Inventions, Patents, and NIH Intellectual Property Policies

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Presenter

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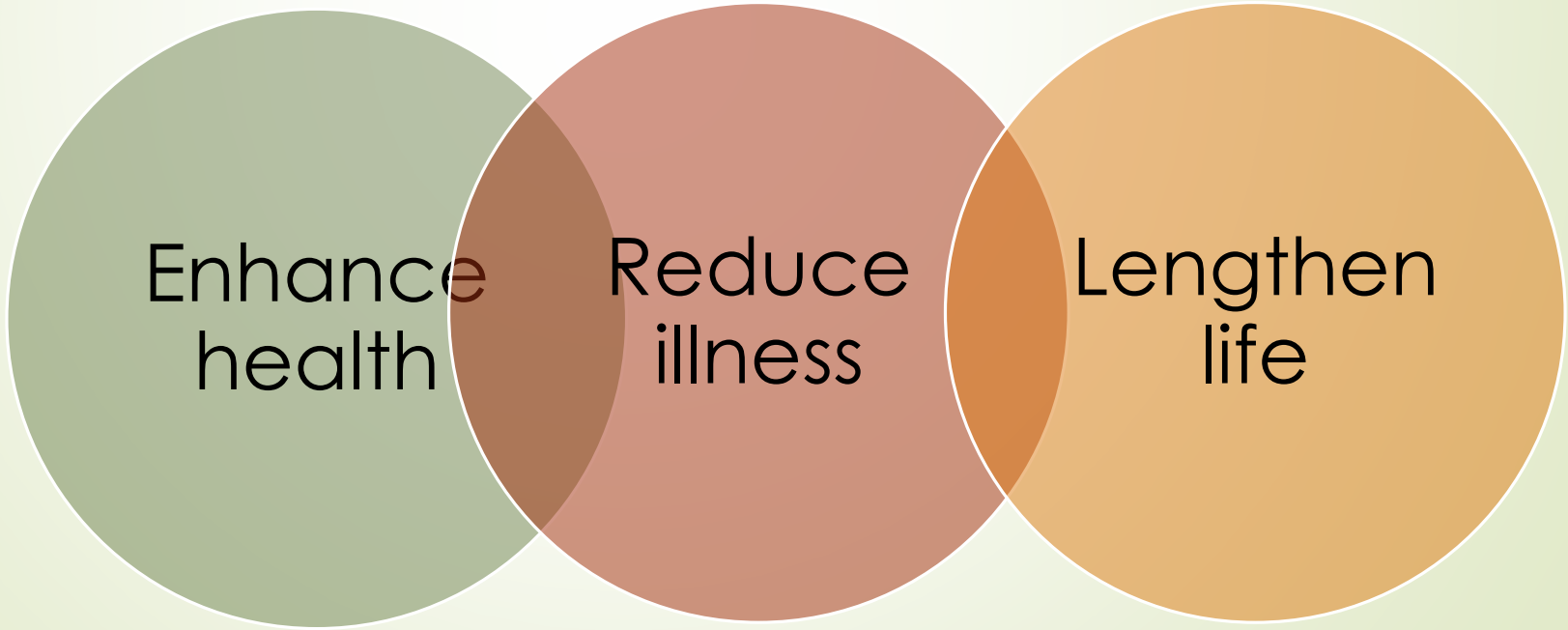
NIH Mission

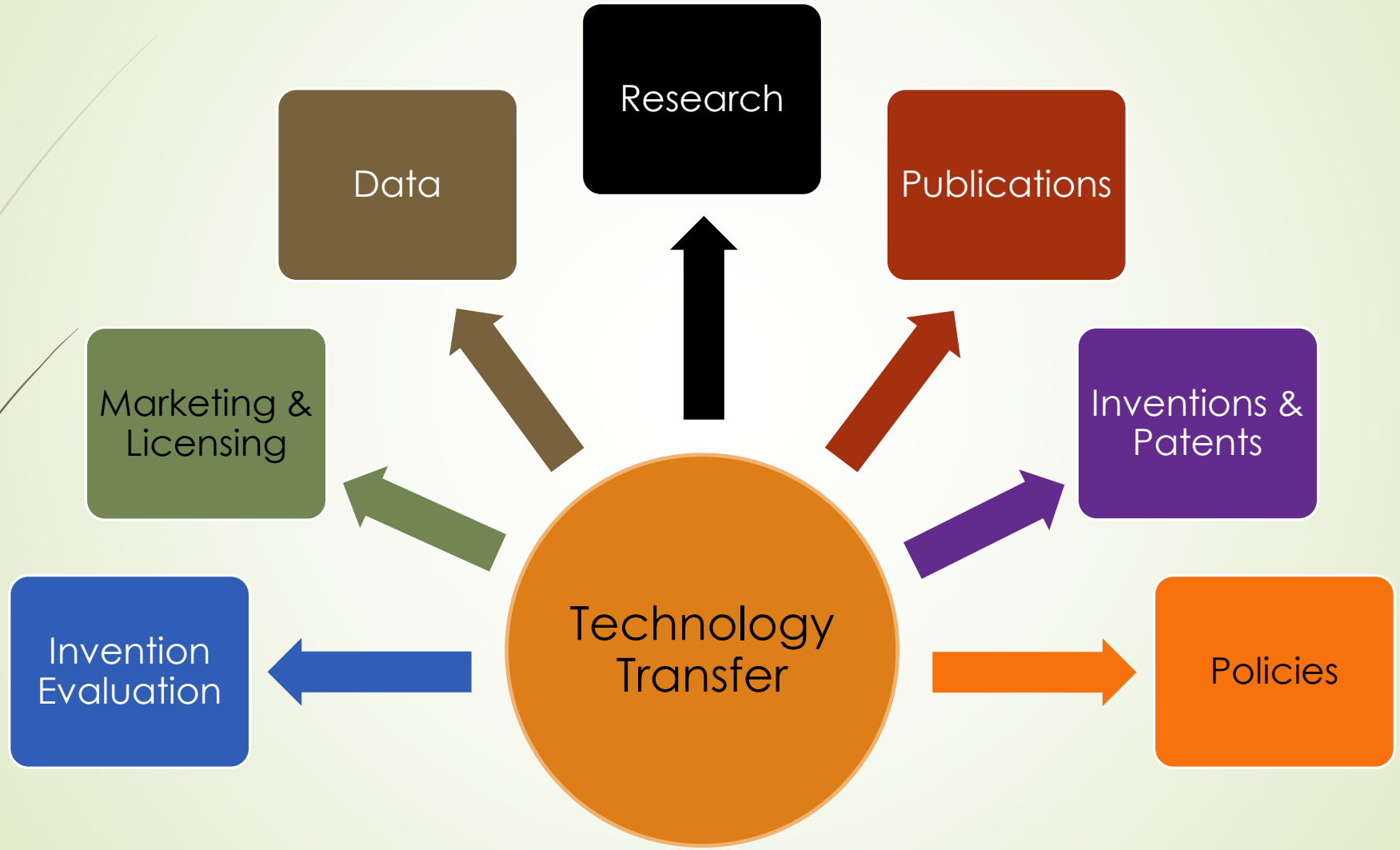
To seek fundamental knowledge about the nature and behavior of living systems and the application of that knowledge to:



Section 1

Intellectual Property, Inventions, and Patents

Technology Transfer



What is Intellectual Property?

- **Intellectual Property =**
  - Creations of the mind.
  - Protected by U.S and International laws:
    - Patent, trademark, unfair competition, copyright, trade secret, the right of publicity, and plant variety protection.
  - **Intellectual Property Systems/laws** aim to foster an environment in which creativity and innovation is created, supported, developed, protected, all with benefits to the public.
  - Enables creator(s) to earn recognition, commercialize product that benefits the public and/or financial benefit from what they invent or create.

Invention Is……..

- **Invention =**
  - Any invention or discovery that is or may be either patentable, plant variety protectable, or otherwise protectable under laws at 35 U.S.C. (Patents) or 7 U.S.C. 2321 et seq. (Plant Varieties)
  - New scientific or technical idea
  - Device, method, composition of material, or process

What is a Patent?

- Patent = the grant of a property right to the inventor:
- Issued by the United States Patent and Trademark Office
- Term of a U.S. patent – 20 years from the date the first application was filed in the U.S. and in some cases filed internationally.
  - **The term can be extended for certain circumstances: delay in the patent office of granting the patent; certain FDA considerations**
- U.S. patents are effective only within the United States, U.S. territories, and U.S. possessions.
- Once patented the patentee must enforce the patent, at their decision, without the USPTO's assistance.

Patents continued

- Types of U.S. Patent Applications:
  - Provisional – term is 1 year from the date of filing and is converted to a full – U.S. patent application (non-provisional) or an international patent application is filed.
  - Non-provisional: 3 Types:
    - Utility patents – any new and useful process, machine, article of manufacture, or composition of matter, or any new or useful improvement thereof.
    - Design Patents – new, original, and ornamental design for an article of manufacture
    - Plant patents – any distinct and new variety of plant
  - Continuations, Continuations In-Part, Divisionals

Patent Rights (continued)

- **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**.

Patents – What Do They Protect?

- Patents – protect inventions = a discovery or finding
- To be granted a patent and invention must be:
  - *Novel* – new – not known before; not a product of nature.
  - *Useful* – has utility, specific, and credible.
  - *Non-obvious* – was not obvious to a person having ordinary skill in the area of the invention.

What Cannot be Patented?

- Laws of nature – anything naturally occurring: genes, plants
  - **Can protect genetically modified products**
  - **Devices and products for practicing or using medical methods can be patentable but the methods themselves are not patentable e.g. surgery methods, etc.**
- Physical phenomena
- Abstract ideas
- Literary, dramatic, musical, and artistic works (these can be copyright protected)
- Inventions which are not useful or cannot work (such as perpetual motion machines)

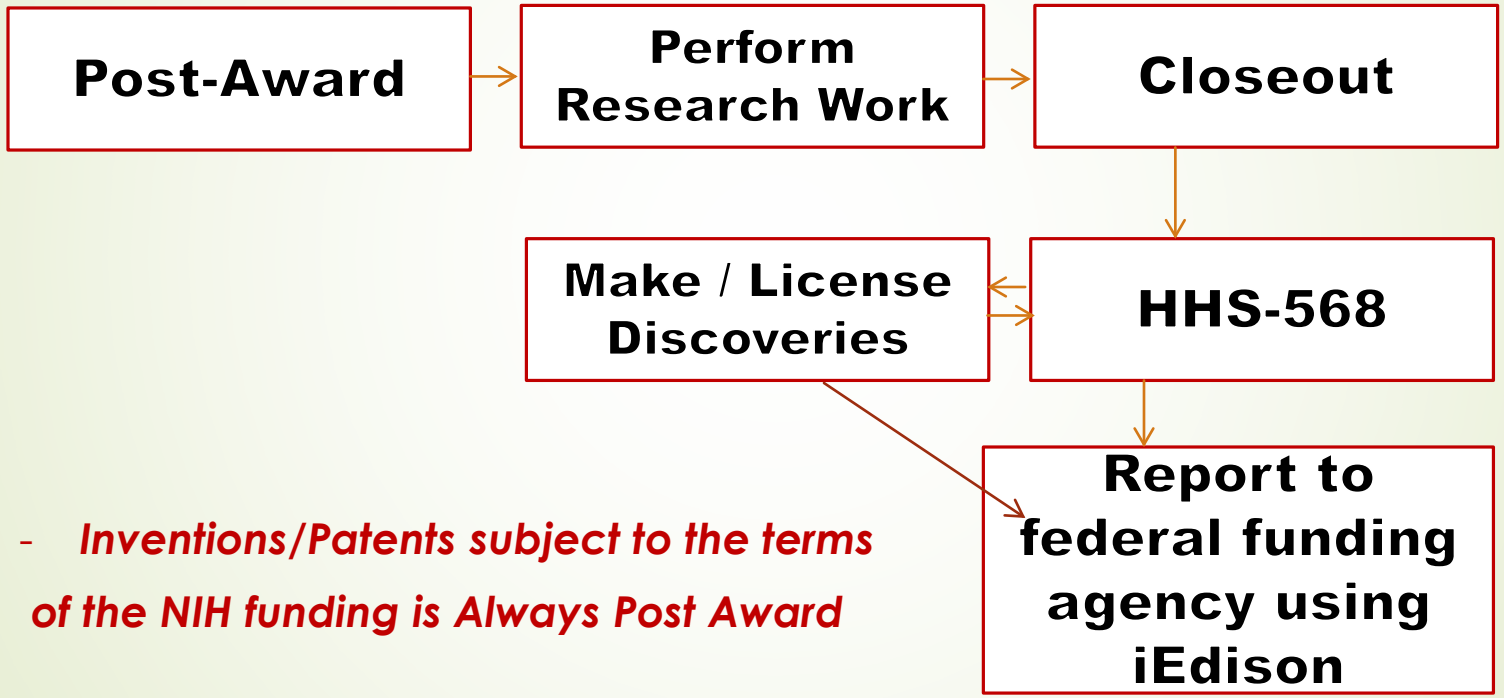
Supreme Court decisions on what can be patented

- Natural, unaltered DNA sequences cannot be patented, whether from virus, bacteria, plant, animal or human
- Genes and DNA sequences spliced together can be patented, for example to produce a vaccine or protein from cell cultures
- Natural proteins and chemicals from nature without modification cannot be patient, e.g. newly discovered peyote chemical that reduces anxiety
- A medication made of the newly discovered peyote chemical and stabilizers in a pill can be patented for use in treating a condition
- Natural associations cannot be patented, e.g. measuring level of protein X in blood to diagnose disease Y.
- Association must be tied to concrete steps that are not previously known or routine, e.g. measuring amount of medication in patients blood, and if not above level A, increase the dose until it reaches level A to have its full effect.

Patents: Protecting Rights prior to Public Disclosure

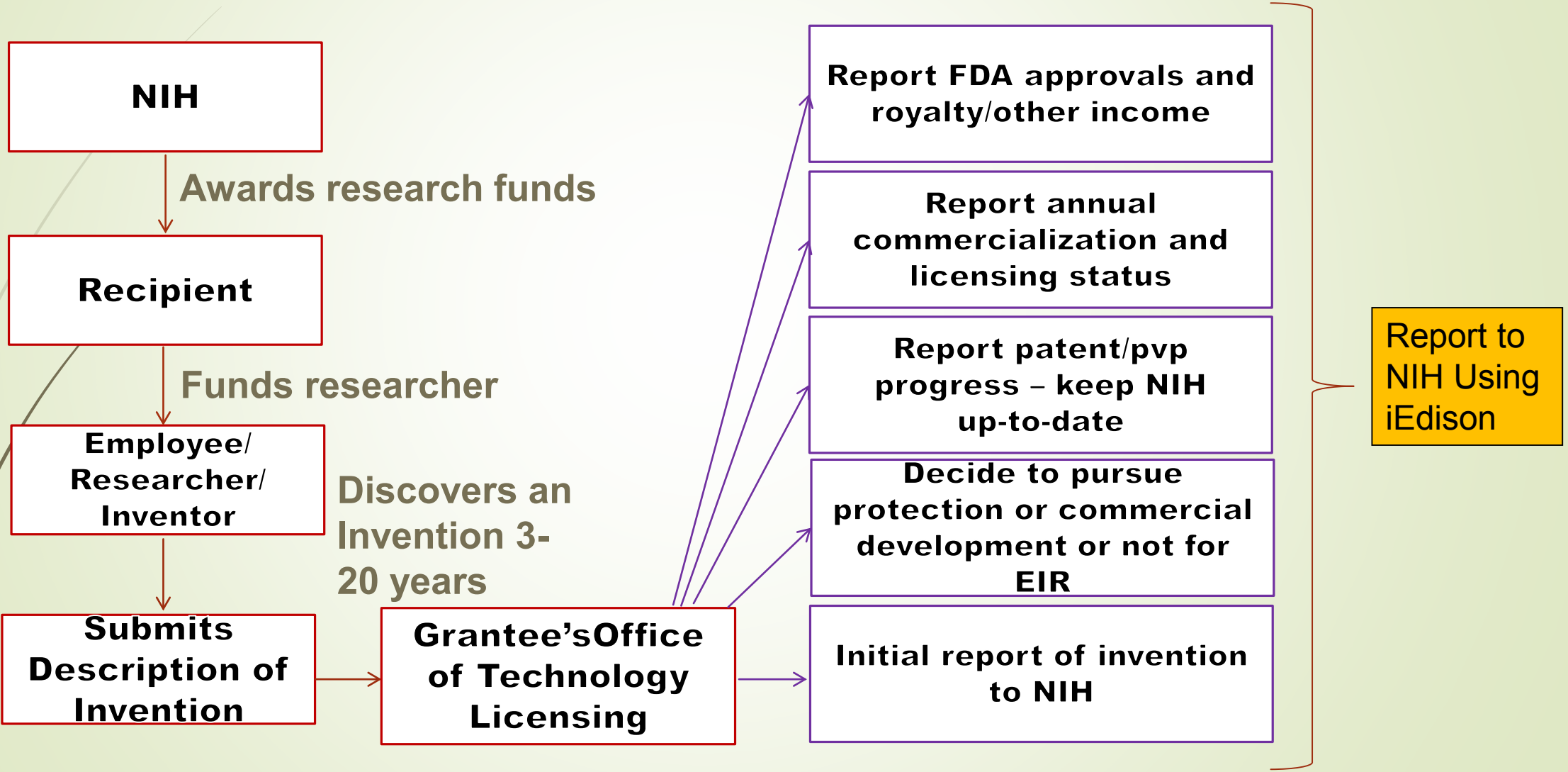
- File enabled patent application prior to disclosing, e.g., disclosing through posters, presentations, publications, talks, etc.
- Do not have substantive discussions/exchanges with third-parties unless they are under confidentiality obligations.
  - **Use confidential disclosure agreements (CDAs) whenever possible for discussions or other exchanges with potential investors, collaborators, licensees, et al.**

Inventions and Patents In the Award Process



- *Inventions/Patents subject to the terms of the NIH funding is Always Post Award*

Research and Invention Process



Section 2

Bayh-Dole Act

What is Bayh-Dole?

- Bayh-Dole Statute (35 U.S.C 200)
  - A term and condition of all federal research funding agreements since 1980
  - First substantive update to Bayh-Dole effective for NIH 10/1/2018
    - Modified some reporting requirements and granted greater rights to federal funding recipients

Bayh-Dole Act: Federal Funding Agreements

- Policies & Objectives (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 and provide to them a preference in licensing by nonprofit organizations.
  - 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.
  - Ensure that the Government obtains sufficient rights in federally supported inventions.

More on the Bayh-Dole Act

- Applies to most U.S, federal funding agreements.
  - **Except: Awards primarily for educational purposes: fellowships, scholarships, and most training awards**
- Sets forth recipient/contactor **rights and responsibilities & government's rights and obligations** for inventions and discoveries made in whole or in part with federal funding.
- Bayh-Dole refers to "**contractor**" as: any person, small business firm, large for-profit corporation, or any organization which is a party to a funding agreement.

Bayh-Dole Act: Recipient Rights and Responsibilities

- Recipient has rights and responsibilities in order to retain its right to elect and keep title:
  - **Filing invention disclosures, patents, annual utilization reports, etc. are done through iEdison.**
- One institutional representative must be approved by their institution and NIH for access to their institutional records
  - **Representative's name needs to be kept up-to-date in iEdison.**
- No access is provided to any other institution's records UNLESS given permission by the other institution.
- iEdison records are confidential and are protected under FOIA.

Bayh-Dole Act: Resources

NIH web resources:

- **Bayh-Dole Regulations:**
  http://grants.nih.gov/grants/bayh-dole.htm
- **Intellectual Property Policy:**
  http://grants.nih.gov/grants/intell-property.htm
- **Invention Reporting Timeline:**
  https://era.nih.gov/iedison/invention_timeline.cfm
- **iEdison & Intellectual Property FAQs and Resources:**
  https://era.nih.gov/iedison/iedison_faqs.cfm

COPYRIGHT ©

Copyright:

- Protects "***original works of authorship***" (books, written articles, software, music, plays, films, photos, art)
  - x NOT raw facts or data
  - x NOT functional aspects of artistic objects
  - x NOT slogans, titles, or monikers
- At the instant the author's work is "***fixed in any tangible medium of expression***"
  - Registration or marking (but each is a good idea)
  - Library of Congress https://www.copyright.gov/

Copyright: Ownership

- In general, the author owns the copyright
  - University policies or grant terms may require assignment of ownership to the institution.
  - Companies usually require assignment of copyright if made during the course and scope of employment
- Works by two or more people with the common intent of making a single final product are jointly owned
- As is the case of real property, but unlike patents, co-owners have a duty to account to each other for royalties collected
- US Government cannot assert © in its works

Section 4

Data and Other NIH Sharing Policies

Guiding Principle of the NIH Genomic Data Sharing Policy

The greatest public benefit will be realized if large-scale genomic data are made available in a timely manner to the largest possible number of investigators. For human data, data are made available under terms and conditions consistent with the informed consent provided by individual participants.

NIH Genomic Data Sharing Policy

- Purpose
  - Sets expectations and responsibilities for investigators and institutions to ensure broad, responsible, and timely sharing of genomic research data

Scope

  - Applies to all NIH-funded research generating ***large-scale human*** or ***non-human*** genomic data and secondary research using these data

  - Applies to all funding mechanisms (grants, contracts, intramural support) regardless of cost

- Effective January 25, 2015

Sharing, Use and Distribution of Research Results

- NIH Sharing Policy webpage at http://sharing.nih.gov
  - NIH policies and examples of sharing plans (e.g., Data, Model Organisms) help program and funding applicants review/match acceptable plans.

Thank You

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

Contact:

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