



# NIH Extramural Intellectual Property and Invention Reporting Policies

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Eighth Principal Investigators (PI) Meeting  
for the NCI Innovative Molecular Analysis  
Technologies (IMAT) Program

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## For Funding Recipient Institutions, Technology Transfer is Handled by:

- Funding Recipient's own Office of Sponsored Research Programs
- Funding Recipient's own Technology Transfer Office (TTO) (a/k/a Office of Technology Transfer (OTT), Office of Technology Licensing (OTL), Office of Technology Development (OTD), etc.)
- Funding Recipient's own Office of the General Counsel (OGC)
- **Clear communication channels among these offices is a key to top-notch technology transfer and correct, complete compliance**



## ***Key Guidance Points: Developing Sponsored Research Agreements (Guidance from Nov 1994)***

- ❖ Grantee's agreements with other sponsors must be consistent with Bayh-Dole Act obligations
- ❖ Maintenance of scientific integrity and academic freedom
- ❖ Dissemination of research results
- ❖ Promote utilization of the technology
- ❖ <https://s-edison.info.nih.gov/Edison/sponsored.html>

# What is an Invention under the Bayh-Dole Act?





## What is an Invention for the Extramural Community?

- 37 CFR Section 401. 14 Standard patent rights clauses.
  - (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 grant or contract, ... of a variety of plant, the date of determination...
- Does not include solely copyrightable materials, e.g., books - But includes software (patentable as of late '90s)



# Who Owns the Invention?





## Federal Requirements

- Bayh Dole Act 1980
- Stevenson Wydler Act 1980
- Federal Technology Transfer Act 1986
- Technology Transfer Commercialization Act 2000



## Bayh Dole Act

- Prior To 1980
  - Technologies languished in laboratories
- Thrust Of The Act
  - Funding recipients may elect title
- Requirements



## Bayh Dole Requirements

- Reporting Of Inventions (e.g., see [iEdison.gov](http://iEdison.gov))
- Election Of Title
- Move to practical application



## Bayh Dole Requirements

- **Confirmatory License**
  - Provide the Federal Government with "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." 37 CFR 401.14(a)(b)(1).
- **Notice On Patent Applications (Fed. Support)**
  - 37 CFR 401.14(a)(f)(4) states: "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."





# Invention Reporting through iEdison - <http://iEdison.gov>

iEdison: Welcome to iEdison - Microsoft Internet Explorer

File Edit View Favorites Tools Help

Back Forward Stop Home Search Favorites Refresh Print Mail Stop Taskbar

Address <https://s-edison.info.nih.gov/iEdison/> Go Links

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United States Patent Application

Interagency Edison

Welcome to iEdison

Log in to your secure account: All fields marked with an asterisk (\*) are required.

**Login** ?

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\* Password

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[Register Institution to use iEdison](#)

[Access iEdison Test Site](#)

**System Notification**

- Edison Version 2.0.19 was deployed on

iEdison (which stands for Interagency Edison) helps government grantees and contractors comply with a federal law, the Bayh-Dole Act. Bayh-Dole regulations require that government funded inventions be reported to the federal agency who made the award.

iEdison is interagency because it provides a single interface for grantees and contractors to interact with any participating agency.

iEdison makes it easy to learn about the law and its regulations and report an invention or patent funded by any of the agencies listed on the right.

AFRL/IF  
AHRQ  
Army/ARL  
Army/ARO  
Army/MRMC  
Army/SMDC  
Army/SSC  
ATSDR  
CDC  
DOD/DMEA  
DOE  
EPA  
FDA  
IHS  
Naw/ONR  
NIH  
NIST  
NOAA  
NSF  
USAF/AFOSR  
USAF/ESC  
USAID  
USDA/IARS

[iEdison Overview](#)

[What's New](#)

[Bayh-Dole Act \(37 CFR 401\)](#)

[Invention reporting Tips](#)

Done Internet

# *iEdison*

- Secure, Interactive Web-Based System for Bayh-Dole Policy and Reporting Compliance
  - Didactic Content to inform investigators & grantee/contractor organizations
    - 37 CFR 401
    - Invention Policy Issues
    - Invention Reporting Procedures/forms
- Current submission of Invention Report Records to any of over 27 participating Federal Agencies including:
  - NSF
  - HHS/FDA
  - HHS/CDC
  - USAID
  - HHS/ATSDR
  - HHS/IHS
  - AFRL/IF
  - NAVY/ONR
  - USAF/AFOSR
  - DOC/NOAA
  - EPA
  - HHS/AHRQ (AHCPR)
  - Army/SSC
  - Army/SMDC
  - USDA/CSREES
  - USDA/Forest Service
  - USDA/ARS
  - USAF/ESC
  - Army/MRMC
  - NIH
  - DOD/DMEA



## Why use iEdison?

- Submission via browser or computer-to-computer datastream
  - Used by ~1300 grantee/contractor organizations
- Help Line: (301) 435-1986
- Email: [Edison@od.nih.gov](mailto:Edison@od.nih.gov)



## When do you report inventions?

- The Bayh-Dole Act and its Implementing Regulations
  - <https://s-edison.info.nih.gov/iEdison/37CFR401.jsp>
- Extramural Invention Reporting Compliance Responsibilities
  - <https://s-edison.info.nih.gov/iEdison/timeline.jsp>

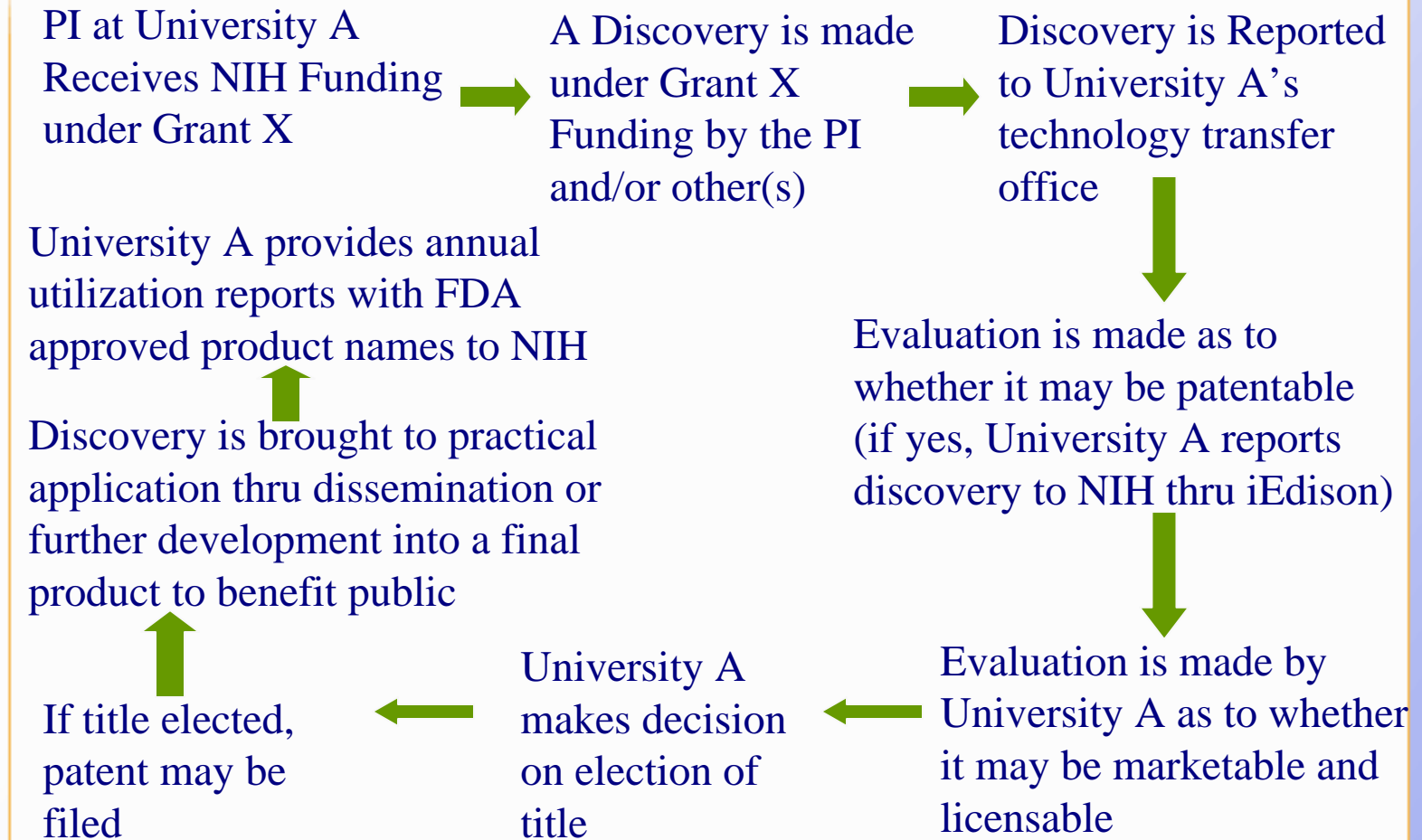


## Invention Reporting Requirements

- Implement Employee Agreements ⇒ *as needed*
- Disclose Each Invention ⇒ *within 60 days*
- Resolve Election or Waive of Title ⇒ *within 2 years*
- File Patent ⇒ *within 1 yr. of election*
- Provide License to the Govt. ⇒ *upon title election*
- Indicate Govt. Support on Patent ⇒ *with patent appl.*
- Product Manufacturing in U.S. ⇒ *required*
- Report on Invention Utilization ⇒ *annually*
  - *Annual invention utilization reports differ from annual grants progress reports*
- Final Invention Report ⇒ *at award close out*
  - *HHS-568 for NIH, but agencies are moving towards uniform federal-wide data elements for reporting*



## The Technology Transfer Process





## More on Ownership of Inventions

- Determination of Exceptional Circumstances (DECs) (e.g., contracts)
- US manufacturing requirement waivers (required if exclusive rights given to use or sell subject invention in the US)



## More on Ownership of Inventions

- Ensure that rights to inventions arising out of NIH funding agreements are properly assigned to the institution in order to fulfill responsibilities under the funding agreement
  - General Waivers
  - Non-profit and university federal funding recipients must seek approval from the NIH to waive or assign title to another party
    - Waivers to the Inventor
    - 3<sup>rd</sup> Party Assignment Waivers



## Noted Misconceptions

- The government owns my invention.

No, rights vest with the funded organization.

- If I report an invention, NIH (the government) will take my invention.

NIH is not in competition with recipients.

- By not reporting my invention to NIH, I will secure rights to an invention.

No, there is a greater risk of loss of rights by not reporting.



## Selected Examples including NIH-funded Extramural Technologies

- Emtriva (NIAID)
- Epogen
- Kaletra (NIAID)
- Neupogen
- Norvir (Ritanovir) (NIAID)
- Procrit
- Taxol (NCI)
- Truvada (NIAID)
- Xalatan (NEI)
- Zerit (NCI)
- FluMist (NIAID)



## Selected Examples including NIH-funded Extramural Technologies

Report of FDA Approved Commercial Products Involving  
NIH Extramural Support

[https://s-  
edison.info.nih.gov/iEdison/commercial\\_report.jsp](https://s-edison.info.nih.gov/iEdison/commercial_report.jsp)



## Congressional Interest

- Appropriations Committee On Protecting Public Interest In Research Technologies (e.g., Health Outcomes)
- GAO Reviews And Reports



## Current Issues and Activities

- Conflict Of Interest/Ethics Conferences
- Recurring Legislative Discussions Of Drug Price Issues and Enhancing Technology Transfer
- Metrics—Economic Development vs. Public Benefit vs. Profit
- Improvement Of Interaction Of Government, Industry And Academia



## Selected NIH Sharing Policies

- NIH Research Tools Policy (Sharing Biomedical Research Resources)  
[http://grants.nih.gov/grants/intell-property\\_64FR72090.pdf](http://grants.nih.gov/grants/intell-property_64FR72090.pdf)
- Developing Sponsored Research Agreements  
<http://iedison.gov/Edison/sponsored.html>
- 2003 NIH Data Sharing Policy  
[http://grants.nih.gov/grants/policy/data\\_sharing/](http://grants.nih.gov/grants/policy/data_sharing/)
- NIH Policy on Sharing of Model Organisms for Biomedical Research  
<http://www.nih.gov/science/models/sharingpolicy.html>
  - Sample Plans  
[http://grants.nih.gov/grants/policy/model\\_organism/index.htm](http://grants.nih.gov/grants/policy/model_organism/index.htm)



## Notice of Grant Award

- Terms and conditions of award, including plans
- Need to have policies and procedures in place to ensure that any agreements entered into with third parties are consistent with the terms and conditions of the award, including the provision of intellectual property rights to the NIH, and third parties are informed of the NIH requirements;
- Need to revise any agreements with third parties that are inconsistent with the terms and conditions of an NIH award to remain in compliance with the NIH award.
- NIH Guide Notice that described aspects of these terms:  
<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-01-033.html>



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