
U.S. Federal Funding Awards & the Bayh-Dole Act in a Global Environment:

Invention Reporting, iEdison, and the NIH



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National Institutes of Health (NIH)



NIH is an Agency of the
U.S. Department of Health & Human Services (HHS)

NIH Overview



- NIH is the U.S.'s medical research agency - making important medical discoveries that improve health and save lives.
- NIH is the primary U.S. federal agency for conducting and supporting medical research.

NIH Mission:

- ★ Science in pursuit of fundamental knowledge about the nature and behavior of living systems and the application of that knowledge to extend healthy life and reduce the burdens of illness and disability.

NIH FY 2008 Budget Overview:

US\$29.457 Billion

★ Research Project Grants

★ 53%

★ R&D Contracts

★ 11%

★ Research Centers

★ 10%

★ Research Management & Support

★ 5%

★ Other Research

★ 6%

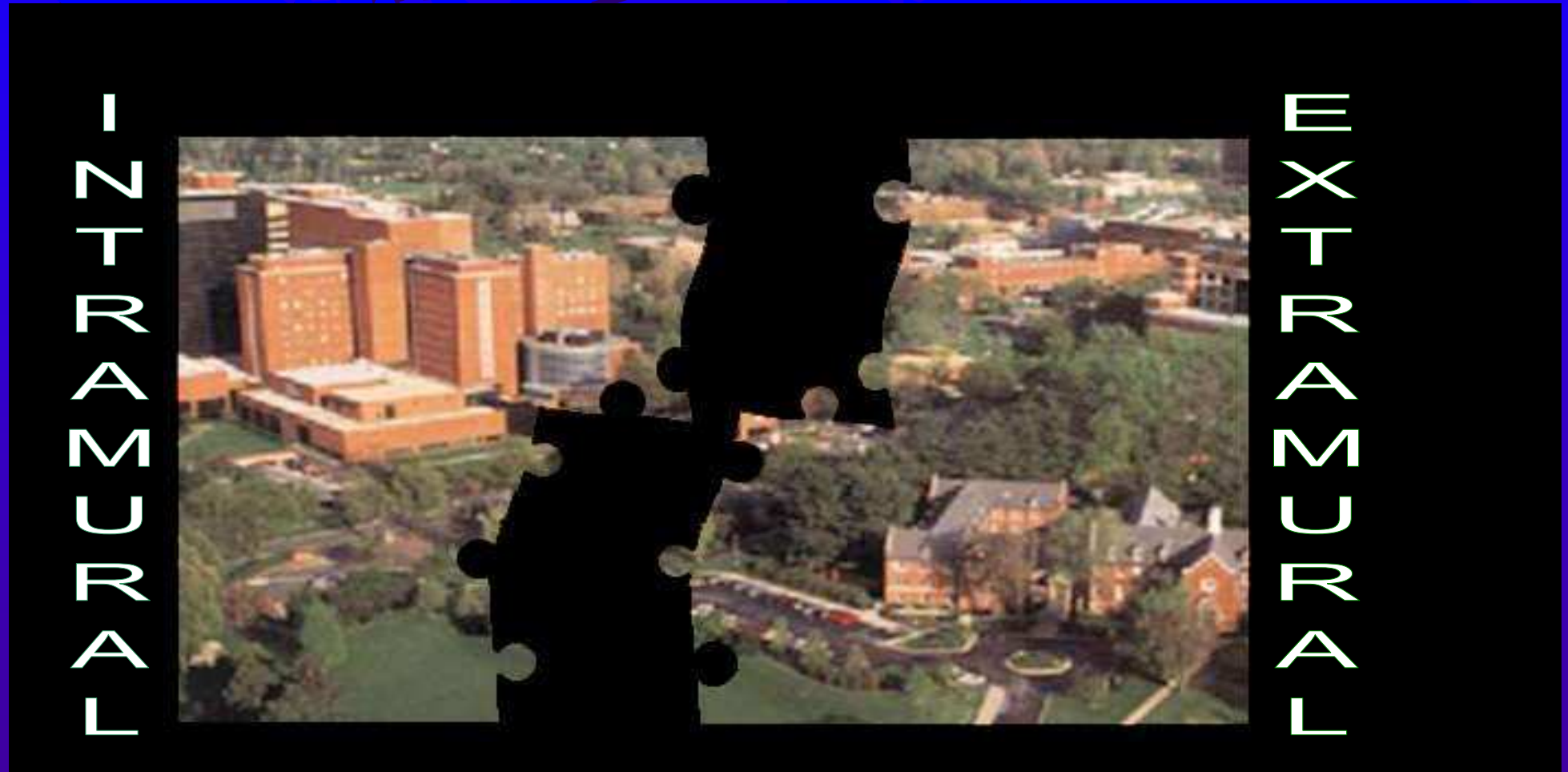
★ All Other

★ 2%

★ Intramural Research

★ 10%

Dual Nature of NIH Supported Research



★ *Office of Extramural Research (OER)*

★ *Office of Intramural Research (OIR)*

NIH Budget – Intramural & Extramural

NIH INTRAMURAL RESEARCH

NIH is an Institution



Supports:

- Over 6,000 scientists
- 10% of NIH budget
- Primary location: Bethesda, MD
- A few other labs throughout the United States (U.S.)

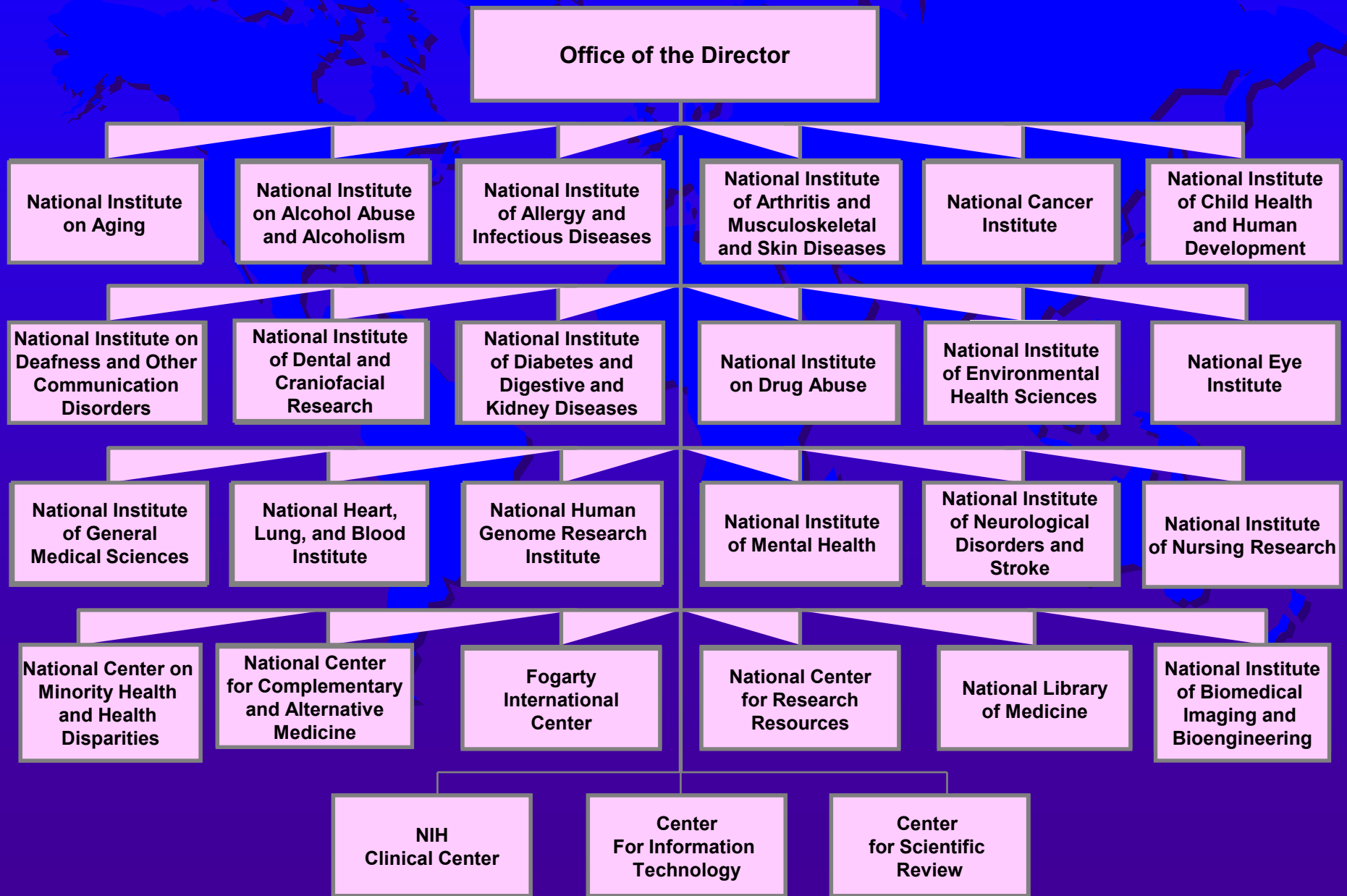
NIH EXTRAMURAL RESEARCH



Supports:

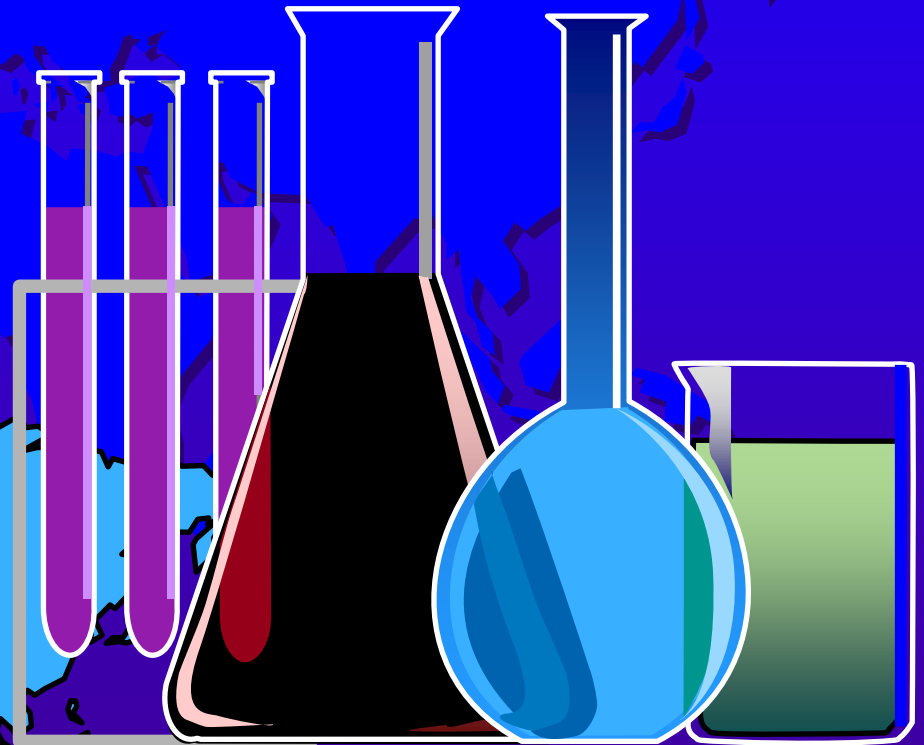
- Over 3,000 Institutions worldwide
- Over 300,000 scientists & research personnel
- Awards issued to over 100 countries
- Clinical, Basic, & Translational Research
- 83% of the NIH budget

NIH Organizational Structure: Office of the Director (OD) & 27 Institutes and Centers (ICs)



NIH Funding Opportunities

- ★ NIH funds research both in the U.S. and internationally.



Identifying NIH Funding Opportunities

- There are numerous grant mechanisms available to each IC at NIH to support research related to their IC's mission.
- NIH uses activity codes (e.g. R01, R43, etc.) to differentiate the wide variety of research-related programs it supports.
- Each mechanism has a specific purpose and each IC uses a mix of mechanisms to structure its research portfolio.

Identifying NIH Funding Opportunities

For more information on NIH Activity Codes and Types of Grant Programs, please refer to:

- http://grants.nih.gov/grants/funding/funding_program.htm;
- http://grants.nih.gov/grants/funding/ac_search_results.htm; and
- <http://grants.nih.gov/grants/funding/ac.pdf>.

NIH Funding Opportunities for Non-U.S. Applicants

- In general, foreign institutions and international organizations, including public or private non-profit or for-profit organizations, are eligible to apply for research project grants and other funding opportunities.
- Foreign institutions and international organizations are generally not eligible to apply for Kirschstein-NRSA institutional research training grants, program project grants, center grants, resource grants, construction grants, Small Business Innovation Research awards (SBIR/STTR), or funding under the American Recovery and Reinvestment Act (ARRA).
- Some activity codes, such as program project grants (P01), may support projects awarded to a domestic institution with a foreign component.

Finding Funding Opportunities

Fed Biz Opps (Federal Business Opportunities)
(<http://https://www.fedbizopps.gov/>)

- The U.S Government's one-stop virtual marketplace, single point-of-entry for the entire Federal contracting community
- Commercial vendors and Government buyers are invited to post, search, monitor, and retrieve opportunities solicited by the entire Federal contracting community

- For NIH-Specific:

NIH Request For Proposals (RFP) Directory

<http://ocm.od.nih.gov/contracts/rfps/MAINPAGE.HTM>

Finding NIH Funding Opportunities

NIH Guide for Grants and Contracts
(<http://grants.nih.gov/grants/guide/>)

- The official publication for NIH medical and behavioral research grant policies, guidelines, and funding opportunities.
- Searchable database for funding opportunities and notices.
- NIH Guide ListServ: Subscribe to Weekly Table of Contents
- E-Mail with New NIH Guide Postings:
<http://grants.nih.gov/grants/guide/listserv.htm>.

Finding NIH Funding Opportunities

Computer Retrieval of Information on Scientific Projects (CRISP)
(<http://www.crisp.cit.nih.gov>)

CRISP on the Web – under the Research Portfolio Online
Reporting Tool (RePort at <http://report.nih.gov/>)
(<http://report.nih.gov/crisp/index.aspx>)

- A searchable database of scientific and administrative information about the intramural and extramural research activities supported by the NIH.
- Also includes data about some of the research supported by other DHHS components.
- Explore the types of research supported .

Finding More Information on NIH Funding Opportunities

NIH Grants Information (GrantsInfo)

- A communications service within the Division of Communications and Outreach, Office of Planning and Communication, OER, NIH.
- Staff respond to inquiries regarding the grant application process and funding opportunities.
- Telephone: 301-435-0714
- Email: GrantsInfo@nih.gov

Federal Funding Opportunities and Invention Reporting at NIH

NIH Division of Extramural Inventions & Technology Resources (DEITR)

- DEITR is in the Office of Policy for Extramural Research Administration (OPERA) (grants policy, oversight, compliance, and extramural inventions) under the NIH Office of Extramural Research (OER), Office of the Director, NIH, HHS
- Extramural invention reporting and related intellectual property and resource sharing policies and issues (<http://inventions.nih.gov>)
- Host of iEdison (<http://iEdison.gov>) (Interagency invention reporting system)

Once your institution has been awarded a funding agreement....

- Understanding the Bayh-Dole Act and its Requirements under U.S. Federal Funding Agreements
 - The Bayh-Dole Act of 1980 ((35 U.S.C. 200-212 and implementing regulations 37 CFR 401), an economic stimulus package of the 1980s).
 - Passed into U.S. law December 12, 1980.
 - Effective Date July 1, 1981.
 - Extended to large businesses February 10, 1982 by Presidential Memorandum.

Bayh-Dole Act Overview

- Prior to the Bayh-Dole Act of 1980, any inventions developed under U.S. federal funding agreements were owned by the U.S. Federal Government.
- Under the Bayh-Dole Act, funding recipients could then elect title/own the inventions (“subject inventions”) they develop under their federal funding agreements.

Bayh-Dole Act Overview

- Bayh-Dole Act and its implementing regulations (35 U.S.C. 200-212 and 37 CFR 401) apply to any contract, grant, or cooperative agreement (or related subaward) for the performance of experimental, developmental, or research work funded in whole or in part by the Federal Government.
- Funding recipients must abide by federal reporting requirements and policies to properly retain title to such subject inventions.
- Right to elect title can vary when the funding recipient 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 (35 USC 202(a)(i)).

Bayh-Dole Act Overview

- For foreign NIH funding recipients:
 - Foreign entities are allowed to continue to retain rights in intellectual property developed under NIH funding agreements as do domestic funding recipients, consistent with current NIH policies and any other terms and conditions of the specific funding agreement awarded.
- Stated October 13, 2005 in the NIH Guide for Grants and Contracts in Notice Number: NOT-OD-06-005
<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-06-005.html>

Bayh-Dole Reporting Requirements

- Reporting On Inventions (e.g., through iEdison.gov)
- Election Of Title
- Move To Practical Application
- Notice On Patent Applications (Federal Government Support Clause)

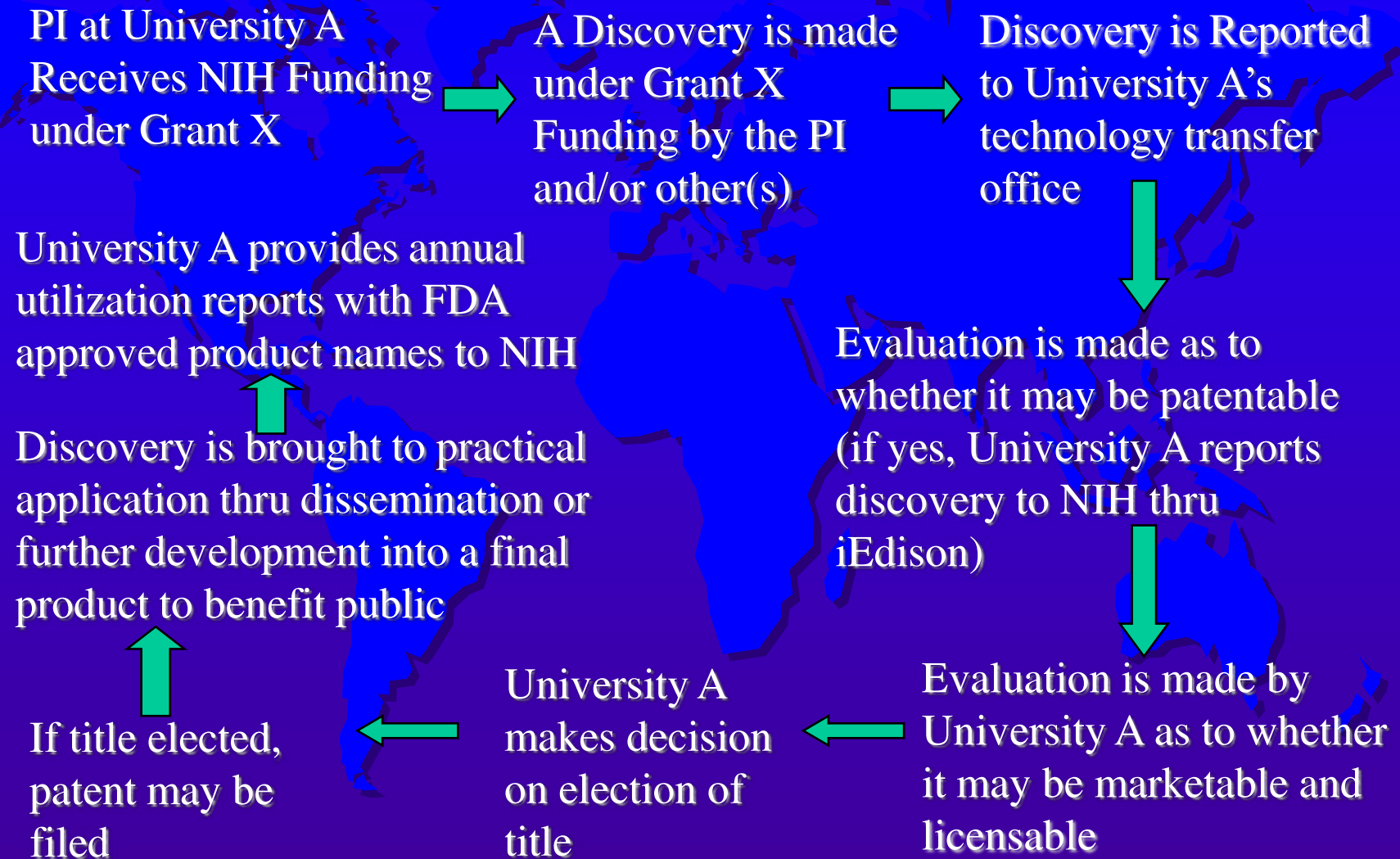
What is a Reportable Invention?

- “Subject inventions” need to be reported:
 - Under 35 USC 201(d) an “invention” means any invention or discovery which is or may be patentable or otherwise protectable under this title 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.).
 - Under 35 USC 201(e) a “subject invention” means any invention of the 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) \1\ of the Plant Variety Protection Act (7 U.S.C. 2401(d))) must also occur during the period of contract performance.

Bayh-Dole 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 application
- Product Manufacturing in U.S. ⇒ required
- Report on Invention Utilization ⇒ annually
 - Note: Annual invention utilization reports differ from annual grants progress reports (for more information on this, please refer to https://s-edison.info.nih.gov/iEdison/twenty_questions_updated.jsp).

Reporting Process Flow



Additional Invention Reporting Requirements and Considerations

- March-In Rights (35 U.S.C. § 203)
 - NIH has never exercised this as of this date
- Recipient must 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
 - 3rd Party Assignments

Additional Invention Reporting Requirements and Considerations

- Manufacturing Requirement for substantially manufacturing in the US
 - Waiver may be requested from funding agency
 - 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
 - under the circumstances domestic (U.S.) manufacture is not commercially feasible.
- For NIH, more information on waiver processing can be found at <https://s-edison.info.nih.gov/iEdison/ManufacturingWaiver.jsp>

Additional Invention Reporting Requirements and Considerations

- Mandatory reporting of “subject” inventions throughout IP lifecycle (20+ years).
- Final Invention Report ⇒ at award close out
 - Form HHS-568 for NIH, but agencies are moving towards a federal-wide data elements for reporting (planned to interface with iEdison).

How To Report on Inventions

- Invention reporting is defined as a term and condition of the U.S. federal funding agreement, providing instructions and contact information on how/where to report on inventions.
- NIH hosts and supports use of iEdison for electronic reporting on inventions under the Bayh-Dole Act at <http://iEdison.gov>.
- over 27 other federal agency offices (in addition to NIH) use iEdison for collecting invention reporting information
- the iEdison system is used by over 1,400 funding recipient organizations/institutions to report their inventions

Why use iEdison for Reporting?

- Secure, relational, real time database with all Bayh-Dole invention reporting business rules built in
 - Offers reminders of time critical reporting obligations
 - iEdison supports full electronic reporting: no paper is needed if you have the information electronically
 - Requires minimal hardware/software
 - Internet connection and Browser

- **iEdison HelpDesk** available

By Telephone: (301) 435-1986

By Email: Edison@nih.gov

For further information on iEdison and NIH Extramural Inventions and related Intellectual Property Issues:

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Websites: <http://inventions.nih.gov>; <http://iEdison.gov>

Main Emails: Edison@nih.gov; Inventions@nih.gov

For information on NIH sharing policies,

Website <http://sharing.nih.gov>; Email: Sharing@nih.gov