



Intellectual Property: An In-Depth Look at Bayh Dole and Reporting Requirements

Presented By:

Office of Extramural Research (OER)

Office of Policy for Extramural Grants Administration (OPERA)

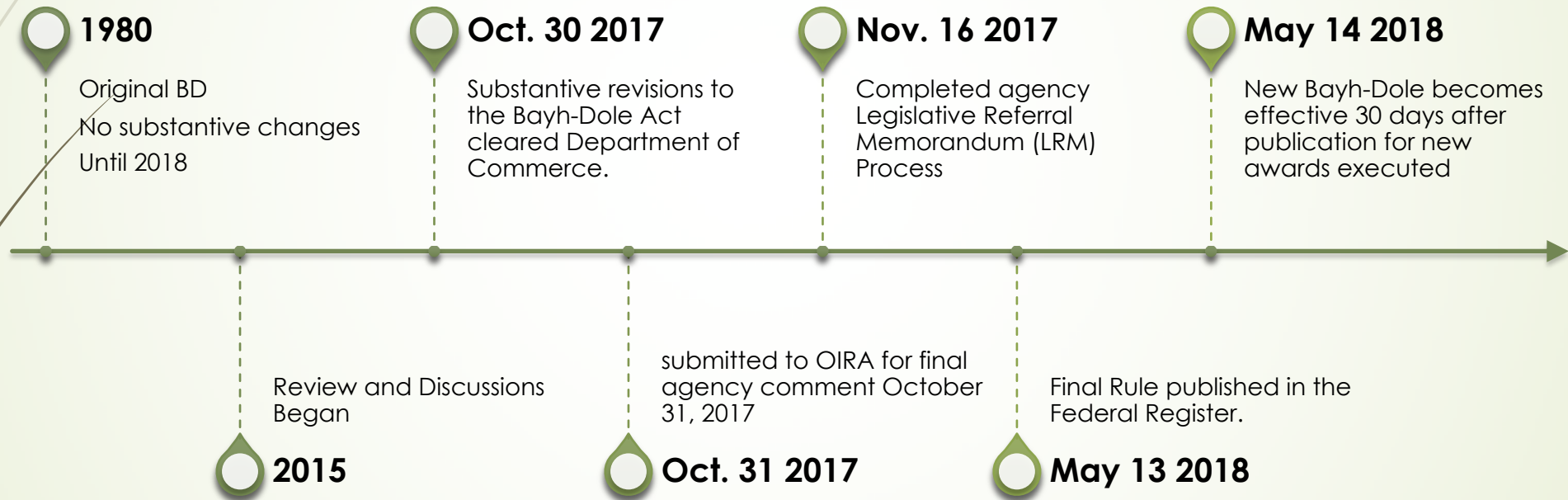
Division of Extramural Inventions & Technology Resources (DEITR)

2018 NIH Regional Seminar on Program Funding and Grants
Administration iEdison Workshop



National Institutes of Health
Office of Extramural Research

Recent Dates for Revisions to Bayh-Dole



Bayh-Dole

- ▶ 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:

[NIH GPS Section 8.2.4 Inventions and Patents](#)



Importance of Reporting

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➤ Reporting Subject Inventions

- Identifies 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 and the public are informed of through annual and final reports and the USPTO.
- 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 are 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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Importance of Reporting (continued)

- ▶ Required by Bayh-Dole and the terms and conditions of NIH's awards. (Grants Policy Statement 8.2.4)
- ▶ If inventions and patents are not reported as required, NIH can:
 - ▶ Take one or more enforcement actions as set forth in the NIH Grants Policy Statement at 8.5.2 or stated in Bayh-Dole.
 - ▶ Withhold further awards to the investigator/inventor or the funding recipient.
 - ▶ Suspend or terminate an award or future awards.
 - ▶ Require the transfer of ownership of the invention and patents to NIH. (BD 37 CFR 401.14 (d)(1))

What Needs to Be Reported to NIH using iEdison?

- Subject Invention Disclosure Information:
- Patent application and issued patent information with the Government Support Clause;
- Confirmatory License;
- Annual Utilization Reports; and
- Keeping updated institutional contact for iEdison.

ALL REPORTING REQUIREMENTS WILL BE DISCUSSED THIS AFTERNOON



Research Performance Progress Report (RPPR)

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- Inventions are listed in Section C “Products” of the annual RPPR.
- All inventions are reported in iEdison.
- **Due Dates of RPPR:**
 - SNAP Awards: due 45 days before start date of next budget period.
 - Non-SNAP Awards: due 60 days before start date of next budget period.
 - Multi-year: due on or before the anniversary date.



HHS 568 Report

- **HHS 568: Final Invention Statement and Certification for Grant or Award.**
- **Reported by grant at the time of grant closeout.**
- **Due: 120 days following the end of the project period.**



NIH Verification of FIS

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- ▶ **Ensure the grant number is complete and accurate**, NIH searches iEdison for disclosed inventions using the Award Number.
- ▶ **For inventions that are generated as a result of the Award search**, NIH determines if the title, grant number and Investigators match what has been reported in iEdison (can be accepted) what is listed on the HHS-568.
- ▶ **For Inventions that are NOT shown on either the HHS-568 or in iEdison**, NIH communicates the findings to the Awardee Institution's invention reporting office with a 30 day reminder.
- ▶ **Failure to report inventions** may result in the risk of losing title to the invention or other actions.



Bayh-Dole Act: Invention Definitions

Invention: “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.).”

35 U.S.C. § 201(d)

Subject Invention: “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) of the Plant Variety Protection Act (7 U.S.C. 2401(d))) must also occur during the period of contract performance.”

35 U.S.C. § 201(e)



What Must Be Reported to NIH using iEdison?

- **Subject Inventions** must be reported to NIH using iEdison within 60 days of disclosure to a technology transfer office or sponsored program office.
- **What is disclosed to NIH?** – Subject Inventions - Any invention conceived or first actually reduced to practice in the performance of the NIH-funded research.
- **Exceptions:**
 - Inventions made with exclusively with scholarship, fellowship, or training funding awards that are primarily for educational purposes should not be reported.
 - Examples of NIH funding awards primarily for educational purposes: “F”, Some “G”, and some “T” awards.



Changes in Bayh-Dole

New For 2018

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► Explanatory Notes:

- Enter the Federal Award Date for every NIH award that funded the invention. The Federal Award Date can be found on the Notice of Award for each funding agreement.
- These dates are now necessary so that the federal awardee and the NIH can determine whether a first filed provisional patent application or first filed international application filed under the Patent Cooperation Treaty (PCT) must now be reported in iEdison as an initial patent application per the new Bayh-Dole regulations.



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Changes in Bayh-Dole

New For 2018

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- ▶ **Government assignment to contractor of rights in invention of government employee - New §401.10:**
 - ▶ Applies when a Federal employee is a co-inventor of any invention made under a funding agreement.
 - ▶ If that Federal employee's employing Federal agency transfers or reassigns to the contractor the right it has acquired in the subject invention from its employee, the assignment will be made subject to the patent rights clause of the contractor's funding agreement.
 - ▶ The employing Federal agency, in consultation with the contractor, may submit an initial patent application, provided that the contractor retains the right to elect to retain title.

Changes in Bayh-Dole

New For 2018

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- **Government assignment to contractor of rights in invention of government employee - New §401.10 (cont'd):**
 - When a Federal employee is a co-inventor of a subject invention developed with contractor-employed co-inventors under a funding agreement from another agency:
 - The federal funding agency must notify the other federal agency of any invention report and whether the contractor elects to retain title.
 - Federal agencies employing such co-inventors may enter into an agreement with a contractor when the agency determines it is a suitable and necessary step to protect and administer rights on behalf of the Federal Government.
 - Federal agencies employing such co-inventors will retain all ownership rights to which they are otherwise entitled if the contractor elects to retain title to the subject invention.

Conditions When Government May Obtain Title to Subject Inventions

- ▶ The contractor will convey to the Federal agency, upon written request, title to any subject invention:



- ▶ If the contractor fails to disclose or elect title to the subject invention within the times specified in paragraph (c) of this clause, or elects not to retain title. **(Under old Bayh-Dole, agency may only request title within 60 days after learning of the failure of the contractor to disclose or elect within the specified times. Under 2018 Bayh-Dole the 60-day restriction is eliminated)** (37 CFR 401.13(d)(1))

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



- ▶ In any country in which the contractor decides not to continue the prosecution of any **non-provisional** patent application for, to pay a maintenance, annuity or renewal fee on, or to defend in a reexamination or opposition proceeding on, a patent on a subject invention. **(Under new Bayh-Dole “non-provisional” added.)** (37 CFR 401.13(d)(2))

Contractor Action to Protect the Government's Interest



- For each subject invention, the contractor will, **no less than 60 days prior to the expiration of the statutory deadline, notify the Federal agency of any decision:** Not to continue the prosecution of a **non-provisional** patent application; not to pay a maintenance, annuity or renewal fee; not to defend in a reexamination or opposition proceeding on a patent, in any country; to request, be a party to, or take action in a trial proceeding before the Patent Trial and Appeals Board of the U.S. Patent and Trademark Office, including but not limited to post-grant review, review of a business method patent, *inter partes* review, and derivation proceeding; or to request, be a party to, or take action in a non-trial submission of art or information at the U.S. Patent and Trademark Office, including but not limited to a pre-issuance submission, a post-issuance submission, and supplemental examination. **(Under old Bayh-Dole contractor must notify the Federal agency no less than 30 days prior to the expiration of the statutory deadline).**

37 CFR §401.14(f)(3)

