

# NEW T2 REGULATIONS: WHAT YOU NEED TO KNOW

**Courtney Silverthorn, Ph.D.**

**National Institute of Standards and  
Technology**

**FLC Webinar – May 22, 2018**

- ▶ **Lab-to-Market Initiative (The Why)**
- ▶ **Timeline and Implementation (The When)**
- ▶ **Changes You Need to Know About (The What)**

OVERVIEW



# LAB-TO-MARKET INITIATIVE

(How did we get here?)



- ▶ Presidential Memorandum (2011); Cross-Agency Priority Goal (2014-2016 and 2018-present); National Science and Technology Subcommittee (2016-present)
- ▶ Original CAP goal had five subgoals:
  - ▶ Developing Human Capital
  - ▶ **Empowering Effective Collaborations**
  - ▶ Opening R&D Assets
  - ▶ Fueling Small Business Innovation
  - ▶ Evaluating Impact

# LAB-TO-MARKET INITIATIVE



▶ **Personnel Exchange (15 CFR 17)**

“Develop regulations under 15 USC 3712 to establish new and expanded mechanisms for the exchange of federal personnel to non-profit and for-profit entities.”

▶ **Bayh-Dole (37 CFR 401/404)**

“Update the Bayh-Dole Act to improve extramural funding partnerships, increase compliance by recipients of extramural funding, and improve agency access to data reported by extramural funding recipients.”

L2M REGULATORY ACTIONS



- ▶ America Invents Act timelines, definitions, and royalty payment requirements were in conflict with regulatory provisions in Bayh-Dole
- ▶ Certain scenarios (provisional applications, joint IP, CRADA background licenses) were not contemplated in original Bayh-Dole Act
- ▶ Codification of EO 12591 in regulation
- ▶ Turns out we numbered sections of the original regulation wrong...

## MAIN GOALS OF BAYH-DOLE UPDATE

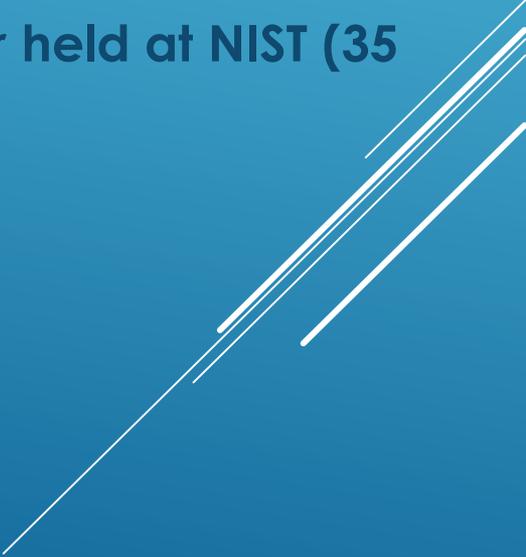
# TIMELINE AND IMPLEMENTATION

(Lots of work behind the scenes!)



- ▶ **November 15, 2015 – Bayh-Dole regulatory update identified as L2M priority**
- ▶ December 2015 – drafting process began at NIST with assistance from NIST Legal and Bayh-Dole Working Group
- ▶ July 2016 – cleared NIST/DOC and sent to OIRA for agency comments
- ▶ October 2016 – completed agency Legislative Referral Memorandum (LRM) process and cleared for publication in Federal Register
- ▶ November 7, 2016 – Notice of Proposed Rulemaking published in the Federal Register
- ▶ November 21, 2016 – Public meeting and webinar held at NIST (35 attendees)

**TIMELINE – YEAR 1**



- ▶ December 9, 2016 – Public comment period closed (17 comments received)
- ▶ March 2017 – NPRM revised at NIST with assistance from NIST Legal and Bayh-Dole Working Group
- ▶ August 2017 – comments addressed from DOC
- ▶ September 2017 – EO 13771 information added
- ▶ October 2017 – DOC Office of Policy and Strategic Planning Clearance
- ▶ November 2017 - completed agency Legislative Referral Memorandum (LRM) process
- ▶ March 2018 – final revisions completed
- ▶ **April 13, 2018 – Final Rule published in the Federal Register (effective date 30 days after publication)**

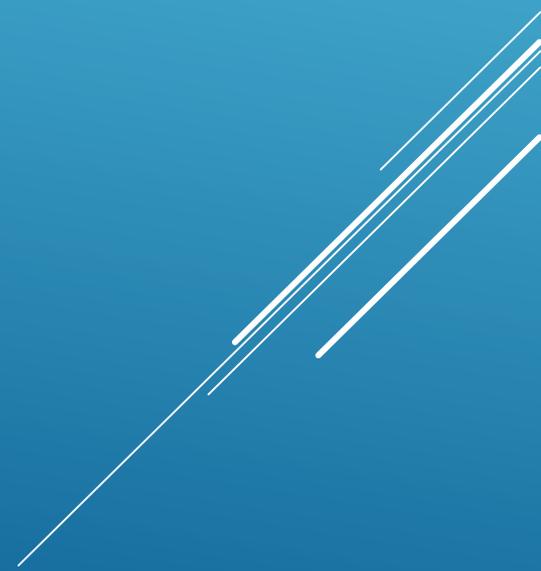


**881 DAYS!!**

## TIMELINE – YEAR 2 AND BEYOND

# CHANGES YOU NEED TO KNOW ABOUT

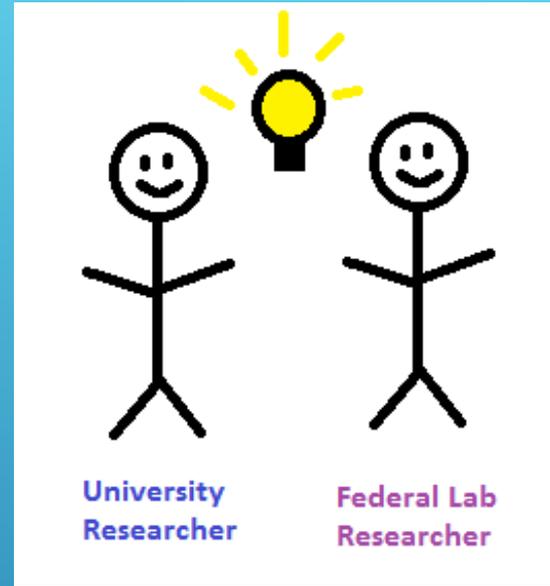
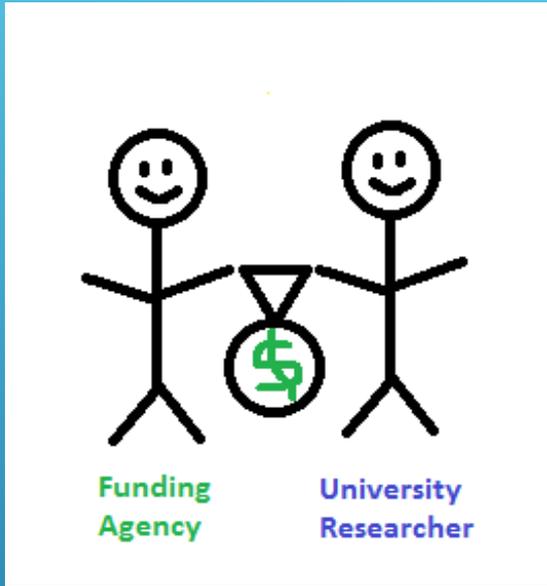
**(What's actually affecting federal T2 offices)**

A decorative graphic consisting of several parallel white lines of varying lengths, slanted diagonally from the bottom right towards the top right, set against a blue gradient background.

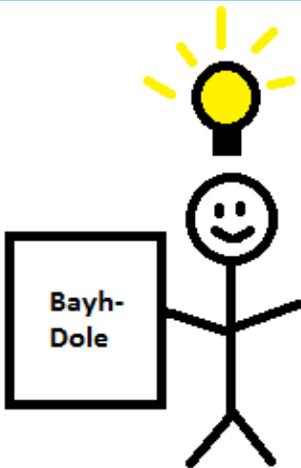
- ▶ “If the contract provides for services and the contractor is not a nonprofit organization and does not promote the commercialization and public availability of subject inventions pursuant to 35 U.S.C. 200.”

DETERMINATION OF EXCEPTIONAL  
CIRCUMSTANCES (401.3)

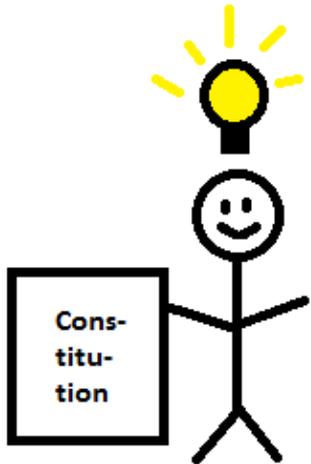
A decorative graphic consisting of several parallel white lines of varying lengths, slanted upwards from left to right, located in the bottom right corner of the slide.



# PRIORITY ORDER FOR CO-INVENTIONS (401.10)



University  
Researcher



Federal Lab  
Researcher



Funding  
Agency

## PRIORITY ORDER FOR CO-INVENTIONS (401.10)

- Contractor has first right to elect title (Bayh-Dole)
- If contractor waives, Inventing Agency has second right to elect title (Constitution)
- Funding Agency has third right if Inventing Agency waives

- ▶ **Creates priority order for ownership of inventions jointly created by an extramural funding recipient and a non-funding agency**
  - ▶ **Contractor**
  - ▶ **Inventing Agency**
  - ▶ **Funding Agency**
- ▶ **Requires Funding Agency to notify Inventing Agency if a contractor waives title to a joint invention**
- ▶ **Requires Funding Agency to provide administrative assistance (but not financial assistance) to the Inventing Agency in securing title to the invention**
- ▶ **Requires Inventing Agency to consult with Funding Agency on the management of the invention**

## **PRIORITY ORDER FOR CO- INVENTIONS (401.10)**

- ▶ Includes provisional applications (as well as PCT applications and Plant Variety Protection certificates) in the definition of *initial patent application*
- ▶ Permits co-inventing agencies to file initial patent applications to protect subject inventions

INITIAL PATENT APPLICATIONS  
(401.2, 401.10, 401.14)

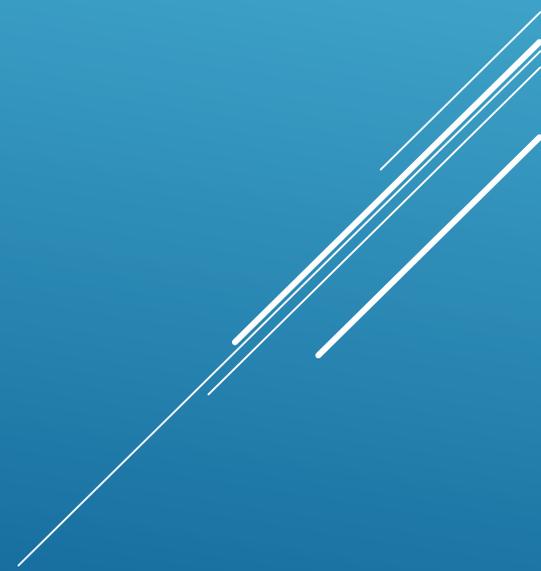


- ▶ “Notice of a prospective license, identifying the invention and the prospective licensee, has been published in the Federal Register or other appropriate manner,”

## NOTIFICATION OF EXCLUSIVE LICENSES (404.7)

- ▶ “An executed CRADA which provides for the use for research and development purposes by the CRADA collaborator under that CRADA of a Federally-owned invention in the Federal laboratory's custody...and which addresses the [required information]...may be treated by the Federal laboratory as an application for a license.”

## CRADA BACKGROUND LICENSES (404.8)

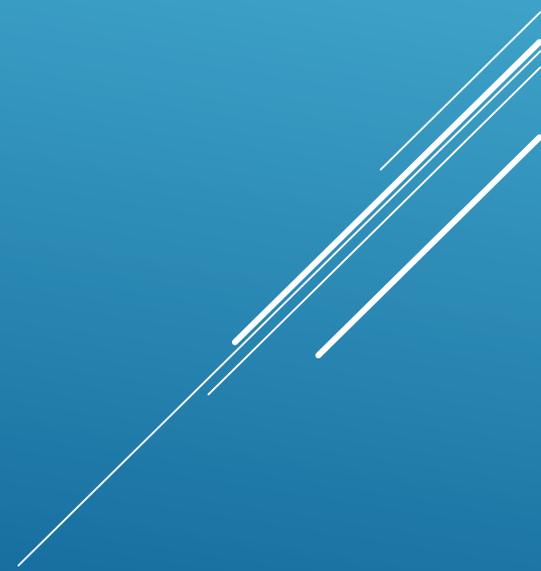


- ▶ Codifies EO 12591 to make Bayh-Dole applicable to all businesses regardless of size
- ▶ AIA updates in reporting timelines and definition of statutory period
- ▶ Requires contractors to have their employees assign rights (result of *Stanford v. Roche*)
- ▶ Requires contractors to file nonprovisional applications within 10 months of provisional filing (can request waiver; automatically granted unless otherwise notified by agency)
- ▶ Requires contractors to notify agency 60 days before end of statutory period if decision is made not to continue patent prosecution
- ▶ No time limit for agency request to elect title as a result of contractor's failure to adhere to BD reporting requirements

## OTHER GENERAL CHANGES

- ▶ **New publication of the FLC Green Book!**
- ▶ **iEdison Rebuild (FY19)**
- ▶ **Return on Investment Initiative:**  
**<http://www.nist.gov/tpo/ROI>**

**NEXT STEPS**



## Bayh-Dole

- ▶ **Docket Information: “Rights to Federally Funded Inventions and Licensing of Government Owned Inventions”**
  - ▶ NPRM Federal Register Notice 81 FR 78090, published November 7, 2016
  - ▶ <https://www.regulations.gov/docket?D=NIST-2016-0002>
  - ▶ Final Rule Federal Register Notice 83 FR 15954, published April 13, 2018
- ▶ **Final Rule: <https://www.gpo.gov/fdsys/pkg/FR-2018-04-13/pdf/2018-07532.pdf>**

# RESOURCES

## Personnel Exchanges

- ▶ Docket Information: “Technology Innovation – Personnel Exchanges”
  - ▶ NPRM Federal Register Notice 81 FR 41468, published June 27, 2016
  - ▶ <https://www.regulations.gov/document?D=NIST-2016-0001-0001>
  - ▶ Final Rule Federal Register Notice 81 FR 73024, published October 24, 2016
- ▶ Final Rule: <https://www.law.cornell.edu/cfr/text/15/part-17>

## RESOURCES

**Courtney Silverthorn, Ph.D.**

**Deputy Director, Technology Partnerships Office**

**National Institute of Standards and Technology**

**301-975-4189**

**[courtney.silverthorn@nist.gov](mailto:courtney.silverthorn@nist.gov)**

**CONTACT**

A series of several parallel white lines of varying lengths and positions, slanted diagonally from the bottom right towards the top right, set against the blue background.