

**BAYH-DOLE
PRESENTATION**
HCCA RESEARCH COMPLIANCE
CONFERENCE
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Technology Transfer

What Is Tech Transfer?

* Movement of information, materials, and technologies from the research laboratories to the commercial enterprise *

* To support further research and develop new products to improve public health *

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Introduction to Bayh-Dole

- Adopted in 1980
- Established a patent policy amongst federal funding agencies to allow for recipient organizations to retain title to inventions made using federal funds
- Prior to the Act, the government retained title to these inventions
 - Many patents accumulated
 - Very few were licensed
 - Thus, the societal impact of federal research funding was not being fully realized
- Sparked what we now refer to as "technology transfer"
- **Bayh-Dole changes pending**
- **CODIFIED in 35 U.S.C. § 200-212. Implemented by 37 C.F.R. 401[2]**

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Bayh-Dole Act: Federal Funding Agreements

Policy & Objective (35 U.S.C. 200):

- Use the patent system to promote the utilization of inventions arising from federally supported research or development;
- Encourage participation of small businesses;
- Promote collaboration between commercial concerns and nonprofit organizations;
- Ensure inventions are used in a manner to promote free competition and enterprise without unduly encumbering future research and discovery;
- Promote the commercialization and public availability of inventions made with federal support; and
- Ensure that the Government obtains sufficient rights in federally supported inventions.

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As a Result – The Contractor . . .

Can timely Elect:

- To retain title to inventions
- To commercialize and receive royalties from the invention

IN EXCHANGE, THE Contractor is Required to:

- File for patent protection (except for research tools)
- Seek commercial development of the technology
- Meet certain obligations establishing the government's rights
- Fulfill reporting requirements
- Use reasonable efforts to attract licenses from small businesses
- Require US manufacture of products and services if invention/patent exclusively licensed
- If a non-profit, will share profits with inventor & use other net royalties to support science or education

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As a Result – The Government . . .

Is Granted:

- A nonexclusive, nontransferable, irrevocable, paid-up license to practice resulting patents throughout the world
- The right to obtain title to IP to pursue, continue patent protection, or dedicate to the public, if the Contractor decides not to (or does not timely report)
- March-in Rights: the ability to require the granting of a license if necessary because
 - Effective steps to achieve practical application have not been taken
 - To alleviate health or safety needs not being satisfied
 - To meet requirements for public use not being satisfied
- Preference for US Industry not given

Government agrees to protect confidentiality of compliance submitted

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Bayh-Dole Reporting

- Bayh-Dole requires, by statute and regulation, reporting to each federal agency an invention (subject invention) made with federal funding and the patents filed on the subject invention.
- All reporting requirements and timeframes to report key compliance documents are stated in Bayh-Dole and are attached/handout and can be found at:

https://grants.nih.gov/grants/policy/nihgps_2013/nihgps_ch8.htm#_Toc271264954

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Importance of Reporting Subject Inventions and Patents

- Identifies to NIH inventions that were conceived or first actually reduced to practice in the performance of the NIH funded work.
- Inventions are one result of the NIH funded research that the NIH Program Officer is informed of through annual and final reports.
- Technical description and information about subject inventions are provided to the public in research publications citing NIH funding.
- Products or services that rely on or incorporate subject inventions is an important public benefit of the results of NIH funding and, as required, reported in the Food and Drug Administration's Orange Book.

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Invention Reporting Requirements of NIH Grantees and Contractors

- Implement Employee Agreements ⇨ as needed
- Disclose Each Invention ⇨ within 60 days to federal funding agency
- Elect title or Waive of Title of invention ⇨ within 2 years of disclosure
- Interim Research Report ⇨ disclose invention in report and in iEdison
- File Patent ⇨ within 1 yr. of election of title
- Provide License to the Govt. ⇨ upon title election; 1 license for family of patents
- Indicate Govt. Support on Patent ⇨ with in each patent appl.
- Product Manufacturing in U.S. ⇨ required
- Report on Invention Utilization ⇨ annually; NIH and other agencies
- Final Invention Report ⇨ at award close out; for HHS 568

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Pending Proposed Changes to Bayh-Dole

- Pending with OMB, etc. (Federal Register notice has been made with comments due by December 2016) are changes to Bayh-Dole 2 major pending changes:
 - (1) **Currently:** *BD requires the disclosure to the federal funding agency of an initial patent application which is defined as the "non-provisional application."*
 - (1) **Proposed:** *initial patent application = the initial patent application and would include the provisional and all other applications include international applications (PCT) filed on a subject invention.*
 - (2) **Currently:** *federal agency has 60 days in which to obtain title for non-compliance of the election of title.*
 - (2) **Proposed:** *the government has unlimited time to take action for non-compliance.*

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Where are Inventions and Patents Reported?

- iEdison: an electronic data system used by 30+ agencies (not all); www.iEdison.gov
- managed by NIH for all federal agencies using iEdison
- Representative at federal funding institution registers on-line with a password.
- Registered representative has access to ALL of their institution's records ONLY UNLESS
 - *Granted access by a co-owner of an invention/patents.*
- iEdison Electronic reminders are sent to each institution when a reporting deadline is coming-up.
- Each federal funding agency reviews/accepts/rejects the compliance document for their funding agreements.

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Where is Reporting Made? - continued

- iEdison electronic messages are sent to institution representative when compliance documents submitted have not been accepted by the federal agency.
- Bayh-Dole states what information and what format the submitted compliance document needs to contain.
- Federal funding agency receives an iEdison message when a new compliance document has been submitted and needs to be reviewed by the agency.

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A Few Words on Waivers

- Following a funding recipients election of title - the funding recipient is responsible for all Bayh-Dole compliance: patenting & licensing.
- The funding recipient may decide that:
 - The inventor not the funding recipient should have title (*Inventor Waiver*)
 - Another funding recipient is taking the lead of reporting on co-owned inventions/patents or the transfer of ownership to a 3rd party (*Third Party Waiver*).
 - Substantial manufacturing of a product will not occur in the United States. (*U.S. Manufacturing waiver/permission*)

ALL WAIVERS ABOVE REQUIRE FEDERAL FUNDING AGENCIES' APPROVAL PRIOR TO THE TRANSFER OF OWNERSHIP OR PERMISSION GIVEN FOR NON-U.S. MANUFACTURING

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Consequences for Non-reporting and Non-Compliance

- NIH: Grants Policy Statement: GPS 8.2.4 and 8.4.1.6
 - Incorporates Bayh-Dole and all rights and obligations of funding recipient and government in terms and conditions.
 - Included in 90%+ of NIH awards.
 - Federal funds for fellowships, training grants and certain career development awards: Bayh-Dole does not apply.

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Consequences for Non-reporting and Non-Compliance - continued

- GPS 8.4.1.6

"A recipient's failure to comply with invention reporting requirements and/or associated NIH policies on intellectual property and resource sharing may result in the loss of patent rights [ownership] or a withholding of grant funds or other enforcement actions, including the imposition of special terms and conditions [into future NIH funding awards.]"

[] - clarification added.

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Consequences for Non-reporting and Non-compliance – continued

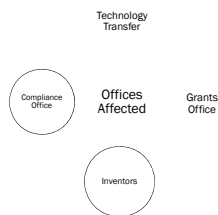
- Bayh-Dole: 37 CFR 401.14(d) Conditions When the Government May Obtain Title:
 - (1) "if the contractor fails to disclose or elect title to the subject invention with the times specified..."
- March-In 37 CFR 401.14(j):
 - "The contractor agrees with respect to any subject invention in which it has acquired title, the Federal agency has the right...to require the contractor, an assignee or exclusive licensee of a subject invention" to grant a license to a 3rd party or the federal agency has the right to grant a license to a 3rd party in 4 circumstances:
 - 1) Steps not taken to achieve practical application; 2) action is necessary to alleviate health or safety needs; 3) necessary to meet requirements for public use; or 4) failure to obtain approval for non-U.S. substantial manufacturing.

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TIPS TO GETTING AND KEEPING YOUR UNIVERSITY BAYH-DOLE COMPLIANT

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Who is involved with BD Compliance?



- Communication is key in Bayh-Dole Compliance. It is important that all of these offices talk to one another throughout the grant, invention disclosure, patenting, and commercialization process.

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Getting & Staying Compliant – Institutional Understanding and Support

- The first (and perhaps most) important step in implementing a Bayh-Dole Compliance Program is obtaining Institutional Support
 - *Ensure your Institution's Administration at the highest levels understands the importance of Bayh-Dole Compliance and its potential effect on the Institution*
 - *Make sure this support is clearly communicated throughout the Institution*
- You may face some sort of push-back when instituting a new BD Compliance Program (inventors, attorneys, licensees, etc.), so this Institutional Support is essential in the program being a success

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Getting & Staying Compliant – Learning the Players

- First determine what office at your institution manages Bayh-Dole Compliance/iEdison reporting
 - *This is normally the technology transfer office*
- Next, find the specific person(s) tasked with iEdison reporting
 - *Have they been adequately trained?*
 - *Should have strong grasp of patent law*
 - *Do they have the bandwidth to fulfill reporting obligations?*
 - *Is there a plan for if this person leaves or will be absent for an extended period of time?*
- Are there Bayh-Dole/iEdison SOPs?
 - *What's your institution's process?*
 - *Is there an audit function or other way to check that reporting is being completed?*

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Getting & Staying Compliant – Ensuring Everything That Should Be Reported is Being Reported

- Invention disclosure form
 - *Place to list federal funding including agency and grant number*
 - *Follow-up process if this is left blank*
- Inventor discussions
 - *Important to discuss funding with the inventor at the time of the disclosure – they may forget as time goes by*
- Checking with grants & contracts office
 - *Effort reporting of inventor*
 - *Aims of inventors' grants*
 - *Communication with the grants office*
- Once grant or contract is confirmed – review grant/contract terms and conditions
- Particularly important at the disclosure and grant close-out phase
 - *Grants cannot be closed out if the invention information in the closeout report does not match what is in iEdison and the iEdison record is complete/accepted*

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Getting & Staying Compliant - EDUCATION

- Education is Key to Bayh-Dole and iEdison Compliance
- Education programs for technology transfer team
 - For Compliance Professional
 - For Licensing Associates
- Those who deal with patenting
- Those who deal with licensing
- Education programs for researchers (required by the Act)
 - Why to disclose
 - When to disclose
 - What to disclose
- Education programs for sponsored programs teams
 - Locating grants
 - Reporting provisions
 - Closeout reports

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Getting & Staying Compliant – iEdison Notifications

- Ask how many iEdison notifications your institution has and if they have a plan and timeline to address them
- Make sure invention disclosure form includes all information necessary
- Make sure that government support clauses are included in ALL applications with associated government support.
 - Ask your technology transfer office for their standard government support clause language
 - **"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."**
 - It's important that your patent attorneys know that this language cannot be changed in any way
 - You can even include this in your engagement agreements with law firms

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Getting & Staying Compliant – iEdison Notifications (cont.)

- Make sure that as soon as patent applications are filed, confirmatory licenses are executed
- Make sure your BD compliance professional is notified of patent decisions in a timely manner
- Make sure that licensee annual report content and timing align with utilization report requirements and due dates

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Getting & Staying Compliant – Beyond iEdison

- iEdison will provide you with “notifications” of certain issues of non-compliance, but iEdison only knows what you put in
- Not all agencies use iEdison
- Policy Compliance
 - Timelines for decisions regarding patenting
 - Policy regarding returning rights
- License Compliance
 - Notice to licensees of government rights
 - US manufacture requirement (or waiver)
 - Patent prosecution timelines
 - Reporting requirements
 - Confidentiality provisions
- Making attempts to commercialize and preference for small businesses

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Resources....

- Where do I get information to appropriately manage data, inventions, publications, and other resources developed with NIH funding?
 - NIH Grants Policy Statement (GPS):
<http://grants.nih.gov/grants/policy.htm>
 - Notice of Award: terms and conditions of award
 - NIH Grants Information:
GrantsInfo@nih.gov
 - NIH Data Sharing Resources:
sharing@nih.gov
 - iEdison and Intellectual Property FAQs and Resources:
https://era.nih.gov/iedison/iedison_faqs.cfm

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Q&A

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