

Inventions, Data Sharing, Reports to NIH, and other Intellectual Property Considerations

Presented By:

M. Hammersla, J.D., Director and Scott A. Cooper, J.D., Policy Officer

Office of Extramural Research

Office of Policy for Extramural Grants Administration (OPERA), OER

Division of Extramural Inventions & Technology Resources (DEITR),

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New Orleans May 5, 2017**



National Institutes of Health
Turning Discovery Into Health

Objectives

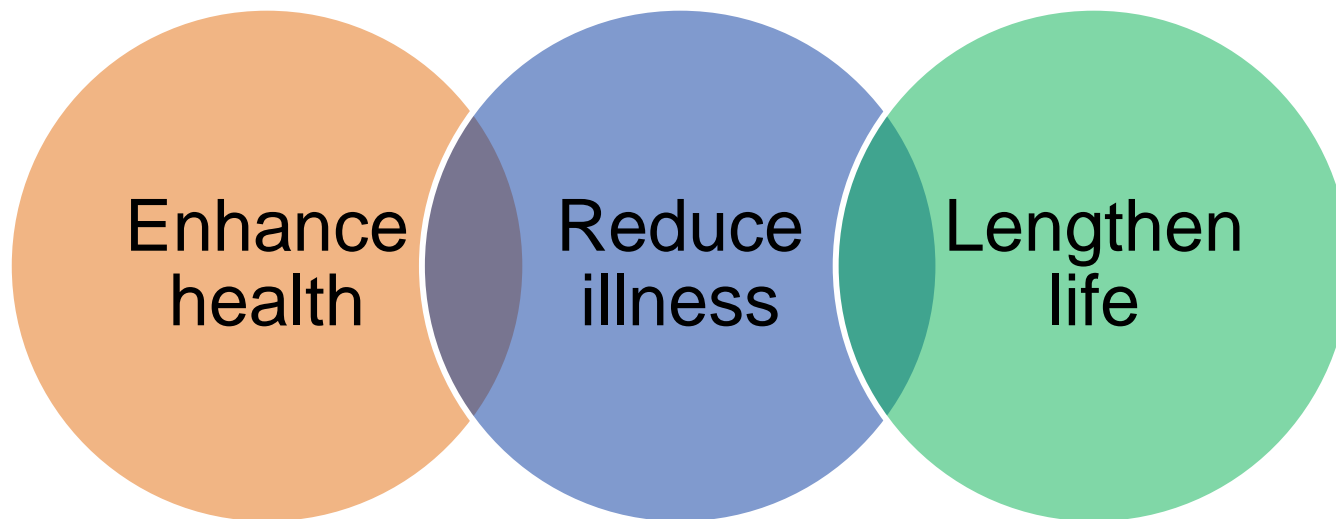
- **Learn where to get information to be able to appropriately manage data, inventions, publications, and other resources developed with NIH funding.**
- **Understand why and how to safeguard intellectual property rights to discoveries and inventions made with NIH funds.**
- **Understand NIH Licensing Principles.**
- **Learn grantees' rights and obligations in inventions made with NIH funding.**
- **Learn when and how to report inventions to NIH.**
- **Learn the invention and patent compliance considerations.**
- **Learn how to work towards sharing NIH-funded data and other research resources to advance research for benefits to the public and public health.**
- **Understand the balance between protecting of inventions and data sharing.**
- **Discussion of your questions and examples.....**

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

NIH Mission

To seek fundamental knowledge about the nature and behavior of living systems and the application of that knowledge to:



Intellectual Property

- **What is Technology Transfer?**
- **What is Intellectual Property?**
- **The why and how of protecting Intellectual Property**
- **What is an Invention?**
- **Patents & Copyrights Generally**
- **The Bayh-Dole Act: Government and Recipient Rights & Responsibilities**
- **Licensing Principles**
- **Data Sharing**
- **Special Considerations**

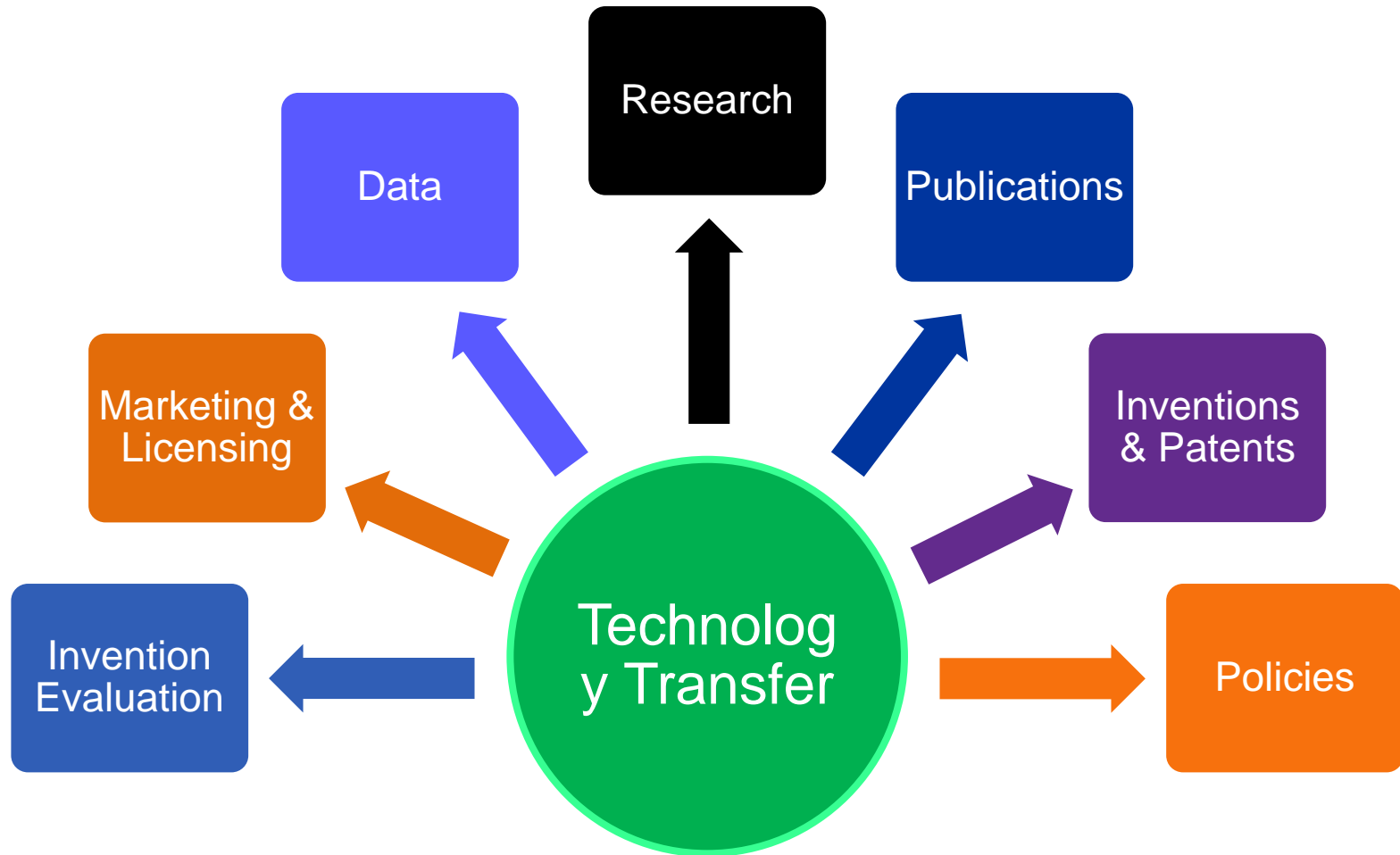
Technology Transfer

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 *

Technology Transfer

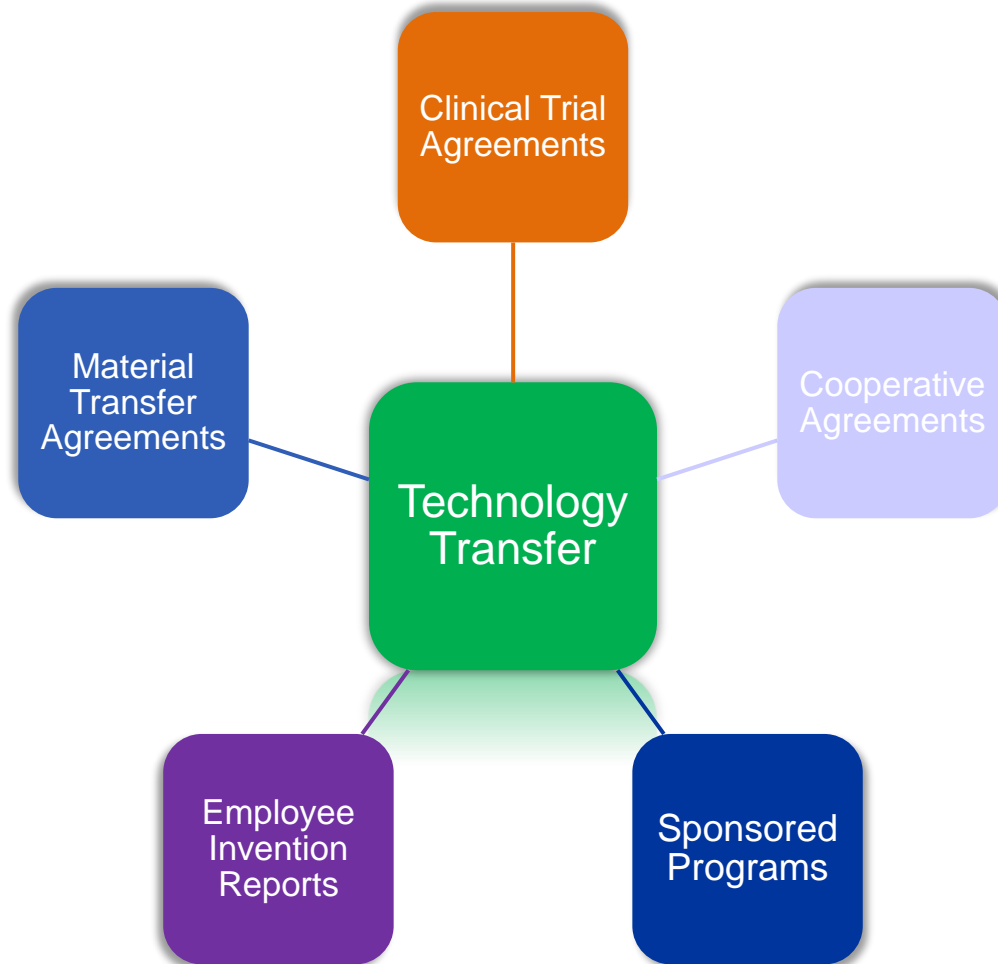


Technology Transfer Goals

- Utilize IP appropriately as incentive for commercial development of technologies
- Attract new R&D resources
- Obtain return on public investment
- Stimulate economic development
- Benefit the public health
- Financial return to owner and inventors
- Can have academic rewards/promotions/tenure



Examples of Technology Transfer Agreements



What is Intellectual Property?

- **Intellectual Property =**
 - **Creations of the mind.**
 - **Protected by laws:**
 - **Patent, trademark, unfair competition, copyright, trade secret, the right of publicity, and plant variety protection**
 - **IP system aims to foster an environment in which creativity and innovation are created, supported, developed, and protected, all to benefit the public.**
 - **Enables creator(s) to earn recognition or financial benefit from what they invent or create.**

Patents & Copyrights - What They Protect?

- **Patents: protect inventions = a discovery or findings.**
 - **Invention must be:**
 - *Novel* – new – not known before; not a product of nature;
 - *Useful* – has utility, specific, and credible; and
 - *Non-obvious* – was not obvious to a person having ordinary skill in the area of the invention.
 - **Types of patents: utility, design, plants.**
 - **See the U.S. Patent and Trademark Office website for more information:**
<http://www.uspto.gov>

Patents and Copyrights

- **Copyrights – protect original works of authorship -- including literary, dramatic, musical, artistic, and certain other intellectual works (including software).**
 - **Must be fixed in a tangible form of expression – thoughts are not eligible for copyright protection.**
 - **See: <http://www.copyright.gov>**

Patents & Copyrights-Rights

- **Patent Protection:**

- The *right to exclude others* from making, using, offering for sale or selling the invention throughout the United States, or importing the invention into the United States and its territories and possessions.

- **Copyright Protection:**

- The *right to (and permit others to):* reproduce, prepare derivative works, distribute, and to perform and display the work publicly, including performing the work by a digital audio transmission.

Patents & Copyrights-Terms

- **Patents – 20 years from earliest filing claimed**
 - Terms may be extended for certain pharmaceuticals and for certain circumstances as provided by law.
- **Copyrights – the life of the (last) author plus 70 years (for Post-1977 creations)**
 - For Works-Made-For-Hire or Anonymous Works, the shorter of 95 years from publication or 120 years from creation.
 - For Pre-1978 creations, up to 95 years.

Patents: What is Patentable?

- **Can be anything new and useful:**
 - **Processes (process, act or method, and primarily includes industrial or technical processes);**
 - **Machines;**
 - **Articles that are manufactured;**
 - **Compositions of matter; or**
 - **Any new and useful improvement of the above (derivative).**

What is copyrightable? And When?

- **Copyright = putting in a tangible form.**
- **Protection occurs as soon as it is in a tangible form.**
- **Tangible form:**
 - **Writing;**
 - **Software – on a disc;**
 - **Design;**
 - **Picture – on canvas; and**
 - **Etc.**
- **No copyright: Speech, spontaneous music (vs written music).**

Patents-Utility Application

- **Not an idea or suggestion.**
- **Extensive data is not required but good to have.**
- **A patent application with descriptive claims describing the metes and bounds of the invention to be protected.**
- **Usually diagrams are included.**
- **Additional supporting data can be submitted later during patent prosecution.**
- **Usual length of patent prosecution = 3 years; \$40-50K+**

Patents: Losing Rights through Public Disclosure

- **Most international rights can be lost by making an enabling public disclosure before filing a patent application (limited exceptions may include the U.S. (1), Canada (1), Australia (0.5;1), Japan (0.5)).**
- **U.S. rights can be lost by making an enabling public disclosure more than one (1) year before filing a patent application.**
- **Risk of losing all rights by failing to timely disclose an invention to the Government (See, the Bayh-Dole Act).**

Patents: Protecting Rights from Public Disclosure

- **File enabled patent application prior to disclosing, e.g., disclosing through posters, presentations, publications, talks, etc.**
- **Limit discussions/exchanges with parties who are under confidentiality obligations.**
 - **Use confidential disclosure agreements (CDAs) whenever possible for discussions or other exchanges with potential investors, collaborators, licensees, et al.**

Patents: Protecting Rights from Public Disclosure

- **Grant application abstracts or summaries should be written as if they will immediately be made publicly available.**
- **Take appropriate steps to protect confidential information, e.g., marking it as “confidential,” withholding it if appropriate, submitting a substitute, or simply filing a patent application as soon as possible.**

Freedom Of Information Act (FOIA) - Safeguarding Grant Application Information & Inventions

- **Take the appropriate precautions (markings, etc.)**
 - **5 U.S.C. § 552(b)(4) provides an exemption for “trade secrets and commercial or financial information obtained from a person and privileged or confidential.”**

Bayh-Dole Act

- **The Bayh-Dole Act (1980) – few changes since 1980**
 - **Codified at 35 U.S.C. § 200**
 - **Implemented at 37 C.F.R. 401**
- **Applies to most federal funding agreements.**
- **Identifies rights and responsibilities of grantee/contactor and government for inventions and discoveries made in whole or in part with federal funding.**

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.

Bayh-Dole Act: Invention

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)

Bayh-Dole Act: Subject Invention

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)

Invention Reporting Requirements of NIH Grantees and Contractors

- 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**
- Final Invention Report ⇒ **at award close out**

Bayh Dole: Compliance Requirements

- **The Final Invention Statement and Certification (FIS).**
- **The Invention Disclosure:**
 - Needs to be complete in technical detail, include inventor names, date of disclosure, grant numbers
- **The Government Support Clause:**
 - Required in all patent applications/issued patents
 - 2 sentences that includes the grant numbers
- **The Confirmatory License:**
 - Grants to the U.S. Government its license to use the subject invention and resulting patents.
- **The Utilization Report**
 - Filed annually and provides summary information on the licensing and commercial development of a subject invention.

The Final Invention Statement and Certification

Original effective date of support through completion or termination
Complete Grant or Award Number

Form Approved Through 10/31/2018
OMB No. 0925-0002
DHHS Grant or Award No.

Department of Health and Human Services
Final Invention Statement and Certification
(For Grant or Award)

A. We hereby certify that, to the best of our knowledge and belief, all inventions are listed below which were conceived and/or first actually reduced to practice during the course of work under the above-referenced DHHS grant or award for the period

_____ through _____
original effective date *date of termination*

B. Inventions (Note: If no inventions have been made under the grant or award, insert the word **"NONE"** under

NAME OF INVENTOR	TITLE OF INVENTION	DATE REPORTED TO DHHS

(Use continuation sheet if necessary)

C. Signature - This block *must* be signed by an official authorized to sign on behalf of the institution.

<small>Title</small>		<small>Name and Mailing Address of Institution</small>
<small>Typed Name</small>		
<small>Signature</small>	<small>Date</small>	

NIH Process for the FIS

- **Final Invention Statement and Certification shall be executed and submitted** through commons within 120 days following the expiration or termination of a grant or cooperative agreement , coordinated with the Grantee OTT office;
- **Ensure the grant number is complete and accurate**, include leading zeroes, search iEdison for disclosed inventions under the grant or award;
- **Inventions that are generated**, determine if the title, grant number and Investigators match what was uploaded in iEdison;
- **Inventions that are NOT generated**, communicate the findings directly with the grantee institution's invention reporting office with a 30 day reminder that failure to report may result in the risk of losing title to the invention, or other actions will be taken as appropriate (reject);
- **Original effective date** of support through the date of completion or termination
- **If no inventions were involved**, insert the word "None" in the first block under item Title of Invention;
- **Each Statement requires the signature of an institution official authorized to sign on behalf of the institution.**

Bayh-Dole Act: Government Rights

- **Government Use License.**
- **Conditions When the Government May Obtain Title.**
- **March-In Rights (35 U.S.C. § 203):**
 - **Compare to Non-Federally Funded Patents under 28 USC § 1498; and**
 - **NIH decisions:**
https://era.nih.gov/iedison/iedison_faqs.cfm
- **Inventor, 3rd Party Waivers and U.S. Manufacturing Waivers.**
- **Subawardee's Bayh-Dole rights.**

Bayh-Dole Act: Government Use License

“For any invention in which the contractor elects rights, the Federal agency shall have a nonexclusive, nontransferrable, irrevocable, paid-up license to practice or have practiced for or on behalf of the United States any subject invention throughout the world.”

35 U.S.C. § 202 (c)(4)

Conditions When the Government May Obtain Title

- **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 those countries in which the *contractor* fails to file patent applications within the times specified;**
or
 - **In any country in which the *contractor* decides not to continue the prosecution of any application.**

37 C.F.R. 401.14(d)

Bayh-Dole Act: Subawardee Has Bayh-Dole Rights

“The subcontractor will retain all rights provided for the contractor in this clause, and the contractor will not, as part of the consideration for awarding the subcontract, obtain rights in the subcontractor's subject inventions.”

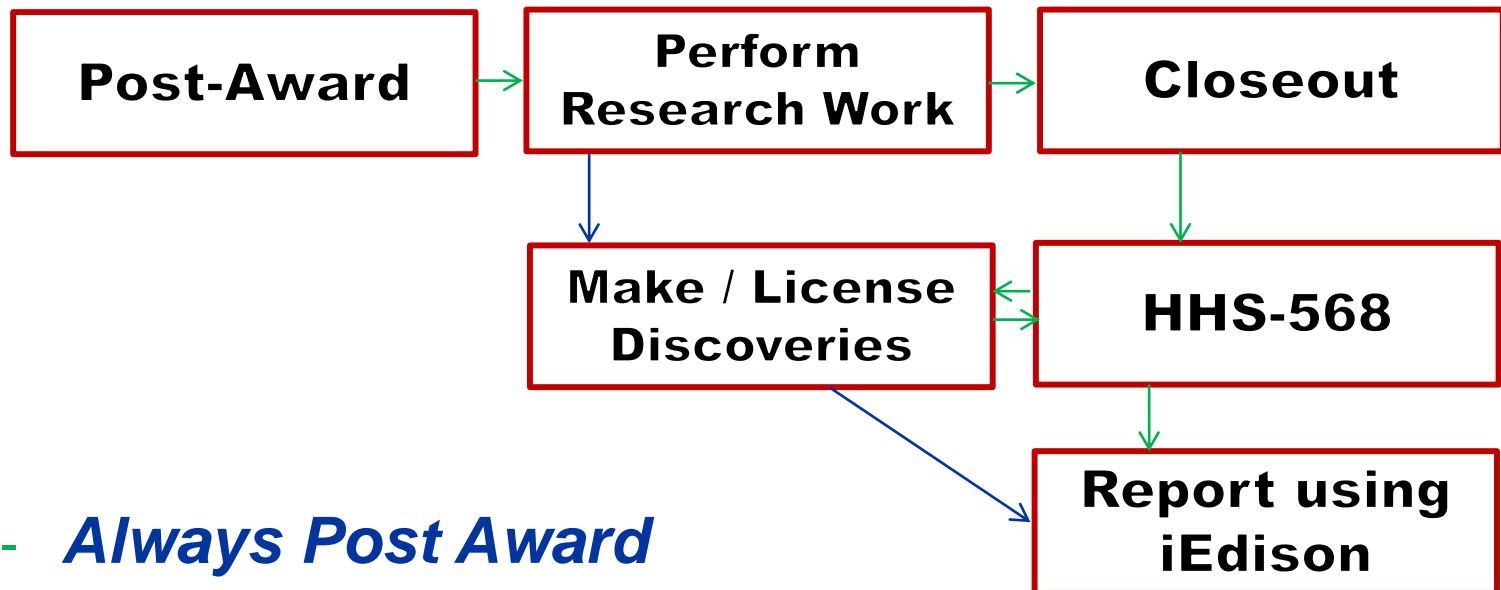
37 CFR § 401.14 (g)(1)

What is iEdison?

- **Electronic Database used by 25+ federal agencies to enable grantees/contractors to report their federally funded discoveries/inventions.**
- **Information submitted is confidential under statute.**
- **Information provided by grantees/contractors:**
 - **Technical information on inventions;**
 - **Identifies legal protection is timely and properly obtained;**
 - **Monitors regulatory compliance;**
 - **Reminder messages for required reports; and**
 - **NIH – annual commercialization reports.**

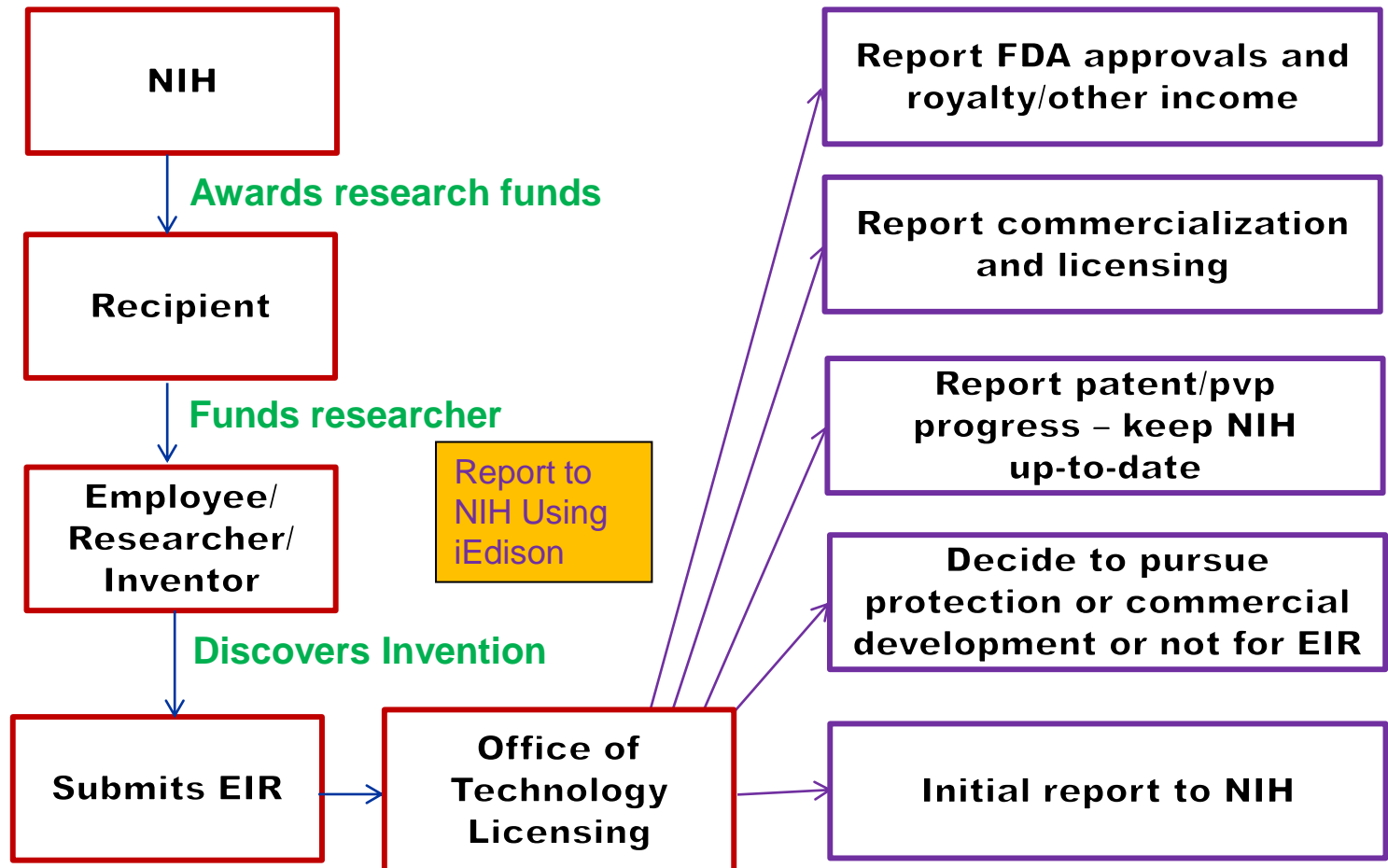
Where does iEdison fit in the Award Process?

At the End (but starts in the middle)



- *Always Post Award*
- Registrant has Award No.
- Direct or Indirect Party to Award or Assignee (usually Inventor) thereof

Recipient Process



Bayh-Dole Act: Four Types of Waivers

- 1. Inventor Waivers**
- 2. U.S. Manufacturing Waivers**
- 3. Third Party Waivers**
- 4. General Waivers or Waivers to the Federal Government**

NIH Waiver Process

The Big Picture

- You might have great idea or plan to:
 - Have the inventors take over prosecution of a patent;
 - Have a product that embodies an invention made overseas; or
 - Have another institution, a co-owner, take over prosecution of a patent
- All transfers of ownership of a subject invention to an inventor or a 3rd party requires NIH's **PRIOR APPROVAL.**
- All requests to permit substantial manufacturing of any product or service outside of the U.S. requires **PRIOR APPROVAL.**

Licensing Principles

- 
- Granting only the appropriate scope of rights
 - Permit research uses
 - Preference for non- or partial exclusivity
 - Specified fields of use
 - Enforceable milestones and benchmarks
 - Maximize development of products for the public health
 - Ensure appropriate return on public investment

Select Data and Copyright Issues

- **Grantees own the data and copyrights they develop with federal funds. (NIH Grants Policy Statement 8.2.1)**
- **Public Access Policy:**
 - **NIH Grants Policy Statement 8.2.2; and**
 - **Final peer reviewed manuscript, upon acceptance for publication needs to be published at:
<http://www.pubmedcentral.nih.gov>**
- **Sharing Research Resources:**
 - **NIH Grants Policy Statement 8.2.3; and**
 - **Requires sharing of unique research materials/biological materials (research tools).**

Select Data and Copyright Issues – continued

- **Data Sharing Policy:**
 - **NIH Grants Policy Statement: 8.2.3.1.**
 - **Requires data sharing plans for proposals of more than \$500,000.**
 - **Select NIH funding programs require data sharing plans. Need to review the funding opportunity announcement.**

Thank You

For any questions on extramural invention reporting, data and resource sharing, or other related extramural intellectual property policy issues:

Contact:

Ann M. Hammersla, J.D., Director

Scott A. Cooper, J.D., Policy Officer

Websites:

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

Email: Sharing@nih.gov; Edison@nih.gov; Inventions@nih.gov

iEdison and Intellectual Property FAQs and Resources:

https://era.nih.gov/iedison/iedison_faqs.cfm

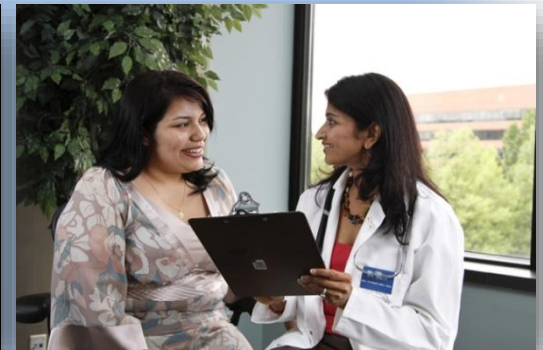
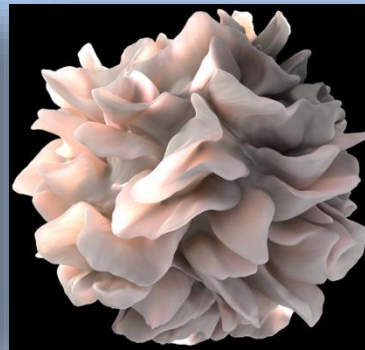
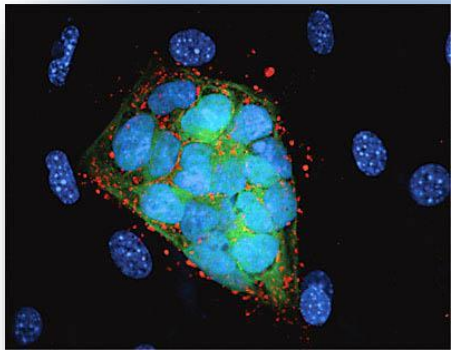
DEITR Telephone & iEdison HelpDesk: (301) 435-1986

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2017 NIH REGIONAL SEMINAR

Session Evaluations: <http://surveymonkey.com/s/nihsessions>

Overall Evaluations: <http://surveymonkey.com/s/nihoverall>



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