STATEMENT OF

RAYMOND J. WOODROW, PRESIDENT

OF THE SOCIETY OF UNIVERSITY PATENT ADMINISTRATORS

BEFORE THE

SUBCOMMITTEE ON DOMESTIC AND INTERNATIONAL SCIENTIFIC PLANNING

AND ANALYSIS

OF THE

HOUSE COMMITTEE ON SCIENCE AND TECHNOLOGY

WITH REGARD TO

UNIVERSITY PATENTS AND FEDERAL GRANTS AND CONTRACTS

SEPTEMBER 23, 1976

Mr. Chairman and Members of the Subcommittee:

I appreciate the opportunity of appearing before the Subcommittee today. My purpose in appearing is to discuss with you the treatment of inventions and patents in grants and contracts from the Federal Government to colleges and universities. The primary matters of concern in what I have to say are the public interest, inventors' equities and university equities.

I should say at this point that a significant portion of my statement has been based upon a 1968 paper issued by the Subcommittee on Patents and Copyrights of the NACUBO* Committee on Governmental Relations. My remarks can be considered to be those of a member of that Sub-Committee in addition to my speaking as President of the Society of University Patent Administrators. We are gratified that your Subcommittee is

*NACUBO stands for National Association of College and University Business Officers.

examining the ownership of inventions resulting from Federally funded research and development, and especially gratified that the unique position of colleges and universities should be taken into consideration.

Universities by their very nature and by their charters have an obligation to serve the public interest. They do this in a variety of ways in a variety of endeavors. In order to do it effectively in the patent area, universities need to have a patent program which will make patentable inventions arising in the course of university research available in the public interest under conditions that will promote effective development and utilization.

It is said that the reason why many organizations apply for at least some patents is as a defensive measure to protect a commercial position. Universities do not apply for patents for defensive reasons, since they have no commercial position to defend. Their motivation is in the direction of seeking objectively the best qualified sources for delivery to the public on the broadest possible scale the results of their research.

Few university inventions are commercially practicable in the form in which they are conceived or reduced to practice in the University. Many, if not most, are in fact unanticipated byproducts of the research effort. Universities do not have the funds, the incentive or the expertise to develop patentable inventions to the point where they can be produced and marketed. Almost always, therefore, further investment is necessary in order to have an invention publicly available. What organization will be willing to make the necessary investment to bring an invention to the market without the kind of protection that a patent gives, protection from others who would pick the fruits without planting the tree?

As a result of what I have said, universities need to retain rights

to inventions whether made in the course of Federally funded research or otherwise. Patent applications can then be filed promptly and negotiations immediately commenced with prospective licenses, with the active assistance of the inventor, so that an invention can be developed to the point of public use. In some fields, such as drugs, agreements can be entered into for the testing of compounds with some protection for the testing firm's expenditures before it is even clear whether there is a patentable invention. By these means patentable inventions can be put into use widely and effectively. As a result, the public will benefit.

Where does the university inventor stand? University personnel, as compared with those in a commerical research organization, are employed and promoted with salaries which give no recognition to the value of any inventions they make. Their interests and in many ways their futures lie primarily in the publication of research results in the open literature. As a matter of equity, therefore, universities, without any exceptions that I know of, provide for a share of royalties from patented inventions to be paid to the inventor. This provides an incentive for him or her to spend the time and effort necessary to disclose an invention properly, to participate in invention evaluation, to work with patent attorneys, and to provide information and assistance to potential or eventual licensees. Without this incentive, and it must be an adequate incentive, experience shows that few inventions are disclosed, for the amount of persuasion which a university can effect with members of the faculty for disclosure is very limited.

In addition to the inventors, the university has an equity in inventions made using its funds or facilities. No matter who pays for the research performed, the payments are invariably for less than the full true

costs. With some exceptions the university has paid for the facilities needed. And it has a huge investment in accumulating and providing a highly competent cadre of personnel without which no Federally funded research would be possible. Should perchance lightning strike and a bonanza invention come forth, the university's share of any funds realized would by the terms of its charter be used for the public interest purposes of education, research and public service.

It is our firm and strong belief that the conditions of Federally funded research grants and contracts with colleges and universities should be consistent with and adapted to the factors I have discussed above. We have seen little evidence that Government ownership of university inventions will promote the public interest in the sense of development and production for public use, since the investment necessary to convert the professor's brainchild to a marketable product is not forthcoming. Government ownership gives the university inventor no incentive to disclose his invention and to divert time and effort to working with patent attorneys and potential users. The university has little incentive to obtain adequate invention disclosures and its equity in inventions is not recognized.

How about the Government's equity in inventions resulting from Government funded research in universities? This ought to be satisfied by a royalty-free nonexclusive license for Governmental use. The Government thus receives the right to use royalty-free the results of the research which it paid for. Greater rights, such as title to inventions, are, for reasons I have already discussed, against the public interest because of the problems of development and marketing, and they vitiate the inventors' equity as well as the university's equity. The Government when it gives a contract or a grant for research is not buying an invention or inventions. One cannot contract for a patentable invention to be made which is as yet

unborn and even unconceived.

I have spoken about a royalty free license for Governmental use. In recent times Governmental use has been extended to use by state and local governments as well as by the Federal Government. This seems unfortunate and undesirable. State and local governments do not have an equity. Licensees balk at tracing the payment or nonpayment of royalties through the almost impenetrable maze of manufacturers, wholesalers, distributors and outlets in order to insure the some fractional royalty hidden in various markups is not being paid by a local township.

A provision for title in the Government with the opportunity for waivers is practiced by some agencies. Sometimes the waiver is granted in advance for a particular grant or contract for all inventions that may be made. Sometimes the waiver is granted after an invention is identified. My experience and that of my colleagues are not favorable in either situation. Waiver applications are complicated and costly. The agency criteria for granting waivers are difficult to satisfy and their administration demonstrates the typical bureaucratic tendency of being more stringent than necessary in order to avoid criticism. Waivers also often carry with them march-in requirements and other strings. Waivers on individual inventions after identification generally make it impossible to enter into drug testing agreements or other cooperative undertakings. Waivers put the shoe on the wrong foot. If what I have said earlier is true, there should be a very strong presumption that the country's interests are best served by vesting title to inventions in university contractors and grantees unless there is good and sufficient reason to do otherwise.

The question can be asked whether leaving title with universities for all inventions resulting from Federally funded research, with only

a royalty free nonexclusive license to the Government, will adequately protect the public interest. If what I have said earlier is true, and I firmly believe it is, the probability should be very high that the public interest will be served. However, there may be the need for even greater assurances. In this case probably the best mechanism that has yet been devised is the Institutional Patent Agreement. The IPA as it is termed was first developed as far as I know by the Department of Health, Education, and Welfare and was more recently adopted by the National Science Foundation. The General Services Administration now has out for comment--and we are in the process of preparing comments--a proposed amendment to the Federal Procurement Regulations which would provide for Institutional Patent Agreements. If this FPR amendment is adopted, IPA's might then be available from all agencies except where the statutes prevent it.

Briefly the Institutional Patent Agreement is an agreement between an agency and a college or university covering the management of all inventions arising from agency grants or contracts to the institution, unless specifically excepted. As an advance condition the institution's patent policy and program must meet certain criteria. There are limitations on how patentable inventions can be handled, and the Government may require licenses or additional licenses if adequate progress is not made towards practical application, or for purposes such as fulfillment of public health or safety needs.

In place of the widely varying and often inequitable patent arrangements now prevalent, we would greatly prefer that the Institutional Patent Agreement principle be applied to all Federal agencies in funding research and development at colleges and universities. This will mean a change in the statutes for some agencies, and a change in attitude in others. There will undoubtedly be some exceptions taken to the

detailed requirements contained in IPA's since nothing is ever perfect, but we would hope that these requirements could be held to a bare minimum, with a termination of the agreement in the unlikely instance of a violation of the spirit of the arrangement, instead of the imposition of onerous conditions on everyone.

To summarize, I urge that the title to inventions arising from Federally funded research at colleges and universities be left with the institutions, that this be done with the Government receiving a royalty-free nonexclusive license for Federal Government purposes, and that the Institutional Patent Agreement with reasonable and minimum requirements, as the best method so far encountered, be the method for implementation. If these objectives can be accomplished, the public interest will be advanced and the equities of university inventors and of universities themselves will be satisfied.

RJW/dh
September 16, 1976

THE PENNSYLVANIA STATE UNIVERSITY
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UNIVERSITY PARK, PENNSYLVANIA 16802

Vice President for
Research and Graduate Studies

Area Code 814
865-6332

General Services Administration
Federal Supply Service
Washington, DC 20406

Attention: Mr. Philip G. Read
Director of Federal Procurement Regulations

Subject: Proposed Amendment to FPR Concerning
Institutional Patent Agreements

Reference: (a) GSA ltr to PSU, dtd August 5, 1976

Dear Mr. Read:

In response to your invitation for submission of my views on the proposed revision concerning Institutional Patent Agreements, the following is set forth:

The Pennsylvania State University has had a formal Patent Policy for over 50 years which is directed to the maximum utilization of inventions for the public good. The University has an Institutional Patent Agreement with HEW, negotiated in 1970 and recently reviewed and renewed in view of a new University Patent Policy. The University Patent Policy was approved under the DOD "list of approved patent policies" during the period that DOD used such a list. The above is set forth to document that the University is willing to cooperate with governmental procedures to enhance the transfer of University-generated technology to industry.

The "proposed FPR revision" is the third detailed patent procedure we have received recently which is considered to be moving in a direction counterproductive to meaningful university/industry technology transfer. The other two documents are the EPRI Patent Provisions and the latest ERDA Patent Procedures. The reasons these three documents may produce negative results are set forth below:

The three parties of vital interest must cooperate if University-generated technology is to reach the maximum utilization -- (1) the Federal agencies; (2) the University, including both faculty inventors and contract and patent administrators; and (3) industrial licensees to accept, develop, and market appropriate technology. The terminology and tenor of the proposed FPR revision is too strongly in favor of the Federal agencies without sufficient consideration and input from the university research community and potential industrial licensees. The general objectives of this proposed revision to the FPR can be achieved with a document that will be clearer and simpler, written in terminology which can be understandable to the average faculty researcher, i.e. simplicity and clarity overall is so desirable that an occasional loss of invention by publication and resulting "dedication to the public" by Statutory Bar may be preferable to a rigidized system without substantial inventor incentives. Specified comments are indicated below:

The University considers that the provisions set forth in the present HEW Institutional Patent Agreement and their administration in the cooperative and sensitive manner are both desirable and effective. Any further encroachment on the inventors incentives and additional procedural complications by Institutional Patent Agreements will reduce the inventors incentive for making inventions and reporting them, and will reduce industry predisposition to invest capital in technology developed under these agreements.

Specific comments are:

Section V(a)(i) This section appears to make an absolute requirement for disclosure submission prior to any publicity. Many inventions, especially in the chemical and pharmaceutical arts, are developed in fragments and a valid patent application cannot be filed at a time prior to publication, since the necessary human physiological and toxicity testing has not yet been achieved. Many of our invention disclosures are triggered by a presentation at a national or international technical meeting and only obtained at that time. Additionally, many inventions are achieved in a manner that the inventors cannot be sure at what stage conception is achieved, especially with respect to chemical, pharmaceutical, and process inventions.

Section V(a)(ii) The words "authorized by or known to" the institution could be construed to require detailed administrative supervision of all presentations, seminars, and meetings; and all publications -- which are presently the responsibility of the principal investigator or research director.

Section V(b) It is not clear whether the "patent agreements" which are required will have to be in the same detail as the Institutional Patent Agreement itself. If so, and the Institutional Patent Agreement must, in effect, be incorporated by reference into the patent agreements to be executed by university employees, then it is critically important that these agreements be as simple, clear and concise as possible.

Section V(c) It is not clear whether this provision would permit the Government to publish an invention disclosure covering a pharmaceutical which was "conceived" but not yet actually reduced-to-practice, and upon which a valid patent application could not be filed because of a lack of human effectiveness testing.

Section VI(b)(i) and (ii) The period of two months set forth in each of these sections is too short in view of the delays in the Patent Office, and the fact that there should be no urgency in these submissions, i.e., six months would be better.

Section IX It is not clear what percentage of royalty income can be paid to the inventors, and it would appear from subsection (c) to 1-9.107-6 "feature (F)" that only "incentive awards" could be paid to inventors, rather than a share of gross royalties which may be essential to obtain the inventors continuing cooperation necessary during the licensing and development effort needed to transfer technology to industry.

Section IX(f)(i) and (ii) These two restrictions on licenses to organizations in which the inventor may be the catalyst for further development are considered to be negative, since they may eliminate the best mode of technology transfer -- the entrepreneurial enthusiasm of the inventive group. Further, the term "substantial financial interest" is vague.

Section 1-9.109-7(b)(3) The administration of this "identification" of inventions could be construed to require administrative surveillance of research, rather than placing the responsibility upon the principal investigator.

In summary, it is considered that more consideration should be given to the fragile nature of inventions and inventors -- which are the indispensable prerequisites of both invention administration and technology transfer. Without the enthusiastic acceptance and support of faculty inventors, the perfectly worded Institutional Patent Agreement will still produce a negative result. In the event GSA would be willing to have a committee of user organizations propose alternative terminology to that set forth in the referenced FPR revision, the University will make available the services of Dr. Robert F. Custard, our full time University Patent Counsel, to serve on such a committee or task force. A useful relationship could be created by a working committee in which the interests of the university and inventors and the industrial licensee/developer were represented in the selection of the terminology rather than the submission for "views" after drafting.

The University has utilized both Battelle and Research Corporation in the past and presently utilizes Research Corporation for our primary evaluation, marketing and licensing activity. It is suggested that Research Corporation should be invited to participate in the drafting of any final Institutional Patent Agreement regulations, since many universities without other resources have no other realistic alternative than to utilize the services of Research Corporation. We have found the services of Research Corporation to be a significant and valuable contribution to the national public interest with respect to University/industry technology transfer. GSA should recognize this "pioneering" contribution and invite their cooperation in developing a master Institutional Patent Agreement which would be acceptable to the U. S. Government and Research Corporation.

Please let me know how the University can be of assistance in this general area.

Very truly yours,

Richard G. Cunningham
Vice President for Research
and Graduate Studies

RGC-RFC:hw

cc: N. Latker
W. Marcy

COMMITTEE ON GOVERNMENTAL RELATIONS
National Association of College and University Business Officers
ONE DUPONT CIRCLE, N.W. • SUITE 510 • WASHINGTON, D.C. 20036 • (Area Code 202) 296-2346

September 28, 1976

Mr. Philip G. Read
Director of Federal Procurement Regulations
Federal Supply Service
General Services Administration
Crystal Square, Bldg. 5, Room 1107
Washington, D.C. 20406

Dear Mr. Read:

The one hundred participating institutions of the Committee on Governmental Relations, National Association of College and University Business Officers, welcome the opportunity to comment on the proposed Federal Procurement Regulations prepared by the Ad Hoc Subcommittee on University Patent Policy, concerning Subpart 1-9.1 Patents.

The COGR believes that university ownership of inventions arising out of government sponsored research is a necessary ingredient in the effective transfer of technology to the market place, since it:

(1) enables the university to grant to the private sector rights that, while limited, are commensurate with product introduction risks;

(2) insures inventor participation in the development of the invention or product; and

(3) encourages the university to bring together industry and inventors, thereby enhancing the probability of successful commercialization of the invention.

Moreover, vesting title to those universities that can qualify under the proposed regulations, represents a giant step forward toward fostering a technology transfer capability among universities that as yet have not been so inclined.

The comments below relate to the proposed Institutional Patent Agreement.

1. I. Scope of the Agreement.

Request deletion of the last sentence of the paragraph and substitute therefor:

> "In cases where the Institution is a subcontractor under a prime contract of the Agency, the Agreement of the Institution shall govern."

Comments.

It sometimes is the case that an educational or nonprofit institution will grant a subcontract to the Institution. Under such circumstances, the inability of the Institution to acquire rights will tend to discourage inter-university research and unfairly treat the university inventor who may well lose his equity interest in his invention. COGR institutions typically do not have patent policies that cover inventions that arise outside of the university. Moreover, the COGR institutions favor retention of rights by a sister institution as a matter of equity and fairness.

Finally, as a matter of law, the requirement to grant back rights to the prime contractor could, under certain facts and circumstances, be in violation of the anti-trust laws or construed as a patent misuse.

2. VIII. Filing of Foreign Patent Applications.

Section VIII should be changed to read Section VII.

Request Paragraph VII (a) (i) be changed to read as follows:

> "ten (10) months from the date of the corresponding United States patent application filed by or on behalf of the Institution, or if such an application is not filed, six (6) months from the date a license is granted by the Commissioner of Patents to file foreign applications providing an election has been made pursuant to section III (a) of this Agreement."

Comments.

Good patent practice dictates that a foreign filing be made just prior to the end of the convention period. Especially in the case of university inventions, additional material is made available subsequent

to the U.S. filing which becomes incorporated in a continuation-in-part. It is advantageous to base the foreign filing on the most complete disclosure available.

If no application has been filed, an export license would be required to foreign file. The time granted to foreign file should be the same as that granted in section VII (a) (ii).

3. VIII. Subcontracts.

Request deletion of (a) in entirety and substitute therefor:

> "(a) Except as provided in (b) below, the Institution shall include in any subcontract where a purpose of that subcontract is the conduct of experimental, developmental or research work the "Patent Rights-Acquisition by the Government" clause, found at 41 CFR 1-9.107-5, or the "Patent Rights Retention by the Contractor" clause, found in ASPR 7-322.23 (b)."

Comments.

The above changes are required to conform to the changes proposed in paragraph 1 herein concerning Section I, Scope of the Agreement.

4. IX. Administration of Inventions in which the Institution Elects to Retain Rights.

Request deletion of Section IX9 (f) in its entirety.

Comments.

Universities, due to their special character, continually must exert their best efforts to protect their good name and the good name of their professors and researchers. The interleaving of interests of government, state, non-profit, and private sponsors dictates that the university exercise due care in its relations with the aforesaid parties. Frequent consultant arrangements between university professors and the private sector make it necessary for the university to inform its professors of their duties and obligations to the U.S. government, the university, and the consulting company with respect to patent rights that might arise out of work performed for the consulting company that also relates to sponsored work done by them at the University.

Consequently, the university is well experienced in policing its own affairs that are sensitive in nature. Adverse or unfavorable reports by the media in this regard would be far more costly by way of loss of alumni funds and gift giving than any potential return from a high-risk, high-gain patent license venture. Accordingly, it is submitted that Section IX as drafted, is unnecessary in view of the university's sensitivity to the potential problems that might arise in this area.

Section IX requires efforts to license others first. Any such license will be time-limited, and the public interest will be protected thereby. A university should not be required to demonstrate that an invention has no takers before directly assisting in the transfer of technology to the marketplace. Moreover, the university is faced with a very real problem if it elects not to make an invention widely available, since it is quite likely that one or more of the trustees or alumni will want to know why his company was precluded from having an opportunity to license the invention. Hence, the university, when it decides to support an invention, must take this fact into consideration.

Therefore, the relationship of the university to those outside of the university community, by its very nature, is such that patent abuses are highly unlikely.

The university community believes that the proposed IPA presents an opportunity for a major improvement in the management of inventions developed under government sponsored research.

If you require additional information, please let me know.

Sincerely yours,

Reagan Scurlock

RS:dk

PHARMACEUTICAL MANUFACTURERS Association

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C. JOSEPH STETLER
PRESIDENT

September 29, 1976

Mr. Philip G. Read
Director of Federal Procurement Regulations
General Services Administration
Washington, D. C. 20406

Dear Mr. Read:

We appreciate the opportunity to present comments on the proposal to amend the Federal Procurement Regulations, at Title 41, Subpart 1-9.1, to include provisions for the Government entering into Institutional Patent Agreements with educational or other nonprofit institutions conducting research with Government funds. As requested, our comments are submitted in duplicate.

The Pharmaceutical Manufacturers Association is a voluntary nonprofit association comprised of 130 member companies engaged in the development and manufacture of prescription drugs and medical devices. PMA and its member companies advocate a strong United States patent system as an effective incentive for developing results of innovative research to commercial applications. Many PMA member companies have negotiated for patent rights with nonprofit institutions who operate under the Institutional Patent Agreement concept fostered by the Department of Health, Education, and Welfare and have entered into patent license arrangements with respect to patentable inventions made by these institutions in the performance of DHEW grants.

The Standard Institutional Patent Agreement, developed over the past several years within the Department of Health, Education, and Welfare, therefore, has facilitated the commercialization of the results of DHEW funded research through nonprofit institutions. The pharmaceutical company experience to date has been favorable. The DHEW IPA concept is consistent with the PMA position that the United States patent system should encourage as fully as possible the commercialization of the innovative results of both Government and privately-funded research.

We further endorse the extension of the Institutional Patent Agreement procedures to those civilian executive agencies subject to the Federal Procurement Regulations. Appropriate amendment of these regulations would allow a Government agency to enter into Institutional Patent Agreements with educational and other nonprofit institutions which have acceptable technology transfer programs. In our view, the use of such agreements would recognize and retain the incentives of the United States patent system to obtain prompt commercialization of the results of Government-sponsored research, with appropriate safeguards to the public interest.

If we can be of additional assistance to you in consideration of this subject, we will be happy to provide whatever additional information is needed.

Respectfully submitted,

C. Joseph Stetler

AEROSPACE INDUSTRIES ASSOCIATION OF AMERICA, INC.

1725 DE SALES STREET, N.W., WASHINGTON, D.C. 20036 TEL. 347-2315

September 27, 1976

Mr. Philip Read
Director, Federal Procurement
Regulations
General Services Administration.
Washington, D. C. 20406

Dear Mr. Read:

This is in reference to the proposed amendments to the Federal Procurement Regulations dealing with patents, transmitted by your letter of August 3, 1976 to Mr. Karl G. Harr, Jr., President of this Association.

In view of the subject matter of the proposed amendments, this Association has not formulated a position thereon. However, comments received from a member company, copy attached, were thought to be of such significance as to warrant being forwarded informally for your consideration.

Very truly yours,

Franz O. Ohlson, Jr.
Vice President
Aerospace Procurement Service

FOO:ph

Attachment

Proposed Amendments to Federal Procurement Regulations on Patents

The idea of leaving title to subject inventions with the Institution where the inventions are made is good, but some of the conditions for qualifying under the program are highly objectionable. Section VIII of the proposed agreement, for example, requires R&D subcontractors to assign their subject inventions to the Institution or to the Government; Section IX, subsection (f) prevents the Institution from granting license rights to employee inventors or to organizations with which the inventor(s) is connected; and Section X prohibits assignment of subject inventions to anyone other than a patent management organization approved by the contracting agency. These conditions are counterproductive and discourage the making of subject inventions and the utilization of the inventions.

Qualifying subcontractors should be allowed to retain at least a defeasible title to their subject inventions, and inventors and their associates should be allowed to participate in achieving utilization of their inventions through licensing or otherwise.

As you well know, there is generally no one more dedicated to achieving utilization of an invention than the inventor, particularly when he stands to share in the profits of a successful venture. Why then tie the hands of these people and their business associates and principals by limiting their participation?

The restriction against assigning rights to anyone other than an approved patent management organization is likewise objectionable as discriminatory and void of any useful purpose in achieving utilization of subject inventions. While reasonable conditions such as granting only a title which is defeasible for failure to achieve utilization might be appropriate, there is no apparent reason why such an assignment should not be available to any qualified applicant willing to accept the same conditions.

The Government procurement patent policy pendulum is showing signs of swinging back from a title-taking position to a license position. Industry should encourage this movement and help guide the return so that the patent system will be able to better serve the public interest in Government funded R&D.

Conditions in regulations which prevent the inventor and those closest to the invention from participating in its commercialization should be opposed. At the same time, however, reasonable conditions aimed at protecting the public against unbridled or unwarranted private economic gain from Government funded research should be recognized as proper. In this regard, the requirements in the proposed amendment to the regulations that the Institution use its royalty receipts, after payment of administrative costs and incentive awards to inventors, for educational or research purposes should not be objectionable.

UNIVERSITY OF WASHINGTON
SEATTLE, WASHINGTON 98195

Government Fiscal Relations and Patent Office
275 Administration Building AG-70

September 23, 1976

Mr. Philip G. Read
Director of Federal Procurement Regulations
General Services Administration
Federal Supply Service
Washington, DC 20406

Dear Mr. Read:

Thank you for your letter of August 5, 1976 inviting comments on a proposal to extend the Institutional Patent Agreement (IPA) concept to all Federal granting and contracting agencies.

The University of Washington has had such an agreement with DHEW for nearly eight years, and we are pleased to note that action is moving forward towards a fuller implementation of the concept. We believe that the Committee on Government Patent Policy has adequately identified the several benefits of using an IPA at approved institutions. In our view, the most beneficial aspect of the IPA is that it establishes a certainty factor that enables the University to move forward promptly with technology transfer arrangements.

In general, we are satisfied with most of the provisions in the proposal you sent to us for review. We are also pleased to note the absence of any clause limiting the maximum amount of royalty income that the grantee-contractor may pay to faculty or staff inventors. Such restrictions are difficult to state in relationship to the various institutional policies, and we feel that the royalty arrangements should be one of the factors, among others, in the total institutional proposal, i.e., on a case-by-case basis.

The remainder of our comments are keyed to the proposal you sent to us:

I. Scope of Agreement

This section suggests piecemeal application of the IPA to the institution's grants and contracts by providing for a cut-off date beyond which contracts would not be affected by the IPA. We think that a complete cut-over would be simple and preferable for all inventions identified after the date of the IPA, irrespective of how long the specific contract had been in effect.

V. Invention Identification, Disclosures, and Reports

Since grantee or contractor's proposals may contain information of patent significance, we recommend that an additional sentence be added to Clause V(d): "The Government agency will take reasonable steps to insure that data or information furnished by the Institution is not released to the public before the agency obtains confirmation from the Institution that the proposed release will not adversely affect the patent interests of the Institution and the Government."

IX. Administration of Inventions in Which the Institution Elects to Retain Rights

We do not agree with the provisions of subparagraph (c) under this section. The Government, rather than the Institution, should have the responsibility to monitor its procurements and claim royalty exemptions at the time of purchase. Moreover, it is not reasonable for the Government to look to the Institution and/or the inventor for royalty refunds (perhaps applicable to transactions occuring several years in the past) if the Government mistakenly pays the full price to a licensee rather than the royalty-free price.

Notes for Completion of IPA

Item 6 suggests that an agency may restrict the IPA to contracts (and exclude grants, for example). We cannot foresee any logical circumstances justifying the exclusion of grants. To the contrary, such exclusion would be counter-productive towards achieving effective technology transfers. We recommend that Item 6 be deleted.

Information to be Submitted by Institution

Sub-clause (a) requires the applicant to furnish detailed data regarding invention and patent administration experience covering the past 10 years. In our opinion, it will be burdensome for most applicants to develop the required statistics for so many years back. We believe that data covering the most recent five years would be adequate to demonstrate the applicants' experience, and would not require as much research of past records in order to summarize the requested information.

The above-stated comments are intended as constructive suggestions to hopefully improve an otherwise excellent proposal. The efforts of the Committee on Government Patent Policy and your office are commendable.

Sincerely yours,

Wallace C. Treibel
Government Fiscal Relations and
Patent Officer

WCT:mb
cc: Mr. Adkisson
Dr. Geballe
Mr. Latker
Mr. McCartney
Mr. Ryan
Mr. Scuriock

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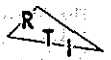

September 10, 1976

Mr. Philip G. Read, Director
Federal Procurement Regulations
General Services Administration
Federal Supply Service
Washington, D. C. 20406

Reference: Proposed amendment to FPR Subpart 1-9.1, Patents

Dear Sir:

Thank you for giving me the opportunity to comment on the proposed amendment.

I have a few comments but first I want to say that it takes a big step in an important direction. I fervently hope it is accepted by all agencies that support university and non-profit research and development because I believe it will go a long way toward introducing technology to the market place where consumers can benefit therefrom.

My comments pertain to the criteria set forth for the institution's technology transfer program. The wording in subparagraph (5) of 1-9.107-7(b) is quite satisfactory. To quote, the institution must have "an active and effective promotional program for the licensing and marketing of inventions." However, in other sections of the Revision and in the sample IPA, there are strong implications that the government has in mind certain currently existing patent management organizations. See for example the emphasis in Section X of the sample IPA on "organizations" rather than "capability." Indeed, the Report of the Interagency Patent Policy Committee went so far as to name two organizations.

There are disadvantages, as well as advantages, to the current nationally known patent management organizations. One prominent disadvantage is that they are self-serving, i.e., they seek patents that will bring them the most income and those that will have a short-term pay-off. There are many inventions which are useful to industry, and through industry useful to the consumer, in which the potential pay-off is below the interest threshold of these companies but is still economically valuable. One accusation that has been made is that they skim the cream off the top.

A further criticism is that they are too far from many universities to provide the personal touch that most inventors need. I would like to see universities encouraged to establish their own technology transfer function or to use local institutions (The University of North Carolina at Chapel Hill and North Carolina State University in Raleigh have arranged with the Research Triangle Institute to undertake their patent management activities). This

also creates the environment whereby a greater patent awareness can be brought to the university research staff. I am not encouraged by the results of the Patent Awareness program of the Research Corporation at the three universities I have observed. Inventors have a strong suspicion of the "traveling salesman" or the "big-city slicker." An effective local capability gets around these problems. I do agree that a demonstrated patent management or technology transfer capability must exist before an IPA is made. Therefore, universities starting their own program must accept case-by-case negotiations of inventions until they have demonstrated their capability or use an existing organization while they develop such capability.

In order to accomplish what I would like to see, I suggest that in Section X of the sample IPA the word "organization(s)" be changed to "agent(s)" including the section title. This should not cause confusion with the word "Agency" if agent is always modified by the words "patent management." In the present version, six of the eight times "organization(s)" is used it is so modified. It would cause no problem to properly modify the word "agent" the other two times it is used.

To make the Revision consistent with this suggestion, the words "patent management organization(s)" appearing elsewhere should be changed to read "patent management agent(s)":

Paragraph (I) of subsection (c) of 1-9.107-6 (Page 3)

Item 9/ of Notes for Completion of IPA (Page 18)

Paragraph (7) of the new section 1-9.109-7(a) (Page 20)

Further, the information requested in subparagraphs (9)(ii) through (9)(vi) of section 1-9.109-7(a) should be broken down by the patent management agent used. This will give the Agency an opportunity to evaluate the effectiveness of the current patent management agent in those cases where a change may have been made recently.

Gentlemen, I applaud your efforts and the results of those efforts. I look forward to seeing this policy widely used by government agencies. Thank you again for the opportunity to comment.

Sincerely,

Ralph L. Ely Jr

Ralph L. Ely, Jr., Director
Office of University Relations

RLEjr:cd

cc: Norman J. Latker

STANFORD UNIVERSITY
STANFORD, CALIFORNIA 94305
Area Code 415 497-3567

OFFICE OF
TECHNOLOGY LICENSING
ENCINA 6-930

September 8, 1976

Mr. Philip G. Read
Director of Federal Procurement Relations
General Services Administration
Federal Supply Service
Washington, D.C. 20406

Subject: Proposed Federal Procurement Regulations dealing with Institutional Patent Agreements with Educational and other Non-Profit Institutions

Dear Mr. Read:

This letter will comment on the proposed standard Government Institutional Patent Agreement with educational and other non-profit institutions, which document was provided with your letter dated August 5, 1976. As a general comment, we wish to observe that the proposed uniform regulations are a substantial improvement from the varying regulations of the various agencies and should enhance the flow of technology to the public from research conducted at the country's educational and other non-profit institutions. The following are directed to revisions which we believe will enhance the utility of the Institutional Patent Agreement (IPA) and its administration both by the universities and other non-profit institutions as well as by the government agencies.

1. Exclusion of certain contracts from the IPA. An intent of the IPA is to reduce the administrative burden on both the agencies and the universities. However, the clauses which pertain to excluding certain contracts from the IPA will add to the administrative burden. It is noted that the very successful HEW IPA does not have such a provision. With such a provision for exclusion of certain contracts, there is then a requirement on the part of the agency grant and contract administration personnel to have grants and contracts reviewed by the agency patent personnel to determine, using unspecified criteria, whether or not a particular grant or contract should be excluded from the IPA. From the contractor's point of view, the contractor must then deal with exceptions to a standard operating procedure which is administratively cumbersome. It can

be observed exceptions to normal rules in administrative requirements are similar to exceptions in the English language in terms of complicating something simple.

It is not clear why the ad hoc subcommittee of the Committee on Government Patent Policy of the Federal Council for Science and Technology saw fit to include this requirement. If there isn't any documented history of abuses leading to the need to have such a provision, we strongly recommend that the clauses pertaining to exclusion of contracts from the IPA's be deleted. (Depending on the motivations of the subcommittee for including this requirement, the reasoning of paragraph 6 below may also call for deletion.)

2. Requirement to normally license non-exclusively. Paragraph (C) of the proposed new subsection (c) to 1-9.107-6 specifies: "A requirement that licensing by the institution will normally be non-exclusive except...". In actual practice, because of the undeveloped nature of university technology, a first license will "normally" be exclusive, not non-exclusive. We recognize the intent of this paragraph is to insure that, where possible, first licensing will be done on a non-exclusive basis, and we have no objection to the intent. However, the subparagraph wording is somewhat misleading, particularly to institutions beginning a licensing program. We thus recommend revised wording such as: "A requirement that the institution make subject inventions available on a non-exclusive basis except...".

3. The inapplicability of the IPA where the institution is a subcontractor (last sentence of Article I of the IPA). It is not clear why the IPA does not apply where the institution is a subcontractor. It would appear the logic of using an IPA applies equally well to subcontracts as well as prime contracts.

4. March-in rights for public health or safety needs or for other public purposes. Subparagraph IV.(b)(B) covers march-in rights for the government to require granting licenses to the extent that the invention is required for public use by government regulations

or as may be necessary to fulfill public health or safety needs, or for other public purposes stipulated in the applicable contract. The need to include this subparagraph is well understood. However, on its surface, it is a potential danger to an exclusive licensee that may be planning to invest substantial risk capital in the development of an invention. This is particularly appropriate in inventions in the health field, where very large sums are expended at risk before first public marketing. It will be helpful if the IPA can include an assurance for potential licensees that this subparagraph is only invoked in rare situations when certain specified conditions occur.

5. Filing of foreign patent applications. Article VII a. specifies certain time periods for filing foreign patent applications (note Article VII is mislabeled as Article VIII). This article also provides that the specified periods can be extended if approved in writing by the agency.

While we can comply with paragraph VII(a), it appears to be an unnecessary and possibly counterproductive "overcontrol." It is readily observed that additional administrative effort is required both on the part of the agency and the institution to follow both the arbitrary periods of VII(a) and actual bar dates. The requirements, intended to administratively insure foreign filing dates are not missed, may possibly be self-defeating of that goal because an institution's licensing officer may be lulled into overlooking the need to take into account many other timing considerations with respect to a foreign filing program than indicated in these paragraphs. For example, if publication has occurred, and the U.S. patent application is not filed until after such publication, an institution still can obtain patent protection in West Germany and Japan if they file within six months of the publication. Other factors also come into play such as the need to obtain an export control license before filing abroad in certain cases, such as filing in Japan after publication but less than six months after the U.S. filing.

As a further observation, in a dynamic licensing program of undeveloped technology of uncertain value, more often than not corresponding foreign patent applications are filed after 8 months from the date of the U.S. application. VII(a) then requires both

the agency and the institution to set up procedures to follow artificial dates, to request and issue approvals for variations from those artificial dates. Economic forces and practical considerations will drive filing before bars, not arbitrary time periods. We recommend that subparagraph VII(a) end after the word "regulations" in line 5. (It is observed Article VI which covers filing of domestic patent applications could similarly be shortened for similar reasons.)

In regard to subparagraph VII(b), we recommend, to reduce administrative burdens upon both the agency and the institution, that rather than notify the agency after filing of each foreign patent application, that data regarding foreign applications filed be included in the annual report.

6. Approval to license. Subparagraph IX(f) prohibits the granting of licenses to certain persons or organizations who have been involved with research leading to the invention, even on a non-exclusive basis, except after organizations which have no involvement decline to license. Rather than having the three criteria indicated in that paragraph treated as prohibitions, the IPA should encourage institutions to make arrangements meeting one or more of the criteria, and on an exclusive basis.

The critical ingredient to any transaction which will transfer a research advance to a product available to the public, in our free enterprise system, is economic incentive. It is apparently perceived a conflict of interest will exist if an individual or organization associated with an invention conceived under government sponsored research becomes motivated by economic factors, and this result will be contrary to the public interest. Clearly, if government funds are diverted from a grant or contract to private pockets, this economic motivation is both corrupt and contrary to the public interest. But being motivated to make money by investing effort and capital at considerable risk in development of a research advance to a product, and then succeeding in making that money (in spite of well known odds against such success) appears both appropriate to our economic system and very much in the public interest.

We also note IX(f) will prohibit licensing by Stanford to Hewlett Packard, Varian and many

more companies because of our clear role as "promoter, organizer, or financier" in those companies (unless other companies in their markets all decline to license). In addition, it is not clear if the definition of "financier" extends to companies represented by investments of our endowment.

The challenge to the ad hoc subcommittee is to develop mechanisms to achieve the goal of early and broad transfer of research findings under government financed research to public use and benefit. The subcommittee has chosen the free enterprise system in lieu of the option of government development or the option to do nothing. Subparagraph IX(f) is in direct contradiction to the correct decision of the subcommittee and to the achievement of its goal. It is ironically also in direct contradiction to programs of the National Science Foundation-Research Applied to National Needs and the Small Business Administration. We strongly recommend that subparagraph IX(f) be deleted in its entirety.

The key to successful implementation of the IPA will be both the process of selection of institutions eligible for the IPA and the provision for termination on 30 days notice for convenience. Thus, if an institution performs incompetently (habitually missing bar dates, for example) or abrogates IPA provisions in letter or spirit, the IPA can be promptly terminated. The funds saved by reducing government administration could beneficially be utilized to improve licensing programs of the institutions--but not the point of removing the risk from their risk/reward equation.

We appreciate the opportunity to have been able to comment on the proposed IPA with educational and non-profit institutions. If amplification of the foregoing comments will be helpful, or if there are any questions, we will be pleased to cooperate.

Very truly yours,

Niels J. Reimers
Manager, Technology Licensing

cc: Norman Latker, DHEW
David Eden, Dept. of Commerce
Urban Faubion, Stanford Research Institute
Howard Bremer, Wisconsin Alumni Research Foundation
Philip Sperber, Cavitron Corp.
Norman Jacobs, Amicon Corp.
Clive Liston, Stanford University

NJR:sh

COUNCIL OF DEFENSE AND SPACE INDUSTRY ASSOCIATIONS (CODSIA)

2001 Eye Street, N.W.
Washington, D.C. 20006

♦

(202) 659-9037

14 September 1976

Mr. Philip G. Read
Director, Federal Procurement Regulations
General Services Administration
Federal Supply Service
Washington, D. C. 20406

Dear Mr. Read:

The member associations of the Council of Defense and Space Industry Associations (CODSIA) appreciated the opportunity provided in your letter of 3 August 1976 to comment on a proposed amendment to the FPR dealing with Institutional Patent Agreements with educational and other non-profit institutions having a technology transfer program meeting specified criteria. However, in this instance, the member associations of CODSIA will not be submitting coordinated comments through CODSIA.

It may be that one or more of the member associations might submit separate comments directly to you.

Sincerely,

George E. Youngblood
Administrative Officer

GEY/m

COPY

THE UNIVERSITY OF ROCHESTER
ROCHESTER, NEW YORK 14642

OFFICE OF RESEARCH & PROJECT ADMINISTRATION
AREA CODE 716 TEL.: 275-4034

31 August 1976

PATENT BRANCH, GSA

SEP 8 1976

Mr. Philip G. Read
Director of Federal Procurement Regulations
General Services Administration
Federal Supply Service
Washington, D.C. 20406

Dear Mr. Read: Re: FPR, Subpart 1-9.1 Amendments

Your letter of 5 August 1976 regarding the above patent provisions and the Institutional Patent Agreement with educational and other nonprofit institutions has been received.

We are pleased to note the general trend toward a more reasonable and realistic approach in bringing inventions to the public sector quickly by means of such agreements.

However, some concern exists in the language which appears to speak of individual agreements negotiated with each of the various agencies. See for example proposed Subsection(6) to 1-9.107-4(a) line 9 referring to "...an..." agreement and also proposed Subsection (c) to 1-9.107-6 line 2 "...an..." agency, and line 3 "...an..." duplicated. This would appear to mean that it is intended that no single agency-wide agreement is contemplated, which we believe to be a mistake resulting in costly and needless duplication of work. It would seem more reasonable to expect that the information required to satisfy one agency in this regard should generally suffice for all others.

Finally, we are in agreement with the deletion of a proscribed award scheme and the resulting proposed Section (F)p.3 providing for incentive awards and utilization for educational and research purposes. The agency imposition by means of a previously determined royalty amount to be awarded to an inventor appears to be an unwarranted intrusion into the relationship between the grantee institution and its employees.

We are pleased to have had this opportunity to offer the above comments.

Very truly yours,

David A. McBride,
Director

DAM:acm
cc: Norman Latker, Esq.

RUTGERS
THE STATE UNIVERSITY
OF NEW JERSEY

RESEARCH AND SPONSORED PROGRAMS • 116 COLLEGE AVENUE • NEW BRUNSWICK • NEW JERSEY 08903 • 201/932-7116

August 10, 1976

Mr. Philip G. Read
Director of Federal Procurement Regulations
General Services Administration
Federal Supply Service
Washington, D.C. 20406

Dear Mr. Read:

This is to acknowledge receipt of your memo concerning the amendment on patents proposed for the Federal Procurement Regulations. I have no questions to pose or views to express that are contrary to the content of the document in its present form.

Sincerely yours,

David Pramer
Associate Vice President for Research

DP:bd

cc: Mr. E. Isaacs

WISCONSIN ALUMNI RESEARCH FOUNDATION

POST OFFICE BOX 7365 • MADISON, WIS. 53707 • TELEPHONE (608) 263-2600

September 17, 1976 263-2831

Mr. Philip G. Read
Director of Federal Procurement Relations
General Services Administration
Federal Supply Service
Washington, D. C. 20406

Dear Mr. Read:

Re: Federal Procurement Regulations - Proposed Institutional Patent Agreement

We appreciate having the opportunity to comment upon the proposed Institutional Patent Agreement with educational and non-profit institutions which accompanied your letter of August 5, 1976. We are pleased to see that consideration to this approach to the transfer of technology from such organizations has progressed to this point. Our comments on the terms and provisions of the proposed Institutional Patent Agreement follow:

1. Scope of Agreement

The comments here can also be readily tied to and should be considered along with the comments to Article IV (b) (B).

We do not understand the need for any exclusion of certain contracts from the Institutional Patent Agreement. To our knowledge there has been no history of abuses leading to the need for such exclusion. More importantly, no criteria have been established upon which the decision to exclude is to be based. Hence, the decision at the outset to exclude a contract from the scope of the Institutional Patent Agreement can be completely arbitrary in nature. The inclusion of such a provision also seems redundant in view of the march-in rights reserved to the Government in Article IV (b) (B).

In addition, for every exclusion from the Institutional Patent Agreement, the only alternative presented to the Institution is to abandon administration of an invention arising under the

excluded contract or to again go back to a case-by-case determination. Experience with this latter approach has established that it is unsatisfactory. I can introduce what can be critical time delays in the transfer of the technology to the private sector with the result that the public may in reality be deprived of that technology. It will certainly serve to significantly increase the burden of administering the invention.

Further in relation to Article I of the proposed Institutional Patent Agreement, we do not understand why the Institutional Patent Agreement should not apply to subject Inventions where the Institution is a contractor under a prime contract of the Agency. By parity of reasoning if the Institutional Patent Agreement is available to an Institution where it is the prime contractor it should also apply when the Institution is a subcontractor.

IV (b) Minimum Rights Acquired by the Government

The general emphasis in the application of Section (b) appears to be the reverse of that in existing like provisions of the Institutional Patent Agreements with both the Department of Health, Education, and Welfare and the National Science Foundation. The format in which this Section has been couched would appear at the outset to shift the burden of proof in the administration of an invention. In other words, it would appear that under the literal language of the proposed provision the Government can request the Institution to grant a license to a third party at any time before the running of the 3-year period after the patent issues. The burden of proof then appears to shift to the Institution to show that effective steps have been taken to bring the invention to the point of practical application, or that the invention has been licensed on reasonable terms or that principle or exclusive rights should be retained - the 3-year "incubation" period being available to the Institution by implication.

It would seem more appropriate that the 3-year "incubation" time should be more specifically set out so that there is no misunderstanding of the intent of the whole of paragraph (b). We believe the language of Article XII (a) of the Institutional Patent Agreement with the Department of Health, Education, and Welfare would be more appropriate.

With regard to paragraph (b) (B) of Article IV the decision (see comments under Scope of Agreement above) can be an arbitrary one. No guidelines or criteria are established upon which such a decision can be based. Moreover, the decision to license others can be made under this provision without even giving the Institution an opportunity to be heard. That opportunity, at the very least, should be included in the provision. The format of the corresponding provisions from the Institutional Patent Agreement with the Department of Health, Education, and Welfare, Section XII (b), which is reproduced below for your convenience, would be more appropriate and equitable:

> "The Grantor reserves the right to license or to require the licensing of other persons under any U. S. patent or U. S. patent application filed by the Grantee on a subject invention on a royalty-free basis or on terms that are reasonable in the circumstances, upon a determination by the Assistant Secretary (Health and Scientific Affairs) that the invention is required for public use by governmental regulations, that the public health, safety, or welfare requires the issuance of such license(s), or that the public interest would otherwise suffer unless such license(s) were granted. The Grantee and its licensees shall be given written notice of any proposed determination pursuant to this subparagraph not less than thirty (30) days prior to the effective date of such determination, and that if requested, shall be granted a hearing before the determination is issued and otherwise made effective."

It is submitted that the Institution should at least have the right to be heard and adoption of the above language from the Department of Health, Education, and Welfare Institutional Patent Agreement is urged in place of Article IV (b) (B).

V. Invention Identification, Disclosures and Reports

The implication of Section (d) is that where no patent application is filed the Institution can bar or prohibit publication without limitation.

VII. Filing of Foreign Patent Applications (This Article is mislabelled at VIII in the proposed Institutional Patent Agreement.)

The time frames established by Subsection (a) (i) are in fact arbitrary in nature and have no relationship to the practices which normally govern the filing of patent applications in foreign countries in a patent-license situation. Traditionally, once the convention date has been established, as by filing in the U. S. before publication, it is the usual practice to delay as long as possible the filing of foreign applications. This is done for a number of reasons, among which are:

(1) to establish a commercial interest or perhaps even enter into an actual license so that a more reasoned decision can be made on where to file corresponding foreign applications;

(2) to determine the effect of publications if and when made since certain countries do have grace periods after publication which do not absolutely bar the filing of a patent application;

(3) administrative considerations such as the obtaining of export licenses under certain conditions; and

(4) the increase in the administrative burden which the establishment of artificial time periods, over and above the normally considered and controlling statutory time periods, which now goven foreign filing considerations, will cause.

In view of the above we would suggest that the portion of Article VII (a) following "regulations" in line 5 be deleted.

Some of the reasoning applied above would also apply to Article VI (a) relating to the filing of domestic patent applications, with, of course, provisions which would protect the agency in the event the Institution decided to file no patent application.

IX. Administration of Inventions in Which the Institution Elects to Retain Rights

Section (b)

In relation to the time provisions of Section (b) of this Article, it has been our experience that development of inventions arising in a University environment, and particularly those in the pharmaceutical field, can take an exceedingly long time. Consequently, the finite period of 8 years from the date of granting an exclusive license for the maximum life of such license may, in many situations, be completely inadequate for the licensee to even introduce an invention into the market, let alone recoupt his expenses from the sale or use of such invention. It is well understood that many of the major delays in reaching the marketplace with an invention relating to the pharmaceutical filed are occasioned by the control exercised by various Federal regulatory agencies. Since these practical considerations do pertain, we would suggest that the running of the 8-year period be tolled for that period of time that the permission to sell or use the invention in the marketplace, up to the receipt of approval for such marketing or use, is in the hands of the regulatory Agency in control. The inclusion of such a provision would be equitable to the licensee without affecting the protection afforded the public by the march-in provisions of the agreement and could be a significant factor to a favorable determination by a company in the private sector to invest the necessary funds to commercially develop a University generated invention.

IX Section (f)

We would suggest the deletion of Section (f) of Article IX.

On the one hand, the effect of Sections (a) and (b) of Article IX is to leave the decision concerning licensing with the Institution and then through the operation of Section IX (f) promptly take away a portion of that prerogative.

The provisions of this Section could have a decidedly adverse affect upon the transfer of technology from the University to the private sector. Thus, who can more quickly transfer the technology of a Subject Invention than one who participated in the research leading to its conception and/or actual reduction to practice? Who is most knowledgeable about the subject matter of the invention? Who has more of the "know-how" which may be an ancillary but unwritten and undefinable part of the invention? In the event the investigator is willing to assume or participate in the high risk involved in transferring technology from the University to the private sector, where there is little doubt that the odds are extremely long in achieving success, why is his investment so different from that of a third party as to become the subject of a specific prohibition? If such a person, or an organization of which such a person is a part, meets all the criteria to qualify for a license, it seems abundantly clear that transfer of technology involved to the public would occur more expeditiously than if third party, which has first to be taught the technology before such transfer can be made, attempts to make such transfer. We firmly believe that there is little dangerof "unjust enrichment", which appears to be the thrust of Section (f), when there is so little capability to adequately forecast of the commercial success of any given invention and where the investment risks have not been changed. It is well recognized that each invention has its moment in time and if an Institution is under compulsion to first try to find organizations other than those specified in Subsections (i) (ii) (iii), the time delay could be fatal to the transfer of technology to the private sector. Also, the time delay occasioned by obtaining special permission from the agency involved, could also mitigate against the timely transfer of the technology and would, without doubt, significantly increase the administrative burden for the Institution as well as the Agency.

A further point with regard to Section IX (f) is that Institutions for the most part have had a great deal of experience with and have had been most cognizant of

potential conflict of interest situations which arise because of their operations and because of the various interrelations between funding arising from private and public sources (the latter including Federal Agency funding) and consulting arrangements entered into by University investigators. We believe that the Institutions' ability to police these problems is well established and that in the great majority of situations such policing is adequate without imposing specific restrictions such as are imposed by this Section.

As a last point, some of the terms used within Section (f) tend to defy definition. For example, in the context of the Section what in fact does "promoter", "organizer" or "financier" mean? These words can have very different connotations depending upon the kind of institution to which they are being applied.

If you or any of your colleagues have any specific questions on the foregoing remarks or would like additional information regarding our experiences with extant Institutional Patent Agreements we will be pleased to give you our complete cooperation.

Very truly yours,

Howard W. Bremer

Howard W. Bremer
Patent Counsel

HWB:rw

CALIFORNIA INSTITUTE OF TECHNOLOGY

PASADENA, CALIFORNIA 91125

PATENT OFFICE

17 August 1976

Mr. Philip G. Read
Director of Federal Procurement Regulations
U. S. General Services Administration
Washington, D. C. 20406

Dear Mr. Read:

This is in response to your August 5 letter announcing the proposed amendment to Chapter 1, Title 41 of the Code of Federal Regulations specfically involving a proposed subpart 1-9.1 dealing with patents and Institutional Patent Agreements.

This is to express our enthusiastic approval for this type of approach to standardization of government patent policy as it affects educational and other nonprofit institutions. However, I do have some suggestions for possible amendment.

First, I would propose that the words ---the reason, including--- be inserted before "any written reports" in the third from the bottom line of Section III(a) of the proposed IPA. This proposal is made because the last sentence of this subsection, at least inferentially, implies a requirement for formal and possibly expensive inquiry as the basis for each negative decision. Under the reporting requirement of Section V(a), and the definition of "subject invention" in Section II(a), many items will be reported which will obviously be of a noncommercial nature. In practice, decisions as to many such items are made informally, and institutions such as ours would be much more comfortable if the language were altered as suggested above.

I would further suggest that a new subsection be added to Section VIII of the proposed IPA to take care of a situation which has troubled us in connection with the existing agreements with HEW and NSF. The problem arises from the fact that some educational institutions (as in our case) have policies which prevent granting of rights in inventions to sponsors other than government. Accordingly, when we are the subcontractor to another educational institution which has an IPA, the requirement that title vest in the prime contractor forces either a deviation from our own policy or negotiation of some sort. We would suggest a new subsection be added to provide that when the subcontractor has an IPA with the agency involved -

(1) the subcontractor inventions be subject to the IPA of the subcontractor;
(2) the reporting responsibility of the subcontractor be directly to the agency; and
(3) information copies be required to be sent to the prime contractor.

It is my feeling the above proposals would improve the proposed Institutional Patent Agreements, and I hope they will receive serious consideration.

Sincerely,

T. L. Stam

T. L. Stam
Patent Officer

S/r

cc: Mr. Norman Latker

MEMORANDUM

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
OFFICE OF THE SECRETARY

TO : Mr. Latker

DATE: 17 August 1976

FROM : Mr. Ferris

SUBJECT: Telecon with Mr. Stam, Cal Tech (213-795-6811) re proposed GSA Institutional Patent Agreements.

Mr. Stam called and advised that he had received a letter from Philip G. Reed at GSA requesting comments regarding the proposed GSA IPAs. He has two suggestions based upon difficulties that he has experienced with IPA's from us and from NSF which he wishes to bring to your attention.

1. Section IIIa provides that if the grantee elects not to administer an invention under the IPA it must provide the documentation upon which the decision was based. This appears to require that they document every turn down. Some inventions reported are so obviously lacking in commercial potential, etc. that a decision is made not to administer under the IPA without further evaluation, surveys, etc. He suggests that this clause be clarified to eliminate the implication that documentation is required in every case, but that it be provided only in those cases in which it has been established.

No change necessary

2. Section VIIIa requires that an IPA holder retain title to inventions made by a contractor of the grantee. This is fine except when the IPA holder is the contracor. Cal Tech's policies preclude granting title to inventions to anyone other than the Government. He suggests that this section be amended by adding a provision that where the contractor has an IPA its responsibility to report is to the agency sponsoring the research and that the disposition be in accordance with the IPA.

Agree change necessary

Mr. Stam would like to discuss these two points with you when you have had a chance to think about them.

UNIVERSITY OF CALIFORNIA SYSTEMWIDE ADMINISTRATION

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SANTA BARBARA • SANTA CRUZ

Vice President--
Business and Finance

BERKELEY, CALIFORNIA 94720

August 16, 1976

Mr. Phillip G. Read
Director of Federal Procurement Regulations
General Services Administration
Federal Supply Service
Washington, D.C. 20406

Dear Mr. Read:

Mr. Norman Latker has transmitted to me a copy of the proposed amendment to Sub-part 1-9.1 of the Federal Procurement Regulations. Although I feel that the information which is required to be filed by institutions seeking Institutional Patent Agreements is somewhat detailed any may be onerous for an educational institution to readily gather together, I nonetheless feel that the overall approach is one that is most commendable and therefore, on balance, I feel that the proposed amendments are satisfactory and would be of benefit to educational institutions.

Very truly yours,

Mark Owens, Jr.

AMERICAN SOCIETY OF CIVIL ENGINEERS
CONSTRUCTION DIVISION
Committee on Contract Administration

4099 Derry Street
Harrisburg, Pennsylvania 17111

August 18, 1976

Mr. Philip G. Read
Director of Federal Procurement Regulations
General Services Administration
Federal Supply Service
Washington, D. C. 20406

Re: Federal Procurement Regulations
Subpart 1-9.1 - Patents

Dear Mr. Read:

Receipt is acknowledged of your letter of August 3rd requesting a review of the proposed subject revision.

Our Committee, at present, has no expertise or experience in the area of patents and, therefore, we will not be able to make a contribution on this particular subject. During and prior to 1971, our Committee had reviewed and offered comments on various proposed revisions to the FPR. Our last contact with your office was on the same subject matter, Patents, in 1972. I suspect that your reference to our organization may have us mis-identified as being interested in patents. Our Committee is involved with the broad field of Construction Contract Administration, and we would be pleased to submit comments in other areas of the FPR's.

Sincerely,

Robert D. Rowland, P. E.

RDR/hg

cc: Robert A. Rubin w/Proposed FPR Revision
: George A. Fox

WASHINGTON UNIVERSITY
ST. LOUIS, MISSOURI 63130
OFFICE OF ASSOCIATE VICE CHANCELLOR FOR RESEARCH

August 17, 1976

Mr. Philip G. Read
Director of Federal Procurement Regulations
Federal Supply Service
General Services Administration
Washington, D.C. 20406

Dear Mr. Read:

I am responding to your letter of August 5, 1976 which forwarded the proposed FPR amendment covering Institutional Patent Agreements.

It is my understanding that development of this amendment by the ad hoc subcommittee of the Committee on Government Patent Policy has been a long and thoughtful process. It is obvious that the amendment draft is workable and represents a major step forward in securing for the American public the material benefits of Government sponsored research not previously obtainable. While no overnight miracles should be anticipated this proposal provides the sound procedures, long term commitments and essential incentive mechanisms, the lack of which has produced the poor results achieved to date. I whole heartedly endorse its acceptance.

There is always room for change in the draft of such a new regulation much of which may represent personal preferences. I would hope that the earliest adoption of this proposed amendment will not be hampered by a deluge of conflicting personal changes. Rather, I would hope that the well thought out product of the ad hoc subcommittee be accepted, placed in practice and then, after a reasonable period of use by the various agencies, improvements based on experience should be sought.

Again let me express my hope that this progressive and innovative amendment be adopted as soon as possible. For the first time the basis for a cooperative relationship among Government research sponsors, institutional research scientists and the production sector of our economy is being established for public benefit. Without the enthusiastic involvement of all three parties the delivery of new and improved products and services stemming from Government research programs will not prosper in the future any more than it has in the past.

Sincerely,

E. L. MacCordy
Associate Vice Chancellor for Research

cc: Norm Latker

ELM/sbe

MASSACHUSETTS INSTITUTE OF TECHNOLOGY
77 MASSACHUSETTS AVENUE · ROOM E19-702
CAMBRIDGE, MASS. 02139

OFFICE OF SPONSORED PROGRAMS
General Counsel
Room E19-722

TELEPHONE (617) 253- 6966

September 13, 1976

Mr. Philip G. Read
Director of Federal Procurement
Regulations
General Services Administration
Federal Supply Service
Washington, D.C. 20406

Dear Mr. Read:

Thank you for your thoughtfulness in providing M.I.T. with a copy of the proposed amendment to the Federal Procurement Regulations concerning patents. M.I.T. supports the addition of provisions dealing with institutional patent agreements for qualified educational and other non-profit institutions.

We would propose that the issuance of IPAs to qualified institutions be made mandatory for all government agencies rather than leaving same to the discretion of each agency. We would assume that if the criteria for the award of an IPA is satisfactory to one government agency, it should normally be satisfactory to other agencies. We would also propose a provision within the IPA that states for the record that the agency granting the IPA recognizes that the 8-year time period for a limited-term exclusive shall automatically be told in those instances where regulatory agency approvals (such as FDA) are required to enable a licensee to market the invention. With these few comments, however, we are in accord with the proposed regulations. Thank you.

Very truly yours,

Arthur A. Smith, Jr.
General Counsel
Office of Sponsored Programs

AAS:LB

UNIVERSITY OF VIRGINIA
CHARLOTTESVILLE
22901

UNIVERSITY PATENTS PROGRAM
OFFICE OF ASSOCIATE PROVOST FOR RESEARCH
THORNTON HALL
(804) 924-7356

September 22, 1976

Philip G. Read, Director
Federal Procurement Regulations
General Services Administration
Federal Supply Service
Washington, D.C. 20406

Reference: Proposed Amendment to FPR Subpart 1-9.1, Patents

Dear Mr. Read:

This is in response to your letter of August 5, 1976 soliciting comments on the proposed FPR changes regarding Institutional Patent Agreements. Needless to say, we are in full agreement with the intent of this legislation and, except for some minor changes, feel that it will be effective and workable.

A few specific comments and proposed changes would be as follows:

1. Subsection (6) to 1-9.107-4 (A):
The language in line 3 indicates that agencies may enter into Institutional Patent Agreements. In our opinion, this should be changed to should or must enter into such agreements with those institutions having an approved technology transfer program. The rationale behind this change is that, those agencies which do not already have Institutional Patent Agreements, particularly ERDA, will certainly not be in any rush to change their system of handling patents without some strong impetus such as a regulation change. Additionally, from the University's end, it would significantly reduce the already demanding paperwork load if such things as annual reports, initial invention reports, request for waivers, etc. could all be handled on an identical basis, no matter which agency is involved.

2. Subsection (C) to 1-9.107-6:
(D) indicates a limiting period for the exclusive license necessary to provide incentive to the commercial firm. In order to prevent continual requests for extensions, some allowance should be made for an exempt period before the period of exclusivity starts running for those inventions which require government agency approval.

For example, a new drug invention may very well take five to six years of intensive effort before it is ready for the marketplace. Under the present terms of the recommended IPA, this would only leave three years of exclusivity remaining, and would effectively prevent a company from licensing such an invention. Another example would be the new regulations on pre-market clearance for medical instrumentation. Again, an exempt period must be allowed before the exclusive license limitation starts so that the licensee can obtain the necessary government clearances.

3. Items under the sample Institutional Patent Agreement IX. (f)

This paragraph should be deleted in its entirety. Although the rationale for this section is certainly laudatory, conflict of interest questions should not be handled at the government agency level, and in fact, are probably impossible to handle at that level. Universities are, by their very nature, highly sensitive to conflict of interest problems, and are already effectively solving this problem. Therefore, this is an area that should be left to the discretion of the University in the Institutional Patent Agreement.

Once again, we appreciate your thoughtfullness in allowing us to comment on this most important subject, and if you need any clarification or further information, please do not hesitate to contact me.

Very truly yours,

C. B. Wootten
Director

CBW:mtk

cc: G. A. McAlpine
Raymond J. Woodrow, President
Society of University Patent Administrators
Norman J. Latker

MICHIGAN STATE UNIVERSITY

OFFICE FOR RESEARCH DEVELOPMENT
258 ADMINISTRATION BUILDING

EAST LANSING · MICHIGAN · 48824

September 17, 1976

Mr. Philip G. Read
Director, Federal Procurement Regulations
General Services Administration
Federal Supply Service
Washington, D.C. 20406

Dear Mr. Read:

Receipt is acknowledged of your letter of August 5 forwarding the proposed Federal Procurement Regulations Revision prepared by the Ad Hoc Subcommittee on University Patent Policy.

We appreciate the opportunity to respond to the proposed revision and respectfully submit the following suggestions.

1. Consideration should be given to the proposed Institutional Patent Agreement (IPA) being mandatory for all federal agencies rather than an item to be employed at an individual agency's discretion (paragraph 1, proposed Federal Procurement Regulations Revision). We believe that in general the university community is supportive of the IPA's developed by the National Science Foundation and the Department of Health, Education, and Welfare (DHEW) and recommend, therefore, that the proposed revision be brought into as close agreement as possible with those agreements. The uniform application of a single IPA by all government agencies would greatly simplify this area of federal grant and contract negotiations and reduce enormously the administrative expense currently associated with such activities.

2. Page 7, Section IV, Minimum Rights Acquired by the Government.

   It is our understanding that this section deals with what is generally referred to as "March-in Rights" of the Government. It is suggested that this section be modified to include a provision whereby the institution can request a hearing prior to the Government exercising these rights. This would bring the proposed agreement more closely in line with the DHEW's Institutional Patent Agreement, which we find very acceptable.

3. Page 13, Section IX (b).

   The limitation of an exclusive license to eight years from the date of issue can be very inadequate and such a restriction could work a particular hardship in those cases of biomedical research where

pre-clinical testing may be required before the product can be brought to market. Such testing can consume years of effort even with the most diligent prosecution. It is suggested that language be introduced to exclude from the eight years of exclusivity allowed, that time which elapses between the submission of a request for clearance from a federal agency and the granting of that request.

4. Page 14, (f).

We recommend that this entire section be deleted. The requirement that clearance or approval must be obtained from the federal agency prior to licensing employees of the institution, etc., is an excessive intrusion on the management prerogatives of the institution.

Thank you again for the opportunity to respond to the proposed amendment. We will follow future developments with interest.

Sincerely,

Henry E. Bredeck
Associate Director

HEB/jms

cc: Cantlon
Latker
Woodrow

THE UNIVERSITY OF ROCHESTER
MEDICAL CENTER P.O. BOX 649
ROCHESTER, NEW YORK 14642

OFFICE OF RESEARCH & PROJECT ADMINISTRATION
Telephone (716) 275-4031

31 August 1976

Mr. Philip G. Read
Director of Federal Procurement Regulations
General Services Administration
Federal Supply Service
Washington, D.C. 20405

Dear Mr. Read: Re: FPR, Subpart 1-9.1 Amendments

Your letter of 5 August 1976 regarding the above patent provisions and the Institutional Patent Agreement with educational and other nonprofit institutions has been received.

We are pleased to note the general trend toward a more reasonable and realistic approach in bringing inventions to the public sector quickly by means of such agreements.

However, some concern exists in the language which appears to speak of individual agreements negotiated with each of the various agencies. See for example proposed Subsection(6) to 1-9.107-4(a) line 9 referring to "...an..." agreement and also proposed Subsection (c) to 1-9.107-6 line 2 "...an..." agency, and line 3 "...an..." duplicated. This would appear to mean that it is intended that no single agency-wide agreement is contemplated, which we believe to be a mistake resulting in costly and needless duplication of work. It would seem more reasonable to expect that the information required to satisfy one agency in this regard should generally suffice for all others.

Finally, we are in agreement with the deletion of a proscribed award scheme and the resulting proposed Section (f)p.3 providing for incentive awards and utilization for educational and research purposes. The agency imposition by means of a previously determined royalty amount to be awarded to an inventor appears to be an unwarranted intrusion into the relationship between the grantee institution and its employees.

We are pleased to have had this opportunity to offer the above comments.

Very truly yours,

David A. McBride,
Director

DAM:acm
cc: Norman Latker, Esq.

Battelle
Memorial Institute
505 King Avenue
Columbus, Ohio 43201
Telephone (614) 424-6424
Telex 24-5454

October 4, 1976

Philip G. Read
Director of Federal Procurement Regulations
General Services Administration
Washington, D.C. 20406

Dear Mr. Read:

We would like to take this opportunity to comment favorably on a proposed amendment to the Federal Procurement Regulations, Subpart 1-9.1, "Patents", which recently came to our attention. The proposed amendment involves the addition of provisions dealing with Institutional Patent Agreements with educational and other nonprofit institutions which have a satisfactory technology transfer program.

It is our belief that this proposed amendment will significantly further the stated objectives of the President's Memorandum and Statement of Government Patent Policy, dated August 23, 1971, by encouraging development and commercialization of inventions arising out of activities supported by the Federal Government. We feel that this proposed amendment quite properly recognizes that the public interest in the availability of inventions arising under Federally-sponsored programs will normally best be served by allowing educational and other nonprofit institutions a first option to take title to such inventions, provided the institution has an effective technology transfer program.

The efforts of the ad hoc subcommittee of the Committee on Government Patent Policy, Federal Council for Science and Technology in developing this proposal are to be commended, and we are pleased to have this opportunity to express our support.

Sincerely,

Paul T. Santilli
Vice President and
General Counsel

PTS:jm

UNITED STATES GENERAL ACCOUNTING OFFICE
WASHINGTON, D.C. 20548

OFFICE OF GENERAL COUNSEL

B-187066

November 12, 1976

PATENT DIVISION, OGC

NOV 22 1976

Mr. Philip G. Read
Director of Federal Procurement
Regulations
Federal Supply Service
General Services Administration

Dear Mr. Read:

By letter dated July 23, 1976, with enclosure, you transmitted for our comment a proposed revision to Federal Procurement Regulations (FPR) Subpart 1-9.1 dealing with Institutional Patent Agreements (IPA).

The present patents section of the FPR (subpart 1-9.1) begins with the assertion that the Government normally acquires principal rights to any invention resulting from federally funded R&D. The contractor is normally granted a nonexclusive license for the invention. On an exceptional basis, the administrator of the funding agency may grant greater rights to the contractor either at the time the contract is granted or on a case-by-case basis after a specific invention is reported. Nonprofit institutions and profitmaking firms are essentially treated alike under the present patent regulations.

The proposed amendment to this patent section concerns IPAs to be entered into by Government agencies with appropriate educational and nonprofit institutions. Under such an agreement with a Government agency, an institution would automatically acquire principal rights to inventions under all of its contracts with the Government agency, subject to various criteria. Prior to entering into this agreement, the agency must assess the institution's patent management capabilities and the ability of the institution to promote rapid commercialization of the invention by the use of a formal technology transfer program. This proposed amendment would extend the licensing authority of Government agencies to nonprofit institutions entering into IPAs. These institutions would be required to aggressively pursue commercial utilization of their inventions by granting licenses to private firms.

We endorse this effort to cast some uniformity over the present confusing jumble of different agency patent policies and we favor the granting of exclusive rights (with appropriate Government protection) to provide incentive for private investment for commercialization. However, there may be some question as to whether it is necessary or advisable for the Government to grant title (as opposed to an exclusive license) to the contractor. Granting of exclusive licenses subject to march-in rights with the Government retaining title, is consistent with the statement on Government Patent Policy by the Comptroller General before the Subcommittee on Domestic and International Scientific Planning and Analysis, House Committee on Science and Technology, on May 5, 1976.

This preference for an exclusive license should also pertain to the relationship between the institution and profit-making firms. The proposed IPAs would require the institution to normally grant nonexclusive licenses, granting exclusive licenses only on an exceptional basis. We feel that the dismal record of commercialization of federally sponsored inventions indicates that a policy which prefers the granting of nonexclusive licenses doesn't provide enough incentive for industrial investment toward commercialization.

Sincerely yours,

Paul G. Dembling
General Counsel

32-535 O - 78 - 45

RESEARCH CORPORATION
405 LEXINGTON AVENUE, NEW YORK, NEW YORK 10017

WILLARD MARCY
VICE PRESIDENT-PATENTS

(212) 986-6022

September 24, 1976

Mr. Philip G. Read
Director of Federal Procurement Regulations
Federal Supply Service
General Services Administration
Washington, D.C. 20406

Re : Proposed FPR Revision relating to Educational and Nonprofit Institutions

Dear Mr. Read:

Copies of the above proposed FPR revision were circulated by your office under the date of August 3, 1976, to a selected mailing list for comment and suggestions. These were to be sent in by October 8, 1976.

While Research Corporation was not on this mailing list, we have received copies from a variety of sources with the request that we formulate our comments and suggestions on the proposed revision for guidance in responding. Specifically, we have received copies from:

Mr. Norman J. Latker, Patent Officer, National Institutes of Health

Mr. Raymond J. Woodrow, President, Society of University Patent Administrators

Dr. Stephen Quigley, American Chemical Society

Several universities with which we have Patent Assistance Agreement.

This letter encloses our considered reply to these requests, entitled " Comments and Suggestions on Proposed FPR Revision". I thought you might like to have a copy for your information and use. We hope you will find this information constructive and useful in making further revisions to the FPR.

Basically, we feel that a revision of this type is long overdue and is a major step in the direction of developing a uniform, rational Government patent policy. The revisions proposed, for the most part, provide administratively workable procedures, even though some specific items could be improved as noted in the attached "Comments and Suggestions".

As you will note we have carefully studied the proposed revision and suggest substantive changes only in these sections of the proposed Institutional Patent Agreement:

Section II(a) and (c) - 2 suggested changes
Section II(e)
Section IV(a)
Section V(c)
Section VI(b) - 4 suggested changes
Section VII(a)
Section IX(c)
Section IX(f)

Other comments in these remarks expand somewhat on our opinions as to the need or advisability of several other sections. A list of typographical errors is also appended for your information as these are frequently difficult to detect.

I am sending copies of these comments and suggestions to the individuals named previously in this letter for their information and use.

I would be pleased to expand on any of these points at your convenience, if you wish.

Sincerely yours,

Willard Marcy

Willard Marcy

WM:kp
Attachment

Comments and Suggestions on Proposed FPR Revision - January 1976

Page 1 - Addition to Present FPR Paragraph 1-9.107-4(a)

No comments. We favor the use of institutional patent agreements wherever feasible. It should be noted, however, that we do not expect that administrative costs or complexities under such agreements will be substantially less than under a case-by-case determination procedure. Nevertheless, these agreements are a major step in the direction of establishing a uniform Government patent policy and providing known criteria and administrative procedures for expediting the transfer of technology developed under Government funding.

Page 1 - Retitled Paragraph 1-9.107-6

No comments.

Page 1 - Addition to Paragraph 1-9.107-6(c)

No comments.

Page 4 - Proposed Standard Institutional Patent Agreement

Second Whereas Clause

Second line - the first "and" should be replaced by "the".

Third line - either a phrase has been unintentionally omitted or the word "in" should be deleted.

Section I - Scope of Agreement

Line 4 - Reference (3) should specifically state:
"Insert a date of approximately 3 years [after date of this agreement]." (Phrase in brackets to be added.)
As it stands and reads in connection with line 4, Section I, this reference is unclear.

Section II - Definitions

Definition (a) - This definition, as stated, applies to inventions conceived before award of a contract or grant on which patent applications may have been filed prior to the date of the award. Some recognition of such a situation should be made in this paragraph. In all fairness to the inventor and any previous sponsors he may have had, in the case of prior-filed patent applications, only the use discovered in the "reduction to practice" under the Government grant or contract should be subject to the terms of the IPA.

A second point - this definition as regards plant varieties is limited to patentable varieties. Does this exclude Plant Protection Certification provided by the U.S. Department of Agriculture? Such certification should come within the scope of the IPA, in our opinion.

Definition (c) - Same comment as under Definition (a) regarding prior filed patent applications.

Definition (e) - We suggest that the extension of Federal government rights to States and domestic municipal governments be placed on a case-by-case discretionary basis. The rationale for such an extension is believed to be an assurance that inventions in the public health area, such as certain drugs, pharmaceuticals and safety devices, would be made widely available at minimum costs through state or municipal sponsorship. This is a reasonable requirement. However, by making the extension mandatory many inventions not having such urgent public health benefits would also be included and would seriously impinge on a just return to the contractor and inventor and reduce the incentive to make improvements or further inventions.

Section III - Allocation of Principal Rights

No comments.

Section IV - Minimum Rights Acquired by Government

Subsection (a) - This subparagraph states that the Government has the right to make, use and sell on behalf of the Government of the United States, etc. By including the right to "sell" this considerably broadens the concepts embodied in previous institutional patent agreements, and enables the Federal Government to enter into competition in the general market with commercial enterprises. In our view, this would be undesirable. Our suggestion is that the right to sell be deleted and that a modifying phrase - "for governmental purposes" - be inserted after the word "Invention" on line 4, page 7.

We would also suggest that the phrase in this subsection be ended at the end of the parenthesis on line 6, thus omitting States and domestic municipal governments from this part of the sentence.

The matter of state and municipal government rights should be set forth in a separate subsection for both clarity and more specific definition of these rights. As mentioned previously such rights should not be mandatory, but decided on a case-by-case basis. The basis for any decision on these rights should be set forth in positive language rather than in the negative sense used in this proposed agreement. For example, the statement might read:

"The Agency may determine after the invention has been identified that it is useful in the area of public health and safety, and, therefore, acquisition of a license for States and domestic municipal governments is required."

A corresponding change will need to be made in Exhibit A, Confirmatory Instrument.

Section V - Invention Identification, Disclosures, Reports

Subsection (a) - In practice this requirement may be difficult to comply with within the time limit imposed. Partial or incomplete disclosures may be necessary and may have to be accepted by the agency. The reason for this is that inventions practically never spring into existence full-blown and most often require considerable trial and testing before the technical details are fully known to the extent that a working model or well-defined products are available; such testing frequently takes months and even years from conception or even the first crude reduction to practive.

Subsection (c) - Care must be taken by the Government that the right to duplicate and disclose invention disclosures is not carelessly or thoughtlessly misused in such a way as to jeopardize foreign patent rights or to inadvertently set an unnecessarily early deadline for filing patent applications in the United States. Patent statutes in the U.S. and foreign countries govern these matters and should be observed. Our suggestion would be to add language limiting duplication and disclosure rights only to those rights required to conform to the Freedom of Information Act. Privileged and confidential information as noted in Section XI (to which this subsection refers) with respect to license information applies equally well to information in disclosures and it should be so noted in this Subsection.

Section VI - Filing of Domestic Patent Applications

Subsection (b) - The time schedule for reporting filing date and serial number prescribed in this subsection is not under the control of the contractor or grantee, but depends on Patent Office administrators. It should be recognized that some flexibility in the times stated must be allowed. Our suggestion is that in VI(b)(i) the application should be submitted within two months after the filing but that the filing date and serial number should be submitted within 30 days after their receipt from the Patent Office. Similarly, in VI(b)(ii), if a copy of the recorded assignment is desired, the date of its submission to the Agency should be set at 30 days after its receipt from the Patent Office. Simple unrecorded copies of the assignment could be submitted within two months of the filing date, however. Likewise, in VI(b)(v), the date for submission of a copy of the issued patent to the Agency should be set at 30 days after printed copies are made available by the Patent Office to the contractor or grantee (as this date frequently follows the date of issue by several weeks).

Subsection (vi) - While we agree that timely notification of discontinuance of prosecution is necessary, we suggest that powers of attorney be issued only on request by the Agency. In the majority of cases, discontinuance of prosecution by the institution is based on the discovery of overwhelming prior art, unlikely prospects for commercial or public use, or other obvious fatal flaws which would preclude obtaining patent coverage. Under these circumstances it would be unlikely that the Agency would find it advisable to continue prosecution. In addition such continuance would involve a waste of public funds. Thus, it would be the exception rather than the rule that powers of attorney would be required.

Section VII - Filing of Foreign Patent Applications

Subsection (a)(i) - The time limit of 8 months from the date of filing a corresponding United States application for filing in foreign countries is unrealistic for two reasons. The primary reason has to do with the practical need to include as much new material as possible, which has been developed after filing in the United States but before the end of the one year of grace under the international Patent Convention. This makes for the strongest patent claims in foreign countries. The second reason is that the mechanics of preparing adequate patent applications for filing in foreign countries, including translation, frequently is difficult to accomplish within 8 months, especially when complex technology is involved. We suggest that the time limit in this subsection for foreign filing be increased to 11 months.

The second part of this subsection is not clear as to its purpose or meaning. This phrase should be eliminated or restated.

Subsection (a)(iii) - If subsection VII(a)(i) is modified as suggested above, subsection VII(a)(iii) would apply only to subsection VII(a)(ii).

Section VIII - Subcontracts

This section will rarely be used since most contracts and grants to educational and nonprofit institutions do not involve subcontracting.

Section IX - Administration of Inventions in which the Institution Elects to Retain Rights

Subsection (b) - The provision for exclusivity of 5 years from date of first commercial sale or 8 years from date of the license, whichever occurs first, is a reasonable restriction. In our experience most exclusive licensees have been able to operate under this provision without difficulty or financial loss. There will be a rare case where an extension of exclusivity can be justified, so it is important to have the opportunity to request such an extension from the Agency, as provided in the proposed agreement.

Subsection (c) - The second sentence in this subsection will put an intolerable burden on the institution and will set up a requirement which will be impossible to administer. To determine what refunds are necessary would require the institution to have complete access to all sales records of every licensee and to determine in many gray area cases whether sales had been made for or on behalf of the Government. The burden of collecting or not collecting royalties on sales must rest with the licensee and this should be so stipulated in the original license agreement. In practice, at present, licensees are generally obligated contractually to report all sales by product (not by customer) listing separately by totals those sales on which royalties are collected and those sales on which royalties are not collected. In this way the sales price originally quoted by contractors in grant and contract proposals to the Government already include a lower price because they are quoted royalty-free. This system is workable administratively and is currently common practice in industry. Our suggestion is to continue this known and workable system rather than to impose a new and administratively complex and difficult system. The language in this subsection should be rewritten accordingly.

Subsection (f) - This subsection is unduly restrictive. Inventors or their co-workers are frequently the very best people to exploit their inventions since they have a dedication and enthusiasm for seeing the fruits of their inventiveness used in the public interest far greater than others who have to be indoctrinated with these attributes before they can become product champions. If the inventors and their co-workers can show they have the requisite abilities in financial, legal, management, production and marketing matters, or can show they can attract people with such abilities, in our opinion, they should be allowed to become personally involved in carrying through to the marketplace the inventions they have given birth to on the same basis and with the same restrictions as third parties. To do otherwise flies in the face of human nature and the competitive spirit on which this country is based. The undue restriction in this subsection can be removed by deletion in its entirety of the last sentence, and we so suggest. The requirement to have Agency approval should be retained and such approval should not unreasonably be withheld.

Section X - Patent Management Organizations

No comments. We feel institutions should have the choice of using such organizations, if they so desire.

Section XI - Reports on Development and Commercial Use

No comments. While the requirements in this section will require a substantial administrative effort by the institution and/or its designated patent management organization, the type and scope of information requested is not unreasonable and will be made available by licensees without any major resistance.

Section XII - Inventions by Federal Employees

No comments.

Section XIII - Termination

No comments.

Section XIV - Communications

No comments.

Page 18 - Reference 6

We feel that it is desirable that institutional patent agreements cover both grants and contracts as noted in this reference.

Page 20 - New Section Paragraph 1-9.109-7(a)(9)

Responses to information requested in this subparagraph relative to past activities of educational and nonprofit institutions should be used as historical data only, and should not be weighed very heavily in deciding whether an adequate capability for patent management exists at a given institution. Such data are fairly meaningless as most institutions have only recently begun to undertake this type of activity and their past record is either non-existent or reflects a very low level. This would have little or no bearing on future activities, provided the other aspects of the institution's policies, administrative procedures and staffing are deemed adequate, as outlined in Paragraph 1-9.109-7(b).

Willard Marcy:kp
24 September 1976

Attachment

Typographical Errors in Proposed Institutional Patent Agreement

Page 1, Line 2 - "America" is misspelled

Page 5, Line 15 - "is" should be "its"

Page 5, Line 19 - "Agencies" is misspelled

Page 5, Line 28 - "to" is misspelled

Page 8, Line 7 - delete "on" before "sale"

Page 8, Line 22 - delete "on" before "sale"

Page 8, Line 31 - add comma after "contract"

Page 9, Line 32 - delete "personnel"

Page 10, Line 19 - "VIII" should be "VII"

Page 10, Line 27 - "it" should be "if"

W. Marcy:kp
24 September 1976

WASHINGTON STATE UNIVERSITY
PULLMAN, WASHINGTON 99163

ASSISTANT VICE PRESIDENT—FINANCE

October 5, 1976

Mr. Norman Latker
Patent Council
Westwood Building, Room 5A03
C/o National Institutes of Health
Bethesda, Maryland 20014

Dear Mr. Latker:

I have made a brief review of the proposed federal procurement regulation revision prepared by the Ad Hoc Committee on University Patent Policy. I have also asked for comments from some fellow administrators and faculty members here at Washington State University.

I would like to make some comment and suggestions based on our review. I support the liberalization of the exclusive license. Anything we can do to make development of our ideas more attractive to the private sector will result in an increased utilization of knowledge developed at our University.

I note that there is a new requirement that scientific employees must sign a statement agreeing to these rules. I would prefer that this be a little more liberal and would allow institutions some flexibility here. For example, we include a statement in our faculty handbook which makes it very clear that it is a condition of employment for all of our faculty and scientific personnel to adhere to our patent policy. This has worked very well and is much less expensive than a procedure which would require a signature on a statement by each individual faculty member. I am sure you are aware of the numbers of pieces of paper they are required to sign right now by other federal regulations.

I noticed also that the new draft contains some very stiff reporting requirements. What stuck in my mind mostly were the reports requiring history going back ten years on the individual university's patent program statistics. This would involve a good deal of expense and I, frankly, question the value that will be produced.

Thank you for the opportunity of reviewing this document. I hope my comments are of some help.

Sincerely yours,

Joseph D. Hamel
Assistant Vice President

JDH/db
cc: Members of Patent Committee

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PLANNING AND MANAGEMENT

NOV 15 1976

Mr. Philip G. Read
Federal Procurement Regulations Staff (FV)
Federal Supply Service
General Services Administration
Crystal Square #5, Room 1107
Washington, D.C. 20406

Dear Mr. Read:

This is in response to your request of July 23, 1976, for our views regarding a proposed amendment of the Federal Procurement Regulations (FPR) which involves the addition of provisions dealing with Institutional Patent Agreements with educational and other nonprofit institutions.

We concur with the proposed amendment and thank you for the opportunity to review proposed FPR changes.

Sincerely yours,

William E. Mathis
Director
Contracts Management Division (PM-214)

NBS Rm 1031 Administ. Bldg

PROPOSED FPR REVISION

Prepared by Ad Hoc Subcommittee on University Patent Policy

January 1976

1. Add the following subsection (6) to 1-9.107-4(a):

(6) In accordance with the exceptional circumstances language of 1-9.107-3(a) and/or the special situations language of 1-9.107-3(c), agencies may enter into Institutional Patent Agreements with educational and other nonprofit institutions having a technology transfer program meeting the criteria set forth in 1-9.109-7(b). Such agreements shall be substantially the same as the standard agreement of 1-9.107-6(c)(2) and provide the institution the right to retain the entire right, title and interest in inventions made in the course of or under contracts subject to certain conditions. When such an agreement has been made with an institution, it shall be made applicable to each contract with the institution in lieu of the Patent Rights clauses in 1-9.107-5 and 1-9.107-6(a) and (b) (unless a determination has been made to exclude the contract from the agreement).

SUBMITTED BY	COMMENT	DISPOSITION	RATIONALE
Cornell University	By virtue of the fact that the proposed revision is basically the addition of a sub-section (6) to 1-9.107-4(a), it is likely that the requirements it contains will be interpreted as being inapplicable to organizations other than educational and non-profit operations. I suspect that this is not the intent, and that further changes to the FPR should be considered.	No action necessary	Cornell's assumption is not correct. The section is applicable to only educational and other nonprofit institutions.

2. Retitle 1-9.107-6 as follows: "Clauses for domestic contracts (short form) and Institutional Patent Agreements."

No comments received.

3. Add the following new subsection (c) to 1-9.107-6:

(c) Patent Rights - Institiutional Patent Agreements. (1) When an agency has determined in accordance with 1-9.109-7 that an Institution should receive an agreement as authorized under 1-9.107-4(a)(6), an Institutional Patent Agreement substantially similar to the standard agreement set forth in paragraph (c)(2) of this section (and appropriately completed as indicated in the numbered notes appearing after the Agreement) shall be used. Changes in the agreement should be kept to a minimum and should be limited to changes dictated by statutes applicable to the agency or by special administrative needs. In any event, agreements should include at least the following features:

(A) A requirement for the prompt reporting of all inventions to the applicable agency along with an election of rights.

No comments received.

1713

(Subsection 1-9.107-6 Contd.)

(B) Reservations of all the rights specified in -19.107-3(e)-(h);

SUBMITTED BY	COMMENT	DISPOSITION	RATIONALE
ERDA	Change "reservations" to singular.	Adopted in last draft	"Reservations" should be singular.

(C) A requirement that licensing by the institution will normally be nonexclusive except where the desired practical or commercial application has not been achieved, or is not likely to be expeditiously achieved through such licensing:

SUBMITTED BY	COMMENT	DISPOSITION	RATIONALE
Stanford University	Requirement to normally license non-exclusively. Paragraph (C) of the proposed new subsection (c) to 1-9.107-6 specifies: "A requirement that licensing by the institution will normally be non-exclusive except ..." In actual practice, because of the undeveloped nature of university technology, a first license will "normally" be exclusive, not non-exclusive. We recognize the intent of this paragraph is to insure that, where possible, first licensing will be done on a non-exclusive basis, and we have no objection to the intent. However, the subparagraph wording is somewhat misleading, particularly to institutions beginning a licensing program. We thus recommend revised wording such as: "A requirement that the institution make subject inventions available on a non-exclusive basis except ..."	Adopted in last draft.	Suggested language is more indicative of the intent of the section.
Society of University Patent Administrators (SUPA)	I recommend deletion of the word "normally." Because of the fact that most inventions, when they come out of a university, are far from the point of commercial production and marketing, most inventions must be licensed exclusively, albeit for a limited period and even for a limited application, if the necessary investment is to be attracted.	Adopted in last draft.	Satisfied by Stanford amendment.
Michigan Technical University	... relating to non-exclusive versus exclusive licensing: Who is to exercise the judgment as to whether "the desired practical or commercial application has not been achieved or is not likely to be expeditiously achieved" through non-exclusive licensing?	No action.	The intent as indicated in section was to permit the University to make such determination.

(Subsection 1-9.107-6 Contd.)

SUBMITTED BY	COMMENT	DISPOSITION	RATIONALE
Department of Justice	In subparagraph 3(c)(1)(C), page 2, line 3 - change "or" to "and." This change would make the agreement contain the requirement that licensing by the institution will normally be nonexclusive, except where the desired practical or commercial application has not been achieved and is not likely to be expeditiously achieved through such licensing. This change will provide a stricter standard for other than nonexclusive licensing, and will eliminate the alternative choices provided by the present structuring. Non-achievement of the desired application can be readily identified, but the alternative provided by the present wording would appear less susceptible of ascertaining and conducive to subjective decision. The existing choice between alternatives may invite resort to the less demanding test of unlikelihood of expeditious achievement as grounds for departure from the normal licensing called for. The weakness of the current language is that it forecloses nonexclusive licensing in the situation where the desired practical or commercial application could, in fact, have been expeditiously achieved contrary to the impression at time of licensing.	No action.	Not considered to be a constructive or necessary change.

(D) A condition limiting any exclusive license to a period not substantially greater than necessary to provide the incentive for bringing the invention to the point of practical or commercial application and to permit the licensee to recoup its costs and a reasonable profit thereon:.

Department of Interior	Proposed section 1-9.107-6(c)(1)(D) should set a definite time limit on the exclusive licenses, but with provisions for allowing the contracting officer to extend the period for an individual contract, if he makes a well supported determination that an extension is warranted. The length of the allowable extension should likewise be limited.	No Action.	Recommendation is accommodated by Sec. IX(B) of IPA.

(Subsection 1-9.107-6 Contd.)

SUBMITTED BY	COMMENT	DISPOSITION	RATIONALE
Michigan Technical University	... also relating to exclusive licensing: Who is to judge what period of time will be necessary to "provide the incentive for bringing the invention ..."?	No action.	Section IX(B) sets out the base period of 5 and 8 years which may be extended by agency based on additional information.
(E) A restriction that royalty charges be limited to what is reasonable under the circumstances or within the industry involved:			
Michigan Technical University	... relating to royalty charges: Who is to decide "what is reasonable under the circumstances"?	No action	The precedents are found in the common law.
(F) A requirement that the institution's royalty receipts, after payment of administrative costs and incentive awards to inventors, be utilized for educational or research purposes:			
	No comments received.	No action. (However, see p. 58 for recommended change)	Comment on p. 58 resulted in changing "incentive awards" to "including payments"
(G) A provision enabling the agency to except individual contracts or grants from the operation of the agreement where this is deemed in the public interest:			
Department of Interior	Proposed section 1-9.107-6(c)(1)(G) should give the Government more discretion in excepting individual contracts or grants from the operation of the agreement. The Government should not have to make an affirmative showing regarding the "public interest" in order to except a contract, but should have discretionary authority to review each contract on its merits and elect whether or not to place the contract under the agreement.	Adopted in last draft.	The recommendation makes section consistent with IPA language ("where this is deemed in public interest" - deleted). Subcommittee changed "enabling" to "permitting" for editorial purposes.
(H) A requirement for progress reports after designated periods and re-execution of the agreement only if the Government deems the institution's performance to be satisfactory:			
	No comments received.		

(Subsection 1-9.107-6 Contd.)

(I) A prohibition against assignment of inventions without Government approval to persons or organizations other than assignments, subject to the above conditions, to approved patent management organizations:

SUBMITTED BY	COMMENT	DISPOSITION	RATIONALE
Michigan Technical University	... assignments "to approved patent management organizations:" What and where is the procedure for a patent management organization to obtain approval for assignment of inventions?	No action.	Uniform standards not yet developed - presently left to discretion of agency. Subcommittee moved "subject to the above conditions" to the end of the sentence for editorial purposes.

(J) A provision permitting termination for convenience by either party upon thirty (30) days written notice.

No comments received.

(2) The following is the standard Institutional Patent Agreement:

INSTITUTIONAL PATENT AGREEMENT

This Agreement is made and entered into by and between the United States of America, as represented by the _____ 1/, hereinafter sometimes referred to as the :Agency," and _____, hereinafter referred to as the "Institution."

SUBMITTED BY	COMMENT	DISPOSITION	RATIONALE
ERDA Research Corp.	"America" is misspelled	Adopted in last draft.	Misspelling. Subcommittee made following editorial changes: 1. :to" in fourth line. 2. Reversed order of "statement" and "memorandum" in first line of "whereAs clause."

32-635 O - 78 - 46

WITNESSETH:

WHEREAS, in accordance with the President's Statement and Memorandum Patent Policy dated August 23, 1971, and the provisions of 41 CFR 1-9.107-4(a)(6), it has been determined by the Agency that the Institution has a technology transfer program meeting the criteria of 41 CFR 1-9.109-7 in that the Institution's technology transfer practices have been reviewed and found acceptable; and

SUBMITTED BY	COMMENT	DISPOSITION	RATIONALE
ERDA	Place comma after "41 CFR 1-9.107-4(a)(6) in lieu of a period.	Adopted in last draft.	Editorial

WHEREAS, the Institution is desirous of entering into an agreement whereby it may retain and entire right, title, and interest subject to certain rights acquired by the Government in and administer inventions made in the course of or under research supported by the Agency;

SUBMITTED BY	COMMENT	DISPOSITION	RATIONALE
DOD	second WHEREAS clause, rewrite the clause to read: WHEREAS, the Institution is desirous of entering into an agreement whereby it may retain the entire right, title, and interest in and administer inventions made in the course of or under research supported by the Agency, subject to certain rights acquired by the Government;	Adopted in last draft.	Considered to be better drafting.
	This change eliminates a typographical error and also enhances the readability of the clause by placing the words "subject to certain rights acquired by the Government" at the end of the WHEREAS clause.	Adopted in last draft.	DOD amendment accommodates recommendation.
ERDA Research Corp.	Change "and" to "the" in the second sentence.		

SUBMITTED BY	COMMENT	DISPOSITION	RATIONALE
Department of State	"Institutional Patent Agreement", the first "and" in the second line of the second "whereas" does not seem to be the right word. Perhaps "an" was intended.	Adopted in last draft.	DOD amendment accommodates recommendation.
Research Corp.	Second line - the first "and" should be replaced by "the". Third line - either a phrase has been unintentionally omitted or the word "in" should be deleted.	Adopted in last draft.	DOD amendment accomodates recommendation.
Dept. of Justice	2nd "WHEREAS" clause, line 2 - "and entire right" should read "an entire right".	Adopted in last draft.	DOD amendment accommodates recommendation.

NOW, THEREFORE, in consideration of the foregoing, the parties hereto agree as follows:

I. Scope of Agreement

This Agreement shall define the rights of the parties hereto regarding the allocation of rights in Subject Inventions reported after the date of this Agreement and made under contracts entered into prior to _____ 3/, unless the Agency specifically provides as a condition of any future contract that this Agreement shall not apply thereto. This agreement shall not apply to Subject Inventions in cases where the Institution is a subcontractor under a prime contract of the Agency. [_____] 4/ 5/

SUBMITTED BY	COMMENTS ON FIRST SENTENCE	DISPOSITION	RATIONALE
ERDA	Change period after "3/" to a comma.	Adopted in last draft.	Editorial.

SUBMITTED BY	COMMENT	DISPOSITION	RATIONALE
DOD	Scope of Agreement, rewrite the first sentence to read: This Agreement defines the rights of the parties hereto regarding the allocation of rights in Subject Inventions reported after the date of this agreement and made under contracts entered into prior to _____ 3/, except contracts specifically excluded by the Agency. This change clarifies the meaning of the first sentence. The sentence as it currently appears in the proposed Institutional Patent Agreement includes the words "prior to" and "any future contract". These words create an ambiguity concerning the applicability of an Institutional Patent Agreement to contracts awarded prior to the effective date of the Institutional Patent Agreement and to the reporting of inventions under such contracts. The substitute words "except contracts specifically excluded by the Agency" clarify the meaning of the sentence. In rewritten form, the sentence can clearly be construed to mean that an Institutional Patent Agreement will be applicable to contracts awarded prior to the effective date of the Institutional Patent Agreement, unless the prior contracts are amended to specifically exclude the applicability of the Institutional Patent Agreement.	Adopted in-part in last draft,	DOD language amended by deleting "prior to _____ 3/" and substituting "with the agency both prior to and after the date of this agreement." This amendment requires deletion of footnote 3. DOD redraft incorporates Univ. of Georgia and SUPA recommendations.

Section I of 1 PA, first sentence (cont.)

SUBMITTED BY	COMMENT	DISPOSITION	RATIONALE
Stanford University	Exclusion of certain contracts from the IPA. An intent of the IPA is to reduce the administrative burden on both the agencies and the universities. However, the clauses which pertain to excluding certain contracts from the IPA will add to the administrative burden. It is noted that the very successful HEW IPA does not have such a provision. With such a provision for exclusion of certain contracts, there is then a requirement on the part of the agency grant and contract administration personnel to have grants and contracts reviewed by the agency patent personnel to determine, using unspecified criteria, whether or not a particular grant or contract should be excluded from the IPA. From the contractor's point of view, the contractor must then deal with exceptions to a standard operating procedure which is administratively cumbersome. It can be observed exceptions to normal rules in administrative requirements are similar to exceptions in the English language in terms of complicating something simple. It is not clear why the ad hoc subcommittee of the Committee on Government Patent Policy of the Federal Council for Science and Technology saw fit to include this requirement. If there isn't any documented history of abuses leading to the need to have such a provision, we strongly recommend that the clauses pertaining to exclusion of contracts from the IPA's be deleted. (Depending on the motivations of the subcommittee for including this requirement, the reasoning of paragraph 6 below may also call for deletion.)	No action.	The requirement to exclude selected contracts from the IPA is deemed necessary at least for the following reasons: (a) There may be situations where the agency can identify that it will provide all development funds. (b) There may be situations where the agency may join with another organization with a different patent policy in a joint venture. (c) Government-owned, company operated facilities may not be appropriate recipients of IPA's.

Sect. I of IPA, first sentence (cont.)

SUBMITTED BY	COMMENT	DISPOSITION	RATIONALE
Wisc. Alumni Research Foundation	Scope of Agreement The comments here can also be readily tied to and should be considered along with the comments to Article IV(b)(B). We do not understand the need for any exclusion of certain contracts from the Intitutional Patent Agreement. To our knowledge there has been no history of abuses leading to the need for such exclusion. More importantly, no criteria have been established upon which the decision to exclude is to be based. Hence, the decision at the outset to exclude a contract from the scope of the Institutional Patent Agreement can be completely arbitrary in nature. The inclusion of such a provision also seems redundant in view of the march-in rights reserved to the Government in Article IV(b)(B). In addition, for every exclusion from the Institutional Patent Agreement, the only alternative presented to the Institution is to abandon administration of an invention arising under the excluded contract or to again go back to a case-by-case determination. Experience with this latter approach has established that it is unsatisfactory. I can introduce what can be critical time delays in the transfer of the technology to the private sector with the result that the public may in reality be deprived of that technology. It will certainly serve to significantly increase the burden of administering the invention.	Ditto	Ditto

Section I of 1 PA, first sentence

SUBMITTED BY	COMMENT	DISPOSITION	RATIONALE
University of Washington	This section suggests piecemeal application of the IPA to the institution's grants and contracts by providing for a cut-off date beyond which contracts would not be affected by the IPA. We think that a complete cut-over would be simple and preferable for all inventions identified after the date of the IPA, irrespective of how long the specific contract had been in effect.	Adopted in last draft.	Redrafted DOD language clarifies.
University of Georgia	It is a great waste of effort to have to renew IPA's periodically. The 30-day notice of cancellation provided is entirely sufficient, and we see no reason whatever to limit the life to three years or any other specific period of time. The cost of maintaining files for governmental and other documents and correspondence is already prohibitive, and IPA's for successive increments of time would undoubtedly add to this burden. This is especially true since it is highly probable that successive agreements will differ, making it necessary to administer each one separately for the life of any patents related to them. Therefore, we recommend that the agreement have no expiration date and that it be changed only for compelling reasons.	Ditto	Ditto
S.U.P.A.	It is not clear why the Agreement must expire after three years. There seems to be little gained, and a considerable amount of renegotiation and change of references will be added. Termination on 30 days notice is provided in XIII. The last part of the first sentence would be deleted if comments under 1 above are accepted.	Ditto	Ditto

p. 4, Section I of IPA

SUBMITTED BY	COMMENTS RECEIVED ON SECOND SENTENCE	DISPOSITION	RATIONALE
National Association of College and Business Officers	Request deletion of the last sentence of the paragraph and substitute therefor: "In cases where the Institution is a subcontractor under a prime contract of the Agency, the Agreement of the Institution shall govern." Comments. It sometimes is the case that an educational or nonprofit institution will grant a subcontract to the Institution. Under such circumstances, the inability of the Institution to acquire rights will tend to discourage inter-university research and unfairly treat the university inventor who may well lose his equity interest in his invention. COGR institutions typically do not have patent policies that cover inventions that arise outside of the university. Moreover, the COGR institutions favor retention of rights by a sister institution as a matter of equity and fairness. Finally, as a matter of law, the requirement to grant back rights to the prime contractor could, under certain facts and circumstances, be in violation of the anti-trust laws or construed as a patent misuse.	Adopted in last draft.	Subcommittee agrees with recommendation.
Stanford University	The inapplicability of the IPA where the institution is a subcontractor (last sentence of Article I of the IPA). It is not clear why the IPA does not apply where the institution is a subcontractor. It would appear the logic of using an IPA applies equally well to subcontracts as well as prime contracts.	Ditto	Ditto

Sec. I of IPA, 2nd Sent. (cont.)

SUBMITTED BY	COMMENT	DISPOSITION	RATIONALE
Wisc. Alumni Research Foundation	Further in relation to Article I of the proposed Institutional Patent Agreement, we do not understand why the Institutional Patent Agreement should not apply to subject Inventions where the Institution is a contractor under a prime contract of the Agency. By parity of reasoning if the Insitutional Patent Agreement is available to an Institution where it is the prime contractor it should also apply when the institution is a subcontractor.	Ditto	Ditto
Purdue Research Foundation	Paragraph I stipulates that "This Agreement shall not apply to Subject Inventions in cases where the Institution is a subcontractor under a prime contract." We are unable to reconcile this statement with paragraph II(b) which states that "Contract" means any contract (agreement, grant, or other arrangement) or subcontract---" The Agreement should permit the Institution to retain rights to inventions under the subcontracts. Such a change would encourage interstitutional research.	Ditto	Ditto
S.U.P.A.	I object vigorously to the second sentence and the pertinent part of VIII with regard to subcontractor rights. These provisions completely overlook the equity of the inventors who are subcontractor employees as well as the equity of the subcontractor itself. The prime contractor has little or no equity. If the subcontractor has a valid IPA, it should get the same treatment as in a prime contract.	Ditto	Ditto

p.4, Section I of 1 PA, 2nd Sent. (Cont.)

SUBMITTED BY	COMMENT	DISPOSITION	RATIONALE
University of Connecticut	It is implied that the University, when it is a subcontractor to a prime contract of a federal agency is bound only by its own statutes and regulations regarding patents and licensing. Is this a correct interpretation? Section VIII does not really answer the question.	No action.	See redrafted Sec. VIII.
California Institute of Technology	I would further suggest that a new subsection be added to Section VIII of the proposed IPA to take care of a situation which has troubled us in connection with the existing agreements with HEW and NSF. The problem arises from the fact that some educational institutions (as in our case) have policies which prevent granting of rights in inventions to sponsors other than government. Accordingly, when we are the subcontractor to another educational institution which has an IPA, the requirement that title vest in the prime contractor forces either a deviation from our own policy or negotiation of some sort. We would suggest a new subsection be added to provide that when the subcontractor has an IPA with the agency involved - (1) the subcontractor inventions be subject to the IPA of the subcontractor; (2) the reporting responsibility of the sub-contractor be directly to the agency; and (3) information copies be required to be sent to the prime contractor.	Adopted in last draft.	Ditto

II. Definitions

SUBMITTED BY	COMMENT	DISPOSITION	RATIONALE
University of Connecticut	Possibly include "institution", clarifying relationship to constituent schools, colleges, institutes and Agricultural Experiment Station.	No action.	This is a matter to be negotiated with the agency at the time of application for an IPA.

(a) "Subject Invention" means any invention or discovery of the Institution conceived or first actually reduced to practice in the course of or under a contract with the Agency, and includes any art, method, process, machine, manufacture, design, or composition of matter, or any new and useful improvement thereof, and any variety of plant, which is or may be patentable under the Patent Laws of the United States of America or any foreign country.

SUBMITTED BY	COMMENT	DISPOSITION	RATIONALE
Research Corp.	This definition, as stated, applies to inventions conceived before award of a contract or grant on which patent applications may have been filed prior to the date of the award. Some recognition of such a situation should be made in this paragraph. In all fairness to the inventor and any previous sponsors he may have had, in the case of prior-filed patent applications, only the use discovered in the "reduction to practice" under the Government grant or contract should be subject to the terms of the IPA.	No action.	This is a matter to be negotiated with the agency at the time of award of contract or grant.
	A second point - this definition as regards plant varieties is limited to patentable varieties. Does this exclude Plant Protection Certification provided by the U.S. Department of Agriculture? Such certification should come within the scope of the IPA, in our opinion.	No action.	Inconsistent with the definition in the existing FPR.
Department of Justice	line 7 - letters transposed.	Adopted in last draft.	Editorial.

SUBMITTED BY	COMMENT	DISPOSITION	RATIONALE
University of Georgia	In Paragraphs II(a) and (c) these definitions should be restated to include only those applications or uses of inventions which are developed under Government funding in those cases where inventions have been conceived and/or applied prior to such funding involvement.	No action.	This is a problem of negotiation - It is the intent of the agreement to cover only those inventions listed in the recommendation.

(b) "Contract" means any contract, [agreement, grant, or other arrangement]6/ or subcontract entered into with or for the benefit of the Government, where a purpose of the contract is the conduct of experimental, developmental, or research work.

No comments received,

(c) "Made," when used in relation to any invention or discovery, means the conception or first actual reduction to practice of such invention in the course of or under a contract.

SUBMITTED BY	COMMENTS	DISPOSITION	RATIONALE
Research Corp.	Definition II(c) - Same comment as under Definition (a) regarding prior filed patent applications.	Ditto	Ditto
University of Georgia	In Paragraphs II(a) and (c) these definitions should be restated to include only those applications or uses of inventions which are developed under Government funding in those cases where inventions have been conceived and/or applied prior to such funding involvement.	Ditto	Ditto

(d) "To bring to the point of practical application" means to manufacture in the case of a composition or product, to practice in the case of a process, or to operate in the case of machine and under such conditions as to establish that the invention is being worked and that is benefits are reasonably accessible to the public.

SUBMITTED BY	COMMENT	DISPOSITION	RATIONALE
Research Corp. ERDA	Line 15 - "is" should be "its"	Adopted in last draft.	Editorial.

(e) "States and domestic municipal governments" means the States of the United States, the District of Columbia, Puerto Rico, the Virgin Islands, American Samoa, Guam, and the Trust Terriroty of the Pacific Islands, and any political subdivision and agencies thereof.

SUBMITTED BY	COMMENT	DISPOSITION	RATIONALE
Research Corp., Dept. of Justice, DOD, ERDA	"Agencies" on next to last line has "g" and "n" transposed.	Adopted in last draft.	Editorial

III. Allocation of Principal Rights

(a) The Institution may retain the entire right, title, and interest throughout the world or in any country thereof in and to each Subject Invention disclosed pursuant to Section V., below, subject to the provisions of this Agreement. The Institution shall include with each Subject Invention disclosure an election whether it will retain the entire right, title, and interest in the invention throughout the world or in any country thereof subject ot the rights, acquired by the Government in Section IV of the agreement; provided that the Institution may request an extension of the time for election. If the Institution elects not to retain rights in a Subject Invention, it shall supply the Agency with any written reports upon which this decision was made, such as marketing reports, patent searches, or other similar reports.

SUBMITTED BY	COMMENTS	DISPOSITION	RATIONALE
Department of Justice and DOD	subpar. (a), line 9 - "any" should read "an." III(a)		
DOD, Research Corp. and ERDA	Line 7 - "to" is misspelled.		
Department of Interior	Section III(a) of the "standard institutional patent agreement" should provide that in deciding whether to grant an extention on the institution's time for making its election, the Government shall consider whether the statutory 1 year period is running. If the period is running, no extension should be granted which would delay the election to within 60 days of the end of the statutory period.	No action.	This matter is left to agency administration.

SUBMITTED BY	COMMENT	DISPOSITION	RATIONALE
University of Connecticut	It is not clear whether the University may assign its rights to the inventor when that person has been associated professionally with a government contract. If the institution wishes to make such assignment, or alternatively an assignement in the public interest to a private corporation, is such permission to be granted only upon application of the inventor or representative of the private corporation to the governmental agency? Are these questions presumed to be covered by the last sentence of section III (a)?	No action.	Sec. X precludes assignment without the consent of the agency.
California Institute of Technology	First, I would propose that the words---the reason, including--- be inserted before "any written reports" in the third from the bottom line of Section III(a) of the proposed IPA. This proposal is made because the last sentence of this subsection, at least inferentially, implies a requirement for formal and possibly expensive inquiry as the basis for each negative decision. Under the reporting requirement of Section V(a), and the definition of "subject invention" in Section II(a), many items will be reported which will obviously be of a non-commercial nature. In practice, decisions as to many such items are made informally, and institutions such as ours would be much more comfortable if the language were altered as suggested above.	No action.	Written reports are not considered to be deliverable to the agency unless available to contractor.

(b) The Institution agrees to convey to the Government, upon request, the entire domestic right, title, and interest in any Subject Invention when the Institution:

(i) does not elect under section III(a) to retain such rights; or

(ii) fails to have a United States Patent Application files on the invention in accordance with section VI(a), or decides not to continue prosecution of such application; or

(iii) at any time, no longer desires to retain title.

(c) The Institution agrees to convey to the Government, upon request, the entire right, title, and interest in any Subject Invention in any foreign country when the Institution:

(i) does not elect under section III(a) to retain such rights in the country; or

(ii) fails to have a patent application filed in the country on the invention in accordance with section VII(a); except that if an application has been filed in a foreign country after the times specified in section VII(a) but prior to such request by the Government, the Institution shall retain the entire right, title, and interest in the Subject Invention in the country involved; or

(iii) decides not to continue prosecution of such application or to pay any maintenance fees covering the invention. To avoid forfeiture of the patent application or patent, the Institution shall notify the Agency not less than sixty (60) days before the expiration period for any action required by the foreign patent office.

SUBMITTED BY	COMMENT	DISPOSITION	RATIONALE
Dept. of Interior	3. Sections III(b)(ii) and III(c)(iii) of the "standards institutional patent agreement" set out under section 1-9. I07-6(c)(2) should define what constitutes a "decision" not to continue prosecution of a patent application. Inaction for a specified length of time without adequate explanation should be deemed to constitute such a decision.	No action.	Section follows FPR. Subcommittee capitalized "section" throughout page.

(d) A conveyance, requested pursuant to sections III(b) or (c) of this Agreement, shall be made by delivering to the Agency duly executed instruments (prepared by the Government) and such other papers as are deemed necessary to vest in the Government the entire right, title, and interest to enable the Government to apply for and prosecute patent applications covering the invention in this or the foreign country, respectively, or otherwise establish its ownership of such invention.

No comments received.

IV. Minimum Rights Acquired by the Government

(a) With respect to each Subject Invention to which the Institution retains principal or exclusive rights, the Institution hereby grants to the Government of the United States a nonexclusive, nontransferable, paid-up license to make, use, and sell each Subject Invention throughout the world by or on behalf of the Government of the United States (including any Government agency) and States and domestic municipal governments, unless the Agency determines after the invention has been identified that it would not be in the public interest to acquire the license for States and domestic municipal governments;

SUBMITTED BY	COMMENT	DISPOSITION	RATIONALE
S.U.P.A.	IV(a) (a) In place of the phrase "make, use, and sell" in the fourth line, a phrase "practice and have practiced" as contained in ASPR 7-302.23 would be much preferable. For some inventions, potential licensees could be greatly turned off by having to compete with the Government in the marketing and sale of a product.	No action.	Language of section follows FPR.
	(a) With regard to the extension of the license to state and local governments, see my testimony. They have no equity. Administratively, the problem is an impenetrable maze.	No action.	License to State and Municipal Governments is negotiable under the President's Statement.

SUBMITTED BY	COMMENTS	DISPOSITION	RATIONALE
University of Connecticut	It is not clear under what circumstances the agency will determine that it is or is not in public interest to acquire licenses for states and domestic municipal governments. Presumably inventions made without government support would be patented and licensed for sale or use by state or municipal governments, and it is not difficult to discern irreconcilable institutional policies concerning federally supported or non-federally supported inventions. I am also uneasy about the meaning of a "non-exclusive, non-transferable paid up license" for the U.S. government, and the requirement that the institution "grant to responsible applicants, upon request of the government, a license ...". It is simply not clear whether the agreement gives the right to own, assign or license patents, or whether the agency retains the right to order the issuance of a license (B)(b), "to fulfill public health or safety	No action.	Language of Section follows FPR and President's Statement.

SUBMITTED BY	COMMENT	DISPOSITION	RATIONALE
Research Corp.	We suggest that the extension of Federal government rights to States and domestic municipal governments be placed on a case-by-case discretionary basis. The rationale for such an extension is believed to be an assurance that inventions in the public health area, such as certain drugs, pharmaceuticals and safety devices, would be made widely available at minimum costs through state or municipal sponsorship. This is a reasonable requirement. However, by making the extension mandatory many inventions not having such urgent public health benefits would also be included and would seriously impinge on a just return to the contractor and inventor and reduce the incentive to make improvements or further inventions.	No action.	Language follows present FPR.
University of Georgia	In Paragraph IV(a), the Government's license to a subject invention should be for governmental purposes only rather than to "make, use, and sell."	Ditto	Ditto

SUBMITTED BY	COMMENT	DISPOSITION	RATIONALE
Research Corp.	Subsection (a) - This subparagraph states that the Government has the right to make, use and sell on behalf of the Government of the United States, etc. By including the right to "sell" this considerably broadens the concepts embodied in previous institutional patent agreements, and enables the Federal Government to enter into competition in the general market with commercial enterprises. In our view, this would be undesirable. Our suggestion is that the right to sell be deleted and that a modifying phrase - "for governmental purposes" - be inserted after the word "Invention" on line 4, page 7. We would also suggest that the phrase in this subsection be ended at the end of the parenthesis on line 6, thus omitting States and domestic municipal governments from this part of the sentence.	Ditto	Ditto

SUBMITTED BY		COMMENT	DISPOSITION	RATIONALE
Research Corp (Contd)		The matter of state and municipal government rights should be forth in a separate subsection for both clarity and more specific definition of these rights. As mentioned previously such rights should not be mandatory, but decided on a case-by-case basis. The basis for any decision on these rights should be set forth in positive language rather than in the negative sense used in this proposed agreement. For example, the statement might read: "The Agency may determine after the invention has been identified that it is useful in the area of public health and safety, and, therefore, acquisition of a license for States and domestic municipal governments is required." A corresponding change will need to be made in Exhibit A, Confirmatory Instrument.	Ditto	Ditto
Amer.Patent Law Association	I.	Whereas, a proposed amendment to the Federal Procurement Regulations dealing with Institutional Patent Agreements has been developed by an Ad Hoc Subcommittee of the United States Government's Committee on Government Patent Policy; and Whereas, on page 7 Paragraph IV(a), with respect to Subject Inventions, a paid-up license is given to State and Domestic municipal governments unless the Agency determines after the invention has been identified that it would not be in the public interest to acquire the license for State and Domestic municipal governments; Now Therefore, it is resolved by the American Patent Law Association that the license to and for State and Domestic municipal governments should be only on an exception basis where special circumstances justify the exception; and not automatic, subject to exclusion.	Ditto	Ditto

SUBMITTED BY	COMMENT	DISPOSITION	RATIONALE
Amer. Patent Law Association (Contd)	Our concern in both resolutions is that the proposed regulations in question would remove the incentive for competent organizations to accept Research and Development grants or contracts or subcontracts, and that as a result the government will be hampered in carrying out its purposes. Inventions are unlikely to be developed and actually made available to the public without reasonable incentives. Institutional Patent Agreements such as utilized by the Department of Health, Education, and Welfare provide adequate safeguards of the public interest, including march-in rights if the patent owner or licensee is not commercializing.	Ditto	Ditto

(b) With respect to each Subject Invention to which the Institution retains principal or exclusive rights, the Institution agrees to grant to responsible applicants, upon request of the Government, a license on terms that are reasonable under the circumstances;

(A) unless the Institution, its licensee, or its assignee, demonstrates to the Government that effective steps have been taken within three (3) years after a patent issues on such invention to bring the invention to the point of practical application or that the invention has been made available for licensing royalty-free or on terms that are reasonable in the circumstances or can show cause why the principal or exclusive rights should be retained for a further period of time; or

(B) to the extent that the invention is required for public use by governmental regulations or as may be necessary to fulfill public health or safety needs, or for other public purposes stipulated in the applicable contract.

SUBMITTED BY	COMMENT	DISPOSITION	RATIONALE
EPDA	Change "in" to "under" in (b)(A)	No action.	Follows present FPR language.
			Subcommittee changed "Government" to "agency" in second line of (b).

Michigan State University	It is our understanding that this section deals with what is generally referred to as "March-in Rights" of the Government. It is suggested that this section be modified to include a provision whereby the institution can request a hearing prior to the Government exercising these rights. This would bring the proposed agreement more closely in line with the DHEW's Institutional Patent Agreement, which we find very acceptable.	Adopted in part.	Redraft provides for hearing and notes designate official responsible.
Cornell University	With regard to "march in rights", it would be helpful if it were possible to develop more specific criteria although we recognize this may be most difficult. We do, however, suggest that the decision on such matters be specified to rest at the highest level within a given agency.	Ditto	Dittp

SUBMITTED BY	COMMENT	DISPOSITION	RATIONALE
W.A.R.F.	Minimum Rights Acquired by the Government The general emphasis in the application of Section (b) appears to be the reverse of that in existing like provisions of the Institutional Patent Agreements with both the Department of Health, Education, and Welfare and the National Science Foundation. The format in which this Section has been couched would appear at the outset to shift the burden of proof in the administration of an invention. In other words, it would appear that under the literal language of the proposed provision the Government can request the Institution to grant a license to a third party at any time before the running of the 3-year period after the patent issues. The burden of proof then appears to shift to the Institution to show that effective steps have been taken to bring the invention to the point of practical application, or that the invention has been licensed on reasonable terms or that principle or exclusive rights should be retained - the 3-year "incubation" period being available to the Institution by implication. It would seem more appropriate that the 3-year "incubation" time should be more specifically set out so that there is no misunderstanding of the intent of the whole paragraph (b). We believe the language of Article XII(a) of the Institutional Patent Agreement with the Department of Health, Education, and Welfare would be more appropriate. With regard to paragraph (b)(B) of Article IV the decision (see comments under Scope of Agreement above) can be an arbitrary one. No guidelines or criteria are established upon which such a decision can be based. Moreover, the decision to license others can be made under this provision without even giving the Institution an opportunity to be heard. That opportunity, at the very least, should be included in the provision. The format of the	Adopted-in-part.	Ditto The 3 year period is considered negotiable.

W.A.R.F. (Contd)	corresponding provisions from the Institutional Patent Agreement with the Department of Health, Education, and Welfare, Section XII(b), which is reproduced below for your convenience, would be more appropriate and equitable: "The Grantor reserves the right to license or to require the licensing of other persons under any U.S. patent or U.S. patent application filed by the Grantee on a subject invention on a royalty-free basis or on terms that are reasonable in the circumstances, upon a determination by the Assistant Secretary (Health and Scientific Affairs) that the invention is required for public use by governmental regulations, that the public health, safety, or welfare requires the issuance of such license(s), or that the public interest would otherwise suffer unless such license(s) were granted. The Grantee and its licensees shall be given written notice of any proposed determination pursuant to this subparagraph not less than thirty (30) days prior to the effective date of such determination, and that if requested, shall be granted a hearing before the determination is issued and otherwise made effective." It is submitted that the Institution should at least have the right to be heard and adoption of the above language from the Department of Health, Education, and Welfare Institutional Patent Agreement is urged in place of Article IV(B)(B).	Adopted-in-part.	Ditto.

SUBMITTED BY	COMMENT	DISPOSITION	RATIONALE
Stanford University	4. March-in rights for public health or safety needs or for other public purposes. Subparagraph IV.(b)(B) covers march-in rights for the government to require granting licenses to the extent that the invention is required for public use by government regulation or as may be necessary		

Stanford University (Contd)	to fulfill public health or safety needs, or for other public purposes stipulated in the applicable contract. The need to include this subparagraph is well understood. However, on its surface, it is a potential danger to an exclusive licensee that may be planning to invest substantial risk capital in the development of an invention. This is particularly appropriate in inventions in the health field, where very large sums are expended at risk before first public marketing. It will be helpful if the IPA can include an assurance for potential licensees that this subparagraph is only invoked in rare situations when certain specified conditions occur.	Adopted-in-part.	Ditto Subcommittee agrees in principle.
S.U.P.A.	(b)(B) In the hearing after my testimony I also referred to the very serious concern, to the extent of refusal, of potential licensee's to agree to license others if an "invention is required for use by governmental regulations or as may be necessary to fulfill public health or safety needs, or for other public purposes stipulated in the applicable contract". The problem is not so much that these are not worthy reasons, but rather that the decision may be made at a low level and without full consideration of all the facts and circumstances. Some assurances should be given that the decision will be made at a high level, with an opportunity for a hearing.	Adopted-in-part.	Ditto.

SUBMITTED BY	COMMENT	DISPOSITION	RATIONALE
Department of Justice	(2) Page 7, subpar. (b) - We urge that a "march-in" right in the Government be spelled out with respect to anti-trust principles. Such right should be absolute and not subject to the provisions of IV(b)(A) and IV(b)(B). Although march-in for competitive reasons could be achieved under the present language of IV(b), such right would not be absolute. The urged addition could provide for the exercise of "march-in" rights "should the Government determine that the retention of principal or exclusive rights by the Institution will tend substantially to lessen competition or to result in undue concentration in any section of the country in any line of commerce to which the technology involved relates, or to create or maintain other situations inconsistent with the antitrust laws." A similar "march-in" provision is included in the proposed draft bill on Government Patent Policy emanating from the Committee on Government Patent Policy this year. The quoted antitrust standard is from the Federal Nonnuclear Energy Research and Development Act of 1974.	No action.	Recommendations go beyond requirements of President's Statement.

(c) Notwithstanding section III(a) or any other provision of this agreement, if a Subject Invention is made under a contract supporting an international agreement or treaty, the Institution agrees to issue all such licenses or assignments as are directed by the Agency and to comply with such other directions of the Agency as are deemed necessary by the Agency to comply with the terms of any applicable international agreements. At the request of the Institution, the Agency will, after an invention is identified, agree to identify the specific obligations of the Institution with respect to such invention which might otherwise conflict with the provisions of this Agreement. [ ] 7/

SUBMITTED BY	COMMENT	DISPOSITION	RATIONALE
DOD	Minimum Rights Acquired by the Government, paragraph (c), rewrite the first sentence to read:		

	Notwithstanding section III(a) or any other provisions of this agreement, the Institution agrees to license or assign Subject Inventions as directed by the Agency to comply with the terms of any applicable international agreement. This change substantially shortens the first sentence of paragraph (c) and considerably enhances the readability thereof.	Adopted in last draft.	Improvement in drafting.
Cornell University	As a case in point, I refer to section IV Minimum Rights Acquired by the Government subsection (c). As I understand the situation, the requirements that led to IV(c) are such that they should be generally applicable. As to the section itself, FPR section 1-9.107-5(e) sets forth the obligations and the applicable clauses to be used in the event the agency head or his duly authorized designee may determine them to be necessary. It specifies that the license to the government shall include the right of the government to sub-license foreign governments pursuant to any treaty or agreement with such foreign governments. Section IV(c) of the IPA is somewhat different in that it requires action on the part of the institution to request identification of those cases in which obligations may exist. The reference to "contract support and international agreement and treaty" seems to us to be vague and we are concerned about the obligation that we must follow "such other directions of the agency as are deemed necessary by the agency to comply with the terms of any applicable international agreements." We believe it should be the obligation of the agency to advise the institution at the time of a proposed grant or contract of any such requirements, and that they should not be retroactive. Directions of the agency to which we will be obligated should be clearly stated and understood prior to contract execution.	No action.	Subcommittee felt that the recommendation was not administratively feasible.

(d) Nothing contined in this section shall be deemed to grant to the Government any rights with respect to any invention other than a Subject Invention.

No comments received.

V. Invention Identification, Disclosures, and Reports

(a) The Institution shall furnish the Agency

(i) a complete technical disclosure for each Subject Invention, within 6 months after conception or first actual reduction to practice, whichever occurs first in the course of or under the contract, but in any event prior to any on sale, public use, or publication of the invention known to the Institution. The disclosures shall identify the contract and inventor and shall be sufficiently complete in technical detail and appropriately illustrated by sketch or diagram to convey to one skilled in the art to which the invention pertains a clear understanding of the nature, purpose, operation, and, to the extent known, the physical, chemical, biological or electrical characteristics of the invention. Such disclosure shall be furnished directly to the Agency in addition to any other requirement under the contract for the submission of progress or financial reports and whether or not reference to the Subject Invention has been made in any other such reports.

(ii) Complete information concerning the date and identity of any on sale, public use, or publication of the invention which may constitute a statutory bar under 35 USC 102, which was authorized by or known to the Institution or any contemplated action of this nature.

(iii) A final report within three months after completion of the work under any contract, listing all Subject Inventions or certifying that there were no such inventions. 8/

SUBMITTED BY	COMMENT	DISPOSITION	RATIONALE
DOD	Invention Identification, Disclosures, and Reports, subparagraph (a)(i), rewrite the last sentence of the subparagraph to read: Such disclosure shall be furnished directly to the Agency even though there are requirements under the contract for the submission of other reports which may reference or disclose the Subject Invention. This change shortens the sentence and also enhances the readability thereof. The change also eliminates the words "progress or financial" and substitutes the word "other".	Adopted with amendment.	Subcommittee inserted words "progress or" after "of" in third line.

Cornell University	Section V(a) requires a complete technical disclosure for each subject invention within six months after conception or first reduction to practice and section III(a) requires that such disclosure be accompanied by the institution's election as to whether it wishes to retain entire right, title and interest in the invention. Assuming the most favorable, but most unlikely situation in which the institution is aware of an invention immediately upon conception or first reduction to practice, this would mean that the decision as to filing would have to be made within six months at best. Our experience indicates to us that this period is unrealistic in terms of normal reporting practices of inventors coupled with the time required for patent and commercial evaluation. Solicitation of commercial interest, analysis of the market, review of industrial requirements on obtaining approvals for new projects usually take a considerably longer period. What we are suggesting here is not omission of time frames but some added flexibility to the institution to make a thorough assessment possible.	Adopted in last draft.	Subcommittee is in agreement with the principle of the recommendation.

Research Corp and S.U.P.A.	Line 5, (a)(i) 7 - delete "on" before "sale" line 2, (a)(ii) 22 - delete "on" before "sale"	No action	Language follows 35 U.S.C.

SUBMITTED BY	COMMENT	DISPOSITION	RATIONALE
Research Corp. and S.U.P.A.	(a) - In practice this requirement may be difficult to comply with within the time limit imposed. Partial or incomplete disclosures may be necessary and may have to be accepted by the agency. The reason for this is that inventions practically never spring into existence full-blown and most often require considerable trial and testing before the technical details are fully known to the extent that a working model or well-defined products are available; such testing frequently takes months and even years from conception or even the first crude reduction to practice.	Adopted in test draft.	See comment on Cornell.
University of Georgia	Paragraphs III(a) and V(a) require the University to report and make an election whether it will retain right and title to an invention within six months after its conception or first reduction to practice, whichever occurs first in the course of or under the contract. Paragraph VI(a) requires the University to file a patent application within six months after such election. It is our opinion that in a university situation it is unreasonable to expect that in all cases a patent application can be filed within 12 months after the conception of the invention. Reduction to practice can be very time-consuming because of the possible lengthy delays infunding and because university priorities are different from those in private industry. These provisions should be changed to allow the election and the filing of patent applications within six months following the conception or reduction to practice, whichever occurs last.	Ditto	Ditto

SUBMITTED BY	COMMENT	DISPOSITION	RATIONALE
Penn. State University	Section V(a)(i) This section appears to make an absolute requirement for disclosure submission prior to any publicity. Many inventions, especially in the chemical and pharmaceutical arts, are developed in fragments and a valid patent application cannot be filed at a time prior to publication, since the necessary human physiological and toxicity testing has not yet been achieved. Many of our invention disclosures are triggered by a presentation at a national or international technical meeting and only obtained at that time. Additionally, many inventions are achieved in a manner that the inventors cannot be sure at what stage conception is achieved, especially with respect to chemical, pharmaceutica, and process inventions.	Ditto	Ditto
	Section V(a)(ii) The words "authorized by or known to" the institution could be construed to require detailed administrative supervision of all presentations, seminars, and meetings; and all publications — which are presently the responsibility of the principal investigator or research director.	No action.	It was the intent of the agreement to impose such administrative responsibility.

The institution shall obtain patent agreements to effectuate the provisions of this Agreement from all persons in its employ who perform any part of the work under any contract except nontechnical personnel, such as clerical and manual labor personnel.

SUBMITTED BY	COMMENT	DISPOSITION	RATIONALE
Research Corp. and S.U.P.A.	add comma after "contract" and - delete second "personnel"	Adopted in draft.	Proposed language follows FPR.
Washington State University	I note that there is a new requirement that scientific employees must sign a statement agreeing to these rules. I would prefer that this be a little more liberal and would allow institutions some flexibility here. For example, we include a statement in our faculty handbook.	Acknowledged.	No action necessary.

Washington State University (Contd)	which makes it very clear that it is a condition of employment for all of our faculty and scientific personnel to adhere to our patent policy. This has worked very well and is much less expensive than a procedure which would require a signature on a statement by each individual faculty member. I am sure you are aware of the numbers of pieces of paper they are required to sign right now by other federal regulations.		

SUBMITTED BY	COMMENT	DISPOSITION	RATIONALE
Penn. State University	Section V(b) It is not clear whether the "patent agreements" which are required will have to be in the same detail as the Institutional Patent Agreement itself. If so, and the Institutional Patent Agreement must, in effect, be incorporated by reference into the patent agreements to be executed by university employees, then it is critically important that these agreements be as simple, clear and concise as possible.	No action.	The instructions of IPA appear to provide adequate guidance.

(c) The Institute agrees that the Government may duplicate and disclose Subject Invention disclosures and, subject to Section XI, all other reports and papers furnished or required to be furnished pursuant to this Agreement.

SUBMITTED BY	COMMENT	DISPOSITION	RATIONALE
Research Corp and S.U.P.A.	Care must be taken by the Government that the right to duplicate and disclose invention disclosures is not carelessly or thoughtlessly misused in such a way as to jeopardize foreign patent rights or to inadvertently set an unnecessarily early deadline for filing patent applications in the United States. Patent statutes in the U.S. and foreign countries govern these matters and should be observed. Our suggestion would be to add	Adopted in draft.	The Subcommittee drafted language which accommodates this comment as best able under the Freedom of Information Act.

	language limiting duplication and disclosure rights only to those rights required to conform to the Freedom of Information Act. Privileged and confidential information as noted in Section XI (to which this subsection refers) with respect to license information applies equally well to information in disclosures and it should be so noted in this Subsection.		
Penn. State University	Section V(c) It is not clear whether this provision would permit the Government to publish an invention disclosure covering a pharmaceutical which was "conceived" but not yet actually reduced-to-practice, and upon which a valid patent application could not be filed because of a lack of human effectiveness testing.	Ditto	Ditto
SUBMITTED BY	COMMENT	DISPOSITION	RATIONALE
Purdue Research Foundation	Paragraph V(c) stipulates that "The Institution agrees that the Government may duplicate and disclose Subject Invention disclosures and subject to Section XI, all other reports and papers furnished or required to be furnished pursuant to this Agreement." At times it is not possible to license and/or evaluate the foreign market potential within the one-year requirement to file a foreign counterpart to a U.S. application. Such publication of the disclosure as stipulated in paragraph V(c) would prohibit filing in most foreign countries after the one-year period. A similar situation could result with respect to paragraph V(d). It is a policy of our Institution to encourage publication but at times such is not feasible until a complete analysis of the commercial opportunities is made in foreign countries.	Ditto	Ditto
Michigan Technological University	-- the Standard Institutional Patent Agreement: V.(c) specifies that "the Government may duplicate and disclose Subject Invention disclosures." My university objects to premature publicity with respect to invention disclosures as being inimical to our interests and the Government's interest in obtaining suitable patent coverage—at least	Ditto	Ditto

Michigan Technological University (Contd)	until after patent applications have been filed. Even in that circumstance, it is often undesirable to publish invention disclosure information. We therefore recommend that paragraphs (c) and (d) be reworded to make public disclosure of invention disclosure materials an optional matter, depending upon the judgment of those who are working on obtaining patent protection for the inventions.		
University of Georgia	It is understandable that the Government should have the right to disclose, eventually, invention disclosures under the IPA (Paragraph V(c), page 8). However, provision should be made to allow the filing of a U.S. Patent Application prior to any such governmental disclosure.	Ditto	Ditto

(d) The Institution shall not bar or prohibit publication of disclosures of Subject Inventions on which patent applications have been filed.

SUBMITTED BY	COMMENT	DISPOSITION	RATIONALE
University of Washington	Since grantee or contractor's proposals may contain information of patent significance, we recommend that an additional sentence be added to Clause V(d): "The Government agency will take reasonable steps to insure that data or information furnished by the Institution is not released to the public before the agency obtains confirmation from the Institution that the proposed release will not adversely affect the patent interests of the Institution and the Government."	Adopted in draft	
W.A.R.F.	The implication of Section (d) is that where no patent application is filed the Institution can bar or prohibit publication without limitation.	Acknowledged.	University has this prerogative.

VI. Filing of Domestic Patent Applications

(a) With respect to each Subject Invention in which the Institution elects to retain domestic rights pursuant to section III(a) of this Agreement the Institution shall have a domestic patent application filed within six (6) months after an election has been made pursuant to section III(a) of this Agreement or such longer period as may be approved in writing by the Agency; provided, however, that if the Agency determines that there has been such use or publication of the invention as to initiate the one-year statutory period, the Agency may prescribe a shorter period for the filing of the application in the event the six-month period would extend beyond such statutory period. Such shorter period, however, shall in no case end more than thirty days before the end of the statutory period. With respect to such invention, the Institution shall promptly notify the Agency of any decision not to file an application.

SUBMITTED BY	COMMENT	DISPOSITION	RATIONALE
Dept. of Interior	4. Section VI(a) of the "standard institutional patent agreement" should provide that when the agency prescribes a period shorter than 6 months for the filing of a patent application, this shorter period shall end no later than 30 days prior to the running of the statutory period. As presently worded, the section might be construed as providing that the shorter period could end no earlier than 30 days before the end of the statutory period.	No action.	The intent of the section is as stated by the commentator.

32-635 O - 78 - 48

(b) For each Subject Invention on which a patent application is filed by or on behalf of the Institution, the Institution shall:

(i) within two (2) months after such filing, or within (2) two months after submission of the invention disclosure if the patent application previously has been filed, deliver to the Agency a copy of the application as filed, including the filing date and serial number;

(ii) within two (2) months after such filing, or within two (2) months after submission of the invention disclosure if the patent application has previously been filed, obtain and deliver a copy to the Agency of an assignment from the inventor or inventors to the Institution of all right, title and interest in the invention properly recorded in the United States Patent and Trademark Office.

(iii) include the following statement, appropriately completed, in the second paragraph of the specification of the application and any patents issued on the Subject Invention, "The Government has rights in this invention pursuant to Contract (or Grant) No. _____ awarded by (identify the Agency)";

SUBMITTED BY	COMMENT	DISPOSITION	RATIONALE
Penn. State Univ.	Section IV(b)(i) and (ii) The period of two months set forth in each of these sections is too short in view of the delays in the Patent Office, and the fact that there should be no urgency in these submissions, i.e., six months would be better.	Adopted in draft.	Language was amended to lengthen period.

SUBMITTED BY	COMMENT	DISPOSITION	RATIONALE
Research Corp. and S.U.P.A.	The time schedule for reporting filing date and serial number prescribed in this subsection is not under the control of the contractor or grantee, but depends on Patent Office administrators. It should be recognized that some flexibility in the times stated must be allowed. Our suggestion is that in VI(b)(i) the application should be submitted within two months after the filing but that the filing date and serial number should be submitted within 30 days after their receipt from the Patent Office. Similarly, in VI(b)(ii), if a copy of the recorded assignment is desired, the date of its submission to the Agency should be set at 30 days after its receipt from the Patent Office. Simple unrecorded copies of the assignment could be submitted within two months of the filing date, however. Likewise, in VI(b)(v), the date for submission of a copy of the issued patent to the Agency should be set at 30 days after printed copies are made available by the Patent Office to the contractor or grantee (as this date frequently follows the date of issue by several weeks).	Accommodated	Ditto
University of Georgia	We recommend the changing of wording on Page 9 in Paragraph VII(b) to specify that the Grantee shall furnish promptly a copy of each U. S. Patent Application with data filing and serial number, and shall promptly obtain and deliver a copy to the Agency an assignment form, etc. The information required here can be obtained only from the Patent Office and the University reporting is subject to the timing of that office.	Substantially accommodated	Ditto

SUBMITTED BY	COMMENT	DISPOSITION	RATIONALE
Michigan Tech. University	VI.(b)--contains onerous reporting requirements which tend to negate the value of the proposed policy. For instance, why is it necessary for the Agency to have a copy of the patent application as filed, and why does the Agency need a copy of the assignment from the inventor to the institution? Unlike Federal agencies, the universities do not have manpower available to prepare and submit copies of sensitive documents to Federal departments which have neither the need for such detail nor the space to store the applications and assignments. It should surely be sufficient for the Agency to receive an annual report listing the titles, filing dates and serial numbers of all invention disclosures on which patent applications have been filed by the institution--with the option of requesting copies of relevant documents, as proposed in subparagraph (viii).	Substantially accommodated.	Ditto.
	Subparagraph (iv) is positively insulting to the universities. Exhibit A confirms, with full legal trappings, the legal responsibility which had already been established by legal agreement and, in addition, confirmed by a statement required in each patent specification, as per paragraph VI.(b)(iii). This is bureaucracy carried to the ultimate extreme, and Michigan Technological University strongly recommends that the entire requirement of that subparagraph (iv), together with Exhibit A, be deleted from the proposed revision.	No action.	The conformatory license is requirement required by FPRs.

VI(b) (iv) within six (6) months after filing the application, or within six (6) months after submitting the invention disclosure if the application has been filed previously, deliver to the Agency a duly executed and approved instrument on the form specified in Exhibit A which is attached hereto and by this reference made a part hereof;

(v) provide that Agency with a copy of the patent within two (2) months after a patent issues on the application;

No comments received

VI(b) (vi) not less than thirty (30) days before the expiration of the response period for any action required by the United States Patent and Trademark Office, notify the Agency of any decision not to continue the prosecution of the application and deliver to the Agency executed instruments granting the Government a power of attorney;

SUBMITTED BY	COMMENT	DISPOSITION	RATIONALE
Research Corp.	Subsection (vi) - While we agree that timely notification of discontinuance of prosecution is necessary, we suggest that powers of attorney be issued only on request by the Agency. In the majority of cases, discontinuance of prosecution by the institution is based on the discovery of overwhelming prior art, unlikely prospects for commercial or public use, or other obvious fatal flaws which would preclude obtaining patent coverage. Under these circumstances it would be unlikely that the Agency would find it advisable to continue prosecution. In addition such continuance would involve a waste of public funds. Thus, it would be the exception rather than the rule that powers of attorney would be required.	Adopted in draft.	Words "upon request" added after "Agency." Adoption will reduce unnecessary administrative workload.

VI(b) (viii) upon request, fully advise the Agency concerning all actions taken during the prosecution of any patent application and furnish copies of any relevant documents as requested.

No comments received.

VII. Filing of Foreign Patent Applications

(a) With respect to each Subject Invention in which the Institution elects to retain principal rights in a foreign country pursuant to section III(a) of this Agreement, the Institution shall have a patent application filed on the invention in such country, in accordance with applicable statutes and regulations, and within one of the following periods:

(i) eight (8) months from the date of a corresponding United States application filed by or on behalf of the Institution; or if such an application is not filed, six (6) months after an election is made pursuant to section III(a) of this Agreement;

(ii) six (6) months from the date a license is granted by the Commissioner of Patents and Trademark to file foreign applications when such filing has been prohibited by security reasons; or

(iii) such longer period as may be approved in writing by the Agency.

SUBMITTED BY	COMMENT	DISPOSITION	RATIONALE
Numberous Commentors	Change "VIII" to "VII"	Adopted in draft.	Editorial.
ERDA and Research Corp.	Change "it" to "if" in (a)(i)	Adopted in draft.	Editorial.
SUBMITTED BY	COMMENT	DISPOSITION	RATIONALE
S.U.P.A.	The time periods need to be flexible.	No action.	Time periods are deemed appropriate.

Research Corporation	The time limit of 8 months from the date of filing a corresponding United States application for filing in foreign countries is unrealistic for two reasons. The primary reason has to do with the practical need to include as much new material as possible, which has been developed after filing in the United States but before the end of the one year of grace under the International Patent Convention. This makes for the strongest patent claims in foreign countries. The second reason is that the mechanics of preparing adequate patent applications for filing in foreign countries, including translation, frequently is difficult to accomplish within 8 months, especially when complex technology is involved. We suggest that the time limit in this subsection for foreign filing be increased to 11 months. The second part of this subsection is not clear as to its purpose or meaning. This phrase should be eliminated or restated. If subsection VII(a)(i) is modified as suggested above, subsection VII(a)(iii) would apply only to subsection VII(a)(ii).	Ditto	Ditto
Michigan Tech. University	Paragraph (a) includes three alternatives; presumably the word "or" should follow the semicolon at the end of subparagraphs (i) and (ii). Even with the addition of this alternative, we object to the specification of fixed time periods--eight months in the first paragraph and six months in the second. In patent matters, it is our experience that each specific case must have decisions of this kind made as a result of circumstances which exist, uniquely, for that particular case. We therefore recommend that subparagraphs (i) and (ii) be rewritten to generalize the elapsed time for foreign	Ditto	Ditto

Michigan Tech. University (Continued)	filings; e.g. "foreign filings shall be made at an appropriate date following the filing of a corresponding U.S. application, so as to obtain suitable foreign protection with a minimum risk of premature disclosure, etc."		
SUBMITTED BY	**COMMENT**	**DISPOSITION**	**RATIONALE**
W.A.R.P.	The time frames established by Subsection (a)(1) are in fact arbitrary in nature and have no relationship to the practices which normally govern the filing of patent applications in foreign countries in a patent-license situation. Traditionally, once the convention date has been established, as by filing in the U.S. before publication, it is the usual practice to delay as long as possible the filing of foreign applications. This is done for a number of reasons, among which are: (1) to establish a commercial interest or perhaps even enter into an actual license so that a more reasoned decision can be made on where to file corresponding foreign applications; (2) to determine the effect of publications if and when made since certain countries do have grace periods after publication which do not absolutely bar the filing of a patent application; (3) administrative considerations such as the obtaining of export licenses under certain conditions; and (4) the increase in the administrative burden which the establishment of artificial time periods, over and above the normally considered and controlling statutory time periods, which now govern foreign filing considerations, will cause.	Ditto	Ditto

W.A.R.F. (Continued)	In view of the above we would suggest that the portion of Article VII(a) following "regulations" in line 5 be deleted. Some of the reasoning applied above would also apply to Article VI(a) relating to the filing of domestic patent applications, with, of course, provisions which would protect the agency in the event the Institution decided to file no patent application.		
SUBMITTED BY	**COMMENT**	**DISPOSITION**	**RATIONALE**
N.A.C.U.B.O.	Request Paragraph VII(a)(i) be changed to read as follows: "ten (10) months from the date of the corresponding United States patent application filed by or on behalf of the Institution, or if such an application is not filed, six (6) months from the date a license is granted by the Commissioner of Patents to file foreign applications providing an election has been made pursuant to section III(a) of this Agreement." Good patent practice dictates that a foreign filing be made just prior to the end of the convention period. Especially in the case of university inventions, additional material is made available subsequent to the U.S. Filing which becomes incorporated in a continuation-in-part. It is advantageous to base the foreign filing on the most complete disclosure available. If no application has been filed, an export license would be required to foreign file. The time granted to foreign file should be the same as that granted in section VII(a)(ii).	Ditto	Ditto

SUBMITTED BY	COMMENT	DISPOSITION	RATIONALE
Stanford University	Filing of foreign patent applications. Article VII a. specifies certain time periods for filing foreign patent applications (note Article VII is mislabeled as Article VIII). This article also provides that the specified periods can be extended if approved in writing by the agency. While we can comply with paragraph VII(a), it appears to be an unnecessary and possibly counterproductive "overcontrol." It is readily observed that additional administrative effort is required both on the part of the agency and the institution to follow both the arbitrary periods of VII(a) and actual bar dates. The requirements, intended to administratively insure foreign filing dates are not missed, may possibly be self-defeating of that goal because an institution's licensing officer may be lulled into overlooking the need to take into account many other timing considerations with respect to a foreign filing program than indicated in these paragraphs. For example, if publication has occurred, and the U.S. patent application is not filed until after such publication, an institution still can obtain patent protection in West Germany and Japan if they file within six months of the publication. Other factors also come into play such as the need to obtain an export control license before filing abroad in certain cases, such as filing in Japan after publication but less than six months after the U.S. filing. As a further observation, in a dynamic licensing program of undeveloped technology of uncertain value, more often than not corresponding foreign patent applications are filed after 8 months from the date of the U.S. application.	Ditto	Ditto

Stanford University (Continued)

VII(a) then requires both the agency and the institution to set up procedures to follow artificial dates, to request and issue approvals for variations from those artificial dates. Economic forces and practical considerations will drive filing before bars, not arbitrary time periods. We recommend that subparagraph VII(a) end after the word "regulations" in line 5. (It is observed Article VI which covers filing of domestic patent applications could similarly be shortened for similar reasons.)

VII(b) The Institution shall notify the Agency promptly of each foreign application filed and, upon written request, shall furnish an English version of such foreign application without additional compensation.

In regard to subparagraph VII(b), we recommend, to reduce administrative burdens upon both the agency and the institution, that rather than notify the agency after filing of each foreign patent application, that data regarding foreign applications filed be included in the annual report. Accommodated. Annual report is deemed sufficient.

VIII. Subcontracts

(a) Except as provided in (b), below, the Institution shall include in any subcontract where a purpose of that subcontract is the conduct of experimental, developmental, or research work either the "Patent Rights-Acquisition by the Government" clause found at 41 CFR 1-9.107-5 or the following clause:

Patent Rights

(a) The Contractor hereby agrees to report fully and promptly to _____ (Institution) any invention conceived or first actually reduced to practice in the course of or under this contract (hereinafter referred to as "Subject Invention(s)," and to assign all right, title, and interest in and to such invention to _____ (Institution) or its designee.

(b) In addition, the Contractor agrees to furnish the following materials, disclosures and reports:

(i) Upon request, such duly executed instruments (prepared by the _____ (Institution) or its designee) and such other papers as are deemed necessary to vest in the _____ (Institution) or its designee the rights granted under this clause and to enable the _____ (Institution) or its designee to apply for and prosecute any patent application, in any country, covering such invention.

(ii) Prior to final settlement of this contract, a final report listing all Subject Inventions or certifying that no inventions were conceived or first actually reduced to practice under the contract.

(c) Except as provided below the Contractor shall include either a clause identical to this clause or the "Patent Rights - Acquisition by the Government" clause found at 41 CFR 1-9.107-5 if a purpose of the subcontract is experimental, developmental, or research work. In the event of a refusal by a subcontractor to accept either of these clauses or if, in the opinion of the Contractor, these clauses are inconsistent with the policy set forth in 41 CFR 1-9.107-3, the Contractor (i) shall promptly notify the Institution and (ii) shall not proceed with the subcontract without the written authorization of the Institution. It is understood that the Institution will seek direction from the _____ (insert name of appropriate Agency).

(d) The Contractor shall report any subcontracts containing a patent rights clause to the Institution. The Contractor shall not be obligated to enforce the agreements of any Subcontractor hereunder relating to the obligations of the Subcontractor to the Government in regard to Subject Inventions.

[End of Clause]

(b) In the event of a refusal by a subcontractor to accept either of the clauses specified in (a), or if, in the opinion of the Institution, these clauses are inconsistent with the policy set forth in 41 CFR 1-9.107-3, the Institution (i) shall promptly submit a written notice to the Agency setting forth reasons for the Subcontractor's refusal and other pertinent information which may expedite disposition of the matter; and (ii) shall not proceed with the subcontract without the written authorization of the Agency.

(c) It is understood that the Government is a third party beneficiary of any subcontract clause granting rights to the Government in Subject Inventions, and the Institution hereby assigns to the Government all rights that it would have to enforce the Subcontractor's obligations for the benefit of the Government with respect to Subject Inventions. The Institution shall not be obligated to enforce the agreements of any subcontractor hereunder relating to the obligations of the Subcontractor to the Government in regard to Subject Inventions.

SUBMITTED BY	COMMENT	DISPOSITION	RATIONALE
DOD	7. Page 12, Patent Rights Clause, paragraph (c) at the top of the page, rewrite the first six lines to read: The Contractor shall include in any subcontract either this clause or the "Patent Rights - Acquisition by the Government" clause found in 41 CFR 1-9.107-5 if a purpose of the subcontract is experimental, developmental, or research work. If a subcontractor refuses to accept either This change shortens the first six lines and also clarifies the meaning of the paragraph. The words "Except as provided below" were intentionally deleted. It is difficult to determine what is meant by the words "provided below". The words "provided below" could be construed as referring to subject matter within the same paragraph or could also be construed as referring to subject matter set forth in paragraph (b) on page 12. It will be noted that paragraph (b) on page 12 is not part of the Patent Rights Clause.	Substantially accommodated.	Improved drafting.
ERDA	Change "at" to "in" in third line of subparagraph (c) of "Patent Rights" clause.	Accommodated	Covered by DOD change.

SUBMITTED BY	COMMENT	DISPOSITION	RATIONALE
Cornell University	With regard to section VIII which provides for assignment of rights to the IPA holder from sub-contractors, we would like to see some language added to eliminate this requirement if the sub-contractor is itself an IPA holder. We assume that for the purposes of section VIII that the requirement is intended to apply to sub-contractors who are not educational or non-profit institutions.		
Research Corporation	This section will rarely be used since most contracts and grants to educational and nonprofit institutions do not involve subcontracting.	No action taken.	Acknowledged.
S.U.P.A.	Subcontractor should have the same rights as it would have were it the prime contractor.	Partially accommodated by redraft.	
N.A.C.U.B.O.	Request deletion of (a) in entirety and substitute therefor: "(a) Except as provided in (b) below, the Institution shall include in any subcontract where a purpose of that sub-contract is the conduct of experimental, developmental or research work the "Patent Rights-Acquisition by the Government" clause, found at 41 CFR 1-9.107-5, or the "Patent Rights Retention by the Contractor" clause, found in ASPR 7-322.23(b)."	No action.	Not considered administratively feasible.

N.A.C.U.B.O. (Continued)	The above changes are required to conform to the changes proposed in paragraph 1 herein concerning Section I, Scope of the Agreement.		
Unknown AIA Member	Qualifying subcontractors should be allowed to retain at least a defeasible title to their subject inventions, and inventors and their associates should be allowed to participate in achieving utilization of their inventions through licensing or otherwise.	Partially accommodated by redraft.	
SUBMITTED BY	COMMENT	DISPOSITION	RATIONALE
University of Connecticut	Is a subcontract by institutions to a private contractor possible in practice under provisions of section VIII? If it is implied by the statement that the institution "will seek direction" from the agency, that the agency will comply, perhaps it would be more expedient to eliminate the entire provision. It is not difficult to imagine that the process of "seeking direction" might require an inordinate period of time, effectively slowing the accomplishment of the purpose of the contract.	No action.	Acknowledged.
APLA	Whereas, Federal Procurement Regulations provide Patent Rights clauses for use and guidance for selection of such clauses in subcontracts for Research and Development work; Now Therefore, it is resolved by the American Patent Law Association that subcontracts for Research and Development work under Institutional Patent Agreement grants or contracts should not require patent title to be assigned to the University or the Government in all cases; rather the Federal Procurement Regulations guidance should be followed in selection of the proper patent rights clauses.	Partially accommodated by redraft.	

APLA (Continued)	Our concern in both resolutions is that the proposed regulations in question would remove the incentive for competent organizations to accept Research and Development grants or contracts or subcontracts, and that as a result the government will be hampered in carrying out its purposes. Inventions are unlikely to be developed and actually made available to the public without reasonable incentives. Institutional Patent Agreements such as utilized by the Department of Health, Education, and Welfare provide adequate safeguards of the public interest, including march-in rights if the patent owner or licensee is not commercializing.

IX. Administration of Inventions in Which the Institution Elects to Retain Rights

(a) The Institution shall administer those Subject Inventions to which it elects to retain title in the public interest and shall, except as provided in subsection (b), below, make them available through licensing on a nonexclusive, royalty-free or reasonable royalty basis to all qualified applicants.

No comment

(b) The Institution may license a Subject Invention on a exclusive basis if it determines that an exclusive license is required in the public interest because it is necessary as an incentive for development of the invention or because market conditions are such as to require licensing on an exclusive basis in order to bring the invention to the point of practical application. Any exclusive license issued by the Institution under a U.S. patent or patent application shall be for a limited period of time and such period shall not unless otherwise approved by the Agency, exceed five (5) years from the date of the first commercial sale or use in the United States of America of a product or process embodying the invention, or eight (8) years from the date of the exclusive license, whichever occurs first. Such license shall also provide that the licensee shall use all reasonable effort to effect introduction into the commercial market as soon as practicable, consistent with sound and reasonable business practices and judgment. Any extension of the maximum period of exclusivity shall be subject to approval of the Agency. Upon expiration of the period of exclusivity or any extension thereof, licenses shall be offered to all qualified applicants at a reasonable royalty rate not in excess of the exclusive license royalty rate.

SUBMITTED BY	COMMENT	DISPOSITION	RATIONALE
Justice Department	(3) Page 13, subparagraph (b) - The periods prescribed regarding exclusive licensing should not be subject to extension; indeed, we believe that the maximum periods should be less than those in the proposed regulation.	No action.	Practice in agencies indicates otherwise.

SUBMITTED BY	COMMENT	DISPOSITION	RATIONALE
Massachusetts Institute of Technology	We would also propose a provision within the IPA that states for the record that the agency granting the IPA recognizes that the 8-year time period for a limited-term exclusive shall automatically be told in those instances where regulatory agency approvals (such as FDA) are required to enable a licensee to market the invention. With these few comments, however, we are in accord with the proposed regulations. Thank you.	Adopted in draft.	Redraft provides for tolling when before regulatory agencies.
University of Virginia	Indicates a limiting period for the exclusive license necessary to provide incentive to the commercial firm. In order to prevent continual requests for extensions, some allowance should be made for an exempt period before the period of exclusivity starts running for those inventions which require government agency approval. For example, a new drug invention may very well take five to six years of intensive effort before it is ready for the marketplace. Under the present terms of the recommended IPA, this would only leave three years of exclusivity remaining, and would effectively prevent a company from licensing such an invention. Another example would be the new regulations on pre-market clearance for medical instrumentation. Again, an exempt period must be allowed before the exclusive license limitation starts so that the licensee can obtain the necessary government clearances.	Ditto	Ditto
Research Corporation	The provision for exclusivity of 5 years from date of first commercial sale or 8 years from date of the license, whichever occurs first, is a reasonable restriction. In our experience most exclusive licensees have been able to operate under this provision without difficulty or financial loss. There will be a rare case where an extension of exclusivity can be justified, so it is important to have the opportunity to request such an extension from the Agency, as provided in the proposed agreement.	No action.	Acknowledged.

SUBMITTED BY	COMMENT	DISPOSITION	RATIONALE
W.A.R.F.	In relation to the time provisions of Section (b) of this Article, it has been our experience that development of inventions arising in a University environment, and particularly those in the pharmaceutical field, can take an exceedingly long time. Consequently, the finite period of 8 years from the date of granting an exclusive license for the maximm life of such license may, in many situations, be completely inadequate for the licensee to even introduce an invention into the market, let alone recoupt his expenses from the sale or use of such invention. It is well understood that many of the major delays in reaching the marketplace with an invention relating to the pharmaceutical filed are occasioned by the control exercised by various Federal regulatory agencies. Since these practical considerations do pertain, we would suggest that the running of the 8-year period be tolled for that period of time that the permission to sell or use the invention in the marketplace, up to the receipt of approval for such marketing or use, is in the hands of the regulatory Agency in control. The inclusion of such a provision would be equitable to the licensee without affecting the protection afforded the public by the march-in provisions of the agreement and could be a significant factor to a favorable determination by a company in the private sector to invest the necessary funds to commercially develop a University generated invention.	Adopted in draft.	Redraft provides for tolling when before regulatory agencies.
Purdue	With respect to paragraph IX(b) stipulating that the period of exclusivity shall not exceed five (5) years from first commercial sale or eight (8) from the date of the exclusive license, whichever occurs first, the eight-year limitation will be a problem when extensive premarket clearance of a product or device is required by the government. This paragraph should be modified to exclude from the eight-year limitation that time required by the government for premarket government clearance.	Adopted in draft.	Ditto

SUBMITTED BY	COMMENT	DISPOSITION	RATIONALE
Michigan State	The limitation of an exclusive license to eight years from the date of issue can be very inadequate and such a restriction could work a particular hardship in those cases of biomedical research where pre-clinical testing may be required before the product can be brought to market. Such testing can consume years of effort even with the most diligent prosecution. It is suggested that language be introduced to exclude from the eight years of exclusivity allowed, that time which elapses between the submission of a request for clearance from a federal agency and the granting of that request.	Ditto	Ditto
Michigan Technical University	IX(b) specifies a period of five or eight years for an exclusive license. It is our experience that these times are not long enough to bring many inventions to the marketplace and still assure a return on the investment of the exclusive licensee. We recommend that these time periods be extended to eight years from the date of the first commercial sale or ten years from the date of the exclusive license, whichever occurs first--if we are to attract a licensee to make an investment in and market new technology developed under Federal contract or grant auspices.	Accommodated-in-part.	See redraft/
University of Georgia	Provision for the extension of the period of exclusivity in rare cases should be made.	No action.	This has been provided for.

SUBMITTED BY	COMMENT	DISPOSITION	RATIONALE
Colorado State University	The restriction of five or eight years placed on the term of exclusive licenses would not always provide adequate time for the product to reach the commercial marketplace or for the licensor and licensee to recover costs and a reasonable royalty. There are examples where this restriction could be a problem. One would be an invention offered on an exclusive basis where additional research and development was necessary to bring the invention to a patentable and marketable stage. Development work of this type could take any number of years to complete. A second example where this restriction could be a problem would occur should an unduly long period of time be required for premarketing approval, i.e., new drug approval. Often, the time required for new drug approval could run as long as five years in itself. A more favorable clause might read in part: "Any exclusive license issued by the institution under a U.S. Patent shall be for a limited period of time and such period shall not, unless otherwise approved by the Agency, exceed the life of the patent (patent renewals excluded) or ten years, whichever is longest. Any exclusive license issued by the institution for a nonpatented invention shall be for a limited period of time and such period shall not, unless otherwise approved by the Agency, exceed ten years from the date of the first commercial sale or use in the United States of America of a product or process embodying the invention." A clause such as this would provide the univeristy and the licensee with an opportunity to recover all costs incurred in the development and patenting of an invention as well as receive a reasonable royalty income. The royalty income to the university would be used to support educational and research activities and provide an incentive to those faculty and staff members involved in research projects.	Accommodated in part.	See redraft.

IX(c) Royalties shall not normally be in excess of accepted trade practice. The Institution also agrees to refund any amounts received as royalty charges on any Subject Invention in procurements for or on behalf of the Government and to provide for that refund in any instrument transferring rights to any party in the invention.

SUBMITTED BY	COMMENT	DISPOSITION	RATIONALE
University of Georgia	Paragraph IX(c) should specify that royalty-free sales to the Government shall be provided for in licenses, to be handled by licensees. It would be completely unthinkable to try and have universities administer royalities by licensee and by consumer and rebate to the Government those royalities on sales to governmental agencies.	Adopted in draft.	See redraft.
University of Washington	We do not agree with the provision of subparagraph(c) under this section. The Government, rather than the Institution, should have the responsibility to monitor its procurements and claim royalty exemptions at the time of purchase. Moreover, it is not reasonable for the Government to look to the Institution and/or the inventor for royalty refunds (perhaps applicable to transactions occuring several years in the past) if the Government mistakenly pays the full price to a licensee rather than the royalty-free price.	Ditto	Ditto
S.U.P.A.	As indicated in the Research Corporation letter, the royalty refund requirement would put a great burden on the universities. A much preferable procedure in my way of thinking would be to incorporate in any license a requirement that no royalty is to be included in the price of an item sold to the Government or for the Government's account.		

SUBMITTED BY	COMMENT	DISPOSITION	RATIONALE
Research Corporation	Subsection IX(c) - The second sentence in this subsection will put an intolerable burden on the institution and will set up a requirement which will be impossible to administer. To determine what refunds are necessary would require the institution to have complete access to all sales records of every licensee and to determine in many gray area cases whether sales had been made for or on behalf of the Government. The burden of collecting or not collecting	Ditto	Ditto

SUBMITTED BY	COMMENT	DISPOSITION	RATIONALE
University of Georgia	(9) The IPA should provide in Paragraph IX(e) that licenses be made subject to the conditions of the royalty-free license to the Government and not subject to the conditions of the IPA itself. Any specific conditions which need to be provided for in licenses in order to meet the terms of the IPA should be stated briefly and concisely in the IPA for inclusion in licenses. Thus, the necessity of making the IPA a part of every license would be avoided, along with a great deal of paper work.	No action.	IPA may be incorporated by reference.

(f) Notwithstanding the provisions of subsections (a) and (b), above, no license, either exclusive or nonexclusive, shall be granted by the Institution to any of the following persons or organizations, except with the approval of the Agency:

(i) any person who participated as an employee of the Institution in the research leading to the conception and/or actual reduction to practice of the subject invention;

(ii) An organization of which a person described in (f)(i) was a promoter or organizer or in which such a person is an officer, director, or holds a substantial financial interest.

(iii) An organization of which the Institution was a promoter, organizer, or financer.

In such cases the Agency's approval will normally be given only if the Institution can show that a bona fide effort was made without success to interest other organizations known to be interested in the subject matter of the invention in licensing and further developing the Subject Invention or otherwise can show why the public interest will best be served by the proposed licensing arrangement.

SUBMITTED BY	COMMENT	DISPOSITION	RATIONALE
NACUBO	Request deletion of Section IX9(f) in its entirety.	Adopted in draft.	Provision deemed unnecessary - and possible administrative burden.

NACIBO (cont.)

Comments.

Universities, due to their special character, continually must exert their best efforts to protect their good name and the good name of their professors and researchers. The interleaving of interests of government, state, nonprofit, and private sponsors dictates that the university exercise due care in its relations with the aforesaid parties. Frequent consultant arrangements between university professors and the private sector make it necessary for the university to inform its professors of their duties and obligations to the U.S. Government, the university, and the consulting company with respect to patent rights that might arise out of work performed for the consulting company that also relates to sponsored work done by them at the Univeristy.

Consequently, the university is well experienced in policing its own affairs that are sensitive in nature. Adverse or unfavorable reports by the media in this regard would be far more costly by way of loss of alumni funds and gift giving than any potential return from a high-risk, high-gain patent license venture. Accordingly, it is submitted that Section IX as drafted, is unnecessary in view of the university's sensitivity to the potential problems that might arise in this area.

1771

Section IX requires efforts to license others first. Any such license will be time-limited, and the public interest will be protected thereby. A university should not be required to demonstrate that an invention has no takers before directly assisting in the transfer of technology to the marketplace. Moreover, the university is faced with a very real problem if it elects not to make an invention widely available, since it is quite likely that one or more of the trustees or alumni will want to know why his company was precluded from having an opportunity to license the invention. Hence, the university, when it decides to support an invention, must take this fact into consideration.

Therefore, the relationship of the university to those outside of the university community, by its very nature, is such that patent abuses are highly unlikely.

SUBMITTED BY	COMMENT	DISPOSITION	RATIONALE
University of Georgia	The provisions of Paragraph IX(f) are contrary to public policy as applied in the Small Business Administration and other agencies of the Federal Government and the states. Individuals are encouraged to benefit from the application of Federal funds in innumerable cases when the public benefits in the long run. Government-supported inventions should not be an exception to this established public policy.	Ditto	Ditto

Purdue	Paragraph IX(f). Some inventions have a very limited specialized market although they could make significant contributions. The public could best be served by licensing the technology to the inventor. Universities are probably more concerned than the government about conflict of interest. Prudent management dictates that the Universities be able to license where the use of the technology will be maximized. If this is the inventor, then such should be permitted without first having to contact a number of companies. For most inventions, the inventor would not have the capital to develop the technology. Paragraph IX(f) should be modified to permit licensing the technology to the inventor without having to obtain permission from the agency when good management dictates licensing to the inventor.	Ditto	Ditto
SUPA	(f) Stanford and Research Corporation have both written throughtful comments on this section. The Government's concern is understandable. One solution that occurs to me is: (1) To have the section applicable only if the person or organization is the sole or exclusive licensee, since more than one licensee should be protection enough. (2) To delete the last sentence entirely. It is impossible to prejudge what the circumstances should be for Agency approval. (3) The word "finance" under (iii) needs better definition. Obviously it can't mean stockholder.	Ditto	Ditto

SUBMITTED BY	COMMENT	DISPOSITION	RATIONALE
Unknown AIA Member	As you well know, there is generally no one more dedicated to achieving utilization of an invention than the inventor, particularly when he stands to share in the profits of a successful venture. Why then tie the hands of these people and their business associates and principals by limiting their participation?. . . Conditions in regulations which prevent the inventor and those closest to the invention from participating in its commercialization should be opposed. At the same time, however, reasonable conditions aimed at protecting the public against unbridled or unwarranted private economic gain from from Government funded research should be recognized as proper. In this regard, the requirements in the proposed amendment to the regulations that the Institution use its royalty receipts, after payment of administrative costs and incentive awards to inventors, for educational or research purposes should not be objectionable.	Ditto	Ditto
University of Virginia	This paragraph should be deleted in its entirety. Although the rationale for this section is certainly laudatory, conflict of interest questions should not be handled at the government agency level, and in fact, are probably impossible to handle at that level. Universities are, by their very nature, highly sensitive to conflict of interest problems, and are already effectively solving this problem. Therefore, this is an area that should be left to the discretion of the University in the Institutional Patent Agreement.	Ditto	Ditto

SUBMITTED BY	COMMENT	DISPOSITION	RATIONALE
University of Connecticut	Does this provision prevent assignment of patent rights to the inventor? Is this section in conflict with last sentence of section III(a)? See also second paragraph of section X.	No action.	Section Deleted.
Stanford University	Approval to license. Subparagraph IX(f) prohibits the granting of licenses to certain persons or organizations who have been involved with research leading to the invention, even on a non-exclusive basis, except after organizations which have no involvement decline to license. Rather than having the three criteria indicated in that paragraph treated as prohibitions, the IPA should encourage institutions to make arrangements meeting one or more of the criteria, and on an exclusive basis. The critical ingredient to any transaction which will transfer a research advance to a product available to the public, in our free enterprise system, is economic incentive. It is apparently perceived a conflict of interest will exist if an individual or organization associated with an invention conceived under government sponsored research becomes motivated by economic factors, and this result will be contrary to the public interest. Clearly, if government funds are diverted from a grant or contract to private pockets, this economic motivation is both	Adopted in draft	Provision deemed unnecessary and possible administrative burden.

corrupt and contrary to the public interest. But being motivated to make money by investing effort and capital at considerable risk in development of a research advance to a product, and then succeeding in making that money (in spite of well known odds against such success) appears both appropriate to our economic system and very much in the public interest.

We also note IX(f) will prohibit licensing by Stanford to Hewlett Packard, Varian and many more companies because of our clear role as "promoter, organizer, or financier" in those companies (unless other companies in their markets all decline to license). In addition, it is not clear if the definition of "financier" extends to companies represented by investments of our endowment.

The challenge to the ad hoc subcommittee is to develop mechanisms to achieve the goal of early and broad transfer of research findings under government financed research to public use and benefit. The subcommittee has chosen the free enterprise system in lieu of the option of government development or the option to do nothing. Subparagraph IX(f) is in direct contradiction to the correct decision of the subcommittee and to the achievement of its goal. It is ironically also in direct contradiction to programs of the National Science Foundation-Research Applied to National Needs and the Small Business Administration. We strongly recommend that subparagraph IX(f) be deleted in its entirety.

SUBMITTED BY	COMMENT	DISPOSITION	RATIONALE
Research Corporation	Subsection (f) - This subsection is unduly restrictive. Inventors or their co-workers are frequently the very best people to exploit their inventions since they have a dedication and enthusiasm for seeing the fruits of their inventiveness used in the public interest far greater than others who have to be indoctrinated with these attributes before they can become product champions. If the inventors and their co-workers can show they have the requisite abilities in financial, legal, management, production and marketing matters, or can show they can attract people with such abilities, in our opinion, they should be allowed to become personally involved in carrying through to the market-place the inventions they have given birth to on the same basis and with the same restrictions as third parties. To do otherwise flies in the face of human nature and the competitive spirit on which this country is based. The undue restriction in this subsection can be removed by deletion in its entirety of the last sentence, and we do suggest. The requirement to have Agency approval should be retained and such approval should not unreasonably be withheld.	Ditto	Ditto
Cornell	While we understand the reasoning that led to the provisions of section IX(f), and find that these restrictions might at times lend force to our decisions in such matters, it is our view that we are in perhaps the best position to assess possible conflicts. It is our interpretation that these provisions will not restrict the institution from licensing a current or former employee (or student) or group of employees or an organization of which an employee is a member if to do so would bring the benefits of the invention promptly to the public. On this point we are referring to X(f) iii.	Ditto	Ditto

Michigan State	We recommend that this entire section be deleted. The requirement that clearance or approval must be obtained from the federal agency prior to licensing employees of the institution, etc., is an excessive intrusion on the management prerogatives of the institution.	Ditto	Ditto

SUBMITTED BY	COMMENT	DISPOSITION	RATIONALE
New York University	Under section IX(f), "Administration of Inventions", it seems that the language is unnecessarily constraining, particularly the last phrase beginning, "In such cases . . ." The implication is that preference would be given to organizations or individuals other than those listed in part (f). Thus, it appears that the regulations require the grantee to act in an unnecessarily discriminatory manner.	Ditto	Ditto
W.A.R.F	We would suggest the deletion of Section (f) of Article IX. On the one hand, the effect of Sections (a) and (b) of Article IX is to leave the decision concerning licensing with the Institution and then through the operation of Section IX(f) promptly take away a portion of that prerogative. The provisions of this Section could have a decidedly adverse affect upon the transfer of technology from the Univeristy to the private sector. Thus, who can more quickly transfer the technology of a Subject Invention than one who participated in the research leading to its conception and/or actual reduction to practice? Who is most knowledgeable about the subject matter of the invention? Who has more of the "know-how" which may be an ancillary but unwritten and	Ditto	Ditto

undefinable part of the invention? In the event the investigator is willing to assume or participate in the high risk involved in transferring technology from the University to the private sector, where there is little doubt that the odds are extremely long in achieving success, why is his investment so different from that of a third party as to become the subject of a specific prohibition? If such a person, or an organization of which such a person is a part, meets all the criteria to qualify for a license, it seems abundantly clear that transfer of technology involved to the public would occur more expeditiously than if third party, which has first to be taught the technology before such transfer can be made, attempts to make such transfer.

We firmly believe that there is little danger of "unjust enrichment", which appears to be the thrust of Section (f), when there is so little capability to adequately forecast of the commercial success of any given invention and where the investment risks have not been changed. It is well recognized that each invention has its moment in time and if an Institution is under compulsion to first try to find organizations other than those specified in Subsections (i) (ii)(iii), the time delay could be fatal to the transfer of technology to the private sector. Also, the time delay occasioned by obtaining special permission from the agency involved, could also mitigate against the timely transfer of the technology and would, without doubt, significantly increase the administrative burden for the Institution as well as the Agency.

A further point with regard to Section IX(f) is that Institutions for the most part have had a great deal of experience with and have had been most cognizant of potential conflict of interest situations which arise because of their operations and because of the various interrelations between funding arising from private and public sources (the latter including Federal Agency funding) and consulting arrangements entered into by University investigators. We believe that the Institutions' ability to police these problems is well established and that in the great majority of situations such policing is adequate without imposing specific restrictions such as are imposed by this Section.

As a last point, some of the terms used within Section (f) tend to defy definition. For example, in the context of the Section what in fact does "promoter", "organizer" or "financier" mean? These words can have very different connotations depending upon the kind of institution to which they are being applied.

X. Patent Management Organizations

The Institution may utilize the services of the following patent management organizations at its discretion:

[ ] 9/

Other patent management organizations will not be utilized by the Institution unless the patent administration agreement between such organization and the Institution is approved by the Agency.

The Institution shall not assign any Subject Invention to parties other than the Agency in circumstances as set forth in this Agreement, except that it may assign rights in the invention to the above-listed patent management organizations or any other patent management organization whose agreement with the Institution has been approved by the Agency. Any reference to an Institution in this Agreement shall also include a patent management organization where applicable and an assignment to such an organization shall specifically be made subject to all the terms and conditions of this Agreement.

SUBMITTED BY	COMMENT	DISPOSITION	RATIONALE
Research Triangle Institute	My comments pertain to the criteria set forth for the institution's technology transfer program. The wording in subparagraph (5) of 1-9.107-7(b) is quite satisfactory. To quote, the institution must have "an active and effective promotional program for the licensing and marketing of inventions." However, in other sections of the Revision and in the sample IPA, there are strong implications that the government has in mind certain currently existing patent management organizations. See for example the emphasis in Section X of the sample IPA on "organizations" rather than "capability " Indeed, the Report of Interagency Patent Policy Committee went so far as to name two organizations. There are disadvantages, as well as advantages, to the current nationally known patent management organizations. One prominent disadvantage is that they are self-serving, i.e., they seek patents that will bring them the most income and those that will have a short-term pay-off. There are many inventions which are useful to industry, and through industry useful to the consumer, in which the potential pay-off is below the interest threshold of these companies but is still economically valuable. One accusation that has been made is that they skim the cream off the top. A further criticism is that they are too far from many universities to provide the personal touch that most inventors need. I would like to see universities encouraged to establish their own technology transfer function or to use local institutions (The University of North Carolina at Chapel Hill and North Carolina State University in Raleigh have arranged with the Research Triangle Institute to undertake their patent management activities). This also creates the environment whereby a greater patent awareness can be brought to the university research staff. I am not encouraged by the results of the Patent Awareness program of the Research Corporation at the three	No action.	Acknowledged.

33-635 O - 78 - 50

universities I have observed. Inventors have a strong suspicion of the "traveling salesman" or the "big-city slicker." An effective local capability gets around these problems. I do agree that a demonstrated patent management or technology transfer capability must exist before an IPA is made. Therefore, universities starting their own program must accept case-by-case negotiations of inventions until they have demonstrated their capability or use an existing organization while they develop such capability.

In order to accomplish what I would like to see, I suggest that in Section X of the sample IPA the word "organization(s)" be changed to "agent(s)" including the section title. This should not cause confusion with the word "Agency" if agent is always modified by the words "patent management." In the present version, six of the eight times "organization(s)" is used it is so modified. It would cause no problem to properly modify the word "agent" the other two times it is used.

To make the Revision consistent with this suggestion, the words "patent management organization(s)" appearing elsewhere should be changed to read "patent management agent(s)":

Paragraph (I) of subsection (c) of 1-9.107 6 (Page 3)

Item 9/ of Notes for Completion of IPA (Page 18)

Paragraph (7) of the new section 1-9.109-9(a) (Page 20)

Unknown AIA Member	The restriction against assigning rights to anyone other than an approved patent management organization is likewise objectionable as discriminatory and void of any useful purpose in achieving utilization of subject inventions. While reasonable conditions such as granting only a title which is defeasible for failure to achieve utilization might be appropriate, there is no apparent reason why such an assignment should not be available to any qualified applicant willing to accept the same conditions.	No action.	Interest is to permit management of any qualified applicant.

XI. Reports on Development and Commercial Use

The Institution shall provide a written annual report to the Agency on or before September 30th of each year covering the preceding year ending June 30th, regarding the status of development and commercial use that is being made or intended to be made of each Subject Invention left for administration to the Institution and the steps that have been taken by the Institution to bring the invention to the point of practical application. 10/ Such reports shall include information regarding status of development, the date of first commercial sale or use, gross royalties received by the Institution, and such other data and information as the Agency may reasonably specify. To the extent data or information supplied pursuant to this section is considered by a licensee to be privileged or confidential and is so marked, the Agency agrees that to the extent permitted by law it will not disclose such information to persons outside the Government.

SUBMITTED BY	COMMENT	DISPOSITION	RATIONALE
Research Corp.	No comments. While the requirements in this section will require a substantial administrative effort by the institution and/or its designated patent management organization, the type and scope of information requested is not unreasonable and will be made available by licensee without any major resistance.	No action.	Acknowledged.

XII. Inventions by Federal Employees

Nothing in this Agreement shall preclude the Government from obtaining greater rights in a Subject Invention made by an inventor while a Federal employee.

SUBMITTED BY	COMMENT	DISPOSITION	RATIONALE
U. of Conn.	Does this section give special rights to the agency concerning employees paid in part by the Agricultural Experiment Station?	No action	Yes

XIII. Termination

This Agreement may be terminated by either party for convenience upon thirty (30) days written notice. Disposition of rights in, and administration of inventions made under contracts subject to this Agreement will not be affected by such a termination; except that in the event the Government terminates this Agreement because of a failure or refusal by the Institution to comply with any of its obligations under sections V(a), VI, IX, and X of this Agreement, the Agency has the right to require that the Institution's entire right, title and interest in and to the particular invention with respect to which the breach occurred be assigned to the United States of America, as represented by the Agency.

SUBMITTED BY	COMMENT	DISPOSITION	RATIONALE
State	The pertinent contract office has expressed concern about Clause XIII. Termination (page 15), does not agree with giving the righ to terminat- for convenience to both parties.	No action.	Question not understood.

XIV. Communications 11/

Requests for Agency approvals, extensions, or similar actions and other correspondence required by this Agreement should be addressed to _____. Except where specifically provided otherwise in this Agreement, the _____ or his designee shall act as the point of authority within the Agency to grant such approvals, extensions, or take such other Agency actions as may be authorized in this Agreement.

No comments received.

IN WITNESS WHEREOF, each of the parties hereto has executed this Agreement as of the day and year below.

UNITED STATES OF AMERICA

By _____
Title _____
Date _____

(Corporate Seal)

_____
(Institution)

By _____
Title _____
Date _____

CERTIFICATE

I, _____, certify that I am the Secretary of _____ named above; that _____, who signed this Agreement on behalf of said corporation was then _____ of said corporation; and that this Agreement was duly signed for and in behalf of said corporation by authority of its governing body and is within the scope of its corporate powers.

Witness my hand and the seal of said corporation this _____ day of _____, 19__.

(Corporate Seal)

By _____

No comments received

Exhibit A 17

CONFIRMATORY INSTRUMENT

Application for: _____ (Title of Invention)
Inventor(s): _____
Serial No. _____ Contract (Grant) No. _____
Filing Date: _____ Institution: _____

The invention identified above is a "Subject Invention" under _____ (identify Institutional Patent Agreement number) to which contract (grant) No. _____ with _____ (specify Government agency) was subject.

This document is confirmatory of the paid-up license granted to the Government under this contract (grant) in this invention, patent application and any resulting patent, and of all other rights acquired by the Government by the referenced Agreement.*

The Government is hereby granted an irrevocable power to inspect and make copies of the above-identified patent application.

Signed this _____ day of _____, 19__.

_____
(Institution)

_____
(Signature)

_____
(Print or type name)

_____
(Official Title)

CERTIFICATE

I, _____, certify that I am the _____ of the Institution named as licensor herein; that _____, who signed this License on behalf of the Institution is _____ of said Institution; and that said License was duly signed for and in behalf of said Institution by authority of its governing body, and is within the scope of its corporate powers.

_____
Signature

* If in accordance with Section IV(a) of the Agreement, the Agency has determined that a license for state and domestic municipal governments will not be obtained, the following should be added to the Confirmatory Instrument:

"The license granted to the Government does not include state and domestic municipal governments."

No comments received

Notes for Completion of IPA

1/ Insert name of agency

2/ Insert reference to Institution's official policy statements.

No comments received

3/ Insert a date of approximately 3 years.

SUBMITTED BY	COMMENT	DISPOSITION	RATIONALE
Research Corporation	Reference (3) should specifically state: "Insert a date of approximately 3 years [after date of this agreement]." (Phrase in brackets to be added.) As it stands and read in connection with line 4, Section I, this reference is unclear.	Adopted.	Footnote 3 deleted

4/ If any current grants or contracts are to be excluded from the agreement, a statement such as the following should be inserted here: "This Agreement shall not apply to the following contracts..."

5/ Agencies may wish to limit the scope of the agreement to contracts entered into after the date of the Agreement. In such case, the first sentence of this section would have to be revised. If such an approach is used, consideration should be given as to how contract extensions will be treated.

No comments received.

6/ The bracketed language may be deleted but normally it is expected that Institutional Patent Agreements will apply to grants as well as contracts.

SUBMITTED BY	COMMENT	DISPOSITION	RATIONALE
University of Washington	Item 6 suggests that an agency may restrict the IPA to contracts (and exclude grants, for example). We cannot foresee any logical circumstances justifying the exclusion of grants. To the contrary, such exclusion would be counter-productive towards achieving effective technology transfers. We recommend that Item 6 be deleted.	No action.	FPR does not make grants mandatory.

7/ Some agencies may wish to include additional or alternative provisions concerning international matters including such language as they consider necessary pursuant to 1-9.107-3(h)(2).

No comments received.

8/ Agencies may find it useful to include more detailed instructions here on the format of these reports and the persons to whom they should be supplies. The exact clause may have to be varied according to the agencies normal contract close-out procedures.