

**Department of Health and Human Services**

**OFFICE OF  
INSPECTOR GENERAL**

**NIH OVERSIGHT OF EXTRAMURAL  
RESEARCH INVENTIONS**



**JUNE GIBBS BROWN  
Inspector General**

**MAY 1994  
OEI-03-91-00930**

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# EXECUTIVE SUMMARY

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## PURPOSE

To review the National Institutes of Health's (NIH) oversight of grantees' compliance with the requirements of the Patent and Trademark Amendments of 1980 (commonly known as the Bayh-Dole Act).

## BACKGROUND

The National Institutes of Health's (NIH) mission is the pursuit of science to improve human health. One way NIH accomplishes its mission is by supporting extramural research in universities, medical schools, hospitals, and research institutions. Over 70 percent of the NIH's 1993 \$10 billion budget supports extramural research.

Prior to 1980, there was no uniform Federal policy for dealing with inventions developed through extramural research. In 1980, Congress passed the Patent and Trademark Amendments Act, commonly known as the Bayh-Dole Act (P.L. 96-517). The purpose of the Act was to allow small businesses and nonprofit organizations to acquire title to inventions produced with Federal research funding.

In 1984, the Bayh-Dole Act was amended by the Trademark Clarification Act (P.L. 98-620), which provided even greater flexibility to certain grantees in licensing inventions. With the passage of the Trademark Clarification Act, the Department of Commerce was assigned responsibility for developing regulations.

The Commerce regulations are applicable to all Federal agencies. The Department of Health and Human Services has chosen not to promulgate its own regulations. Instead, the Commerce regulations are used to implement the Bayh-Dole requirements at NIH. The Division of Extramural Invention Reports within NIH is responsible for oversight of these regulations.

We reviewed pertinent legislation and regulations regarding federally-supported inventions. We interviewed officials at the Department of Commerce and NIH and reviewed their extramural invention policies and procedures.

## FINDINGS

*The NIH has the primary role in ensuring that its grantees comply with federal regulations for inventions.*

While the NIH and the Department of Commerce are both granted certain areas of review by the Commerce regulations, both agree that NIH has the primary responsibility for tracking grantee compliance with the regulations.

*The NIH has limited its oversight of grantees by not requiring documentation for some federal requirements.*

The NIH requires documentation for only certain Bayh-Dole requirements. Some of this documentation is required by regulation, some is allowed but not required, and some is not mentioned in the regulation at all.

*The NIH lacks a systematic process for ensuring that grantees submit all required invention information.*

The NIH does not follow up systematically with grantees to ensure that required documents are submitted. In addition, it has no system for determining whether documents are submitted timely.

*The NIH does not fully utilize its invention database to monitor grantee compliance.*

The NIH is not fully utilizing its database's potential for monitoring or reporting out information. Information from the database could be used periodically to inform grantees that certain requirements have not yet been met. More complete information on commercialization could be recorded in the database and then reported to NIH management and the public. This outcome information would illustrate one benefit of public research funding.

## **RECOMMENDATIONS**

This report describes how NIH carries out its oversight role in ensuring grantee compliance with the Federal regulations implementing the Bayh-Dole Act. We realize that in designing its role, NIH has had to balance several priorities. These priorities include encouraging the commercialization of NIH-supported inventions, minimizing the administrative burden of grantee monitoring, and ensuring that the rights of the government and public are upheld. We also recognize the dedication of the Division of Extramural Invention Reports staff for handling a large volume of work with limited resources.

The following recommendations address fundamental problems with NIH's existing oversight role. These recommendations are consistent with the findings of a review done by the Office of Audit Services (OAS) within the Office of Inspector General. The OAS found that one NIH grantee had not fully complied with Bayh-Dole reporting requirements and that NIH did not have effective procedures to detect this non-compliance.

Accordingly, we recommend the following.

- o **The NIH should reexamine its current oversight role to determine if improvements could be made in the monitoring of grantee compliance with Bayh-Dole requirements. While we believe the NIH monitoring role should not**

be so constricting as to hinder the overriding purpose of commercialization that is central to the intent of the Bayh-Dole Act, we also believe that NIH needs to have an effective monitoring role to preserve the additional Bayh-Dole Act objectives of protecting the public investment in research and promoting small businesses and U.S. manufacturing. We do not believe that grantee self-monitoring would ensure that all of these objectives are met.

We believe the NIH needs to increase its monitoring of grantee compliance especially in the areas of royalties, and small business and U.S. manufacturing preferences. However, we recognize the need to consider the views of the full spectrum of affected parties, including the research community, when implementing an improved monitoring process.

To create more effective monitoring procedures, the NIH may determine the need to recommend that the Department of Health and Human Services issue its own regulations for implementing Bayh-Dole requirements. This may clarify NIH and grantee responsibilities under the Bayh-Dole Act.

- o **The NIH should (1) add more detailed licensing and utilization information to its invention database and (2) use the database to track grantees for timely compliance.** The data could be aggregated periodically and used to gauge progress in commercializing NIH-supported inventions.

## AGENCY COMMENTS

The NIH commented on the draft report and the full text of their comments appears in Appendix E. The NIH concurred with our recommendations. The NIH indicated it had made a major step in evaluating its current oversight role of Bayh-Dole through the sponsoring of a two-day public forum by the Task Force on the Commercialization of Intellectual Property Rights from Extramural Research. However, while we agree with the finding of the forum that NIH monitoring should not overburden research institutions to the point of hindering the goal of technology transfer and commercialization, we are not convinced that self-monitoring by grantee institutions will ensure that the objectives of Bayh-Dole will be met. We continue to believe that NIH must exercise a strong monitoring role in order to ensure that an equitable balance is struck between commercializing federally-supported inventions and protecting the public's investment in research.

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# INTRODUCTION

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## PURPOSE

To review the National Institutes of Health's (NIH) oversight of grantees' compliance with the requirements of the Patent and Trademark Amendments of 1980 (commonly known as the Bayh-Dole Act).

## BACKGROUND

### *Extramural Research*

The National Institutes of Health's (NIH) mission is the pursuit of science to improve human health. One way NIH accomplishes its mission is by supporting extramural research in universities, medical schools, hospitals, and research institutions. Over 70 percent of the NIH's 1993 \$10 billion budget supports extramural research.

Funds are awarded to extramural organizations mainly through research grants and research and development contracts.<sup>1</sup> In FY 1991, almost 93 percent of awards were to domestic nonprofit institutions, with universities receiving the majority of these funds.<sup>2</sup>

### *Patent Legislation*

Prior to 1980, there was no uniform Federal policy for dealing with grantees' inventions. Each agency developed its own guidelines for allocating patent rights to grantee inventions. Concerns that conflicting patent policies for federally-supported research were impeding commercialization led to the passage of new patent legislation.

In 1980, Congress passed the Patent and Trademark Amendments Act, commonly known as the Bayh-Dole Act (P.L. 96-517). The law allowed small businesses and nonprofit organizations to acquire title to their subject inventions<sup>3</sup> in any country in

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<sup>1</sup>NIH Data Book 1992, Table 18, p. 25, September 1, 1992.

<sup>2</sup>NIH Data Book 1992, Table 21, p. 31, September 1, 1992.

<sup>3</sup>The term "subject invention" means any invention that the grantee conceived or first actually reduced to practice in the performance of work under a funding agreement. A funding agreement includes grants, contracts, or cooperative agreements. For the purpose of this report, we will use grantee to mean any institution which has a funding agreement with NIH that would fall under these regulations (35 USC 201).



which they file a patent application within a reasonable time. However, under certain exceptional circumstances, the Federal Government may retain title to subject inventions.

The goal of the Bayh-Dole Act is comprised of seven objectives. These objectives are to:

- o use the patent system to promote the utilization of inventions arising from federally supported research or development;
- o encourage maximum participation of small business firms in federally supported research and development efforts;
- o promote collaboration between commercial concerns and nonprofit organizations, including universities;
- o ensure that inventions made by nonprofit organizations and small business firms are used in a manner to promote free competition and enterprise;
- o promote the commercialization and public availability of inventions made in the United States by United States industry and labor;
- o ensure that the Government obtains sufficient rights in federally supported inventions to meet the needs of the Government and protect the public against nonuse or unreasonable use of inventions; and
- o minimize the costs of administering policies in this area.

In 1984, the Bayh-Dole Act was amended by the Trademark Clarification Act (P.L. 98-620), which provided even greater flexibility to certain grantees in licensing inventions.

***Incorporation of the Bayh-Dole and Trademark Clarification Acts into U.S. Codes***

Although under most circumstances patent rights are allocated to grantees, the government is allowed certain minimum rights in any federally-funded invention (35 U.S.C. 202). Grantees must disclose inventions, elect to retain title, and file patent applications for each subject invention within a reasonable time frame. If the grantee does not perform these functions in a reasonable time frame, the government may receive title to the invention.

When the grantee retains rights to the invention, Federal agencies retain a non-exclusive, non-transferable, irrevocable, paid-up license to practice the subject invention. Federal agencies also have the right to require periodic reporting on the

utilization or efforts at obtaining utilization of the invention. In addition, the grantee is required to include a statement in the patent specifying that the invention was made with Government support and that the Government has certain rights in the invention.

If a grantee chooses to license a subject invention, certain requirements apply. All grantees must make an effort to license to firms that will manufacture the invention substantially in the United States. Nonprofit organizations must make a reasonable effort to give preference to small businesses when licensing. Finally, royalties accrued to nonprofit organizations must be shared with the inventor and the remainder must be used to support scientific research or education.

If certain requirements are not met, granting agencies may employ "march-in rights". March-in rights allow the granting agency to require grantees or licensees to grant a nonexclusive, partially exclusive, or exclusive license to responsible applicants if the agency determines that the grantee or licensee is not fulfilling certain requirements. The agency may employ this march-in right if (1) the grantee has not taken effective steps to commercialize the invention, (2) action is necessary to alleviate health or safety needs, (3) action is necessary to meet requirements for public use, or (4) action is necessary because the requirement for manufacturing the invention in the United States is not being fulfilled.

### ***Federal Regulations***

The Office of Federal Procurement Policy was initially charged with issuing regulations for implementing the Bayh-Dole Act. With the passage of the Trademark Clarification Act, the Department of Commerce was assigned responsibility for developing regulations.

The Commerce regulations (37 CFR 401) include a standard patent clause that is to be incorporated in all funding agreements. The clause outlines the rights and responsibilities of Federal agencies and grantees regarding subject inventions. The Commerce regulations are applicable to all Federal agencies. The Department of Health and Human Services has chosen not to promulgate its own regulations. Instead, the Commerce regulations are used to implement the Bayh-Dole requirements at NIH. See Appendix A for the Commerce regulations.

### ***The NIH Administration of the Bayh-Dole Act***

The Division of Extramural Invention Reports (DEIR) is responsible for overseeing grantee compliance with Federal regulations concerning invention reporting. Since 1991, DEIR has been under the direction of the Office of Policy for Extramural Research Administration (OPERA).

The DEIR is composed of two staff members. The Director and one additional support person handle the invention information that comes from the thousands of funding agreements awarded each year.

### *Concerns About Commercialization of Federally-Supported Inventions*

Recent congressional hearings have questioned the appropriateness of collaborative agreements between research institutions receiving Federal support and private firms. The research environment has changed since the passage of Bayh-Dole more than a decade ago. Research institutions are increasingly turning to private funding as Federal research dollars grow scarce. Along with the growing number of collaborative agreements comes a growing concern that the public investment in research is not being adequately protected.

The Bayh-Dole Act has been successful in encouraging the commercialization of federally-supported inventions and collaboration between commercial concerns and universities. Between 1980 and 1990, the number of patent applications for NIH-supported inventions increased nearly 300 percent. The commercialization agreements and licenses to produce these inventions have provided universities and other research institutions with millions of dollars in royalties.<sup>4</sup>

Although NIH, universities, and private firms point to the success of Bayh-Dole, others believe the increased collaboration between researchers and industry can lead to conflicts of interest and a lack of accountability to the public.<sup>5</sup> In response to these concerns, NIH recently surveyed approximately 100 universities to review their invention information and research-support agreements.<sup>6</sup> The NIH has also asked its internal Task Force on the Commercialization of Intellectual Property Rights from NIH-Supported Extramural Research to evaluate the issues surrounding commercialization.

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<sup>4</sup>Bernadine Healy, M.D., Director of the National Institutes of Health, Statement before the House Committee on Small Business, Subcommittee on Regulation, Business Opportunities, and Energy, June 17, 1993.

<sup>5</sup>Ralph Nader, Statement before the House Committee on Small Business, Subcommittee on Regulation, Business Opportunities, and Energy, March 11, 1993

Representative Ron Wyden, Opening statement before the House Committee on Small Business, Subcommittee on Regulation, Business Opportunities, and Energy, March 11, 1993.

Sheldon Krinsky, Ph.D., Statement before the House Committee on Small Business, Subcommittee on Regulation, Business Opportunities, and Energy, June 17, 1993.

<sup>6</sup>Research-support agreements are agreements between outside firms and research institutions, where in exchange for research dollars, the institution provides the outside firm the first right to license or commercialize inventions that arise during the supported research.

## METHODOLOGY

We reviewed pertinent patent legislation (PL 96-517, PL 98-620), including legislative histories, to determine the purposes and objectives of the laws. We examined current regulations covering the assignment and management of patent rights for federally-funded inventions promulgated by the Departments of Commerce and Health and Human Services.

We interviewed both NIH and Commerce officials and asked them to define their oversight responsibilities. We also interviewed officials at the National Science Foundation to see how an agency with grantees similar to those funded by NIH viewed their oversight responsibilities.

We reviewed all pertinent procedures and policy statements that NIH has developed to oversee grantees' compliance with Bayh-Dole requirements. We also reviewed information provided to grantees to inform them of their rights and responsibilities under Bayh-Dole. To learn what information is collected and stored by the Inventions Office, we examined the computer database of grantee invention information.

We limited our review to what procedures were in place at NIH to ensure grantee compliance. We did not evaluate whether grantees were complying with regulations.

We conducted our inspection in accordance with the *Quality Standards for Inspections* issued by the President's Council on Integrity and Efficiency.

## FINDINGS

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### THE NIH HAS THE PRIMARY ROLE IN ENSURING THAT ITS GRANTEES COMPLY WITH FEDERAL REGULATIONS FOR INVENTIONS.

While the National Institutes of Health (NIH) and the Department of Commerce are both granted certain areas of review by the regulations promulgated by Commerce, both agree that NIH has the primary responsibility for tracking its grantees' compliance with the regulations. The table below illustrates which agency has a responsibility for overseeing the principal requirements of the Federal regulations.

#### Agencies' Oversight Responsibilities

Federal Requirements	Department of Commerce	National Institutes of Health
For All Grantees:		
Exceptional Circumstances	X	X
Invention Disclosures		X
Election of Title		X
Utilization Reports		X
Preference for US Industry		X
For Nonprofit Grantees:		
Sharing Royalties with Inventors		X
Using Royalties for Research and Education		X
Preference Given to Small Business When Licensing	X	X

Although NIH has primary oversight responsibility, they apply regulations designed by Commerce. Therefore, NIH has on occasion requested clarification from Commerce when determining what would constitute compliance with certain parts of the regulations.

*While the Department of Commerce shares some responsibility with NIH, it does not have a monitoring role.*

The Department of Commerce views itself as an ombudsman for complaints concerning compliance with the regulations. If a complaint were received, it would be sent to the appropriate agency for review with a request that the agency share the results with Commerce.

According to Commerce, their regulations allow for decentralized agency decisions on how to implement policies. Commerce relies on individual agencies to implement their policies within the broad legal parameter of the regulations. Commerce recognizes that agencies differ in their level of oversight and has no official opinion on what the appropriate level should be.

There are two areas where NIH and Commerce share responsibility for oversight: exceptional circumstances and ensuring that nonprofit grantees give preference to small businesses when making licensing decisions.

#### Exceptional Circumstances

In cases of exceptional circumstances, NIH is responsible for making the determination and the Secretary of Commerce for reviewing NIH's determination. Exceptional circumstances occur when NIH determines that restriction or elimination of the grantee's right to retain title would better achieve the Bayh-Dole objectives.

When NIH determines that exceptional circumstances exist, it is required to prepare a written analysis justifying its decision. It shares this analysis with the grantee and the Secretary of Commerce. The Secretary reviews NIH's determination. If NIH's determination is found not to conform with the policies and objectives of the regulations, the Secretary may recommend corrective action.

#### Small Business Preference

While both agencies agree that Commerce would handle complaints, neither actively monitors grantee compliance with the small business preference requirement. Under this regulation, nonprofit grantees are required to make reasonable efforts to attract small business licensees. Grantees must also give preference to small businesses when their marketing plans are as likely to bring about commercialization as the plans of larger businesses.

While NIH indicated that problems would be forwarded to Commerce for review, there is no formal mechanism either for identifying problems or for sharing information with Commerce.

*The NIH has defined its role based on three Bayh-Dole objectives.*

The NIH's oversight has centered mainly on three of the Bayh-Dole Act's objectives. The primary objective is encouraging grantees to use the patent system to promote the utilization of inventions arising from federally-supported research. According to the former NIH Director, "NIH must continue to seek the rapid development of discoveries into useful products in order to fulfill our mission to save and improve the lives of the American people."<sup>7</sup>

Through the activities of DEIR, NIH has also focused on two more objectives. The first is ensuring the government retains its rights to federally-supported inventions. The NIH protects these rights by securing a non-exclusive license from the grantee and verifying that the patent contains a clause stating that the invention was made with NIH support.

The second objective is to minimize the cost of administrative policies. In determining its oversight role, NIH has focused not on strict monitoring of grantees but rather has relied on the grantees' self-interest to ensure compliance. The NIH believes that compliance with the regulations occurs because it is in the best interest of the grantee to have clear title to an invention.

*The NIH is responsible for making grantees aware of requirements.*

Both NIH and Commerce agree that the granting agency is responsible for making grantees aware of their rights and obligations under Bayh-Dole. The NIH fulfills this responsibility by providing several documents to grantees.

All Public Health Service (PHS) grantees receive the PHS Grants Policy Statement, a resource manual. Unlike the National Science Foundation which places the standard patent rights clause in its manual, the PHS manual provides only the citation for the pertinent Commerce regulations under the Patent and Invention section. It also explains the different invention reporting requirements.

New grantees receive a "welcome wagon" letter advising them of their responsibilities. The Institutional Patent Policy Section of this letter cites the Commerce regulations and advises grantees to refer questions to the appropriate NIH extramural inventions office. The letter also states, "It is expected that institutions will rely primarily on their own legal counsel for advice and interpretation of relevant laws and regulations."

Several notices explaining invention reporting requirements have been published in the NIH Guide for Grants and Contracts, a weekly publication sent to all grantees and

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<sup>7</sup>Bernadine Healy, M.D., Statement before the House Committee on Small Business, Subcommittee on Regulation, Business Opportunities, and Energy, March 11, 1993.

interested parties. To make grantees aware of their obligations, invention and patent requirement information has been published in the Guide five times since February 1990.

Information about patent requirements also appear in the Application for Public Health Service grants and in the application for contracts and Small Business Innovation Research (SBIR).

### **THE NIH HAS LIMITED ITS OVERSIGHT OF GRANTEEES BY NOT REQUIRING DOCUMENTATION FOR SOME FEDERAL REQUIREMENTS.**

The NIH requires documentation for only certain requirements thereby limiting its oversight role. Some of this documentation is required by regulation, some is allowed but not required, and some is not mentioned in the regulation at all.

The regulations require grantees to submit written documentation to granting agencies for invention disclosure and election of title. In the case of utilization reports, the regulations allow but do not require agencies to collect them. For the remaining requirements, the regulations do not outline what information should be required to document compliance.

The NIH requires documentation for some of these requirements. However, for four requirements, NIH does not require grantees to send any documentation or certification of compliance. The table on the following page identifies NIH's documentation requirements.

#### ***As required in the regulations, NIH requests written disclosure of inventions and election of title.***

If an invention occurs during the life of a funding agreement, NIH requires the grantee to send an invention disclosure and election of title. In accordance with the regulations, NIH directs grantees to send a written disclosure within 2 months after the inventor discloses it in writing to the personnel responsible for handling patent matters at the grantee institution. Within 2 years after disclosure, NIH requires grantees to elect to retain or release title to the invention.

#### ***As allowed by regulation, NIH requests utilization reports from grantees.***

As of October 23, 1992, NIH began requesting that grantees send annual utilization reports. Since 1990, NIH had been requiring them every 2 years. Before 1990, NIH did not specifically require that utilization reports be sent to them.

Under Federal regulations, agencies may request reports on the grantee's effort to utilize the invention. These utilization reports include information on the development status of the invention, date of first commercial use, and gross royalties collected by grantee.



## Documentation Required by NIH to Ensure Grantee Compliance

Federal Requirements	Documentation Required by NIH
For All Grantees:	
Invention Disclosures	Written Disclosure
Election of Title	Written Election
Utilization Reports	Annual report
Filing Patents	Patent Application and Patent
Ensuring Government Rights	Patent Application and Patent, U.S. license
Preference for US Industry	None
For Nonprofit Grantees:	
Sharing Royalties with Inventors	None
Using Royalties for Research and Education	None
Preference Given to Small Business When Licensing	None

***The NIH chooses to require documentation verifying that patent applications are filed and ensuring government rights.***

The NIH requires grantees to submit copies of the patent application, issued patent, and the non-exclusive government license even though not specifically required by the regulation. The NIH has determined that copies of these documents are needed to ensure grantee compliance.

The regulation requires grantees to file a patent application within one year after election of title and acknowledge government support in the patent application and issued patent. It further states that when the grantee elects to retain title to an invention, the Federal government shall have a nonexclusive, nontransferable, irrevocable, paid-up license to practice the subject invention throughout the world.

***The NIH does not monitor grantees to ensure compliance with U.S. industry and small business preferences and royalty requirements.***

The NIH does not require grantees to submit licensing agreements, certification of meeting royalty requirements, or certification of efforts to give licensing preference to U.S. industry and small businesses. While the regulations outline these requirements, they are silent on how the requirements should be documented. Since NIH does not

require documentation of these requirements, it is unable to determine the extent of grantee compliance.

### U.S. Industry and Small Business Preference

Since NIH neither reviews the licensing process nor obtains a copy of the invention license, it is unable to determine whether grantees are complying with the U.S. industry and small business preference requirements. When a grantee licenses an invention, it allows a firm to use the invention to commercialize the product in exchange for a licensing or royalty fee. Regulations require that all grantees license to companies that will manufacture the invention substantially in the U.S. and that nonprofit grantees give preference to small business.

In the case of the U.S. manufacturing requirement, grantees may apply for a waiver if reasonable efforts to meet it are unsuccessful. With no formal documentation required, the only way NIH learns this requirement is not being met is when a grantee requests a waiver or if a complaint is received. The recent university survey found that only 20 percent of the research-support agreements (from some 100 universities surveyed) had clearly established U.S. manufacturing clauses.<sup>8</sup>

The NIH has no formal mechanism to determine whether nonprofit grantees have given preference to small business. According to their recent survey, approximately 44 percent of research-support agreements collected were with small businesses.<sup>9</sup>

### Royalty Requirements

The NIH does not require any certification, financial reports, or other information from nonprofit grantees to verify compliance with the royalty requirements in the Federal regulations. The NIH considers this proprietary information. They also consider the royalty requirements to be self-enforcing, believing that inventors would advise NIH if grantees failed to comply.

According to Federal regulations, any royalties received from the licensing of inventions must be shared with inventors. In addition, the balance of royalties after expenses must be used to support scientific research and education. The Federal regulations do not specify what information granting agencies need to collect to verify that royalty requirements are being met.

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<sup>8</sup>Bernadine Healy, M.D., Statement before the House Committee on Small Business, Subcommittee on Regulation, Business Opportunities, and Energy, June 17, 1993.

<sup>9</sup>Bernadine Healy, M.D., Statement before the House Committee on Small Business, Subcommittee on Regulations, Business Opportunities, and Energy, June 17, 1993.

## **THE NIH LACKS A SYSTEMATIC PROCESS FOR ENSURING THAT GRANTEES SUBMIT ALL REQUIRED INVENTION INFORMATION.**

The NIH does not follow up systematically with grantees to ensure that required information is submitted. Although NIH does require grantees at the end of a grant to certify if any invention occurred during the granting period, NIH has no way of knowing if grantees are providing accurate information. Without this information, NIH may not be aware of inventions funded with their research dollars and can not be certain that grantees are complying with Federal requirements. As outlined in the previous finding, NIH requires grantees to send them documentation for invention disclosures, elections of title, utilization reports, patent applications, issued patents, and the U.S. non-exclusive licenses. The DEIR has created a database to store the information collected from grantees.

Although NIH requires grantees to submit this documentation within specific time frames, it has not created a system for determining whether documents are submitted timely. Due to a lack of staff time and resources, the DEIR has not made reviewing grantees for timeliness a priority. The Division has stated that it instead focuses on ensuring that government rights are recognized through the acknowledgement of government support in the patent and through the granting of the government's non-exclusive license.

According to NIH, they do not perform strict monitoring of grantees believing that grantees are responsible for ensuring that the terms of their funding agreements are met. The NIH explained that it is in the best interest of the grantees to comply because the title to inventions is at stake.

The DEIR has chosen not to penalize grantees who do not send information when required. While the regulations allow granting agencies to take title to grantees' inventions if they do not meet certain requirements, NIH believes this punitive approach is contrary to the primary Bayh-Dole objective of allowing grantees to retain the rights to their inventions. Instead, when problems arise, DEIR informs grantees of their requirements and asks that the necessary information be sent.

A detailed explanation of the invention reporting process is provided in Appendix B.

***The NIH does not review invention disclosures and elections of title for timeliness and has no way of knowing if grantees are in compliance.***

Invention disclosures are not entered into the computer database to ensure that elections of title are received within 2 years after disclosure. When DEIR receives a disclosure it files the paper copy by grantee name, but does not enter the information into the database as it is considered preliminary in nature. A computer file is opened and the information is input only after DEIR receives the election of title.

Disclosures are accepted at any time because without reviewing grantee and inventor files DEIR can not ascertain if they were sent within the 2 month time limit. The DEIR considers late disclosures and elections to be de facto requests for time limit extensions. By regulation, grantees can request extensions of time and agencies can grant them at their discretion. The DEIR always grants extensions to grantees when requested.

The DEIR has no method for ensuring that grantees are making all the necessary disclosures and elections of title. Once again, without reviewing grantee files, NIH is unable to ascertain whether it is receiving disclosures to all inventions that occurred during the funding period.

***The NIH does not examine annual utilization reports to monitor grantees' commercialization efforts.***

Even though NIH has required grantees to submit utilization reports since 1990, it has not established procedures to ensure that the reports are submitted when due, and does not review forms to monitor grantees' commercialization efforts.

Earlier this year, NIH specified that utilization reports are required only for licensed inventions that have generated income. Since grantees who have yet to license their products no longer need to report, NIH no longer has a means of monitoring grantees' commercialization efforts. This is significant since NIH can exercise its march-in rights if it determines a grantee has not taken effective steps to commercialize an invention.

Prior to 1990, NIH grantees may have sent these utilization reports to Commerce. Commerce developed a standardized Invention Utilization Report that grantees were encouraged to use. Once received, Commerce shared copies of the form with the appropriate granting agencies. Although Commerce no longer shares the reports, they noted that they continue to receive these forms occasionally from grantees.

In order to clear up confusion and assure receipt of utilization reports, DEIR developed a Subject Invention Utilization Form for its grantees earlier this year. Among other items, the form requests proprietary information on licensing and royalties. The DEIR indicates on the new form that reports should now be sent directly to their office. See Appendix C for a sample form.

***The NIH has no system to ensure timely filing of patent applications.***

The NIH does not monitor grantees to ensure that patent applications are filed within one year of election of title. However, when applications or issued patents are sent, DEIR's policy is to review them for the statement acknowledging government support. If the statement is missing, DEIR requests the grantee to include the acknowledgement.

When grantees send the patent application, NIH also requires them to send a copy of the government license. If the license is not sent at this time, DEIR will inform them of the requirement. The DEIR provides a sample licensing form to universities upon request. An example of this form appears in Appendix C.

After the patent application, issued patent, and license are received, DEIR records this information in the database file. Some grantees submit patent applications for inventions that were never disclosed or where rights were never elected. In these cases, DEIR opens a new computer file and no penalties are applied.

*As a check to the process, NIH does provide additional opportunities for grantees to report inventions and patents.*

Grantees are required to certify whether inventions or patents have occurred when applying for a continuing grant and also when a grant is completed. The DEIR receives copies of all these certifications and compares them with their records. If there are inconsistencies, information is requested from grantees.

On the grant application filed for a continuation grant, the grantee must check if any inventions or patents occurred and if they were reported. When a grant is completed, the grantee must certify on the Final Invention Statement and Certification whether inventions occurred and when they were reported. Institutions who hold NIH contracts are also required to certify if inventions were made on a Contractor's Certification. Examples of these forms can be found in Appendix C.

#### **THE NIH DOES NOT FULLY UTILIZE ITS INVENTION DATABASE TO MONITOR GRANTEE COMPLIANCE.**

The NIH is not fully utilizing the DEIR database's potential for monitoring or reporting out information. The DEIR developed the easy-to-use REFLEX database for storing invention information. Prior to the creation of the database, invention information was stored on the Patent Management Information System (PMIS). The PMIS contains about 5000 files and the new database about 3800. An example of an invention record is shown on the next page. A sample computer file record and a description of what is stored in the record fields appears in Appendix D.

By using the fields already containing dates (Disclosed, Application Date) and adding a date field for retaining rights, the DEIR could use the database to determine when information is due from grantees and thereby have a mechanism for measuring grantee timeliness. Information from the database could be used periodically to inform grantees that certain requirements have not yet been met.

The information now in the system is not utilized for any purpose or reported out to any NIH office. More complete information on commercialization from the utilization

reports could be recorded in the database and then reported to NIH management and the public. This outcome information would illustrate one benefit of public funding of research.

### Sample Database Record

Grantee:		Code:
Name 1:	Name 2:	Name 3:
Grant 1:	Grant 2:	Grant 3:
Patent Title:		
Disclosed:	CIP CON DIV Applns:	
Retained Rights:	Lead Agency:	
US License:	Old G code:	
Support Acknowledged:	Case abandoned:	
Serial Number:	Application Date:	
Patent Serial:	Patent Issue Date:	
Special Note:		
Licensed:		

While DEIR is aware of its database capabilities, large workloads and little staff time have not allowed them to fully use the database. A limited DEIR review of the invention and licensing information sent by approximately 30 universities recently surveyed found that in more than half of the cases the information sent by the universities did not match the information in DEIR's files. Improving the monitoring capabilities of the database could improve grantee compliance with requirements.

reports could be recorded in the database and then reported to NIH management and the public. This outcome information would illustrate one benefit of public funding of research.

### Sample Database Record

Grantee:		Code:
Name 1:	Name 2:	Name 3:
Grant 1:	Grant 2:	Grant 3:
Patent Title:		
Disclosed:		CIP CON DIV Applns:
Retained Rights:		Lead Agency:
US License:		Old G code:
Support Acknowledged:		Case abandoned:
Serial Number:		Application Date:
Patent Serial:		Patent Issue Date:
Special Note:		
Licensed:		

While DEIR is aware of its database capabilities, large workloads and little staff time have not allowed them to fully use the database. A limited DEIR review of the invention and licensing information sent by approximately 30 universities recently surveyed found that in more than half of the cases the information sent by the universities did not match the information in DEIR's files. Improving the monitoring capabilities of the database could improve grantee compliance with requirements.

# RECOMMENDATIONS

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This report describes how NIH carries out its oversight role in ensuring grantee compliance with the Federal regulations implementing the Bayh-Dole Act. We realize that in designing its role, NIH has had to balance several priorities. These priorities include encouraging the commercialization of NIH-supported inventions, minimizing the administrative burden of grantee monitoring, and ensuring that the rights of the government and public are upheld. We also recognize the dedication of the Division of Extramural Invention Reports staff for handling a large volume of work with limited resources.

The following recommendations address fundamental problems with NIH's existing oversight role. These recommendations are consistent with the findings of a review done by the Office of Audit Services (OAS) within the Office of Inspector General. The OAS found that one NIH grantee had not fully complied with Bayh-Dole reporting requirements and that NIH did not have effective procedures to detect this non-compliance.

Accordingly, we recommend the following.

- o **The NIH should reexamine its current oversight role to determine if improvements could be made in the monitoring of grantee compliance with Bayh-Dole requirements.** While we believe the NIH monitoring role should not be so constricting as to hinder the overriding purpose of commercialization that is central to the intent of the Bayh-Dole Act, we also believe that NIH needs to have an effective monitoring role to preserve the additional Bayh-Dole Act objectives of protecting the public investment in research and promoting small businesses and U.S. manufacturing. We do not believe that grantee self-monitoring would ensure that all of these objectives are met.

We believe the NIH needs to increase its monitoring of grantee compliance especially in the areas of royalties, and small business and U.S. manufacturing preferences. However, we recognize the need to consider the views of the full spectrum of affected parties, including the research community, when implementing an improved monitoring process.

To create more effective monitoring procedures, the NIH may determine the need to recommend that the Department of Health and Human Services issue its own regulations for implementing Bayh-Dole requirements. This may clarify NIH and grantee responsibilities under the Bayh-Dole Act.

- o **The NIH should (1) add more detailed licensing and utilization information to its invention database and (2) use the database to track grantees for timely compliance.** The data could be aggregated periodically and used to gauge progress in commercializing NIH-supported inventions.



## AGENCY COMMENTS

The NIH commented on the draft report and the full text of their comments is in Appendix E.

The NIH concurred with our first recommendation that NIH reexamine its oversight role to determine if improvements could be made in the monitoring of grantee compliance with Bayh-Dole requirements. The NIH indicated it had made a major step in evaluating its current oversight role of Bayh-Dole through the sponsoring of a two day public forum by the Task Force on the Commercialization of Intellectual Property Rights from Extramural Research.

The forum, entitled "Forum on Sponsored Research Agreement: Perspectives, Outlook and Policy Development," was held to solicit the views of an external panel of experts and the public on issues related to research support agreements between grantees and industry in which NIH funding was involved.

The preliminary recommendations of the panel suggest that:

- (1) the grantee institutions rather than the Federal Government should be the primary monitors of compliance with the Bayh-Dole Act provisions concerning the utilization and preference for small business, and
- (2) NIH should focus on providing educational , and/or policy guidance to the institutions on this matter.

The panel also stated that stringent guidelines and reporting requirements could have a detrimental effect on technology transfer and the ultimate commercialization of Federally funded research.

We commend NIH for convening both the task force and the public forum to address issues surrounding the commercialization of federally-funded extramural research. We also commend NIH for eliciting the views of universities and parties who will in the end be affected by any NIH policy decisions.

We agree with the panel that NIH monitoring should not overburden research institutions to the point of hindering the goal of technology transfer and commercialization. However, the Bayh-Dole Act also outlines the following objectives:

- o ensure that inventions made by nonprofit organizations and small business firms are used in a manner to promote free competition and enterprise;
- o promote the commercialization and public availability of inventions made in the United States by United States industry and labor; and

- o ensure the Government obtains sufficient rights in federally supported inventions to meet the needs of the Government and protect the public against nonuse or unreasonable use of inventions.

We are not convinced that self-monitoring by grantee institutions will ensure that the above objectives will be met. Under the minimum requirements of NIH's current monitoring, universities did not always adequately support these objectives. In a recent draft report, the Office of Audit Services detailed one research institution's lack of compliance with the Bayh-Dole requirement that grantees acknowledge federal support when filing a patent for a new invention. The NIH also found during its recent 100 university survey that only 20 percent of research-support agreements between universities and outside companies had clearly established U.S. manufacturing clauses. In addition, only 44 percent of these agreements were with small businesses.

We believe that NIH's current lack of grantee monitoring in the areas of preference for U.S. industry in manufacturing and preferences to small businesses when licensing may have led to the universities' inadequate promotion of these objectives.

We continue to believe that NIH must exercise a strong monitoring role in order to ensure that an equitable balance is struck between commercializing federally-supported inventions and protecting the public's investment in research.

The NIH concurred with our second recommendation that more detailed licensing and utilization information should be added to their invention database and that the database should be used to track grantees for timely compliance. Although NIH stated that it is not certain that requiring grantees to submit more detailed reports is the most effective means of ensuring compliance with the Act, they did agree to evaluate the usefulness of information currently collected and consider requesting different or additional information for use in monitoring compliance and illustrating public benefits from federally-funded research.

We support NIH's evaluation of the usefulness of reporting information received from grantees. We believe that the issue may not be one of increasing the volume of information requested but improving the content and method of grantee reporting. Therefore, we regard NIH's intention to establish electronic transfer of reporting information as an important step toward improving the grantee reporting process.

# APPENDIX A

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Regulations Implementing the Bayh-Dole Act  
37 CFR 401

# CHAPTER IV—ASSISTANT SECRETARY FOR TECHNOLOGY POLICY, DEPARTMENT OF COMMERCE

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<i>Part</i>		<i>Page</i>
401	Rights to inventions made by nonprofit organizations and small business firms under Government grants, contracts, and cooperative agreements.....	460
404	Licensing of Government owned inventions .....	476

**PART 401—RIGHTS TO INVENTIONS  
MADE BY NONPROFIT ORGANIZATIONS  
AND SMALL BUSINESS FIRMS  
UNDER GOVERNMENT GRANTS,  
CONTRACTS, AND CO-OPERATIVE  
AGREEMENTS**

Sec.

- 401.1 Scope.
- 401.2 Definitions.
- 401.3 Use of the standard clauses at § 401.14.
- 401.4 Contractor appeals of exceptions.
- 401.5 Modification and tailoring of clauses.
- 401.6 Exercise of march-in rights.
- 401.7 Small business preference.
- 401.8 Reporting on utilization of subject inventions.
- 401.9 Retention of rights by contractor employee inventor.
- 401.10 Government assignment to contractor of rights in invention of government employee.
- 401.11 Appeals.
- 401.12 Licensing of background patent rights to third parties.
- 401.13 Administration of patent rights clauses.
- 401.14 Standard patent rights clauses.
- 401.15 Deferred determinations.
- 401.16 Submissions and inquiries.

**AUTHORITY:** 35 U.S.C. 206 and the delegation of authority by the Secretary of Commerce to the Assistant Secretary of Commerce for Technology Policy at sec. 3(g) of DDO 10-18.

**SOURCE:** 52 FR 8554, Mar. 18, 1987, unless otherwise noted.

§ 401.1 Scope.

(a) Traditionally there have been no conditions imposed by the government on research performers while using private facilities which would preclude them from accepting research funding from other sources to expand, to aid in completing or to conduct separate investigations closely related to research activities sponsored by the government. Notwithstanding the right of research organizations to accept supplemental funding from other sources for the purpose of expediting or more comprehensively accomplishing the research objectives of the government sponsored project, it is clear that the ownership provisions of these regulations would remain applicable in any invention "conceived or first actually reduced to practice in performance" of the project. Separate accounting for

the two funds used to support the project in this case is not a determining factor.

(1) To the extent that a non-government sponsor established a project which, although closely related, falls outside the planned and committed activities of a government-funded project and does not diminish or distract from the performance of such activities, inventions made in performance of the non-government sponsored project would not be subject to the conditions of these regulations. An example of such related but separate projects would be a government sponsored project having research objectives to expand scientific understanding in a field and a closely related industry sponsored project having as its objectives the application of such new knowledge to develop usable new technology. The time relationship in conducting the two projects and the use of new fundamental knowledge from one in the performance of the other are not important determinants since most inventions rest on a knowledge base built up by numerous independent research efforts extending over many years. Should such an invention be claimed by the performing organization to be the product of non-government sponsored research and be challenged by the sponsoring agency as being reportable to the government as a "subject invention", the challenge is appealable as described in § 401.11(d).

(2) An invention which is made outside of the research activities of a government-funded project is not viewed as a "subject invention" since it cannot be shown to have been "conceived or first actually reduced to practice" in performance of the project. An obvious example of this is a situation where an instrument purchased with government funds is later used, without interference with or cost to the government-funded project, in making an invention all expenses of which involve only non-government funds.

(b) This part implements 35 U.S.C. 202 through 204 and is applicable to all Federal agencies. It applies to all funding agreements with small business firms and nonprofit organizations

executed after the effective date of this part, except for a funding agreement made primarily for educational purposes. Certain sections also provide guidance for the administration of funding agreements which predate the effective date of this part. In accordance with 35 U.S.C. 212, no scholarship, fellowship, training grant, or other funding agreement made by a Federal agency primarily to an awardee for educational purposes will contain any provision giving the Federal agency any rights to inventions made by the awardee.

(c) The *march-in* and appeals procedures in §§ 401.6 and 401.11 shall apply to any march-in or appeal proceeding under a funding agreement subject to Chapter 18 of Title 35, U.S.C., initiated after the effective date of this part even if the funding agreement was executed prior to that date.

(d) At the request of the contractor, a funding agreement for the operation of a government-owned facility which is in effect on the effective date of this part shall be promptly amended to include the provisions required by §§ 401.3(a) unless the agency determines that one of the exceptions at 35 U.S.C. 202(a)(i) through (iv) § 401.3(a)(8) through (iv) of this part is applicable and will be applied. If the exception at § 401.3(a)(iv) is determined to be applicable, the funding agreement will be promptly amended to include the provisions required by § 401.3(c).

(e) This regulation supersedes OMB Circular A-124 and shall take precedence over any regulations dealing with ownership of inventions made by small businesses and nonprofit organizations which are inconsistent with it. This regulation will be followed by all agencies pending amendment of agency regulations to conform to this part and amended Chapter 18 of Title 35. Only deviations requested by a contractor and not inconsistent with Chapter 18 of Title 35, United States Code, may be made without approval of the Secretary. Modifications or tailoring of clauses as authorized by § 401.5 or § 401.3, when alternative provisions are used under § 401.3(a)(1) through (4), are not considered devi-

ations requiring the Secretary's approval. Three copies of proposed and final agency regulations supplementing this part shall be submitted to the Secretary at the office set out in § 401.16 for approval for consistency with this part before they are submitted to the Office of Management and Budget (OMB) for review under Executive Order 12291 or, if no submission is required to be made to OMB, before their submission to the **FEDERAL REGISTER** for publication.

(f) In the event an agency has outstanding prime funding agreements that do not contain patent flow-down provisions consistent with this part or earlier Office of Federal Procurement Policy regulations (OMB Circular A-124 or OMB Bulletin 81-22), the agency shall take appropriate action to ensure that small business firms or nonprofit organizations that are subcontractors under any such agreements and that received their subcontracts after July 1, 1981, receive rights in their subject inventions that are consistent with Chapter 18 and this part.

(g) This part is not intended to apply to arrangements under which nonprofit organizations, small business firms, or others are allowed to use government-owned research facilities and normal technical assistance provided to users of those facilities, whether on a reimbursable or non-reimbursable basis. This part is also not intended to apply to arrangements under which sponsors reimburse the government or facility contractor for the contractor employee's time in performing work for the sponsor. Such arrangements are not considered "funding agreements" as defined at 35 U.S.C. 201(b) and § 401.2(a) of this part.

#### § 401.2 Definitions.

As used in this part—

(a) The term *funding agreement* means any contract, grant, or cooperative agreement entered into between any Federal agency, other than the Tennessee Valley Authority, and any contractor for the performance of experimental, developmental, or research work funded in whole or in part

by the Federal government. This term also includes any assignment, substitution of parties, or subcontract of any type entered into for the performance of experimental, developmental, or research work under a funding agreement as defined in the first sentence of this paragraph.

(b) The term *contractor* means any person, small business firm or nonprofit organization which is a party to a funding agreement.

(c) The term *invention* means any invention or discovery which is or may be patentable or otherwise protectable under Title 35 of the United States Code, or any novel variety of plant which is or may be protectable under the Plant Variety Protection Act (7 U.S.C. 2321 *et seq.*).

(d) The term *subject invention* means any invention of a contractor conceived or first actually reduced to practice in the performance of work under a funding agreement; provided that in the case of a variety of plant, the date of determination (as defined in section 41(d) of the Plant Variety Protection Act, 7 U.S.C. 2401(d)) must also occur during the period of contract performance.

(e) The term *practical application* means to manufacture in the case of a composition of product, to practice in the case of a process or method, or to operate in the case of a machine or system; and, in each case, under such conditions as to establish that the invention is being utilized and that its benefits are, to the extent permitted by law or government regulations, available to the public on reasonable terms.

(f) The term *made* when used in relation to any invention means the conception or first actual reduction to practice of such invention.

(g) The term *small business firm* means a small business concern as defined at section 2 of Pub. L. 85-536 (15 U.S.C. 632) and implementing regulations of the Administrator of the Small Business Administration. For the purpose of this part, the size standards for small business concerns involved in government procurement and subcontracting at 13 CFR 121.5 will be used.

(h) The term *nonprofit organization* means universities and other institutions of higher education or an organization of the type described in section 501(c)(3) of the Internal Revenue Code of 1954 (26 U.S.C. 501(c) and exempt from taxation under section 501(a) of the Internal Revenue Code (26 U.S.C. 501(a)) or any nonprofit scientific or educational organization qualified under a state nonprofit organization statute.

(i) The term *Chapter 18* means Chapter 18 of Title 35 of the United States Code.

(j) The term *Secretary* means the Secretary of Commerce or his or her designee.

§ 401.3 Use of the standard clauses at § 401.14.

(a) Each funding agreement awarded to a small business firm or nonprofit organization (except those subject to 35 U.S.C. 212) shall contain the clause found in § 401.14(a) with such modifications and tailoring as authorized or required elsewhere in this part. However, a funding agreement may contain alternative provisions—

(1) When the contractor is not located in the United States or does not have a place of business located in the United States or is subject to the control of a foreign government; or

(2) In exceptional circumstances when it is determined by the agency that restriction or elimination of the right to retain title to any subject invention will better promote the policy and objectives of Chapter 18 of Title 35 of the United States Code; or

(3) When it is determined by a government authority which is authorized by statute or executive order to conduct foreign intelligence or counterintelligence activities that the restriction or elimination of the right to retain title to any subject invention is necessary to protect the security to such activities; or

(4) When the funding agreement includes the operation of the government-owned, contractor-operated facility of the Department of Energy primarily dedicated to that Department's naval nuclear propulsion or weapons related programs and all funding

agreement limitations under this subparagraph on the contractor's right to elect title to a subject invention are limited to inventions occurring under the above two programs.

(b) When an agency exercises the exceptions at § 401.3(a)(2) or (3), it shall use the standard clause at § 401.14(a) with only such modifications as are necessary to address the exceptional circumstances or concerns which led to the use of the exception. For example, if the justification relates to a particular field of use or market, the clause might be modified along lines similar to those described in § 401.14(b). In any event, the clause should provide the contractor with an opportunity to receive greater rights in accordance with the procedures at § 401.15. When an agency justifies and exercises the exception at § 401.3(a)(2) and uses an alternative provision in the funding agreement on the basis of national security, the provision shall provide the contractor with the right to elect ownership to any invention made under such funding agreement as provided by the Standard Patent Rights Clause found at § 401.14(a) if the invention is not classified by the agency within six months of the date it is reported to the agency, or within the same time period the Department of Energy does not, as authorized by regulation, law or Executive order or implementing regulations thereto, prohibit unauthorized dissemination of the invention. Contracts in support of DOE's naval nuclear propulsion program are exempted from this paragraph.

(c) When the Department of Energy exercises the exception at § 401.3(a)(4), it shall use the clause prescribed at § 401.14(b) or substitute thereto with such modification and tailoring as authorized or required elsewhere in this part.

(d) When a funding agreement involves a series of separate task orders, an agency may apply the exceptions at § 401.3(a)(2) or (3) to individual task orders, and it may structure the contract so that modified patent rights provisions will apply to the task order even though the clauses at either § 401.14(a) or (b) are applicable to the remainder of the work. Agencies are

authorized to negotiate such modified provisions with respect to task orders added to a funding agreement after its initial award.

(e) Before utilizing any of the exceptions in § 401.3(a) of this section, the agency shall prepare a written determination, including a statement of facts supporting the determination, that the conditions identified in the exception exist. A separate statement of facts shall be prepared for each exceptional circumstances determination, except that in appropriate cases a single determination may apply to both a funding agreement and any subcontracts issued under it or to any funding agreement to which such an exception is applicable. In cases when § 401.3(a)(2) is used, the determination shall also include an analysis justifying the determination. This analysis should address with specificity how the alternate provisions will better achieve the objectives set forth in 35 U.S.C. 200. A copy of each determination, statement of facts, and, if applicable, analysis shall be promptly provided to the contractor or prospective contractor along with a notification to the contractor or prospective contractor of its rights to appeal the determination of the exception under 35 U.S.C. 202(b)(4) and § 401.4 of this part.

(f) Except for determinations under § 401.3(a)(3), the agency shall also provide copies of each determination, statement of fact, and analysis to the Secretary. These shall be sent within 30 days after the award of the funding agreement to which they pertain. Copies shall also be sent to the Chief Counsel for Advocacy of the Small Business Administration if the funding agreement is with a small business firm. If the Secretary of Commerce believes that any individual determination or pattern of determinations is contrary to the policies and objectives of this chapter or otherwise not in conformance with this chapter, the Secretary shall so advise the head of the agency concerned and the Administrator of the Office of Federal Procurement Policy and recommend corrective actions.

(g) To assist the Comptroller General of the United States to accomplish



his or her responsibilities under 35 U.S.C. 202, each Federal agency that enters into any funding agreements with nonprofit organizations or small business firms shall accumulate and, at the request of the Comptroller General, provide the Comptroller General or his or her duly authorized representative the total number of prime agreements entered into with small business firms or nonprofit organizations that contain the patent rights clause in this part or under OMB Circular A-124 for each fiscal year beginning with October 1, 1982.

(h) To qualify for the standard clause, a prospective contractor may be required by an agency to certify that it is either a small business firm or a nonprofit organization. If the agency has reason to question the status of the prospective contractor as a small business firm, it may file a protest in accordance with 13 CFR 121.9. If it questions nonprofit status, it may require the prospective contractor to furnish evidence to establish its status as a nonprofit organization.

§ 401.4 Contractor appeals of exceptions.

(a) In accordance with 35 U.S.C. 202(b)(4) a contractor has the right to an administrative review of a determination to use one of the exceptions at § 401.3(a) (1) through (4) if the contractor believes that a determination is either contrary to the policies and objectives of this chapter or constitutes an abuse of discretion by the agency. Paragraph (b) of this section specifies the procedures to be followed by contractors and agencies in such cases. The assertion of such a claim by the contractor shall not be used as a basis for withholding or delaying the award of a funding agreement or for suspending performance under an award. Pending final resolution of the claim the contract may be issued with the patent rights provision proposed by the agency; however, should the final decision be in favor of the contractor, the funding agreement will be amended accordingly and the amendment made retroactive to the effective date of the funding agreement.

(b)(1) A contractor may appeal a determination by providing written notice to the agency within 30 working

days from the time it receives a copy of the agency's determination, or within such longer time as an agency may specify in its regulations. The contractor's notice should specifically identify the basis for the appeal.

(2) The appeal shall be decided by the head of the agency or by his/her designee who is at a level above the person who made the determination. If the notice raises a genuine dispute over the material facts, the head of the agency or the designee shall undertake, or refer the matter for, fact-finding.

(3) Fact-finding shall be conducted in accordance with procedures established by the agency. Such procedures shall be as informal as practicable and be consistent with principles of fundamental fairness. The procedures should afford the contractor the opportunity to appear with counsel, submit documentary evidence, present witnesses and confront such persons as the agency may rely upon. A transcribed record shall be made and shall be available at cost to the contractor upon request. The requirement for a transcribed record may be waived by mutual agreement of the contractor and the agency.

(4) The official conducting the fact-finding shall prepare or adopt written findings of fact and transmit them to the head of the agency or designee promptly after the conclusion of the fact-finding proceeding along with a recommended decision. A copy of the findings of fact and recommended decision shall be sent to the contractor by registered or certified mail.

(5) Fact-finding should be completed within 45 working days from the date the agency receives the contractor's written notice.

(6) When fact-finding has been conducted, the head of the agency or designee shall base his or her decision on the facts found, together with any argument submitted by the contractor, agency officials or any other information in the administrative record. In cases referred for fact-finding, the agency head or the designee may reject only those facts that have been found to be clearly erroneous, but must explicitly state the rejection and indicate the basis for the contrary

finding. The agency head or the designee may hear oral arguments after fact-finding provided that the contractor or contractor's attorney or representative is present and given an opportunity to make arguments and rebuttal. The decision of the agency head or the designee shall be in writing and, if it is unfavorable to the contractor shall include an explanation of the basis of the decision. The decision of the agency or designee shall be made within 30 working days after fact-finding or, if there was no fact-finding, within 45 working days from the date the agency received the contractor's written notice. A contractor adversely affected by a determination under this section may, at any time within sixty days after the determination is issued, file a petition in the United States Claims Court, which shall have jurisdiction to determine the appeal on the record and to affirm, reverse, remand, or modify as appropriate, the determination of the Federal agency.

**§ 401.5 Modification and tailoring of clauses.**

(a) Agencies should complete the blank in paragraph (g)(2) of the clauses at § 401.14 in accordance with their own or applicable government-wide regulations such as the Federal Acquisition Regulation. In grants and cooperative agreements (and in contracts, if not inconsistent with the Federal Acquisition Regulation) agencies wishing to apply the same clause to all subcontractors as is applied to the contractor may delete paragraph (g)(2) of the clause and delete the words "to be performed by a small business firm or domestic nonprofit organization" from paragraph (g)(1). Also, if the funding agreement is a grant or cooperative agreement, paragraph (g)(3) may be deleted. When either paragraph (g)(2) or paragraphs (g)(2) and (3) are deleted, the remaining paragraph or paragraphs should be renumbered appropriately.

(b) Agencies should complete paragraph (l), "Communications", at the end of the clauses at § 401.14 by designating a central point of contact for communications on matters relating to the clause. Additional instructions on

communications may also be included in paragraph (l).

(c) Agencies may replace the italicized words and phrases in the clauses at § 401.14 with those appropriate to the particular funding agreement. For example, "contracts" could be replaced by "grant," "contractor" by "grantee," and "contracting officer" by "grants officer." Depending on its use, "Federal agency" can be replaced either by the identification of the agency or by the specification of the particular office or official within the agency.

(d) When the agency head or duly authorized designee determines at the time of contracting with a small business firm or nonprofit organization that it would be in the national interest to acquire the right to sublicense foreign governments or international organizations pursuant to any existing treaty or international agreement, a sentence may be added at the end of paragraph (b) of the clause at § 401.14 as follows:

This license will include the right of the government to sublicense foreign governments, their nationals, and international organizations, pursuant to the following treaties or international agreements:

The blank above should be completed with the names of applicable existing treaties or international agreements, agreements of cooperation, memoranda of understanding, or similar arrangements, including military agreements relating to weapons development and production. The above language is not intended to apply to treaties or other agreements that are in effect on the date of the award but which are not listed. Alternatively, agencies may use substantially similar language relating the government's rights to specific treaties or other agreements identified elsewhere in the funding agreement. The language may also be modified to make clear that the rights granted to the foreign government, and its nationals or an international organization may be for additional rights beyond a license or sublicense if so required by the applicable treaty or international agreement. For example, in some exclusive licenses or

even the assignment of title in the foreign country involved might be required. Agencies may also modify the language above to provide for the direct licensing by the contractor of the foreign government or international organization.

(e) If the funding agreement involves performance over an extended period of time, such as the typical funding agreement for the operation of a government-owned facility, the following language may also be added:

The *agency* reserves the right to unilaterally amend this *funding agreement* to identify specific treaties or international agreements entered into or to be entered into by the government after the effective date of this *funding agreement* and effectuate those license or other rights which are necessary for the government to meet its obligations to foreign governments, their nationals and international organizations under such treaties or international agreements with respect to subject inventions made after the date of the amendment.

(f) Agencies may add additional subparagraphs to paragraph (f) of the clauses at § 401.14 to require the contractor to do one or more of the following:

(1) Provide a report prior to the close-out of a funding agreement listing all subject inventions or stating that there were none.

(2) Provide, upon request, the filing date, serial number and title; a copy of the patent application; and patent number and issue date for any subject invention in any country in which the contractor has applied for patents.

(3) Provide periodic (but no more frequently than annual) listings of all subject inventions which were disclosed to the agency during the period covered by the report.

(g) If the contract is with a nonprofit organization and is for the operation of a government-owned, contractor-operated facility, the following will be substituted for paragraph (k)(3) of the clause at § 401.14(a):

(3) After payment of patenting costs, licensing costs, payments to inventors, and other expenses incidental to the administration of subject inventions, the balance of any royalties or income earned and retained by the *contractor* during any fiscal year on subject inventions under this or any successor *contract* containing the same require-

ment, up to any amount equal to five percent of the budget of the facility for that fiscal year, shall be used by the contractor for scientific research, development, and education consistent with the research and development mission and objectives of the facility, including activities that increase the licensing potential of other inventions of the facility. If the balance exceeds five percent, 75 percent of the excess above five percent shall be paid by the contractor to the Treasury of the United States and the remaining 25 percent shall be used by the *contractor* only for the same purposes as described above. To the extent it provides the most effective technology transfer, the licensing of subject inventions shall be administered by *contractor* employees on location at the facility.

(h) If the contract is for the operation of a government-owned facility, agencies may add the following at the end of paragraph (f) of the clause at § 401.14(a):

(5) The contractor shall establish and maintain active and effective procedures to ensure that subject inventions are promptly identified and timely disclosed and shall submit a description of the procedures to the *contracting officer* so that the *contracting officer* may evaluate and determine their effectiveness.

#### § 401.6 Exercise of march-in rights.

(a) The following procedures shall govern the exercise of the march-in rights of the agencies set forth in 35 U.S.C. 203 and paragraph (j) of the clause at § 401.14.

(b) Whenever an agency receives information that it believes might warrant the exercise of march-in rights, before initiating any march-in proceeding, it shall notify the contractor in writing of the information and request informal written or oral comments from the contractor as well as information relevant to the matter. In the absence of any comments from the contractor within 30 days, the agency may, at its discretion, proceed with the procedures below. If a comment is received within 30 days, or later if the agency has not initiated the procedures below, then the agency shall, within 60 days after it receives the comment, either initiate the procedures below or notify the contractor, in writing, that it will not pursue

march-in rights on the basis of the available information.

(c) A march-in proceeding shall be initiated by the issuance of a written notice by the agency to the contractor and its assignee or exclusive licensee, as applicable and if known to the agency, stating that the agency is considering the exercise of march-in rights. The notice shall state the reasons for the proposed march-in in terms sufficient to put the contractor on notice of the facts upon which the action would be based and shall specify the field or fields of use in which the agency is considering requiring licensing. The notice shall advise the contractor (assignee or exclusive licensee) of its rights, as set forth in this section and in any supplemental agency regulations. The determination to exercise march-in rights shall be made by the head of the agency or his or her designee.

(d) Within 30 days after the receipt of the written notice of march-in, the contractor (assignee or exclusive licensee) may submit in person, in writing, or through a representative, information or argument in opposition to the proposed march-in, including any additional specific information which raises a genuine dispute over the material facts upon which the march-in is based. If the information presented raises a genuine dispute over the material facts, the head of the agency or designee shall undertake or refer the matter to another official for fact-finding.

(e) Fact-finding shall be conducted in accordance with the procedures established by the agency. Such procedures shall be as informal as practicable and be consistent with principles of fundamental fairness. The procedures should afford the contractor the opportunity to appear with counsel, submit documentary evidence, present witnesses and confront such persons as the agency may present. A transcribed record shall be made and shall be available at cost to the contractor upon request. The requirement for a transcribed record may be waived by mutual agreement of the contractor and the agency. Any portion of the march-in proceeding, including a fact-finding hearing that involves testimo-

ny or evidence relating to the utilization or efforts at obtaining utilization that are being made by the contractor, its assignee, or licensees shall be closed to the public, including potential licensees. In accordance with 35 U.S.C. 202(c)(5), agencies shall not disclose any such information obtained during a march-in proceeding to persons outside the government except when such release is authorized by the contractor (assignee or licensee).

(f) The official conducting the fact-finding shall prepare or adopt written findings of fact and transmit them to the head of the agency or designee promptly after the conclusion of the fact-finding proceeding along with a recommended determination. A copy of the findings of fact shall be sent to the contractor (assignee or exclusive licensee) by registered or certified mail. The contractor (assignee or exclusive licensee) and agency representatives will be given 30 days to submit written arguments to the head of the agency or designee; and, upon request by the contractor oral arguments will be held before the agency head or designee that will make the final determination.

(g) In cases in which fact-finding has been conducted, the head of the agency or designee shall base his or her determination on the facts found, together with any other information and written or oral arguments submitted by the contractor (assignee or exclusive licensee) and agency representatives, and any other information in the administrative record. The consistency of the exercise of march-in rights with the policy and objectives of 35 U.S.C. 200 shall also be considered. In cases referred for fact-finding, the head of the agency or designee may reject only those facts that have been found to be clearly erroneous, but must explicitly state the rejection and indicate the basis for the contrary finding. Written notice of the determination whether march-in rights will be exercised shall be made by the head of the agency or designee and sent to the contractor (assignee or exclusive licensee) by certified or registered mail within 90 days after the completion of fact-finding or 90 days after oral arguments, whichever is later, or the pro-

ceedings will be deemed to have been terminated and thereafter no march-in based on the facts and reasons upon which the proceeding was initiated may be exercised.

(h) An agency may, at any time, terminate a march-in proceeding if it is satisfied that it does not wish to exercise march-in rights.

(i) The procedures of this part shall also apply to the exercise of march-in rights against inventors receiving title to subject inventions under 35 U.S.C. 202(d) and, for that purpose, the term "contractor" as used in this section shall be deemed to include the inventor.

(j) An agency determination unfavorable to the contractor (assignee or exclusive licensee) shall be held in abeyance pending the exhaustion of appeals or petitions filed under 35 U.S.C. 203(2).

(k) For purposes of this section the term *exclusive licensee* includes a partially exclusive licensee.

(l) Agencies are authorized to issue supplemental procedures not inconsistent with this part for the conduct of march-in proceedings.

#### § 401.7 Small business preference.

(a) Paragraph (k)(4) of the clauses at § 401.14 Implements the small business preference requirement of 35 U.S.C. 202(c)(7)(D). Contractors are expected to use efforts that are reasonable under the circumstances to attract small business licensees. They are also expected to give small business firms that meet the standard outlined in the clause a preference over other applicants for licenses. What constitutes reasonable efforts to attract small business licensees will vary with the circumstances and the nature, duration, and expense of efforts needed to bring the invention to the market. Paragraph (k)(4) is not intended, for example, to prevent nonprofit organizations from providing larger firms with a right of first refusal or other options in inventions that relate to research being supported under long-term or other arrangements with larger companies. Under such circumstances it would not be reasonable to seek and to give a preference to small business licensees.

(b) Small business firms that believe a nonprofit organization is not meeting its obligations under the clause may report their concerns to the Secretary. To the extent deemed appropriate, the Secretary will undertake informal investigation of the concern, and, if appropriate, enter into discussions or negotiations with the nonprofit organization to the end of improving its efforts in meeting its obligations under the clause. However, in no event will the Secretary intervene in ongoing negotiations or contractor decisions concerning the licensing of a specific subject invention. All the above investigations, discussions, and negotiations of the Secretary will be in coordination with other interested agencies, including the Small Business Administration; and in the case of a contract for the operation of a government-owned, contractor operated research or production facility, the Secretary will coordinate with the agency responsible for the facility prior to any discussions or negotiations with the contractor.

#### 401.8 Reporting on utilization of subject inventions.

(a) Paragraph (h) of the clauses at § 401.14 and its counterpart in the clause at Attachment A to OMB Circular A-124 provides that agencies have the right to receive periodic reports from the contractor on utilization of inventions. Agencies exercising this right should accept such information, to the extent feasible, in the format that the contractor normally prepares it for its own internal purposes. The prescription of forms should be avoided. However, any forms or standard questionnaires that are adopted by an agency for this purpose must comply with the requirements of the Paperwork Reduction Act. Copies shall be sent to the Secretary.

(b) In accordance with 35 U.S.C. 202(c) (5) and the terms of the clauses at § 401.14, agencies shall not disclose such information to persons outside the government. Contractors will continue to provide confidential markings to help prevent inadvertent release outside the agency.

§ 401.9 Retention of rights by contractor employee inventor.

Agencies which allow an employee/inventor of the contractor to retain rights to a subject invention made under a funding agreement with a small business firm or nonprofit organization contractor, as authorized by 35 U.S.C. 202(d), will impose upon the inventor at least those conditions that would apply to a small business firm contractor under paragraphs (d)(1) and (3); (f)(4); (h); (i); and (j) of the clause at § 401.14(a).

§ 401.10 Government assignment to contractor of rights in invention of government Employee.

In any case when a Federal employee is a co-inventor of any invention made under a funding agreement with a small business firm or nonprofit organization and the Federal agency employing such co-inventor transfers or reassigns the right it has acquired in the subject invention from its employee to the contractor as authorized by 35 U.S.C. 202(e), the assignment will be made subject to the same conditions as apply to the contractor under the patent rights clause of its funding agreement. Agencies may add additional conditions as long as they are consistent with 35 U.S.C. 201-206.

§ 401.11 Appeals.

(a) As used in this section, the term *standard clause* means the clause at § 401.14 of this part and the clauses previously prescribed by either OMB Circular A-124 or OMB Bulletin 81-22.

(b) The agency official initially authorized to take any of the following actions shall provide the contractor with a written statement of the basis for his or her action at the time the action is taken, including any relevant facts that were relied upon in taking the action.

(1) A refusal to grant an extension under paragraph (c)(4) of the standard clauses.

(2) A request for a conveyance of title under paragraph (d) of the standard clauses.

(3) A refusal to grant a waiver under paragraph (i) of the standard clauses.

(4) A refusal to approve an assignment under paragraph (k)(1) of the standard clauses.

(5) A refusal to grant an extension of the exclusive license period under paragraph (k)(2) of the clauses prescribed by either OMB Circular A-124 or OMB Bulletin 81-22.

(c) Each agency shall establish and publish procedures under which any of the agency actions listed in paragraph (b) of this section may be appealed to the head of the agency or designee. Review at this level shall consider both the factual and legal basis for the actions and its consistency with the policy and objectives of 35 U.S.C. 200-206.

(d) Appeals procedures established under paragraph (c) of this section shall include administrative due process procedures and standards for fact-finding at least comparable to those set forth in § 401.6 (e) through (g) whenever there is a dispute as to the factual basis for an agency request for a conveyance of title under paragraph (d) of the standard clause, including any dispute as to whether or not an invention is a subject invention.

(e) To the extent that any of the actions described in paragraph (b) of this section are subject to appeal under the Contract Dispute Act, the procedures under the Act will satisfy the requirements of paragraphs (c) and (d) of this section.

§ 401.12 Licensing of background patent rights to third parties.

(a) A funding agreement with a small business firm or a domestic nonprofit organization will not contain a provision allowing a Federal agency to require the licensing to third parties of inventions owned by the contractor that are not subject inventions unless such provision has been approved by the agency head and a written justification has been signed by the agency head. Any such provision will clearly state whether the licensing may be required in connection with the practice of a subject invention, a specifically identified work object, or both. The agency head may not delegate the authority to approve such provisions or

to sign the justification required for such provisions.

(b) A Federal agency will not require the licensing of third parties under any such provision unless the agency head determines that the use of the invention by others is necessary for the practice of a subject invention or for the use of a work object of the funding agreement and that such action is necessary to achieve practical application of the subject invention or work object. Any such determination will be on the record after an opportunity for an agency hearing. The contractor shall be given prompt notification of the determination by certified or registered mail. Any action commenced for judicial review of such determination shall be brought within sixty days after notification of such determination.

§ 401.13 Administration of patent rights clauses.

(a) In the event a subject invention is made under funding agreements of more than one agency, at the request of the contractor or on their own initiative the agencies shall designate one agency as responsible for administration of the rights of the government in the invention.

(b) Agencies shall promptly grant, unless there is a significant reason not to, a request by a nonprofit organization under paragraph (k)(2) of the clauses prescribed by either OMB Circular A-124 or OMB Bulletin 81-22 inasmuch as 35 U.S.C. 202(c)(7) has since been amended to eliminate the limitation on the duration of exclusive licenses. Similarly, unless there is a significant reason not to, agencies shall promptly approve an assignment by a nonprofit organization to an organization which has as one of its primary functions the management of inventions when a request for approval has been necessitated under paragraph (k)(1) of the clauses prescribed by either OMB Circular A-124 or OMB Bulletin 81-22 because the patent management organization is engaged in or holds a substantial interest in other organizations engaged in the manufacture or sale of products or the use of processes that might utilize the invention or be in competition

with embodiments of the invention. As amended, 35 U.S.C. 202(c)(7) no longer contains this limitation. The policy of this subsection should also be followed in connection with similar approvals that may be required under Institutional Patent Agreements, other patent rights clauses, or waivers that predate Chapter 18 of Title 35, United States Code.

(c) The President's Patent Policy Memorandum of February 18, 1983, states that agencies should protect the confidentiality of invention disclosure, patent applications, and utilization reports required in performance or in consequence of awards to the extent permitted by 35 U.S.C. 205 or other applicable laws. The following requirements should be followed for funding agreements covered by and predating this part 401.

(1) To the extent authorized by 35 U.S.C. 205, agencies shall not disclose to third parties pursuant to requests under the Freedom of Information Act (FOIA) any information disclosing a subject invention for a reasonable time in order for a patent application to be filed. With respect to subject inventions of contractors that are small business firms or nonprofit organizations, a reasonable time shall be the time during which an initial patent application may be filed under paragraph (c) of the standard clause found at § 401.14(a) or such other clause may be used in the funding agreement. However, an agency may disclose such subject inventions under the FOIA, at its discretion, after a contractor has elected not to retain title or after the time in which the contractor is required to make an election if the contractor has not made an election within that time. Similarly, an agency may honor a FOIA request at its discretion if it finds that the same information has previously been published by the inventor, contractor, or otherwise. If the agency plans to file itself when the contractor has not elected title, it may, of course, continue to avail itself of the authority of 35 U.S.C. 205.

(2) In accordance with 35 U.S.C. 205, agencies shall not disclose or release for a period of 18 months from the filing date of the application to third

parties pursuant to requests under the Freedom of Information Act or otherwise copies of any document which the agency obtained under this clause which is part of an application for patent with the U.S. Patent and Trademark Office or any foreign patent office filed by the contractor (or its assignees, licensees, or employees) on a subject invention to which the contractor has elected to retain title. This prohibition does not extend to disclosure to other government agencies or contractors of government agencies under an obligation to maintain such information in confidence.

(3) A number of agencies have policies to encourage public dissemination of the results of work supported by the agency through publication in government or other publications of technical reports of contractors or others. In recognition of the fact that such publication, if it included descriptions of a subject invention could create bars to obtaining patent protection, it is the policy of the executive branch that agencies will not include in such publication programs copies of disclosures of inventions submitted by small business firms or nonprofit organizations, pursuant to paragraph (c) of the standard clause found at § 401.14(a), except that under the same circumstances under which agencies are authorized to release such information pursuant to FOIA requests under paragraph (c)(1) of this section, agencies may publish such disclosures.

(4) Nothing in this paragraph is intended to preclude agencies from including in the publication activities described in the first sentence of paragraph (c)(3), the publication of materials describing a subject invention to the extent such materials were provided as part of a technical report or other submission of the contractor which were submitted independently of the requirements of the patent rights provisions of the contract. However, if a small business firm or nonprofit organization notifies the agency that a particular report or other submission contains a disclosure of a subject invention to which it has elected title or may elect title, the agency shall use reasonable efforts to restrict its publication of the material for six

months from date of its receipt of the report or submission or, if earlier, until the contractor has filed an initial patent application. Agencies, of course, retain the discretion to delay publication for additional periods of time.

(5) Nothing in this paragraph is intended to limit the authority of agencies provided in 35 U.S.C. 205 in circumstances not specifically described in this paragraph.

#### § 401.14 Standard patent rights clauses.

(a) The following is the standard patent rights clause to be used as specified in § 401.3(a).

##### *Patent Rights (Small Business Firms and Nonprofit Organizations)*

###### (a) Definitions

(1) *Invention* means any invention or discovery which is or may be patentable or otherwise protectable under Title 35 of the United States Code, or any novel variety of plant which is or may be protected under the Plant Variety Protection Act (7 U.S.C. 2321 et seq.).

(2) *Subject invention* means any invention of the contractor conceived or first actually reduced to practice in the performance of work under this contract, provided that in the case of a variety of plant, the date of determination (as defined in section 41(d) of the Plant Variety Protection Act, 7 U.S.C. 2401(d)) must also occur during the period of contract performance.

(3) *Practical Application* means to manufacture in the case of a composition or product, to practice in the case of a process or method, or to operate in the case of a machine or system; and, in each case, under such conditions as to establish that the invention is being utilized and that its benefits are, to the extent permitted by law or government regulations, available to the public on reasonable terms.

(4) *Made* when used in relation to any invention means the conception or first actual reduction to practice of such invention.

(5) *Small Business Firm* means a small business concern as defined at section 2 of Pub. L. 85-536 (15 U.S.C. 632) and implementing regulations of the Administrator of the Small Business Administration. For the purpose of this clause, the size standards for small business concerns involved in government procurement and subcontracting at 13 CFR 121.3-8 and 13 CFR 121.3-12, respectively, will be used.

(6) *Nonprofit Organization* means a university or other institution of higher education or an organization of the type de-



scribed in section 501(c)(3) of the Internal Revenue Code of 1954 (26 U.S.C. 501(c) and exempt from taxation under section 501(a) of the Internal Revenue Code (25 U.S.C. 501(a)) or any nonprofit scientific or educational organization qualified under a state nonprofit organization statute.

(b) Allocation of Principal Rights

The *Contractor* may retain the entire right, title, and interest throughout the world to each subject invention subject to the provisions of this clause and 35 U.S.C. 203. With respect to any subject invention in which the *Contractor* retains title, the Federal government shall have a nonexclusive, nontransferable, irrevocable, paid-up license to practice or have practiced for or on behalf of the United States the subject invention throughout the world.

(c) Invention Disclosure, Election of Title and Filing of Patent Application by *Contractor*

(1) The *contractor* will disclose each subject invention to the *Federal Agency* within two months after the inventor discloses it in writing to *contractor* personnel responsible for patent matters. The disclosure to the agency shall be in the form of a written report and shall identify the *contract* under which the invention was made and the inventor(s). It shall be sufficiently complete in technical detail to convey a clear understanding to the extent known at the time of the disclosure, of the nature, purpose, operation, and the physical, chemical, biological or electrical characteristics of the invention. The disclosure shall also identify any publication, on sale or public use of the invention and whether a manuscript describing the invention has been submitted for publication and, if so, whether it has been accepted for publication at the time of disclosure. In addition, after disclosure to the *agency*, the *Contractor* will promptly notify the *agency* of the acceptance of any manuscript describing the invention for publication or of any on sale or public use planned by the *contractor*.

(2) The *Contractor* will elect in writing whether or not to retain title to any such invention by notifying the *Federal agency* within two years of disclosure to the *Federal agency*. However, in any case where publication, on sale or public use has initiated the one year statutory period wherein valid patent protection can still be obtained in the United States, the period for election of title may be shortened by the *agency* to a date that is no more than 60 days prior to the end of the statutory period.

(3) The *contractor* will file its initial patent application on a subject invention to which it elects to retain title within one year after election of title or, if earlier, prior

to the end of any statutory period wherein valid patent protection can be obtained in the United States after a publication, on sale, or public use. The *contractor* will file patent applications in additional countries or international patent offices within either ten months of the corresponding initial patent application or six months from the date permission is granted by the Commissioner of Patents and Trademarks to file foreign patent applications where such filing has been prohibited by a Secrecy Order.

(4) Requests for extension of the time for disclosure, election, and filing under subparagraphs (1), (2), and (3) may, at the discretion of the *agency*, be granted.

(d) Conditions When the Government May Obtain Title

The *contractor* will convey to the *Federal agency*, upon written request, title to any subject invention—

(1) If the *contractor* fails to disclose or elect title to the subject invention within the times specified in (c), above, or elects not to retain title; provided that the *agency* may only request title within 60 days after learning of the failure of the *contractor* to disclose or elect within the specified times.

(2) In those countries in which the *contractor* fails to file patent applications within the times specified in (c) above; provided, however, that if the *contractor* has filed a patent application in a country after the times specified in (c) above, but prior to its receipt of the written request of the *Federal agency*, the *contractor* shall continue to retain title in that country.

(3) In any country in which the *contractor* decides not to continue the prosecution of any application for, to pay the maintenance fees on, or defend in reexamination or opposition proceeding on, a patent on a subject invention.

(e) Minimum Rights to *Contractor* and Protection of the *Contractor* Right to File

(1) The *contractor* will retain a nonexclusive royalty-free license throughout the world in each subject invention to which the Government obtains title, except if the *contractor* fails to disclose the invention within the times specified in (c), above. The *contractor's* license extends to its domestic subsidiary and affiliates, if any, within the corporate structure of which the *contractor* is a party and includes the right to grant sublicenses of the same scope to the extent the *contractor* was legally obligated to do so at the time the *contract* was awarded. The license is transferable only with the approval of the *Federal agency* except when transferred to the successor of that party of the

*contractor's* business to which the invention pertains.

(2) The *contractor's* domestic license may be revoked or modified by the *funding Federal agency* to the extent necessary to achieve expeditious practical application of the subject invention pursuant to an application for an exclusive license submitted in accordance with applicable provisions at 37 CFR part 404 and *agency* licensing regulations (if any). This license will not be revoked in that field of use or the geographical areas in which the *contractor* has achieved practical application and continues to make the benefits of the invention reasonably accessible to the public. The license in any foreign country may be revoked or modified at the discretion of the *funding Federal agency* to the extent the *contractor*, its licensees, or the domestic subsidiaries or affiliates have failed to achieve practical application in that foreign country.

(3) Before revocation or modification of the license, the *funding Federal agency* will furnish the *contractor* a written notice of its intention to revoke or modify the license, and the *contractor* will be allowed thirty days (or such other time as may be authorized by the *funding Federal agency* for good cause shown by the *contractor*) after the notice to show cause why the license should not be revoked or modified. The *contractor* has the right to appeal, in accordance with applicable regulations in 37 CFR part 404 and *agency* regulations (if any) concerning the licensing of Government-owned inventions, any decision concerning the revocation or modification of the license.

(f) *Contractor Action to Protect the Government's Interest*

(1) The *contractor* agrees to execute or to have executed and promptly deliver to the *Federal agency* all instruments necessary to (i) establish or confirm the rights the Government has throughout the world in those subject inventions to which the *contractor* elects to retain title, and (ii) convey title to the *Federal agency* when requested under paragraph (d) above and to enable the government to obtain patent protection throughout the world in that subject invention.

(2) The *contractor* agrees to require, by written agreement, its employees, other than clerical and nontechnical employees, to disclose promptly in writing to personnel identified as responsible for the administration of patent matters and in a format suggested by the *contractor* each subject invention made under *contract* in order that the *contractor* can comply with the disclosure provisions of paragraph (c), above, and to execute all papers necessary to file patent applications on subject inventions and to establish the government's rights in the subject inventions. This disclosure format

should require, as a minimum, the information required by (c)(1), above. The *contractor* shall instruct such employees through employee agreements or other suitable educational programs on the importance of reporting inventions in sufficient time to permit the filing of patent applications prior to U.S. or foreign statutory bars.

(3) The *contractor* will notify the *Federal agency* of any decisions not to continue the prosecution of a patent application, pay maintenance fees, or defend in a reexamination or opposition proceeding on a patent, in any country, not less than thirty days before the expiration of the response period required by the relevant patent office.

(4) The *contractor* agrees to include, within the specification of any United States patent applications and any patent issuing thereon covering a subject invention, the following statement, "This invention was made with government support under (identify the *contract*) awarded by (identify the Federal agency). The government has certain rights in the invention."

(g) *Subcontracts*

(1) The *contractor* will include this clause, suitably modified to identify the parties, in all subcontracts, regardless of tier, for experimental, developmental or research work to be performed by a small business firm or domestic nonprofit organization. The subcontractor will retain all rights provided for the *contractor* in this clause, and the *contractor* will not, as part of the consideration for awarding the subcontract, obtain rights in the subcontractor's subject inventions.

(2) The *contractor* will include in all other subcontracts, regardless of tier, for experimental developmental or research work the patent rights clause required by (cite section of *agency implementing regulations or FAR*).

(3) In the case of subcontracts, at any tier, when the prime award with the Federal agency was a contract (but not a grant or cooperative agreement), the *agency*, subcontractor, and the *contractor* agree that the mutual obligations of the parties created by this clause constitute a contract between the subcontractor and the Federal agency with respect to the matters covered by the clause; provided, however, that nothing in this paragraph is intended to confer any jurisdiction under the Contract Disputes Act in connection with proceedings under paragraph (j) of this clause.

(h) *Reporting on Utilization of Subject Inventions*

The *Contractor* agrees to submit on request periodic reports no more frequently than annually on the utilization of a subject invention or on efforts at obtaining such

utilization that are being made by the *contractor* or its licensees or assignees. Such reports shall include information regarding the status of development, date of first commercial sale or use, gross royalties received by the *contractor*, and such other data and information as the *agency* may reasonably specify. The *contractor* also agrees to provide additional reports as may be requested by the *agency* in connection with any march-in proceeding undertaken by the *agency* in accordance with paragraph (j) of this clause. As required by 35 U.S.C. 202(c)(5), the *agency* agrees it will not disclose such information to persons outside the government without permission of the *contractor*.

(i) Preference for United States Industry

Notwithstanding any other provision of this clause, the *contractor* agrees that neither it nor any assignee will grant to any person the exclusive right to use or sell any subject inventions in the United States unless such person agrees that any products embodying the subject invention or produced through the use of the subject invention will be manufactured substantially in the United States. However, in individual cases, the requirement for such an agreement may be waived by the *Federal agency* upon a showing by the *contractor* or its assignee that reasonable but unsuccessful efforts have been made to grant licenses on similar terms to potential licensees that would be likely to manufacture substantially in the United States or that under the circumstances domestic manufacture is not commercially feasible.

(j) March-in Rights

The *contractor* agrees that with respect to any subject invention in which it has acquired title, the *Federal agency* has the right in accordance with the procedures in 37 CFR 401.6 and any supplemental regulations of the *agency* to require the *contractor*, an assignee or exclusive licensee of a subject invention to grant a nonexclusive, partially exclusive, or exclusive license in any field of use to a responsible applicant or applicants, upon terms that are reasonable under the circumstances, and if the *contractor*, assignee, or exclusive licensee refuses such a request the *Federal agency* has the right to grant such a license itself if the *Federal agency* determines that:

(1) Such action is necessary because the *contractor* or assignee has not taken, or is not expected to take within a reasonable time, effective steps to achieve practical application of the subject invention in such field of use.

(2) Such action is necessary to alleviate health or safety needs which are not reason-

ably satisfied by the *contractor*, assignee or their licensees;

(3) Such action is necessary to meet requirements for public use specified by Federal regulations and such requirements are not reasonably satisfied by the *contractor*, assignee or licensees; or

(4) Such action is necessary because the agreement required by paragraph (i) of this clause has not been obtained or waived or because a licensee of the exclusive right to use or sell any subject invention in the United States is in breach of such agreement.

(k) Special Provisions for Contracts with Nonprofit Organizations

If the *contractor* is a nonprofit organization, it agrees that:

(1) Rights to a subject invention in the United States may not be assigned without the approval of the *Federal agency*, except where such assignment is made to an organization which has as one of its primary functions the management of inventions, provided that such assignee will be subject to the same provisions as the *contractor*;

(2) The *contractor* will share royalties collected on a subject invention with the inventor, including Federal employee co-inventors (when the *agency* deems it appropriate) when the subject invention is assigned in accordance with 35 U.S.C. 202(e) and 37 CFR 401.10;

(3) The balance of any royalties or income earned by the *contractor* with respect to subject inventions, after payment of expenses (including payments to inventors) incidental to the administration of subject inventions, will be utilized for the support of scientific research or education; and

(4) It will make efforts that are reasonable under the circumstances to attract licensees of subject invention that are small business firms and that it will give a preference to a small business firm when licensing a subject invention if the *contractor* determines that the small business firm has a plan or proposal for marketing the invention which, if executed, is equally as likely to bring the invention to practical application as any plans or proposals from applicants that are not small business firms; provided, that the *contractor* is also satisfied that the small business firm has the capability and resources to carry out its plan or proposal. The decision whether to give a preference in any specific case will be at the discretion of the *contractor*. However, the *contractor* agrees that the Secretary may review the *contractor's* licensing program and decisions regarding small business applicants, and the *contractor* will negotiate changes to its licensing policies, procedures, or practices with the Secretary when the Secretary's review discloses that the *contractor* could take rea-

sonable steps to implement more effectively the requirements of this paragraph (k)(4).

(l) Communication

(Complete According to Instructions at 401.5(b))

(b) When the Department of Energy (DOE) determines to use alternative provisions under § 401.3(a)(4), the standard clause at § 401.14(a), of this section, shall be used with the following modifications unless a substitute clause is drafted by DOE:

(1) The title of the clause shall be changed to read as follows: *Patent Rights to Nonprofit DOE Facility Operators*

(2) Add an "(A)" after "(1)" in paragraph (c)(1) and add subparagraphs (B) and (C) to paragraph (c)(1) as follows:

(B) If the subject invention occurred under activities funded by the naval nuclear propulsion or weapons related programs of DOE, then the provisions of this subparagraph (c)(1)(B) will apply in lieu of paragraphs (c)(2) and (3). In such cases the contractor agrees to assign the government the entire right, title, and interest thereto throughout the world in and to the subject invention except to the extent that rights are retained by the contractor through a greater rights determination or under paragraph (e), below. The contractor, or an employee-inventor, with authorization of the contractor, may submit a request for greater rights at the time the invention is disclosed or within a reasonable time thereafter. DOE will process such a request in accordance with procedures at 37 CFR 401.15. Each determination of greater rights will be subject to paragraphs (h)-(k) of this clause and such additional conditions, if any, deemed to be appropriate by the *Department of Energy*.

(C) At the time an invention is disclosed in accordance with (c)(1)(A) above, or within 90 days thereafter, the contractor will submit a written statement as to whether or not the invention occurred under a naval nuclear propulsion or weapons-related program of the *Department of Energy*. If this statement is not filed within this time, subparagraph (c)(1)(B) will apply in lieu of paragraphs (c)(2) and (3). The contractor statement will be deemed conclusive unless, within 60 days thereafter, the Contracting Officer disagrees in writing, in which case the determination of the Contracting Officer will be deemed conclusive unless the contractor files a claim under the Contract Disputes Act within 60 days after the Contracting Officer's determination. Pending

resolution of the matter, the invention will be subject to subparagraph (c)(1)(B).

(3) Paragraph (k)(3) of the clause will be modified as prescribed at § 401.5(g).

**§ 401.15 Deferred determinations.**

(a) This section applies to requests for greater rights in subject inventions made by contractors when deferred determination provisions were included in the funding agreement because one of the exceptions at § 401.3(a) was applied, except that the Department of Energy is authorized to process deferred determinations either in accordance with its waiver regulations or this section. A contractor requesting greater rights should include with its request information on its plans and intentions to bring the invention to practical application. Within 90 days after receiving a request and supporting information, or sooner if a statutory bar to patenting is imminent, the agency should seek to make a determination. In any event, if a bar to patenting is imminent, unless the agency plans to file on its own, it shall authorize the contractor to file a patent application pending a determination by the agency. Such a filing shall normally be at the contractor's own risk and expense. However, if the agency subsequently refuses to allow the contractor to retain title and elects to proceed with the patent application under government ownership, it shall reimburse the contractor for the cost of preparing and filing the patent application.

(b) If the circumstances of concerns which originally led the agency to invoke an exception under § 401.3(a) are not applicable to the actual subject invention or are no longer valid because of subsequent events, the agency should allow the contractor to retain title to the invention on the same conditions as would have applied if the standard clause at § 401.14(a) had been used originally, unless it has been licensed.

(c) If paragraph (b) is not applicable the agency shall make its determination based on an assessment whether its own plans regarding the invention will better promote the policies and objectives of 35 U.S.C. 200 than will

contractor ownership of the invention. Moreover, if the agency is concerned only about specific uses or applications of the invention, it shall consider leaving title in the contractor with additional conditions imposed upon the contractor's use of the invention for such applications or with expanded government license rights in such applications.

(d) A determination not to allow the contractor to retain title to a subject invention or to restrict or condition its title with conditions differing from those in the clause at § 401.14(a), unless made by the head of the agency, shall be appealable by the contractor to an agency official at a level above the person who made the determination. This appeal shall be subject to the procedures applicable to appeals under § 401.11 of this part.

**§ 401.16 Submissions and inquiries.**

All submissions or inquiries should be directed to Federal Technology Management Policy Division, telephone number 202-377-0659, Room H4837, U.S. Department of Commerce, Washington, DC 20230.

## APPENDIX B

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### Flow of Invention Reporting Process

Grant is awarded. It is at this stage that NIH would have to make the decision if an exceptional circumstance exists that warrants an alternate provision to automatic retention of rights by grantee.

|

If NIH asserts exceptional circumstance, then NIH must inform the grant and write an analysis of why the alternate provision will better achieve the objective set forth by Bayh-Dole. A copy of this must be sent to the Secretary of Commerce within 30 days after the award of the funding agreement. The Chief Counsel of Small Business Administration would also be sent a copy if the award is to a small business.

If the Secretary believes that the determination is contrary to the policies and objectives of the regulation governing invention rights for grantees, the Secretary would advise NIH and recommend corrective actions.

|

NIH sends "welcome wagon" letter to new grantee advising them of their responsibilities citing 37 CFR 401. NIH also provides grantee with PHS Grants Policy Statement and weekly copies of the NIH Guide for Grants and Contracts that periodically discusses grantees invention reporting responsibilities.

|

If an invention occurs during grant, the grantee would disclose it in writing to DEIR within 2 months after inventor discloses to grantee personnel responsible for patent matters.

|

When NIH receives the written disclosure, the paper copy is filed by grantee name.

|

Grantee elects in writing to retain or release rights to invention within two years of disclosure.

If grantee declines rights but requests that rights be waived to inventor, the case is sent to the Licensing Branch in the Office of Technology Transfer. The file is sent to the Office of Technology transfer who in consultation with the appropriate Institute determines whether the government wishes to retain rights or waive rights to the inventor. If rights are assigned to the inventor, they must follow the condition set forth in the regulations.

If the grantee declines rights and does not indicate whether the inventor request rights. The disclosure is put in a pending file for one year to see if inventor petitions for rights. If the inventor fails to file within year, case is discarded.

If after two years, no additional information is sent concerning election, the disclosure is abandoned and no entry is made in data base.

|

DEIR would open computer record when election is received and input information received.

|

Within one year of electing title, grantee must file patent application. Grantee send the patent application and the standard U.S.government non-exclusive license to DEIR.

If the grantee files a patent application and then abandons it but requests that rights be waived to the inventor, the case is sent to the Licensing Branch in the Office of Technology Transfer. The file is sent to the Office of Technology transfer who in consultation with the appropriate Institute determines whether the government will retain rights or waive rights to the inventor.

If the grantee files a patent application and then abandons and does not indicate the inventor is interested, the case is put in a pending file for one year to see if inventor petitions for rights. If the inventor fails to file within year, case is discarded.

|

DEIR adds patent application and license to paper file and inputs information in computer file. DEIR checks to see if the government support clause is in the patent application. If the information sent by grantee is incomplete, notice will be sent to university asking for additional information.

|

Grantee begins to send annual utilization reports to NIH identifying their commercialize efforts.

|

DEIR would file these in paper copy and update previous fields if information was missing or incorrect.

|

Grantee sends patent when it issues. NIH checks for government funding clause.

|

During this process, if grantee indicates in a progress report or on the application for continuing grants that inventions have been made, DEIR will check to see if a case file has been set up and if information in the file is complete and matches the information from the report or application. If the information is not complete, a letter is sent to grantee requesting information.

|

Following the expiration or termination of grant, a Final Invention Statement and Certification (Form HHS 568) must be sent to NIH certifying that no inventions were involved or listing the inventions. NIH reviews the form to see if a case file has been set up and if information in the file is complete and matches the information from the report or application. If the information is not complete, a letter is sent to grantee requesting information.

|

After 17 years, when the patent expires the files will be purged unless legal actions were involved.



# APPENDIX C

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NIH Sample Forms for Licensing and Invention Reporting

**SUBJECT INVENTION UTILIZATION REPORT**

per authority of 35 U.S.C. §202(c)(5)

Period Ending \_\_\_\_\_ (Month, Year)

(PRIVILEGED AND CONFIDENTIAL per 5 U.S.C. §552)

**IDENTIFICATION**

1. Federal Agency National Institutes of Health
2. Grant/contract No.(s) \_\_\_\_\_
3. Date Disclosed to NIH \_\_\_\_\_
4. Date of Election to Retain Rights \_\_\_\_\_
5. Invention Title \_\_\_\_\_
6. Case/file No. of Reporting Entity \_\_\_\_\_
7. Inventor(s) \_\_\_\_\_

**FILING STATUS**

8. U.S. Pat. Appln. No. \_\_\_\_\_
9. Filing Date \_\_\_\_\_
10. U.S. Patent No. \_\_\_\_\_
11. Issue Date \_\_\_\_\_
12. Countries where foreign patent applications are pending or where patents have issued \_\_\_\_\_

**STATUS OF DEVELOPMENT**

13. Date of first commercial sale or use, if any \_\_\_\_\_
14. Gross royalties received during report period \$ \_\_\_\_\_
15. Number of licenses or related agreements in effect \_\_\_\_\_
16. If not licensed or under development, describe a) action taken to obtain utilization or b) comment on likelihood of licensing or practical application \_\_\_\_\_
17. Reporting entity (Grantee institution or assignee) \_\_\_\_\_
18. Signed \_\_\_\_\_ Date \_\_\_\_\_  
Title \_\_\_\_\_

LICENSE TO THE UNITED STATES GOVERNMENT

**Invention Title:**

**Inventor(s):**

**Patent or Application Serial No.**

**U.S. Filing/Issue Date:**

**Grant/Contract Identification Number:**

**Grantee/Contractor File #:**

**Foreign Applications filed/intended in (countries):**

The invention identified above is a Subject Invention under 35 U.S.C. 200, et seq., and the Standard Patent Rights clause at 37 CFR 401.14 or FAR 52.227-11, which are included among the terms of the above-identified grant/contract award from the Public Health Service/National Institutes of Health. This document is confirmatory of:

1. The nonexclusive, nontransferable, irrevocable, paid-up license granted to the Federal Government in the invention described in the patent application and in any and all divisions, continuations, and continuations in part, and in any and all patents and re-issues granted thereon; and
2. All other rights acquired by the Government by reason of the above identified grant/contract award and the laws and regulations which are applicable to the award.

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

Signed this \_\_\_\_\_ day of \_\_\_\_\_, 19\_\_\_\_.

By \_\_\_\_\_  
(Grantee/Contractor Official and Title)

For \_\_\_\_\_  
(Organization)

At \_\_\_\_\_  
(Business Address)

DEPARTMENT OF HEALTH AND HUMAN SERVICES  
PUBLIC HEALTH SERVICE

**GRANT APPLICATION**

Follow instructions carefully. Type in the unshaded areas only.  
Type density must be 10 c.p.i.

**LEAVE BLANK FOR PHS USE ONLY.**

Type	Activity	Number
Review Group		Formerly
Council/Board (Month, Year)		Date Received

1. TITLE OF PROJECT (Do not exceed 56 typewriter spaces.)

2a. RESPONSE TO SPECIFIC REQUEST FOR APPLICATIONS OR PROGRAM ANNOUNCEMENT  NO  YES (If "YES," state number and title)

Number: Title:

2b. TYPE OF GRANT PROGRAM

3a. NAME (Last, first, middle) 3b. DEGREE(S) 3c. SOCIAL SECURITY NO.

3d. POSITION TITLE 3e. MAILING ADDRESS (Street, city, state, zip code)

3f. DEPARTMENT, SERVICE, LABORATORY, OR EQUIVALENT

3g. MAJOR SUBDIVISION

3h. TELEPHONE AND FAX (Area code, number and extension)

TEL:

FAX:

4. HUMAN SUBJECTS 5. VERTEBRATE ANIMALS 5a. NO YES 5b. Animal welfare assurance no.

4a. NO YES If "Yes," exemption no. or IRB approval date 4b. Assurance of compliance no.

6. DATES OF ENTIRE PROPOSED PROJECT PERIOD 7. COSTS REQUESTED FOR INITIAL BUDGET PERIOD 8. COSTS REQUESTED FOR ENTIRE PROPOSED PROJECT PERIOD

From (MMDDYY) Through (MMDDYY) 7a. Direct Costs (\$) 7b. Total Costs (\$) 8a. Direct Costs (\$) 8b. Total Costs (\$)

9. PERFORMANCE SITES (Organizations and addresses) 10. INVENTIONS AND PATENTS (Competing continuation application only)

NO  YES If "YES," Previously reported  Not previously reported

11. NAME OF APPLICANT ORGANIZATION

ADDRESS

12. TYPE OF ORGANIZATION 13. ENTITY IDENTIFICATION NUMBER Congressional District

Public: Specify  Federal  State  Local  Private Nonprofit  Forprofit (General)  Forprofit (Small Business)

14. BIOMEDICAL RESEARCH SUPPORT GRANT CREDIT

Code: Identification:

15. NAME OF ADMINISTRATIVE OFFICIAL TO BE NOTIFIED IF AWARD IS MADE 16. NAME OF OFFICIAL SIGNING FOR APPLICANT ORGANIZATION

TELEPHONE

FAX

TITLE

ADDRESS

TELEPHONE

FAX

TITLE

ADDRESS

BITNET/INTERNET ADDRESS

BITNET/INTERNET ADDRESS

17. PRINCIPAL INVESTIGATOR PROGRAM DIRECTOR ASSURANCE. I agree to accept responsibility for the scientific conduct of the project and to provide the required progress reports if a grant is awarded as a result of this application. Willful provision of false information is a criminal offense under U.S. Code, Title 18, Section 1001. I am aware that any false, fictitious, or fraudulent statement or claim, in addition to other remedies available to the Government, subject me to civil penalties under the Program Fraud Civil Remedies Act of 1986 (45 CFR 79). SIGNATURE OF PERSON NAMED IN 3a. DATE

18. CERTIFICATION AND ACCEPTANCE. I certify that the statements herein are true and complete to the best of my knowledge, and accept the obligation to comply with Public Health Service terms and conditions if a grant is awarded as the result of this application. A willfully false certification is a criminal offense under U.S. Code, Title 18, Section 1001. I am aware that any false, fictitious, or fraudulent statement may, in addition to other remedies available to the Government, subject me to civil penalties under the Program Fraud Civil Remedies Act of 1986 (45 CFR 79). SIGNATURE OF PERSON NAMED IN 16. DATE



**CONTRACTOR'S CERTIFICATION**

**(FAR General Provisions)**

<b>CONTACT NUMBER</b>	
<b>CONTRACTOR</b>	
<b>PRINCIPAL INVESTIGATOR</b>	

In accordance with the terms and conditions of the above contract, I hereby certify that the following information is true to the best of my knowledge as it pertains to the reports required by the General Provisions of the contract.

**1. PATENT/COPYRIGHT INFRINGEMENT and PATENT RIGHTS:**

**a. Patent/Copyright Infringement Report (FAR 52.227-2).**

There was ( ), was not ( ) a notice of claim of patent or copyright infringement based on the performance of the contract.

If answered in the affirmative, please submit one (1) copy of each disclosure statement to this office; and one (1) copy to: Extramural Invention Reports Office (EIRO), Office of Extramural Programs, NIH, Building 31, Room 5B41, 9000 Rockville Pike, Bethesda, Maryland 20892. EIRO telephone number is (301) 402-0850

**b. Patent Rights/Invention Disclosure (FAR 52.227-11).**

There was ( ), was not ( ) an invention or discovery made by the Contractor or its employees as a result of performance under the contract.

If answered in the affirmative, please submit one (1) copy of each disclosure statement to this office; and one (1) copy to: Extramural Invention Reports Office (EIRO), Office of Extramural Programs, NIH, Building 31, Room 5B41, 9000 Rockville Pike, Bethesda, Maryland 20892. EIRO telephone number is (301) 402-0850.

**2. FINAL INVENTORY OF GOVERNMENT PROPERTY:**

Government Property was ( ), was not ( ) purchased or furnished under this contract.

If answered in the affirmative, using form HHS-565, please submit 3 copies of a final inventory report indicating Government Property in possession of the Contractor or subcontractor in accordance with instructions in the DHHS Manual, entitled **CONTRACTOR'S GUIDE FOR CONTROL OF PROPERTY GOVERNMENT PROPERTY, 1990.**

<b>CONTRACTOR BUSINESS OFFICIAL'S SIGNATURE</b>	
<b>OFFICIAL TITLE</b>	

# APPENDIX D

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## Sample Database Record

Grantee:		Code:
Name 1:	Name 2:	Name 3:
Grant 1:	Grant 2:	Grant 3:
Patent Title:		
Disclosed:		CIP CON DIV Applns:
Retained Rights:		Lead Agency:
US License:		Old G code:
Support Acknowledged:		Case abandoned:
Serial Number:		Application Date:
Patent Serial:		Patent Issue Date:
Special Note:		
Licensed:		

**Grantee:** Institution name

**Code:** Institution Code

**Name 1,2,3:** Name of principal investigators

**Grant 1,2,3:** Grant numbers - sometimes several grants have supported an invention

**Patent Title:** Title given to invention by grantee

**Disclosed:** Disclosure Date

**CIP CON DIV Applns:** Coded with Yes, No, Blank - indicates if patent application has been continued in part, continued, or divided.

**Retained Rights:** Coded with Yes, No, or Blank - has grantee elected rights

**Lead Agency:** If there are grants involved from other agencies, which agency is taking the lead for collecting information

Grantee:		Code:
Name 1:	Name 2:	Name 3:
Grant 1:	Grant 2:	Grant 3:
Patent Title:		
Disclosed:		CIP CON DIV Applns:
Retained Rights:		Lead Agency:
US License:		Old G code:
Support Acknowledged:		Case abandoned:
Serial Number:		Application Date:
Patent Serial:		Patent Issue Date:
Special Note:		
Licensed:		

**US License:** Coded with Yes, No, or Blank - has grantee provided the government's non-exclusive license

**Old G code:** If the grant is older than 1985 a different coding system used, this is filled with the old grant code

**Support Acknowledged:** Coded with Yes, No, Blank - is the clause about agency support in the patent application

**Case Abandoned:** Coded with Yes or Blank - has Patent Office rejected or grantee decided not to pursue patent

**Serial Number:** Patent application serial number

**Application Date:** Date of filing application with Patent and Trademark Office

**Patent Serial:** Serial Number of patent

**Patent Issue Date:** Issue date of patent if successful

**Special Note:** Additional information

**Licensed:** Code with Yes, No, Blank - if known, has the invention been licensed



# APPENDIX E

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Agency Comments



Memorandum

Date . MAR 24 1994

From Assistant Secretary for Health

Subject Office of Inspector General (OIG) Draft Report "NIH Oversight of Extramural Research Inventions," OEI-03-91-00930

To Inspector General, OS

Attached are the Public Health Service comments on the subject draft report. We concur with the report's recommendations. Our comments delineate the actions that the National Institutes of Health plans to take to implement them.

*Philip R. Lee*  
Philip R. Lee, M.D.

Attachment

IG	_____
SAIG	_____
PDIG	_____
DIG-AS	_____
DIG-EI	_____
DIG-OI	_____
AIG-MP	_____
OGC/IG	_____
EXSEC	_____
DATE SENT	2-24

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PUBLIC HEALTH SERVICE (PHS) COMMENTS ON THE OFFICE OF  
INSPECTOR GENERAL (OIG) DRAFT REPORT "NIH OVERSIGHT OF  
EXTRAMURAL RESEARCH INVENTIONS," OEI-03-91-00930

The PHS is in agreement with the recommendations of the OIG report. The implementation of the recommendations, however, must take into account the prerogatives established for grantee institutions in the Bayh-Dole Act (Act), the rights of the public and the government, and the competing demands for staff and administrative resources.

OIG Recommendation

1. The National Institutes for Health (NIH) should reexamine its current oversight role to determine if improvements could be made in the monitoring of grantee compliance with Bayh-Dole requirements.

PHS Comment

We concur. Under the direction of its internal Task Force on the Commercialization of Intellectual Property Rights from Extramural Research, the NIH has just taken a major step in evaluating its current oversight role of grantee compliance under the Bayh-Dole Act by holding a public forum entitled "Forum on Sponsored Research Agreements: Perspectives, Outlook and Policy Development." The forum was held on January 25 and 26, 1994.

The purpose of the forum was to solicit the views of an external panel of experts and the public on issues related to research support agreements between grantees and industry in which NIH funding was involved. The meeting focused on certain provisions of the Act, including the utilization of inventions arising from extramural research, preference for small business, and U.S. manufacturing requirement.

The outside panel questioned the usefulness and necessity of: requiring additional data from grantees, or of additional oversight by NIH, regarding the commercialization or utilization of inventions; the preference for small business; and the U.S. manufacturing requirement. The panel stated that stringent guidelines and reporting requirements could have a detrimental effect on technology transfer and the ultimate commercialization of Federally-funded research. In fact, the preliminary recommendations of the panel suggest that:

(1) the grantee institutions rather than the Federal Government should be the primary monitors of compliance with the Bayh-Dole Act provisions concerning the utilization and preference for small business, and (2) NIH should focus on providing educational and/or policy guidance to the institutions on these matters.

A draft report on the panel's activities is currently being reviewed by panel members. It is expected that this report will be finalized in the next several weeks. It will then be submitted to the Advisory Committee to the Director, NIH, at the next Advisory Committee meeting scheduled for June 1, 1994. The panel's findings and recommendations, as well as the Task Force's ongoing work in this area, will be considered in NIH's implementation of recommendations in the report.

#### OIG Recommendation

2. The NIH should (1) add more detailed licensing and utilization information to its invention data base and (2) use the database to track grantees for timely compliance.

#### PHS Comment

We concur. As noted in the OIG report, NIH currently collects utilization reports from its grantees even though the Act does not specifically require such reports. However, as recognized at the forum held in January, the usefulness of these reports for actually tracking compliance with the utilization requirement of the Act may be questionable because the practical difficulty of actually assessing or utilizing information such as performance benchmarks could require extensive staff effort and expertise with little guarantee of improved program results.<sup>1</sup>

Therefore, at this time it is not certain that requiring grantees to submit more detailed reports is the most effective means of ensuring compliance with the Act. Nonetheless, NIH will evaluate the usefulness of the information that is currently collected from grantee institutions, and consider requesting different or additional information, for use in monitoring compliance under the Act and for other purposes such as illustrating the public benefits derived from Federal funding of research. NIH expects to complete this evaluation in FY 1994.

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<sup>1</sup>According to a recent licensing survey conducted by the Association of University Technology Managers, 98 U.S. universities reported a total of 5,645 invention disclosures; executed 1,387 licenses and options; and had 1,112 of their patents issued in fiscal year 1992. In addition, the survey indicated that these 98 universities, which represent only a small fraction of the universities that receive Federal funding, have over 5,500 active licenses and options.

Regardless of the approach taken concerning the utilization reports, NIH intends to establish an electronic means to transfer the information between an institution and NIH. It is expected that this electronic transfer mechanism will be operational in Fiscal Year 1995.