DEPARTMENT OF HEALTH & HUMAN SERVICES

National Institutes of Health
Office of the Director

Office of Extramural Research
Building 1 Room 144
Bethesda, Maryland 20892
(301)496-1096
(301)402-3469 - FAX
http://grants.nih.gov/grants/

February 22, 2000

TO: Extramural Staff

FROM: Deputy Director for Extramural Research

SUBJECT: Policy Announcement 2000-01: NIH Compliance Policy for Extramural Invention Reporting

Background: Extramural funding from NIH supports biomedical research in an effort to gain new knowledge that will lead to better health for everyone. This knowledge often manifests itself as intellectual property, i.e., unique findings that result in new products, materials and processes. In the past, ownership of these inventions vested with the Federal Government. As the government had no means to manufacture or commercialize these advances, Congress passed the Bayh-Dole Act in 1980 (P.L. 96-517). The Bayh-Dole Act allows grantee/contractor organizations to retain principal rights to inventions resulting from grants, cooperative agreements and contracts. The Act also contains a provision that the Government will receive a non-exclusive, non-transferable, irrevocable, paid-up license to practice or have practiced, the invention for or on behalf of the U.S. throughout the world. Consequently, NIH has a major responsibility in protecting, promoting, and monitoring inventions that result from the extramural research programs it funds.

It should be noted that fellowships and training grants, which are made by NIH primarily for educational purposes, do not contain provisions giving NIH rights to inventions, including any resulting income. However, trainees are often associated with a research project and when the project is a federally funded research grant, an invention stemming from this research is normally subject to invention reporting requirements.

To facilitate NIH and grantee/contractor compliance with these regulations and help ensure invention reporting compliance, NIH's Office of Policy for Extramural Research (OPERA), OER, developed Interagency Edison (IEdison) and Edison Report Lite (ERL). These two Internet-based systems allow, respectively, for grantee/contractor organizations to report and track inventions derived through NIH funding agreements, and for NIH IC staff to play a role in

monitoring grantee/contractor organization compliance, consistent with NIH grant and contract policy.

The purpose of this announcement is to broadly delineate the roles, responsibilities and involvement of extramural staff and provide general guidance for ensuring grantee/contractor compliance of the Bayh-Dole Act and related 37 CFR Section 401 regulations.

Policy Statement: NIH extramural staff must ensure that grantee/contractor organizations are in compliance with existing regulations regarding invention reporting and provide stewardship in protecting the government's rights to inventions funded through extramural research programs. Although the primary responsibility for oversight and monitoring extramural invention activities resides with the OPERA, OER, all extramural staff who administer grant and contract programs are responsible for understanding the laws and policies governing invention reporting and for ensuring that grantee/contractor organizations are in compliance with the Bayh-Dole Act.

Discussion: The Bayh-Dole Act is implemented through Department of Commerce regulations 37 CFR 401. These regulations define terms, parties, responsibilities, prescribe the order of disposition of rights, prescribe a chronology of reporting requirements, and delineate the basis for and extent of government actions to retain rights. The patent rights clauses are found at 37 CFR Part 401.14 and are accessible from the Interagency Edison web page, www.iedison.gov , and in the NIH Grants Policy Statement. In the case of contracts, Title 48, Chapter 1, Subchapter E, Part 27 of the Federal Acquisition Regulations (FAR), pertains to inventions and patents. The Standard Patent Rights Clause for use in contracts is contained in Subchapter H, Part 52 of the FAR. Terms and definitions relating to extramural inventions were published in the NIH Guide for Grants and Contracts, dated September 22, 1995, as a "20-20 View of Invention Reporting to the NIH" and are available at on the OER Extramural web site http://grants.nih.gov/grants/guide/index.html as a Guide Notice. This and other issues of the NIH Guide for Grants and Contracts referring to invention reporting and intellectual property are located centrally on the Grants Management Advisory Committee (GMAC) Infonet at http://odoerdb2.od.nih.gov/gmac/home.html under the Patents and Inventions link, as well as from the IEdison home page at http://www.iedison.gov/nihprocs.html . A timeline for invention reporting compliance is available at: www.iedison.gov on the NIH link under "FAQs and Information."

It is also important to consider how invention reporting will be conducted, the ethical issues involved in this process, as well as the need for confidentiality. Each of these topics will be discussed as follows.

> **Electronic Invention Reporting:** The deployment of the extramural invention database system (originally known as Edison) in 1995, has improved invention reporting compliance processes at NIH. Beginning in 1998 Edison was renamed Interagency Edison (IEdison) as other Federal agencies adopted this electronic system for reporting, storing and monitoring their invention report documentation. This system meets all federally mandated invention reporting compliance requirements for both Federal agencies and their grant and contract recipients. A proactive messaging component of the system automatically alerts grantee/contractor organizations of compliance deadlines (i.e.,

election of title, patent deadlines, etc.) and other time sensitive reporting requirements (i.e., the automatic approval of time extensions, etc.). Edison Report-Lite (ERL) was developed as a companion system to accommodate the needs of NIH extramural managers and staff, the NIH Office of Technology Transfer, and IC public affair offices. The ERL interface includes the IEdison database invention report records submitted by grantee/contractor organizations with access provided for each specific I/C. Thus, ERL provides a mechanism for NIH staff to verify information.

Ethical Considerations: All NIH employees must avoid actual conflicts of interest and/or the appearance of such conflicts in so far as intellectual property rights are concerned. Extramural employees' impartiality may be questioned if they have funding or administrative responsibilities with respect to grantee/contractor inventorship. Employees are advised to consult their Deputy Ethics Counselor for guidance in this area. A list of these counselors can be found at **http://www3.od.nih.gov/ogcethics/findthe.htm** .

Confidentiality of Invention Reporting Documents: All information regarding inventions is very time-sensitive and proprietary in nature. Consequently, all documents relating to invention reporting must be considered highly confidential. Invention reporting information is normally exempt from disclosure, subject to the FOIA, and invention-related documents should not be routinely copied. Except as indicated below, documentation pertaining to inventions (i.e., "disclosures"), waivers, licenses, patent applications, etc., should **not** be filed in the IC grant or contract file. Rather, these documents should be forwarded to OPERA for inclusion in the IEdison system of records.

Roles and Responsibilities: Extramural invention reporting involves many organizational components and individuals at the NIH. The staff of grants and contracts management offices, extramural scientist administrators, IC technology transfer offices, OPERA staff, the NIH Office of Technology Transfer, and the NIH Office of General Counsel, HHS, all provide stewardship and oversight of the invention reporting enterprise. The following descriptions summarize the role of each of these components. Since responsibilities require concurrent or sequential interactions with other components, all parties should read this entire document.

Office of Extramural Research: OPERA serves as the primary point of contact for extramural invention reports, disclosures, confirmatory licenses, and other documentation required by the Bayh-Dole Act. To enhance compliance with Bayh-Dole requirements, OPERA develops policies and procedures; conducts training for extramural staff; and performs outreach to the extramural research community by conducting seminars and participating in regional and national meetings of professional societies related to research administration. These efforts also include preparing policy and informational announcements for the NIH Guide for Grants and Contracts and other NIH publications. OPERA also maintains and enhances the capabilities of IEdison and Edison Report-Lite

and provides user support for these compliance tools.

OPERA staff will monitor invention reporting by performing random compliance checks and conducting site visits with grantee/contractor organizations. Staff will work with representatives from the Council on Governmental Relations and the Association of University Technology Managers, Inc., as well as other national societies representing grantee/contractor organizations in an effort to improve understanding and compliance with the Bayh-Dole Act.

The address for the invention reporting function of OPERA is:

Chief, Extramural Inventions and Technology Resources Branch, OPERA, OER, NIH
6705 Rockledge Dr. Room 1136 MSC 7980
Bethesda, MD 20892-7980
(301) 435-1986
FAX (301) 480-0272; Email: edison@od.nih.gov ;
See also: www.iedison.gov for relevant information.

Grants Management Staff: Grants management staff play a vital role in protecting government rights to federally funded intellectual property. IC grants management staff should take every opportunity to remind grantees of their invention reporting obligations. Particular emphasis should be applied to recipients with limited grant funding experience (i.e., commercial organizations and small business entities). Toward this end, ICs are encouraged to include, at time of award, an informational letter that details invention reporting requirements. Such a letter is now routinely included with the Notice of Grant Award for SBIRs and STTRs. A copy of this letter is available internally from the Grants Management Infonet at: http://odoerdb2.od.nih.gov/gmac/topics/patents_main.html .

There are circumstances where special terms of award are warranted to ensure that any resulting invention will be made available for public use. Before implementing special terms and conditions of award, ICs should consult with OER.

If an invention report is included in a competing or non-competing grant application or on the Final Invention Statement and Certification (HHS 568), a search of the IEdison database should be conducted to verify whether or not any inventions have been reported under the specific grant number. Using the ERL interface (https://dali.cc.nih.gov/erl/), if the search shows *any* reported inventions, it will be assumed the grantee institution is reporting inventions and no further action will be required. If information regarding inventions as reported in the application is not consistent with IEdison records, OPERA must be notified via the ERL interface. OPERA will take any additional steps necessary to reconcile the discrepancy with the grantee organization. All actions taken by grants management must be documented and made part of the official file. A copy of an invention report from ERL or other information sent to OPERA is acceptable

documentation for the official grant file.

All invention related documentation (i.e., correspondence, disclosures, etc.) directed by the grantee to IC staff must be forwarded to OPERA for inclusion in the IEdison record system. The only exception is the HHS 568, which should be filed in the official grant file. However, if a copy of the HHS 568 reflects any inventions, a copy must be forwarded to OPERA for inclusion in the IEdison system of records.

Contract Management Staff: Contracts management staff must ensure that the solicitation and the contract document adequately describe the rights and responsibilities of the Government and the contractor with respect to inventions that may be made in the performance of work under the contract. This is accomplished by including the Patent Rights clause at FAR 52.227-11 and an Invention Reporting provision in the solicitation and the contract. If the work under the contract is to be performed outside of the United States, its possessions, and Puerto Rico, the contract and the solicitation will include the FAR clause at 52.227-13, in lieu of the clause at FAR 52.227-11.

Upon receipt of an annual invention report (only required if an invention has been developed during the reporting period), or a final invention statement reporting an invention, contract management is responsible for conducting a search of the IEdison database to verify whether or not any inventions are being reported under the specific contract number. Using the ERL interface (https://dali.cc.nih.gov/erl/), the contract manager will enter the contract number to query the IEdison database. If the search shows *any* reported inventions, it will be assumed the contractor is reporting inventions and no further action will be required. If an invention activity has been reported in either an annual or final report but has not been included in IEdison OPERA must be notified using the ERL interface. Beyond this notification, OPERA will take any additional steps necessary to reconcile the discrepancy with the contractor organization.

The annual and final reports are maintained in the IEdison record system, as well as in the official contract file. Any other invention related documentation (i.e., correspondence, disclosures, etc.) directed by the contractor to IC staff must be forwarded to OPERA for inclusion in the IEdison system.

Program Staff: Monitoring compliance for invention reporting is a responsibility that often requires scientific expertise. Review of a grant/contract application, including the scientific progress report, may reveal information that relates to the development of intellectual property (i.e., direct, indirect, or tangential references to the creation of an invention, a biological material, a unique research resource, etc.). An Extramural Scientist Administrator (ESA) possesses the scientific expertise to make a determination whether an invention is related to the research project and should be cognizant that references to commercialization, manufacturing, or marketing may be a result of NIH funding. In such cases the ESA must either inform grant/contract management staff of

this research outcome and grants management will take responsibility for seeing that the grantee/contractor fully complies with all reporting requirements, or the ESA will fulfill this function by conducting a search of the ERL system to establish whether or not this research outcome has been reported to NIH. If necessary, the ESA will obtain additional information from the grantee/contractor and see that an invention report is filed, if appropriate, and properly document the official file. If necessary, grant/contract management staff may assist in these efforts, as may OPERA staff.

Program staff must avoid any actual, apparent, or perceived conflict of interest with regard to their role as scientific advisor to grantees and contractors. ESAs who provide expert advice to grantees/contractors, or become co-inventors, must be aware of ethical issues and avoid impropriety. Recusal of any funding decision or program responsibility would normally be appropriate.

NIH Office of Technology Transfer: The Office of Technology Transfer (OTT) has the predominant responsibility for policy development and interpretation and administration of NIH intramural intellectual property. The office also has responsibility for providing guidance and consultation on interpretation and application of extramural technology transfer policy and procedures.

OTT provides assistance to NIH extramural awarding units to resolve technology transfer problems, including Declarations of Exceptional Circumstances (DEC), contents of Requests for Applications (RFA), Requests for Proposals (RFP), and application requirements. In coordination with other offices in the Office of the Director, NIH, OTT also prepares documents requesting assistance from HHS, PHS and provides assistance to grantee institution officials and others on extramural technology transfer policy matters.

Additionally, OTT has been delegated authority for extramural inventions in four areas: (1) election of title or assignment of title to an extramural invention on behalf of the government; (2) waiver of the preference for domestic manufacture (i.e., no contractor or grantee or their assignee shall grant to any person the exclusive right to use or sell a subject invention in the United States unless that person agrees that any products embodying the invention or produced trough its use will be manufactured substantially in the United States; (3) retention of title by the inventor; and (4) initiation and pursuit of government *march in* rights.

OTT's expertise is necessary in these areas due to the technical, legal and scientific ramifications associated with rights to intellectual property and the need to promote commercialization opportunities.

Technology Development Coordinators (TDC): The role of an IC TDC is to review extramural inventions where rights have been waived by the grantee/contractor organization and where the IC has an express interest in the invention. Inventions that are abandoned or waived by the grantee/contractor organization are reviewed by the TDC for

any possible IC interest. Results of these reviews are forwarded to OPERA, and the IEdison database is updated to reflect a change in status.

Special Programs Office, OER: The Special Programs Office provides the administrative oversight for the annual Omnibus Solicitation for SBIRs and STTRs. This office provides basic information for this community needed to comply with the requirements of the Bayh-Dole Act. This office also provides information through a Web site for small business organizations at http://www.nih.gov/grants/funding/sbir.htm.

Office of General Counsel: This office acts as the legal advisor to NIH on any issue where NIH's position or rights to inventions are involved.

This policy announcement is effective upon signature.

/s/
Wendy Baldwin, Ph.D.

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cc:
IC Directors
EPMC
POPOF
RPC
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OTT
AMC
Dr. Stone