

PROPOSED FPR REVISION

NBS
 RM 1031
 Administrative
 Bldg.

Prepared by Ad Hoc Subcommittee on University Patent Policy

January 1979

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 - Institutional 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.

(Subsection 1-9.107-6 Contd.)

(B) Reservations of all the rights specified in 1-9.107-3(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	<p>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.</p>	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	<p>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.</p>	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 _____, 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,"

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
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DOD	second WHEREAS clause, rewrite the clause to read:	Adopted in last draft.	Considered to be better drafting.
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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;

	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.
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ERDA Research Corp.	Change "and" to "the" in the second sentence.		
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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	<p><u>Exclusion of certain contracts from the IPA.</u> 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 <u>not</u> 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.</p> <p>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.)</p>	No action.	<p>The requirement to exclude selected contracts from the IPA is deemed necessary at least for the following reasons:</p> <ul style="list-style-type: none">(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.

SUBMITTED BY	COMMENT	DISPOSITION	RATIONALE
Wisc. Alumni Research Foundation	<p data-bbox="588 337 887 362"><u>Scope of Agreement</u></p> <p data-bbox="588 402 1526 464">The comments here can also be readily tied to and should be considered along with the comments to Article IV(b) (B).</p> <p data-bbox="588 505 1526 862">We do not understand the need for <u>any</u> 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).</p> <p data-bbox="588 902 1526 1286">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.</p>	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 <u>only</u> 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.	Ditto	Ditto
	The last part of the first sentence would be deleted if comments under 1 above are accepted.		

p. 4, Section I of IPA

SUBMITTED BY	COMMENTS RECEIVED ON SECOND SENTENCE	DISPOSITION	RATIONALE
National Association of College and Business Officers	<p>Request deletion of the last sentence of the paragraph and substitute therefor:</p> <p>"In cases where the Institution is a subcontractor under a prime contract of the Agency, the Agreement of the Institution shall govern."</p> <p><u>Comments.</u></p> <p>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.</p> <p>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.</p>	Adopted in last draft.	Subcommittee agrees with recommendation.
Stanford University	<p><u>The inapplicability of the IPA where the institution is a subcontractor (last sentence of Article I of the IPA).</u> 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.</p>	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 Institutional 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 interstitial 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	<p>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 -</p> <ol style="list-style-type: none"> (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. 	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 <u>only</u> 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 <u>only</u> 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 its 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 Territory 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 to 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 extension 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	<p>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 assignment 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?</p> <p>Are these questions presumed to be covered by the last sentence of section III (a)?</p>	No action.	Sec. X precludes assignment without the consent of the agency.
California Institute of Technology	<p>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.</p>	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. 107-6(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 <u>sell</u> ."	Ditto	Ditto

SUBMITTED BY	COMMENT	DISPOSITION	RATIONALE
Research Corp.	<p><u>Subsection (a)</u> - 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.</p> <p>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.</p>	Ditto	Ditto

SUBMITTED BY	COMMENT	DISPOSITION	RATIONALE
Research Corp (Contd)	<p>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:</p> <p>"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."</p> <p>A corresponding change will need to be made in Exhibit A, Confirmatory Instrument.</p>	Ditto	Ditto
Amer. Patent Law Association	<p>I. <u>Whereas</u>, 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</p> <p><u>Whereas</u>, 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;</p> <p><u>Now Therefore</u>, 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.</p>	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
ERDA	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.	<p data-bbox="513 337 1499 370"><u>Minimum Rights Acquired by the Government</u></p> <p data-bbox="513 402 1499 993">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.</p> <p data-bbox="513 1026 1499 1221">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.</p> <p data-bbox="513 1253 1499 1518">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. <u>The format of the</u></p>	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:

Adopted-in-part.

Ditto.

"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).

SUBMITTED BY	COMMENT	DISPOSITION	RATIONALE
Stanford University	4. <u>March-in rights for public health or safety needs or for other public purposes.</u> 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	Adopted-in-part.	Ditto.

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. [17/

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.

Adopted in last draft.

Improvement in drafting.

This change substantially shortens the first sentence of paragraph (c) and considerably enhances the readability thereof.

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.

No action.

Subcommittee felt that the recommendation was not administratively feasible.

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.

(d) Nothing contained 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"

No action

Language follows 35 U.S.C.

line 2, (a) (ii) 22 - delete "on" before "sale"

SUBMITTED BY	COMMENT	DISPOSITION	RATIONALE
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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 in funding 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	<p>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, pharmaceuticals, and process inventions.</p>	Ditto	Ditto
	<p>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.</p>	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	<p>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.</p>	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 pay 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.

(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.	<p>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).</p>	Accommodated	Ditto
University of Georgia	<p>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.</p>	Substantially accommodated	Ditto

SUBMITTED BY	COMMENT	DISPOSITION	RATIONALE
Michigan Tech. University	<p>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).</p>	Substantially accommodated.	Ditto.
	<p>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.</p>	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.

Ditto

Ditto

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).

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.F.	<p>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:</p> <ol style="list-style-type: none"><li data-bbox="615 781 1534 911">(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;<li data-bbox="615 946 1521 1076">(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;<li data-bbox="615 1112 1521 1177">(3) administrative considerations such as the obtaining of export licenses under certain conditions; and<li data-bbox="615 1213 1521 1367">(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	<p>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.</p>	Ditto	Ditto
	<p>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.</p>		
	<p>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 <u>after 8 months</u> from the date of the U.S. application.</p>		

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 _____ or its designee. (Institution)

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

(i) Upon request, such duly executed instruments (prepared by the _____ or its designee) and such other _____ (Institution) 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	Substantially accommodated.	Improved drafting.
	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.		
ERDA	Change "at" to "in" in third line of subparagraph (c) of "Patent Rights" clause.	Accommodated	Covered by DOD change.

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.

SUBMITTED BY	COMMENT	DISPOSITION	RATIONALE
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 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). "	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	<p>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.</p>	No action.	Acknowledged.
APLA	<p>Whereas, Federal Procurement Regulations provide Patent Rights clauses for use and guidance for selection of such clauses in subcontracts for Research and Development work;</p> <p>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.</p>	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 tolled 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.	<p>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 recoup 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 field 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.</p>	Adopted in draft.	Redraft provides for tolling when before regulatory agencies.
Purdue	<p>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.</p>	Adopted in draft.	Ditto

SUBMITTED BY	COMMENT	DISPOSITION	RATIONALE
Michigan State	<p>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.</p>	Ditto	Ditto
Michigan Technical University	<p>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.</p>	Accommodated-in-part.	See redraft/
University of Georgia	<p>Provision for the extension of the period of exclusivity in rare cases should be made.</p>	No action.	This has been provided for.

SUBMITTED BY	COMMENT	DISPOSITION	RATIONALE
Colorado State University	<p>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:</p> <p>"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."</p> <p>A clause such as this would provide the university 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.</p>	Accommodated in part.	See redraft.
<p>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.</p>			

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 royalties <u>by licensee and by consumer</u> and rebate to the Government those royalties 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 occurring 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	<u>Subsection IX(c)</u> - 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 financier.

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.

Comments.

NACUBO (cont.)

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 inter-leaving 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.

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.

Ditto

Ditto

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.

SUPA

(f) Stanford and Research Corporation have both written thoughtful 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,

Ditto

Ditto

(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.

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 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

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.

SUBMITTED BY

COMMENT

DISPOSITION

RATIONALE

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	<p>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.</p>	Ditto	Ditto
Cornell	<p>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.</p>	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	<p>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.</p> <p>There are disadvantages, as well as advantages, to the current nationally known patent management organizations. One prominent disadvantage is that they are self-serving, <u>i.e.</u>, 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.</p> <p>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</p>	No action.	Acknowledged.

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 right 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 _____ 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

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
<p>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..."</p> <p>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.</p> <p style="text-align: center;">No comments received.</p> <p>6/ The bracketed language may be deleted but normally it is expected that Institutional Patent Agreements will apply to grants as well as contracts.</p>			

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.
<p>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).</p> <p style="text-align: center;">No comments received.</p> <p>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.</p>			

SUBMITTED BY	COMMENT	DISPOSITION	RATIONALE
TRDA	"Agencies" on last line should be "Agency's"	Adopted.	Editorial.
	9/ Insert the names of any patent management organizations that have been approved. If none are approved, insert "none."		
	10/ Different dates may be substituted depending on the Agency's needs.		
	11/ Insert applicable addresses and officers.		
	No comments received		
	4. Add a new section 1-9.109-7 as follows:		
	§1-9.109-7 Negotiation of Institutional Patent Agreements		
	(a) Information to be submitted by Institution		

SUBMITTED BY	COMMENT	DISPOSITION	RATIONALE
U. of Calif.	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.	No action.	Acknowledged.

An institution desiring to enter into an Institutional Patent Agreement shall provide the agency with the following information:

(1) General information concerning the institution, including:

(i) A copy of its Articles of Incorporation;

- (ii) A statement of the institution's purpose and aims; and
 - (iii) A statement indicating the source of the institution's funds;
- (2) A copy of the institution's established patent policy, together with the date and manner of its adoption;
 - (3) The name, title, address, and telephone number of the officer responsible for administration of patent and invention matters and a description of staffing in this area, including all offices which contribute to the institution's patent management capabilities;
 - (4) A description of the institution's procedures for identifying and reporting inventions and a description of the procedures for evaluation of such inventions for inclusion in the institution's promotional program;
 - (5) A copy of the agreement signed by employees engaged in research and development, indicating their obligation in regard to inventions conceived or for the first time reduced to practice in the course of their assigned duties;
 - (6) A copy of the invention report form or outline utilized for preparation of invention reports;
 - (7) A statement whether the institution has an agreement with any patent management organizations or consultants and a copy of any such agreements;
 - (8) A description of the plans and intentions of the institution to bring to the marketplace inventions to which it retains title, including a description of the efforts typically undertaken by the institution to license its inventions;

No comments received

- (iii) Number of patents obtained during each of the past ten years;
- (iv) Number of exclusive licenses issued during each of the past ten years;
- (v) Number of nonexclusive licenses, other than those to sponsoring Government agencies, issued during each of the past ten years;
- (vi) Gross royalty income during each of the past ten years;
- (vii) A general description of royalties charged, including minimum and maximum royalty rates;

SUBMITTED BY	COMMENT	DISPOSITION	RATIONALE
University of Washington	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.	Adopted in draft.	5 years of records was deemed enough.

SUBMITTED BY	COMMENT	DISPOSITION	RATIONALE
Research Triangle Institute	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.	No action.	Nothing now precludes advising on this matter.

Search Corporation

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).

No action.

Acknowledged.

Washington State
University

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.

Adopted in draft.

5 years of records deemed sufficient.

SUPA

It would seem that a description of institutional patent activities during the past five years would suffice, and even that will not prove a great deal for many institutions. A ten year history as called for can be a very big job.

Ditto

Ditto

- (10) A list of subsidiary or affiliate institutions, which would be covered by an agreement signed by the institution;
- (11) If the institution is a subsidiary or affiliate organization, the name of the other organization and a description of the relationship;
- (12) The amount of Government support for research and development activities currently being administered by the institution, giving Government agency and breakdown;
- (14) A statement of the institution's policies with respect to the sharing of royalties with employees; and
- (15) A description of the uses made of any net income generated by the institution's patent management program.

(b) Criteria for evaluation of a technology transfer program

Before an Institutional Patent Agreement is entered into with an institution, the institution shall have a technology transfer program which, as a minimum shall include:

- (1) An established patent policy which is consistent with the policy in §1-9.107-3 and is administered on a continuous basis by an officer or organization responsible to the institution;

No comments received

- (2) Agreements with employees requiring them to assign to the institution or its designee or the Government any invention conceived or first actually reduced to practice by them in the course of or under Government contracts and awards or assurance that such agreements are obtained prior to the assignment of personnel to Government-supported research and development projects;

SUBMITTED BY	COMMENT	DISPOSITION	RATIONALE
SUPA	(b) (2) A requirement that employees must assign to the institution or its designee or the Government is too inflexible. It does not allow for the unusual but occasional case where neither the institution nor the designee nor the Government wants to prosecute a patent application, but the inventor does (many university patent policies permit this). Exactly the same protection would be provided by a clause stating "Agreements with employees requiring them to assign or license as directed by the institution any invention conceived"	No action.	Rights to an inventor may be available.

(3) Procedures for insuring that inventions are promptly identified and timely disclosed to the officer or organization administering the patent policy of the institution;

SUBMITTED BY	COMMENT	DISPOSITION	RATONALE
Michigan Tech. University	A final comment concerns the use of the word "insuring" in paragraph (b) (3) and (4) of the last section. Our experience indicates that one can never insure that inventions are promptly identified and timely disclosed or that, consequently, they can be evaluated for inclusion in the institution's program. We can demonstrate, of course, that our institution has procedures for the prompt identification and timely disclosure and procedures for the evaluation for inclusion of inventions disclosed ... but, unfortunately, we can never insure that inventions will always be identified and disclosed. Perhaps some more appropriate wording might be substituted?	Adopted in draft.	Editorial.

SUBMITTED BY	COMMENT	DISPOSITION	RATIONALE
Penn State	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.	Adopted in draft.	

(4) Procedures for insuring that inventions disclosed to the institution are evaluated for inclusion in the institution's promotional program; and

No comments received

(5) An active and effective promotional program for the licensing and marketing of inventions.

SUBMITTED BY	COMMENT	DISPOSITION	RATIONALE
	<p>Under section 1-9.109-7(b) (5) the wording does not make clear the evaluation criteria for assessing "an active and effective promotional program." This is of particular concern to us since the Department of the Navy, for example, has interpreted technology transfer capability to mean that the grantee must demonstrate representative patents and licenses in specific fields of technology. (ONR memorandum of February 17, 1976, ref: 610:JKP;dcl). The Navy's interpretation thus clearly favors those organizations which have already secured patents and licenses and effectively eliminates the entry of other institutions into the field of technology transfer. We would therefore recommend that part 1-9.109-7(b) (5) be worded to read "Procedures for insuring an active and effective program of licensing and marketing of inventions."</p>	No action.	Based evaluation of age