for support of research and of those investigators whose research is supported under the authority of that Act, and (2) to protect the patent rights of discoveries and innovations resulting from research supported by the Department of Health, Education, and Welfare.

The Panel is convinced that an area of vital national interest--the federal biomedical and behavioral research effort and its impact on the health of the nation--is likely to be impaired unless such legislative action is taken. Several findings of the present study support that conviction.

First, on the basis of the number and nature of requests for disclosure of information and the review of responses to the questionnaire, the Panel did not find indication that the opportunity for disclosure of previously protected information has had more than isolated impact on the interest in the protection of human subjects. The exact extent to which proprietary interests and future patent rights may already have been jeopardized by disclosure can only be assessed at a future date, although there is no question that disclosure does infringe upon such rights.

Second, the Panel found that intellectual property rights of researchers whose investigations are federally supported cannot be protected adequately by the federal government under present court rulings. Further, the Panel found clear evidence that the existence of a licensable patent right, which is contingent on protection of intellectual property rights, is a primary factor in the successful transfer of research innovation to industry and the marketplace. In light of the effect of disclosure of research information on intellectual property rights and in light of the importance of such rights to the transfer of research innovations to the delivery of health care, it is clear that the present mechanism of complete "openness" ensures public accountability at the cost of sacrificing protection of intellectual property rights of demonstrable potential benefit to the nation.

Third, the Panel found no evidence that disclosure of information had contributed, or appeared relevant, to improvements in the ability of the peer review system to ensure high-quality federally funded research. The Panel did

find reason to believe that the possibility of uncontrolled disclosure could impair the ability of the peer review system to ensure high quality. The Panel also found from its questionnaire a high proportion of requests to review successful research applications and proposals indicating the potential for derivative and imitative research projects.

Fourth, the Panel's consideration of the relationship of protection of human subjects in research and informed consent procedures to disclosure of information contained in research protocols, hypotheses, and designs led to three conclusions.

- There does not appear to be any direct, necessary, or inherent connection between disclosure of such information and protection of human subjects in research under the present system of federal regulations and review bodies, nor did testimony before the Panel argue for such full disclosure.

- There has been extremely limited interest in using large-scale disclosure of such information as a means of monitoring compliance with standards and regulations of protection, and no documented results of use of such information were presented to the Panel.

- As a consequence, uncontrolled disclosure of research information seems to offer neither compelling grounds nor a convincing record that it serves the aim of protecting human subjects of research. But such disclosure does leave unprotected the intellectual property rights of researchers and, in all probability, jeopardizes the timely transfer of research innovations to the delivery of health care.

REQUESTS FOR DISCLOSURE OF INFORMATION

In order to fulfill its legislative mandate, specifically Section 301(a)(1)(A) and (B) of Public Law 94-278 (Appendix A), the Panel received from the Secretary of Health, Education, and Welfare records of requests for disclosure of information contained in research protocols, hypotheses, and designs in connection with applications and proposals for grants, fellowships, or contracts submitted, during the period January 1, 1975, through December 31, 1975, under the Public Health Service Act.

The agencies of the Department of Health, Education, and Welfare that award grants, fellowships, or contracts under the Public Health Service Act were asked by the Panel to forward records of requests. These agencies included the National Institutes of Health (NIH), the Alcohol, Drug Abuse, and Mental Health Administration (ADAMHA), the Health Services Administration (HSA), the Health Resources Administration (HRA), the Center for Disease Control (CDC), and the Food and Drug Administration (FDA). The Panel requested these agencies to forward records of requests received prior to May 1, 1976.

Number of Requests for Disclosure. The agencies reported a total of 160 requests that met the stipulations of the specified legislative mandate. Inasmuch as several persons had submitted multiple requests either to the same agency or to different agencies, the total number of requestors was only 124. Although most of the requests concerned awards made by the NIH, some requests were also directed to the ADAMHA, the HSA, and the CDC regarding awards made by those agencies. The FDA and the HRA reported no requests that met the stipulations of the legislation. The requests covered a total of 586 separate information items.*

The records of the requests did not always indicate the interests represented by the persons or organizations making the requests. Often, the records did not provide explanation about the purposes for which the information was to be used. The Panel, therefore, sought more complete and current information by inquiring directly of the requestors by means of a brief questionnaire (Appendix B) approved by the Office of Management and Budget.

*Records of four of the requests were not sufficiently detailed to allow determination of the precise number of information items requested.

Responses to the Panel's Questionnaire. Questionnaires were mailed to the 124 persons who had requested information and 76 replies were received--a response rate of 61 percent. 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.)

In relation to Section 301(a)(1)(B) of Title III, the persons to whom questionnaires were sent were asked to state briefly the purposes for which the disclosed information was used. Responses to this question could be classified into eight general categories that indicated the respondents' purposes in requesting information contained in applications and proposals.** These eight general categories are described in the following paragraphs.

1. Examination of Winning Contract Proposals. The seven respondents who wished to examine winning proposals indicated their interest in learning why the winning proposals were selected over their own. Of the seven respondents, six were individuals representing research and development organizations and one was an individual representing an academic institution. (One respondent in this category also provided a second reason, which is included in the next category.)

*Although the records of requests from individuals who did not respond to the questionnaire sometimes contained an indication of the interests represented by the requestors, the indications were not considered to be sufficiently complete or uniform to permit inclusion of nonrespondents in the final classification scheme.

**Of the 76 replies, 71 provided responses that could be used in the Panel's condiderations. The responses included three from federal agencies, which were not included in the compilation but were included in the total number of requests received. In addition, replies were received from requestors who returned the questionnaire and indicated their reasons for not providing the requested information. One, a representative of a public interest group, objected to the questionnaire; the other, who represented a legal firm, declined to answer the questionnaire because the purpose of the original request for information concerned a client involved in litigation.

2. Attempts to Improve Applications or Proposals. By far the largest number of responses were in the category concerned with attempts of investigators to improve their own applications or proposals. Of the nineteen responses in this category, eight were from individuals who represented private research and development organizations and eleven were from academic institutions. In general, the respondents noted that the purpose for which the information was requested was related to their attempts to improve anticipated applications or proposals, or simply to examine a model of a successful application or proposal.

3. Attempts to Learn of Other Research in a Particular Field. Of the fourteen responses classified in the category concerned with attempts to learn of other research in a particular field, eight represented research and development firms, two submitted the request as private citizens, and four were associated with academic institutions. The respondents in this category explained that their initial requests were for purposes of keeping abreast of developments in a field, determining if any new research methods were being employed, and surveying current literature in a particular research area.

4. Attempts to Avoid Duplication of Research Efforts. Five respondents, including three representing private firms and two associated with academic institutions, stated that their purpose in requesting information in applications or proposals was related to their efforts to avoid duplication of research activities.

5. Collection of Material for Publication. The ten respondents who were collecting material for publication indicated that the requested information was needed either to fulfill a contract to prepare an inventory or to publish research reviews or reports. The ten respondents in this category included two representatives of professional associations, three private citizens, four members of private firms, and one individual associated with an academic institution.

6. Examination of Research Involving Human or Animal Subjects. Only three respondents were interested in research involving human subjects. Of these, one was attempting to determine whether the research specified in the request involved identifiable intervention in a child-family relationship, and two, who represented a public interest organization, were attempting to determine the extent to which existing procedures for review of applications and proposals at both the institutional and the federal level were adequate for the protection of child subjects. The fourth respondent in this category was a private citizen who was attempting to determine whether the use of public funds for experimentation with animals could be justified.

7. Interests in Patent and License Applications. The two individuals interested in patent and license applications were representatives of commercial firms; one sought information on the ownership of a patent and the other was interested in a possible license agreement with another firm.

8. Miscellaneous Purposes. The category of miscellaneous purposes included ten respondents: one was attempting to use the rating of the grant application as justification for desired professional advancement; one wished to determine whether a contractor could appropriately use a facility at the respondent's institution; three were representatives of public interest groups interested in determining whether public funds were being spent according to their criteria of appropriateness; two were reporters seeking information for their respective publications; one was from an individual who had brought charges of violation of civil rights; one was an individual who was attempting to determine whether certain grantees were performing within the stated purposes of the grants; and one was a representative of a private firm who was attempting to determine whether that firm's studies could be utilized in other specific studies.

To summarize, the results of the Panel's survey of persons who requested information from applications and proposals confirm the validity of congressional concerns about proprietary rights and about the effect of disclosure on the peer review system. 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.

EFFECT OF DISCLOSURE ON PROPRIETARY INTERESTS AND ON PATENT RIGHTS

In relation to Section 301(a)(1)(C)(i) of Title III regarding the effect of disclosure of information on proprietary interests in a research protocol, hypothesis, or design and on patent rights, the findings of the Panel identify a serious problem. The problem has two primary aspects. The first aspect is the question of whether, under the Freedom of Information Act as interpreted by the courts, there are adequate safeguards for the intellectual property rights of scientific researchers whose investigations receive financial support from the federal government under the Public Health Service Act.

The second aspect of the problem relates to the promotion of urgent health-related research and its timely application to health needs of the nation. The second aspect is closely connected to the first for the following reason. Evidence presented to the Panel clearly indicates that the successful transfer of a research innovation to industry and the marketplace depends on the existence of a licensable patent right. Adequate safeguards for the intellectual property rights of researchers are necessary to maintain licensable patent rights. Clearly, protection of such important rights is in the interests not only of researchers but also of society generally.

Adequate safeguards for the intellectual property rights of researchers are a matter of basic principle and sound policy. Protection of intellectual property is a right recognized by the Congress and the courts in implementing Article I, Section 8, and the Fifth Amendment of the Constitution of the United States.[2] Moreover, the remarkably productive partnership between the federal government and the nonfederal biomedical research community, which has been thoroughly studied by the Panel,[3] is based on the principle of full protection of the ideas of scientists whose research is ultimately in the interest of the American people. An examination of the present state of the law regarding the protection of intellectual property rights of researchers who, in the national interest, make information about their research available to the government, leads to the conclusion that these rights are not adequately protected.

The disclosure of information generally required under the Freedom of Information Act as interpreted by the courts appears to narrow greatly the protection provided by the Congress' and the court's implementation of the Constitution and certainly undermines the protection that has been accorded to the ideas of researchers by the federal government as a matter of right. Such disclosure under the Freedom of Information Act jeopardizes the intellectual property rights of researchers as regards eventual filing of a patent application for the following reason. Within the patent laws, publication has been broadly defined as any *unconditioned disclosure* by its owner of information on an innovation of interest. For example, even a thesis available on the shelves of a university library but not necessarily reviewed by any researcher has been deemed, within the patent laws, a publication of the innovation disclosed therein. Patent laws of both the United States and foreign countries are drafted against the interest of those parties making or permitting publication of their invention prior to the filing of a patent application. In the United States, publication of an invention prior to the filing of a patent application initiates a one-year statutory period during which time a patent application must be filed on the invention disclosed so that valid patent protection can be established. The laws of most foreign countries preclude obtaining valid protection for a disclosed invention if a patent application had not been filed prior to the date on which the information was first disclosed. Accordingly, the intellectual property rights of researchers in respect to eventual filing of patent applications are jeopardized by disclosure under the Freedom of Information Act.

Recent Court Interpretations of the Freedom of Information Act. The Freedom of Information Act exempts from disclosure "trade secrets and commercial and financial information which is privileged or confidential" [U.S.C. 552 (b)(4)]. The decision, however, from the leading case on this exemption [National Parks and Conservation Association versus Morton, 498 Fed. 765 (1974), D.C. Circuit Court] states that the exemption applies if it can be shown that disclosure was likely either, first, to impair the government's ability to obtain necessary information or, second, to cause substantial harm to a competitive position of a person providing the information. The court toughened the qualification in Petkas versus Staats [501 F. 2d 887 (1974)] by refusing to accept a

government assurance of nondisclosure in a regulation requiring information where filing the information was conditioned on confidentiality. The court held that the government assurance and the corporations' respective filings conditioned on confidentiality were not determinative and remanded the case for disposition in accordance with the test of the National Parks case noted above. Consequently, a pledge of confidentiality by the government in and of itself may not prevent disclosure.

As a result of the above cases, the Office of Legal Counsel of the Justice Department has advised that government protection of intellectual property and its withholding under the "trade secrets" exemption in a Freedom of Information Act suit is, at best, very unpredictable.

Further, Title 18 U.S.C. 1905 does not appear to have any effect in a Freedom of Information Act suit. This statute, if applicable, would impose criminal penalties on government officials who disclose proprietary information in the possession of the government. It is a deterrent to unauthorized disclosure, but it takes effect only after the disclosure and the damage to the owner. Title 18 U.S.C. 1905 has been virtually ignored by the courts in Freedom of Information Act suits because of a general exemption contained in the statute, "unless otherwise provided by law." Courts generally have interpreted the quoted passage as exempting disclosure under the Freedom of Information Act. The penalties specified in Section 1905, therefore, would not be applied to an official who disclosed proprietary information in response to a Freedom of Information suit.

Even though commercial concerns might with predictable difficulty meet the "substantial harm to a competitive position" test of the National Parks case, universities and nonprofit organizations wishing to deny access to their research proposals appear to have little hope of meeting this test in light of Washington Research Project, Inc., versus Weinberger [504 F. 2d 238 (U.S.C.A.D.C., 1974)]. In that case, Washington Research Project, Inc., sought access to a number of research proposals from different universities and nonprofit organizations in order to investigate the ethics of the experiments in question. Washington Research Project, Inc., supported its claim to access to the proposals with indications that "it is essential for researchers to be held accountable, and the research process has to be something other than the closed society which it

is now." The court indicated, in denying the use of the "trade secrets" exemption, that:

> It is clear enough that a noncommercial scientist's research design is not literally a trade secret or item of commercial information, for it defies common sense to pretend that the scientist is engaged in trade or commerce. This is not to say that the scientist may not have a preference for or an interest in nondisclosure of this research design, only that it is not of trade or commercial interest . . .

Certainly an argument can be made that protection, under law, of the intellectual property of researchers employed at universities and other nonprofit institutions ought to be equal to that protection accorded commercial firms. At the least, the protection provided researchers at universities and other nonprofit institutions should be predictable. At present, the protection that federal agencies are able to provide for university researchers is considerably less than that, as illustrated by the procedure for withholding information contained in a funded research proposal.

Under this procedure, and in order to deny information, the federal administrator handling the request must apply the National Parks test to the situation and provide to the Department Public Information Officer a written *prima facie* case recommending denial. (The case would need to include arguments on how a nonprofit organization could have a competitive position in order to overcome the general negation, which resulted from the case of the Washington Research Project, Inc., of the possibility of a competitive position.) If the information the federal administrator believes should be denied involves a disclosure of an idea, invention, or discovery, a prior art review indicating that such idea, invention, or discovery is in fact novel in comparison to the prior art would need to be conducted before a *prima facie* case could be made. If novelty cannot be shown, it seems clear that the government could not prevail in a suit to show that there will be "substantial harm to the owner's competitive position." It is worth asking whether a federal administrator, even with the aid of the researcher whose idea is involved, can show during the early stages of funded research that a research protocol, hypothesis, or design is novel compared to the prior art. The primary purpose of conducting the research is to demonstrate that the idea is, indeed, novel.

In addition, at the time disclosure is requested, it is unrealistic to expect that researchers or their institutions could take steps independently under patent laws to protect their intellectual property rights by filing a patent application at an early stage of research. The clinical or other corroborating data necessary to support a patent claim would obviously be lacking. The filing of a patent application without such data, if possible at all, would be based on the uneconomic, speculative basis of possible future findings.

The Federal Research Effort. An additional factor complicates this problem. The federal government is by far the principal source of support for the nation's health research and development. More than three-fifths of the expenditures for health research and development are from federal sources. The greatest portion of the federal biomedical and behavioral research effort is founded on the concept of a partnership with the nonfederal research community. In 1974, federal funds for support of biomedical and behavioral research conducted outside federal agencies amounted to almost $2.1 billion, or 76 percent of federal expenditures for health research and development. This amount represented about 55 percent of the total national expenditures for health research and development conducted outside federal agencies. This interface of the federal government with universities, nonprofit organizations, and private industry requires submission of documentation that contains disclosures of ideas, inventions, and technical and clinical data--an array of intellectual property that represents a substantial portion of past, present, and future investment towards meeting the health needs of the nation and the world.

Presuming that submissions of such documentation must continue, pursuant to longstanding federal policies in support of health-related research, it follows that unrestricted disclosure could have either of two results. First, there could be a real risk of the total loss of the property value in such intellectual property not already covered by patent protection. Second, there could occur significant alteration, perhaps deterioration, in the enormously successful federal-nonfederal partnership in biomedical and behavioral research because it is not possible to guarantee adequately the protection of intellectual property rights. In the Panel's judgment, either result would be disastrous and could permanently impair the nation's research capability by compromising the partnership basis on

which the capability has been built. The Panel concludes that it is in the national interest that government protection of intellectual property be made predictable by appropriate legislative action.

The Congress has already investigated the problems of protecting proprietary information under the "trade secrets" exemption of the Freedom of Information Act [5 U.S.C. 552 (b)(4)]. The unpredictability of protection of proprietary information under the "trade secrets" exemption was discussed at length during consideration of the amendments to H.R. 3474, the Energy Research and Development Administration (ERDA) authorization bill for fiscal year 1976 [*Congressional Record*, H 12374-81]. Of special importance is the agreement arrived at between Congressmen Goldwater (R. California) and Moss (D. California) as set out on page H 12379, the essence of which appears in paragraph (6):

> We agreed that, in light of the apparent state of unpredictability of protection of proprietary information under Exemption (b)(4) and the need for ERDA to provide such predictable protection in order to ensure the full cooperation and participation of the private sector, Congress could conclude that there was a legitimate national interest in ERDA's having the specific authority to predictably protect proprietary information. Further, Congress could strike a reasonable and acceptable balance of that national interest and the national interest in freedom of information and create a (b)(3) exemption for ERDA for that purpose.

In December 1975, the Congress amended the Federal Non-nuclear Energy Research and Development Act of 1974 to provide positive and predictable protection for trade secrets and other proprietary information. In commenting on the provision, Senator Fannin (R. Arizona) stated (*Congressional Record*, H 12374):

> The conferees took this action because . . . under existing law, primarily the Freedom of Information Act, court holdings have made government protection of trade secrets and other proprietary information completely unpredictable . . . Our action here is intended to remedy that situation for ERDA. Our national energy research and development efforts are far too important to allow such an impediment to exist.

The Panel is not in a position to determine whether the existing laws as interpreted by the courts actually do, in effect, narrow congressional and court interpretations of the constitutional safeguards to intellectual property rights.

The Panel is able, however, to estimate the potential harm that can come to the nation's biomedical and behavioral research effort if protection of individual intellectual property by government agencies remains unpredictable. The Panel has been concerned with "the problems of transfer of research progress, technology, and information from the 'bench to the bed,' an area frequently referred to as the interface between research and the health-care delivery system," which the conferees refer to in their report regarding Title III (Disclosure of Research Information) of the Health Research and Health Services Amendments of 1976 that mandates the present study (*Conference Report* 94-1005, April 2, 1976, page 22).

In its previous investigation the Panel commissioned several studies to assist it in identifying such problems. The studies are contained in "Appendix B. Approaches to Policy Development for Biomedical Research: Strategy for Budgeting and Movement from Invention to Clinical Application."[4] Two of the studies examined the sequence by which a laboratory discovery moves to widespread clinical application. Both studies cited the absence of industry interest as a factor delaying the transfer of research progress. The study by Julius H. Comroe, Jr., M.D., "Lags Between Initial Discovery and Clinical Application to Cardiovascular Pulmonary Medicine and Surgery," lists the absence of industry research and development as one of the causes of delay most frequently mentioned by over 140 scientist consultants:[5]

> The full application of a new discovery required research and development by industry but corporate decisions which involve market analysis, patent application and assured profits often delayed widespread use of equipment, materials, and drugs.
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> - Of 65 new types of equipment needed for advances in cardiovascular-pulmonary medicine and surgery, the basic principles, prototype, and early modifications came from university or other nonindustrial laboratories in 55 cases. Lags of at least several years occurred before private industry decided to produce these items of equipment and make them widely available. On the other hand, when the president of a company took a personal interest in developing a new product (IBM and Gibbon's pump-oxygenator), progress was rapid.
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> - Of 50 new drugs (new chemical entities) needed for advances in cardiovascular-pulmonary advances, about half originated in university or hospital research laboratories and half in pharmaceutical company laboratories. Industry was often slow to purify and develop for clinical use compounds that originated in university laboratories (e.g., penicillin after Fleming's 1929 work; heparin after McLean's 1916 work).

The present study has yielded evidence of a clear link between the need to protect intellectual property rights and the successful transfer of research innovations to the delivery of health care. In a 1968 report, "Problem Areas Affecting Usefulness of Results of Government-Sponsored Research in Medicinal Chemistry" [GAO Report No. B-164031 (2)], the General Accounting Office pointed out that from 1962 to 1968 there was a virtual industry boycott of development of drug research leads generated by research sponsored by the National Institutes of Health. This report by the General Accounting Office made a forceful point. Where substantial risk investment is involved, such as required for premarket clearance of potential therapeutic agents and, now, of some classes of medical devices, there is an identified likelihood that transfer will not occur if the entrepreneur is not afforded some property protection in the innovation offered for development.

The most obvious problem affecting ultimate utilization of an innovation depicted in a research protocol, hypothesis, or design eventually enhanced or corroborated in performance of research funded by the Department of Health, Education, and Welfare at universities or other nonprofit organizations is the fact that these organizations do not engage in the direct manufacture of commercial embodiments. It is industry that must bring such innovation to the marketplace.

Since 1968, there have been specific efforts through the patent program of the Department of Health, Education, and Welfare to close the identified gap between the fundamental innovation the Department supports and the private industrial developers who may be necessary to the delivery of end items to the marketplace. The main thrust of the Department's patent policy has been to assure that the innovating group has the right to convey whatever intellectual property rights are necessary for possible licensing of industrial developers. Not all transfers of potentially marketable innovations from such organizations require an exchange of intellectual property rights in the innovation, but it is unpredictable in which transfers the entrepreneur will demand an exchange to guarantee his collaborative aid.

From 1969 through the fall of 1974, estimates of the Department show that the intellectual property rights to 329 innovations either initially generated, enhanced, or corroborated in performance of Department-funded research were under control of university patent-management offices for the purpose of eventually

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soliciting industrial support for development. During the period from 1969 to 1974, 44 nonexclusive and 78 exclusive licenses had been negotiated under the patent applications filed through these university patent-management offices. According to the figures furnished by the Department, the 122 licenses negotiated have generated investments of around $100 million of private risk capital, in complete contrast to the period 1962 to 1968 during which there was almost no industry interest in research leads of Department-funded research. In the period 1969 to 1974, two licenses resulted in the marketing of two drugs, while a number of other licenses cover potential therapeutic agents in various stages of pre-market clearance. This record is even more impressive in view of the fairly lengthy period required to obtain approval to market a new drug.

In the above context, it is apparent that the existence of a licensable patent right may be a primary factor in the successful transfer of a university innovation to industry and the marketplace. The Panel is concerned that the failure to protect and define such right may fatally affect a transfer of a major health innovation.

For this reason, the Panel is seriously concerned that the unpredictability of government protection for intellectual property rights, owing to the uncontrolled and unconditioned disclosure of research information under current court interpretation of the Freedom of Information Act, is likely, in the Panel's view, to stifle industry interest in developing potentially important research innovations. Without industry involvement, the transfer of research findings to clinical practice will be impeded. In the judgment of the Panel, there are strong reasons to conclude that the interface between research and health care delivery, an area of vital national interest, is likely to be impaired unless adequate protection is provided for intellectual property rights of biomedical and behavioral researchers whose research is conducted with federal financial support.

With these considerations in mind, the Panel examined the data gathered by its survey of the persons requesting information about research protocols, hypotheses, and designs. Of the 71 respondents who indicated the purposes for which the information was used, 47 (67 percent) sought research information concerning the specific research, protocols, hypotheses, and designs of other scientists to give better definition to their own research, or to improve the competitiveness of their own applications for research support. These data indicate that the

intellectual property rights of researchers may not be sufficiently protected because they are subject to disclosure that could not only benefit less innovative researchers but could also jeopardize the original researcher's intellectual property rights under patent law.

Furthermore, the Panel found evidence that the present "openness" constitutes a distinct danger that industrial developers will, as in the 1962 to 1968 period described in the General Accounting Office report, find little incentive to develop research leads generated by investigators under support provided by the Department of Health, Education, and Welfare. The patentability of eventual discoveries and innovations having been precluded by disclosure, it is not unreasonable to surmise that industrial developers will hesitate to risk capital investment when they are unlikely to gain rights to the intellectual property. For example, the request of one public interest group for appreciable numbers of research applications raises the prospect of large-scale multiple requests under a short deadline for reply. Since it is difficult or impossible to ascertain whether research at an early stage may contain information regarding potentially patentable innovations, the effect of disclosure on patentable material will be to thwart or to nullify any present measures agencies may use to attempt to provide some protection to intellectual property rights of researchers. This additional uncertainty is likely to deter industrial developers from exploring research leads generated by federally supported research, which at present amounts to more than three-fifths of all the nation's health research and development.

In light of the effect of disclosure of research information on intellectual property rights and in light of the importance of such rights to the transfer of research innovations to the delivery of health care, it is clear that the present mechanism of complete "openness" attempts to ensure public accountability at the cost of sacrificing protection of intellectual property rights of demonstrable potential benefit to the nation.

EFFECT OF DISCLOSURE ON THE PEER REVIEW SYSTEM

The Panel, in its recent deliberations, gained familiarity with the peer review system used by the NIH and the ADAMHA as the method of evaluating proposed research projects. The Panel believes that peer review is one of the most valuable management tools for ensuring that public funds are spent on technically sound projects with high probability of yielding significant data.[6] Consequently, judgments regarding the effect of disclosure of information concerning research protocols, hypotheses, and designs on the peer review system must take into account the high level of accountability represented by the peer review system[7] and its existence as only one in a series of steps toward actual award of public funds.

Disclosure of information contained in research protocols, hypotheses, and designs does not appear to contribute to the improvement of the technical and scientific assessment that characterizes peer review. That assessment is made by technical and scientific specialists whose judgments could not ordinarily be evaluated outside the scientific community. Since a summary of the assessment of each proposed research project is available to the individual researcher who submitted it, an explanation of the basis for the judgment is available, without full public dislcosure, to the person in the scientific community immediately affected by it. In addition, the successful record of the peer review system of the NIH and the confidence which researchers place in it generally indicate that no pattern of abuses might make imperative full public scrutiny of the scientific and technical aspects.[6] If documentable abuses should occur, either in the peer review system of the NIH or in the procedures used by other agencies, then specific measures to remedy the abuses would seem more appropriate than full public scrutiny with its potentially disruptive effects.

As to those aspects of the peer review system not related solely to scientific merit (for example, protection of human subjects or controverted types of research), disclosure of research protocols, hypotheses, and designs subsequent to funding does allow for examination and discussion of broad issues which could conceivably benefit all. There are, however, two caveats to be observed in this respect. First, it is all too easy to confuse the scientific and technical merit

of a research project with the alleged benefits or harms of such a project. It is fortunate that the peer review system has remained largely free of what are often intrusive issues. Second, it is possible and even preferable to review the broader issues that surround scientific and technical merit of research projects without the step of uncontrolled disclosure of research protocols, hypotheses, and designs, especially because uncontrolled disclosure, by jeopardizing protection of intellectual property rights, directly conflicts with the interests both of society and of the individual researcher.

Certainly, the examples of the recent initiatives of the Congress, the federal biomedical and behavioral research agencies, and the scientific community in the regulation of recombinant DNA research and in the protection of human subjects demonstrate the effectiveness of steps that address such problems in a more focused way than the measure of uncontrolled disclosure. For example, if there were no other way to assure adequate protection of human research subjects than by full public scrutiny, it might be proper to speak of a balance in the national interest between the objective of such protection and the objective of protection of intellectual property rights of researchers both as regards the researchers and as regards the benefits to society generally. But ethical reviews of proposed research by Institutional Review Boards with public representation and congressionally and administratively constituted bodies of ethical review, as well as the broad recognition by society of the need to protect human beings in scientific research, are effective means of continuing scrutiny that better serve the aim of protection of human research subjects--with far less possibility of conflicting rights. Furthermore, no review of findings, preliminary or final, has yet appeared that might serve as reassurance that the large-scale disclosure of research information, with attendant disadvantages, has been justified by a documentable set of abuses regarding peer review, or protection of subjects of research, or other such problems necessitating public scrutiny.

Although no improvements in the scientific aspects of the peer review system can be specifically traced to the disclosure of research information, there are specific results that could impair the ability of the system to ensure high-quality federally funded research. As was indicated earlier, the federal research effort is a partnership or collaborative effort, heavily, if not essentially, dependent upon the resources and contributions of the nonfederal

research community. Nowhere is this more true than in the matter of scientific and technical evaluation of proposed research. Because of the federal government's dependence on the expert judgment of highly specialized professionals, no reasonable alternative to the peer review system appears to exist.

By definition, the peer review system is based on the reliability of scientific judgments about accurate and complete scientific information regarding research protocols, hypotheses, and designs. The ability of the system to ensure high-quality federally funded research would be impaired if incomplete or vague information made it difficult to determine whether a specific research project were technically sound. If researchers could expect that their own research ideas would be subject to disclosure that might result in imitation, or jeopardy to their intellectual property rights, it is possible that they would provide less informative applications and proposals for review. Consequently, judgments by peer review groups would become less reliable.

Concerned about such a prospect, the Panel sought to determine whether the quality and detail of applications and proposals had changed since the court ruling in the case of the Washington Research Project, Inc. Time did not permit the kind of exhaustive study necessary to make a definitive determination. In an effort, however, to obtain a reliable indication about actual and (or) potential effects of the Freedom of Information Act on the operation of the peer review system at the NIH and the ADAMHA, the Panel requested information from the members and the Executive Secretaries of the Study Sections in the Division of Research Grants, NIH, and of the Review Committees in the Institutes of the ADAMHA. The Panel believed that it would be instructive to have the impressions provided by the Executive Secretaries and members of Study Sections and Review Committees regarding any perceived change in the manner in which individual grant applications might have been written since the court ruling that requires that funded proposals be available to the public upon request.

The members and Executive Secretaries of the 68 Study Sections and Review Committees replied that they had perceived no change in the quality or quantity of information provided in research grant applications since inception of the ruling that requires that funded applications be made available to the public upon request. Many of those polled 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.

Another finding of the Panel's study, however, may indicate a trend that is less reassuring. By far the greatest portion of respondents to the Panel's present questionnaire frankly indicated that they wanted to review other proposals in attempts to improve their own applications or proposals and to use information in other proposals to assist their own research. No doubt, reviewing other proposals may help a researcher be more effective in his research, but it is also possible that less innovative researchers will merely be imitating more successful researchers and that, instead of improved research, derivative research might be expected. There is indication that the information disclosed is being used to gain a competitive advantage by exacting disclosure of ideas of other researchers who are in a position of being deprived of full control of the intellectual property rights to their innovations. Should this practice grow, peer review might be undermined because of uncertainty about the extent that proposals reflect any genuine standard of creative excellence. It would be unfortunate if applications reflecting only derivative ideas were submitted and approved when each year funds have not been sufficient to support all approved applications that represent original, if not exceptionally innovative, high-quality work.

Furthermore, the credibility of peer review would certainly be undermined if it were compromised by the submission of derivative proposals and applications and if the judgments by peer review groups were based on incomplete information.

The peer review system serves another purpose, as well, that would be undermined by uncontrolled disclosure of research information. Peer review ensures responsible and adequate scientific evaluation of proposed research projects as an indispensable method of protecting the public. If the prospect of uncontrolled disclosure of research information discourages investigators from furnishing complete and detailed information about their proposed projects, peer review bodies will be hindered in making judgments about the possible harms of such research. The protection of responsible, scientific evaluation can be undermined by uncontrolled disclosure in another way. The premature disclosure of research protocols, hypotheses, and designs may also involve release of scientific hypotheses before adequate validation. The public could be subject to potential hazards of untested hypotheses or be misled by arguments advanced by unqualified or irresponsible persons for application of research advances

before sufficient long-range evaluation is complete. In the long run, the public's interest is better served by controlling disclosure of research protocols, hypotheses, and designs.

It is in the light of this contribution of the peer review system to society that one should read the professional advice to the Panel from the 160 members of the Interdisciplinary Clusters commissioned to review the state of the science and to assess the peer review system. These scientists have an essential role in safeguarding the public by assuring the integrity of scientific research. Professionally, they would find it difficult or impossible to participate in a system where premature and uncontrolled disclosure would thwart their strenuous efforts to ensure technically and scientifically sound as well as potentially beneficial research. Their reservation about serving as members of peer review bodies whose function would be rendered ineffective by an "open" deliberative process is a valid professional concern on their part. Should provision not be made, furthermore, to guarantee the exclusion from disclosure of unfunded research applications and proposals, the ability of members of peer review boards to contribute to protecting the public from unsound or questionable research would be even more severely hampered. In the event unfunded proposals were subject to public disclosure or public discussion, it is difficult to see how the peer review system could continue to provide effective protection from potential harm to the public.

Finally, researchers have no interest in concealing their ideas indefinitely from the scientific community or from the public. They have every interest in publishing their findings as soon as possible upon verification. The point of disagreement is really over when such information should be released and who will control the release. The measure of protection necessary to safeguard the ideas of the researcher and the integrity of the peer review system does not require exemption from disclosure for an indeterminate time or from disclosure in a proper and controlled fashion.

EFFECT OF DISCLOSURE ON PROTECTION OF HUMAN SUBJECTS IN RESEARCH AND ON INFORMED CONSENT PROCEDURES

The Panel's concern throughout its earlier study of the federal biomedical and behavioral research effort was to ensure that the public funds used to support research achieved the maximum return possible. Part of that concern was directed to the difficult problem of maintaining balance between diverse and, at times, conflicting research priorities. Not every line of research is equally promising. Not every disease or health problem exacts the same toll of society.[8] Clearly, the scope of such deliberations required the Panel to invite testimony and expert advice from all possible sectors of the public and the scientific research community.[9]

In this connection, and during deliberations for its initial report, the Panel heard testimony of diverse and opposing views on the issue of protection of human subjects in research. Some witnesses contended that current regulations of the Department of Health, Education, and Welfare impeded the progress of research. Other witnesses, representing public interest groups, expressed the opinion that further special measures were necessary to protect the public against research that presents an unreasonable risk. In view of the vast numbers of complex issues and in view of the fact that the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research continues to examine specific issues in this area, the Panel limited its earlier deliberations to the recognition that clinical research required an opportunity to ensure, by public scrutiny if necessary, that human subjects of research are adequately protected. While the Panel continues to support that principle, it is important to point out that the arguments advanced by proponents of full openness of peer review do not convincingly make the case that full and unconditioned disclosure of information in research protocols, hypotheses, and designs is related to, or assures, the protection of human subjects of research.

Advocates of full disclosure of research information, as presented in testimony to the Panel,[10] argue that ethical and scientific review are "in some senses indistinguishable." The basis for their being indistinguishable is left unexplained. Yet, quite clearly, it is "deficiencies in the informed consent

procedures, the monitoring of informed consent, and the monitoring of research after funding" that are cited as areas in which rights of human subjects of research are likely to be abused. None of these areas relates directly to the scientific basis of research--the research protocol, hypothesis, or design.

In addition, the initial review of ethical aspects of research is conducted at the institution sponsoring the proposed research project. At that review, consideration is given not to scientific merit but to assurance of compliance to ethical and legal standards of the community and of more universal recognition as incorporated in regulations of the Department of Health, Education and Welfare.[11] In the course of peer review at the national level, reviewers are required to take into consideration, among other pertinent factors, the apparent risks to the subjects, the adequacy of protection against these risks, the potential benefits of the activity to the subjects and to others, and the importance of the knowledge to be gained. On the basis of this review, peer review groups may recommend to the Secretary that he approve, defer for further evaluation, or disapprove support of the proposed activity in whole or in part. The issues of informed consent, monitoring of informed consent, and monitoring after funding are not specifically taken into account. The reasons for this are obvious. Consent is governed not by national law, but by applicable common and statute law in the several states, and must be judged at the local level.

It is also at the level of the Institutional Review Board that one can reasonably expect responsibility to be assumed for protection of human subjects in research. Peer review at the national level involves brief periodic meetings of nationally recognized scientists. Such peer review can apply its collective judgment with respect to ethical norms, but has no opportunity to judge the applicability of those norms under state and municipal laws or at institutions governed by the ethical views of differing religious and secular organizations. Generally, the research institution appears to have legal responsibility for the professional research activities of its staff. Also, federal regulations require as a condition for obtaining funds that the local Institutional Review Board certify, prior to submission to federal agencies, approval of proposed research projects on the basis of ethical considerations.

Moreover, if the peer review system is considered inadequate for ethical review because it almost never involves monitoring of the recruitment of subjects,

the consent process, or the actual experimental procedures as they take place, then it hardly seems appropriate to require that it be open to the public or that scientific information reviewed by scientific and technical review groups be disclosed. It was not made clear to the Panel why the scientific and technical review--peer review of merit--should require community participation, public representatives, or a public meeting. In fact, the case made by the proponents of disclosure would appear to be that the peer review system is not the appropriate focus for ethical review. The Panel is inclined to agree that scientific and technical review committees are not the mechanisms for monitoring actual compliance with ethical standards in conducting research. Scientific and technical review committees ought to concentrate primarily on scientific and technical review. The Panel recognizes that all reasonable measures must be taken to ensure protection of human subjects in research and that all review committees must have responsibility for that protection. No evidence, however, of systematic, recurrent, or sporadic abuses of subjects' rights has been presented to the Panel that would appear to call for full disclosure of what otherwise would be considered privileged information.

Finally, the recommendations of advocates of openness of peer review, as presented to the Panel, call for only limited portions of review meetings to be open to the public in order to protect the privacy of investigators and so as not to prohibit candor. It is only "when particular proposals present difficult ethical dilemmas, [that] there should be an open debate."[10] Uncontrolled and unconditioned disclosure of information in research protocols, hypotheses, and designs does not seem necessary nor even intrinsically related to the protection of human subjects in research. In fact, it may be that the commissions and boards now in place or proposed at the level of national review are already serving the purpose of supplying the proper forum for "open debate" of difficult ethical dilemmas.

As to the question of the effect of disclosure on adequacy of informed consent procedures, the Panel believes that the comprehensive study of this and related issues already in progress under the aegis of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research would provide fuller information than the Panel could provide in the short period of its present investigation. Moreover, variations in the legal definition of informed consent among states and among experts in the ethics of research make specific recommendations by the Panel inappropriate.

In connection with the Panel's present questionnaire on these issues, only one public interest group has considered the opportunity of disclosure of information in research protocols, hypotheses, and designs as a vehicle for ensuring protection of the public against research that presents an unreasonable risk to human subjects of research and for ensuring the adequacy of informed consent procedures. Two other respondents reported interest in these issues but gave no indication of initiatives aimed at significant impact on the problem. (One public interest group declined to volunteer the requested information.)

On the basis of the requests for information, the Panel is most concerned that, while uncontrolled disclosure seems to offer neither compelling grounds nor convincing record that it serves the aim of protecting human subjects of research, such disclosure does leave unprotected the rights of researchers and, in all probability, the rights of those who would benefit from timely transfer of research innovations to the delivery of health care.

REFERENCES

1. *Report of the President's Biomedical Research Panel.* DHEW Publication No.(OS)76-500, pp. 19-21. U.S. Government Printing Office, Washington, D.C., April 30, 1976.

2. Latker, N.J. "Intellectual Property: Private Rights and Public Use," in *Technology Transfer: University Opportunities and Responsibilities.* A report on the proceedings of the National Conference on the Management of University Technology Resources, Case Western Reserve University, pp. 136-148, 1975.

3. *Report of the President's Biomedical Research Panel.* DHEW Publication No.(OS)76-500, pp. 1-2 and 18-20. U.S. Government Printing Office, Washington, D.C., April 30, 1976.

4. "Appendix B. Approaches to Policy Development for Biomedical Research: Strategy for Budgeting and Movement from Invention to Clinical Application," *Report of the President's Biomedical Research Panel.* DHEW Publication No.(OS)76-502. U.S. Government Printing Office, Washington, D.C., April 30, 1976.

5. Ibid., p. 28.

6. *Report of the President's Biomedical Research Panel.* DHEW Publication No.(OS)76-500, pp. 17-21; and also "Appendix D. Selected Staff Papers," *Report of the President's Biomedical Research Panel.* DHEW Publication No.(OS)76-504, pp. 67-77. U.S. Government Printing Office, Washington, D.C., April 30, 1976.

7. Carter. G.M. *Peer Review, Citations, and Biomedical Research Policy: NIH Grants to Medical School Faculty.* (R-1583-HEW, 1974) The Rand Corporation, Santa Monica, 1974, pp. 90.

8. "Appendix A. The Place of Biomedical Science in Medicine and the State of the Science," *Report of the President's Biomedical Research Panel.* DHEW Publication No.(OS)76-501, pp. 1-22. U.S. Government Printing Office, Washington, D.C., April 30, 1976.

9. *Report of the President's Biomedical Research Panel.* DHEW Publication No.(OS)76-500, pp. 40-45. U.S. Government Printing Office, Washington, D.C., April 30, 1976.

10. The President's Biomedical Research Panel: Meeting No. 11, January 26-27, Washington, D.C., 1976. Transcript of Proceedings, pp. 1-137 to 1-155.

11. Title 45 - Public Welfare; Subtitle A - Department of Health, Education, and Welfare; Part 46 - Protection of Human Subjects (39 *Federal Register* 18914 and 40 *Federal Register* 11854).

APPENDIX A

Report to congressional committees.
42 USC 2891-2.

TITLE III—DISCLOSURE OF RESEARCH INFORMATION

Investigations and study.
42 USC 2891-1 note.

SEC. 301. (a) (1) The President's Biomedical Research Panel (established by section 201(a) of the National Cancer Act Amendments of 1974 (Public Law 93-352)) and the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research (established by section 201 of the National Research Act (Public Law 93-348)) shall each conduct an investigation and study of the implication of the disclosure to the public of information contained in research protocols, research hypotheses, and research designs obtained by the Secretary of Health, Education, and Welfare (hereinafter in the subsection referred to as the "Secretary") in connection with an application or proposal submitted, during the period beginning January 1, 1975, and ending December 31, 1975, to the Secretary for a grant, fellowship, or contract under the Public Health Service Act. In making such investigation and study the Panel and the Commission shall each determine the following:

42 USC 2891-1 note.

42 USC 201 note.

(A) The number of requests made to the Secretary 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.

(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.

Report to congressional committees.

(2) (A) Not later than May 31, 1976, the Panel shall complete the investigation and study required to be made by the Panel by paragraph (1), and, not later than June 30, 1976, the Panel shall submit to the Committee on Interstate and Foreign Commerce of the House of Representatives and the Committee on Labor and Public Welfare of the Senate a report on such investigation and study. The report shall contain such recommendations for legislation as the Panel deems appropriate.

Report to congressional committees.

(B) Not later than November 30, 1976, the Commission shall complete the investigation and study required to be made by the Commission by paragraph (1), and, not later than December 31, 1976, the Commission shall submit to the Committee on Interstate and Foreign Commerce of the House of Representatives and the Committee on Labor and Public Welfare of the Senate a report on such investigation and study. The report shall contain such recommendations for legislation as the Commission deems appropriate.

42 USC 218 note.

(b) Section 211(b) of the National Research Act (Public Law 93-348) is amended by striking out "July 1, 1976" and inserting in lieu thereof "January 1, 1977".

APPENDIX B

O.M.B. No. 68-S76032
Expires June, 1976

Questionnaire

The Privacy Act of 1974 [(5 U.S.C. 552a(e)(3)] requires that an individual asked to furnish information to a government agency be informed as to the authorizing source and the principal purpose for which the information will be used. The President's Biomedical Research Panel seeks this information pursuant to Title III of Public Law 94-278, by which the Panel is directed to investigate and to report to the Congress the implication of disclosure of information contained in research protocols, research hypotheses, and research designs submitted to the Department of Health, Education, and Welfare in connection with an application or proposal for a grant, fellowship, or contract under the Public Health Service Act. Your cooperation in responding voluntarily will contribute greatly to the accuracy, timeliness, and comprehensiveness of this survey.

(1) Please indicate the interests represented by you or by the persons on whose behalf you have made the request(s).

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(2) Please state briefly the purposes for which the information disclosed to you by the Secretary was used.

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U.S. DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
Public Health Service
DHEW Publications No. (OS) 76-513