KU Center for Technology Commercialization

Supporting Innovation for All KU

From The Lab to the Market

The role of innovation and commercialization in research

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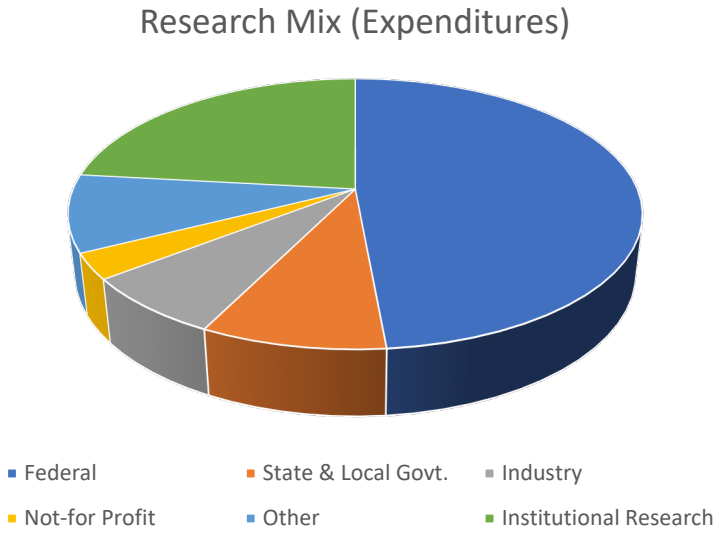
Overview

- Part 1
  - Federal Research Funding
  - The Bayh-Dole Act
- Part 2
  - Tech Transfer Basics
  - Common Questions
- Part 3
  - Tech Transfer at KU

Part 1 –
The Government's Role in Academic Innovation & Research

Federal Funding for Research

- Largest supporter of university research and discovery
- Typically accounts for about 60% of research funding at most universities
  - Has been decreasing over time
  - At KU ~ 50% of all expenditures are from Fed (2021)
- 1972: $1.8 billion (first year tracking)
- 2021: $50 billion in basic & applied research
  - Includes NIH, NSF, DOD, DOE, DOA, etc. (GAO)
  - Had been flat since; recent bumps due to CARES & CHIPS Acts
  - Some countries now spend a higher proportion of their annual budgets on academic research than US (JP, KR, DE, etc.)



A Bit of History

1900

Today

Pre-WWII – No coordinated federal research system

- University research mostly funded by universities and private donors

Post-WWII – lots of scientific advances, lots of gov't $$$ into research

- Creation of federal research system, but each agency has own policies
- Federal Government owned inventions, filed lots of patents
- Very few inventions licensed to companies, little direct public benefit

1970's – Economy ↓, US losing its competitive edge

1980's – Bayh-Dole Act

- Designed to promote transfer and application of government-sponsored research for benefit of inventors and the general public

2000's – Increased number of inventions reaching the public & increased impact

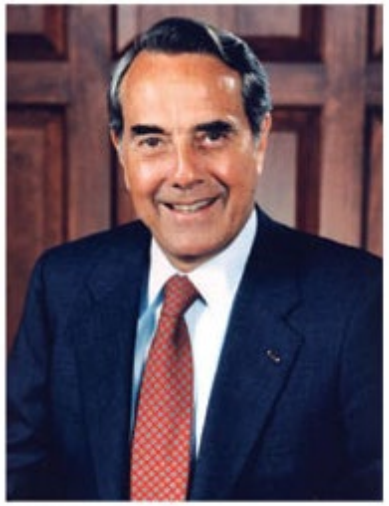
What was it like before BD?

- Every invention created using federal funding was owned by the U.S. Government and administered by the individual funding agency
- No uniform policy among federal agencies for the transfer of the invention to an industry partner for further development
  - Every agency had their own policies which were inconsistent
- U.S. Government controlled every patent
  - No exclusive licensing - little incentive for private industry to develop and invest in technology
  - Separated the inventors from their inventions
  - Inventions disclosed began to decline even though funding grew
  - By 1978 the U.S. Government owned over 28,000 patents but had licensed less than 4%

What is the Bayh-Dole Act?

- Bipartisan act passed by congress in 1980 and amended twice since
  - 37 CFR 401
- Created uniform federal intellectual property policy
- Enables universities, non-profits and small business to own inventions & discoveries made using federally sponsored research dollars
  - 37 CFR 401.14 - Standard Patent Rights Clauses
- Includes several requirement for universities in return for ability to own inventions & discoveries

Birch Bayh



Bob Dole

"Innovation's golden goose"

The Economist, 2002

After Bayh-Dole

- Steady increase in U.S. academic patenting, licensing, & associated revenues
  - $1.7 trillion in gross industrial output, 9,000 companies & 5.9 million jobs since 1996
- Public Benefit – new products (drugs, vaccines, devices, technologies, agricultural products)
- Industry relying more on academia for new ideas
- Other countries passed similar laws that promote the patenting of publicly funded research
  - Other Countries: IN, UK, DE, CN, JP, BR, etc.
- Some agencies are changing their approach - DOE

Bayh Dole Act is what allows KU to own new inventions coming from sponsored research

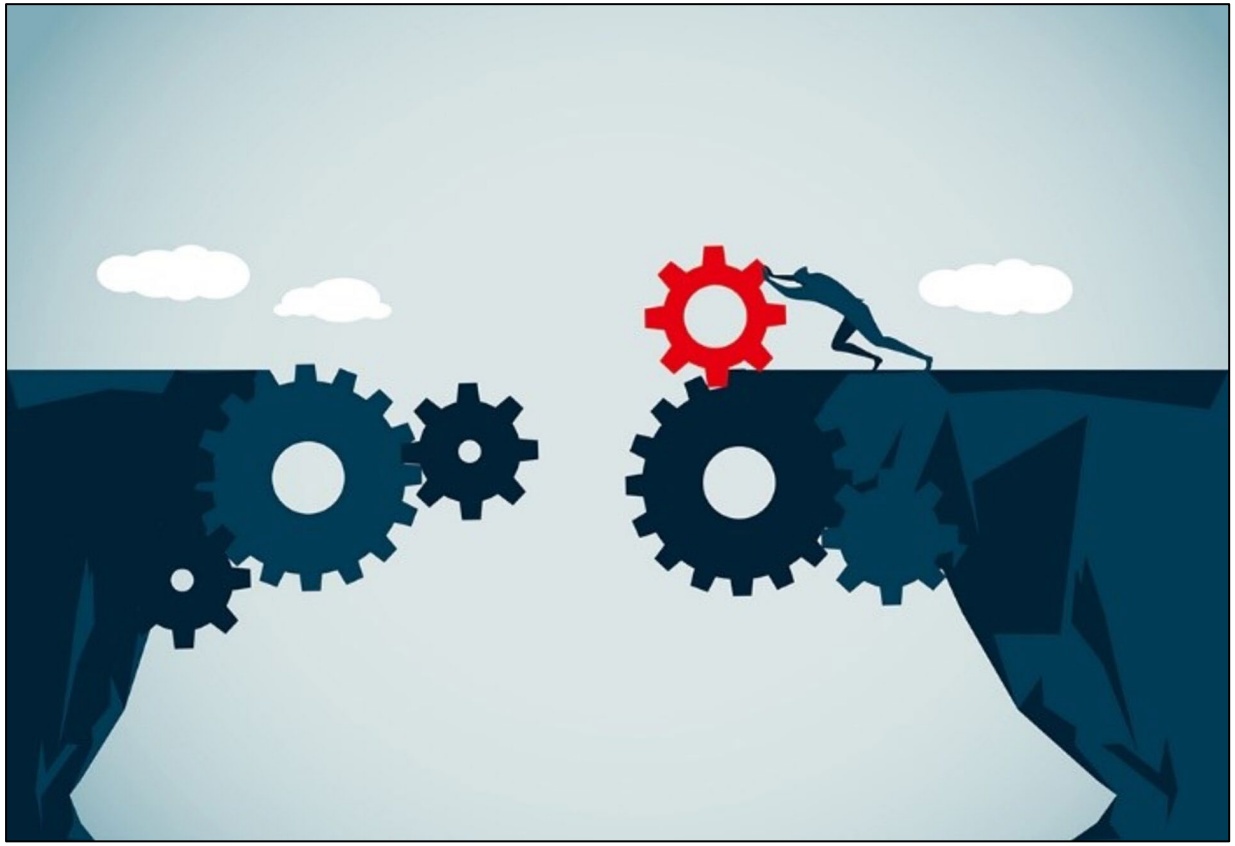
Bayh-Dole Requirements

- Applies to federal grants; find similar requirements in some contracts
- Universities own inventions – spurs creation of TTOs
- University required to –
    1. Within 2 months of disclosure must report invention to agency
    2. University must elect title within 2 years of disclosure to agency
    3. **Must confirm grant of non-exclusive license to U.S. Government**
    4. Allow for Federal March-in-rights (more on that soon!)
    5. Must be diligent in pursing patent rights and commercialization
    6. Annual updates required (utilization)
    7. **Royalties must be shared with inventors**
    8. **Must preference small and US businesses when licensing rights**
- Most University obligations are reported via iEdison
- If University doesn't take these steps it may lose rights

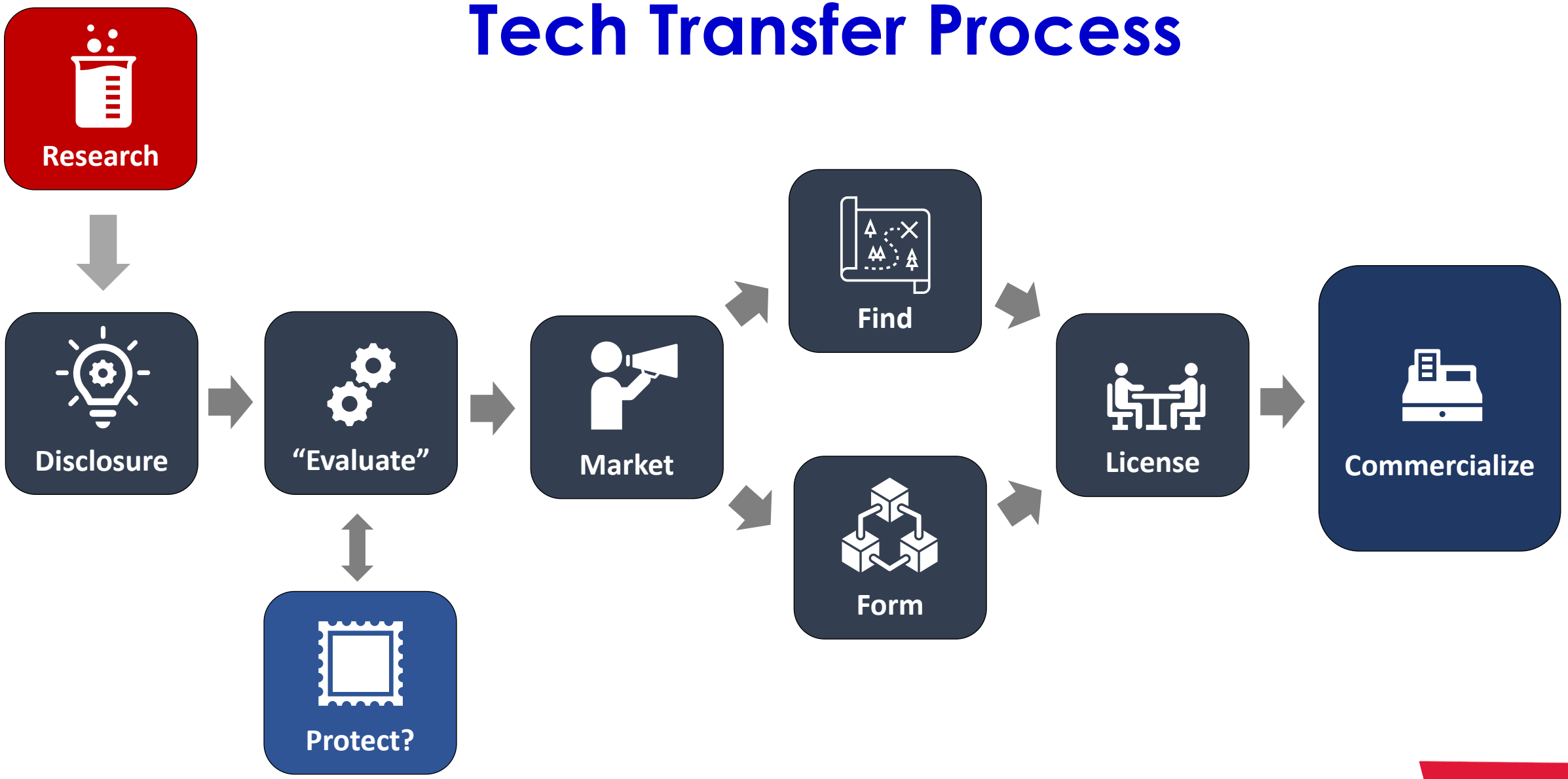
A Special Note on March-in-rights

- What are March-in-rights
  - Allows agency to ignore exclusivity of a patent & grant licenses to other "reasonable applicants"
- A Federal agency can exercise march-in rights if action is necessary
  - Because the grantee has not taken, or is not expected to take steps to achieve a practical application of the invention
  - To alleviate health or safety needs that have not been reasonably satisfied
  - To meet requirements for public use specified by Federal regulations that have not been reasonably satisfied
  - If the preference for U.S. industry has not been obtained
- To date no Federal Agency has exercised its march-in rights
  - 5 Petitions to NIH all denied
  - NIH has clarified repeatedly that “the extraordinary remedy of march-in is not an appropriate means of controlling prices of drugs broadly available”

Part 2 - The Basics



Tech Transfer Process



How does KU own IP arising from research?

KU IP Policy – applies to all full and part-time KU employees (faculty, staff, postdocs, etc.) including student employees

Copyrighted

- KU does not own the copyright to scholarly works or course materials (unless institution directed)
- KU does own copyright to software resulting from the use of KU resources or from sponsored work

Patentable

- KU does own rights in inventions created using KU resources or which result from sponsored work

Policy generally requires disclosure of potential IP to TTO (KUCTC)

A few notes on KU IP ownership

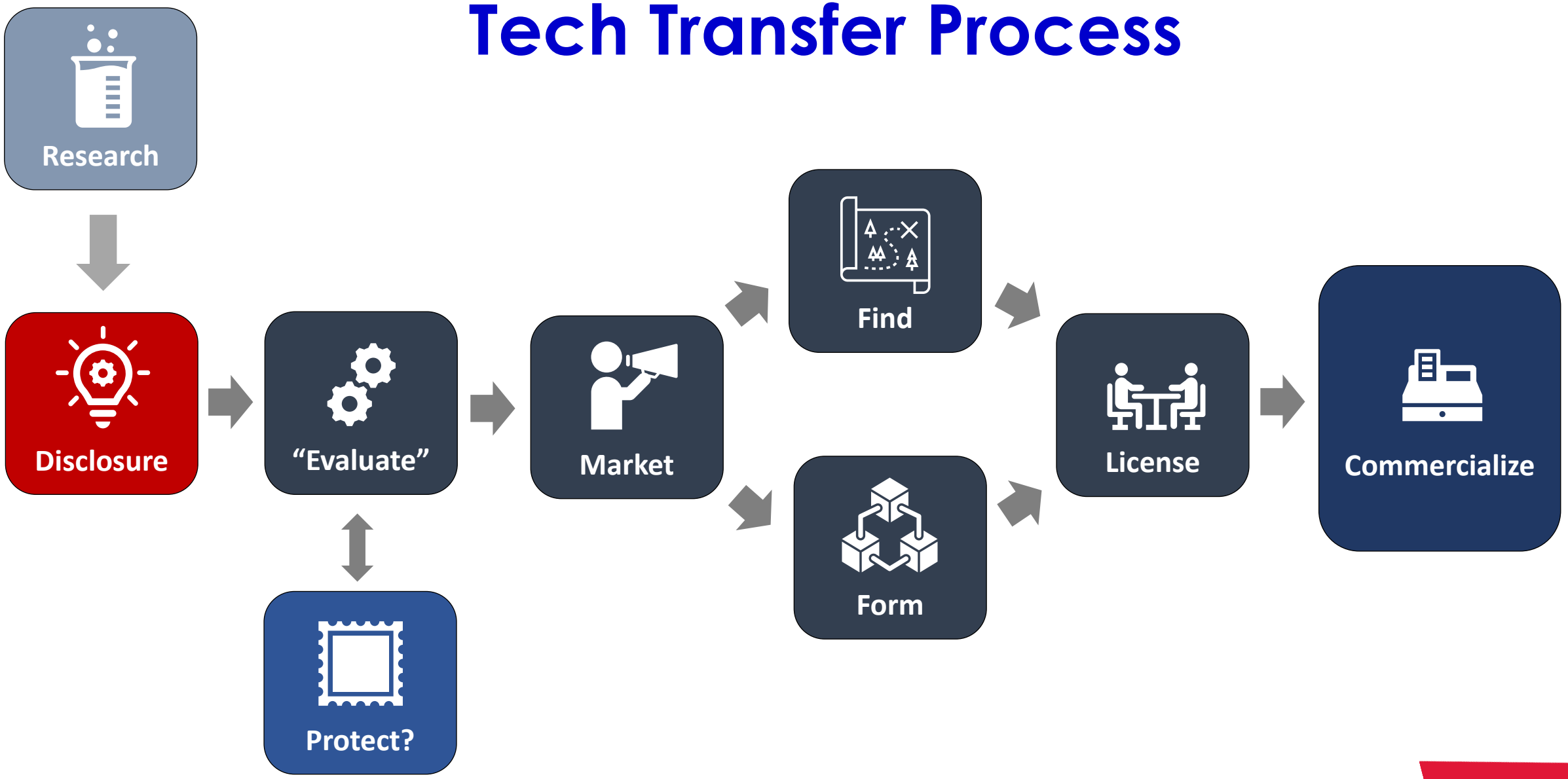
Undergraduate Students –

- Generally KU owns IP when it results from sponsored work, uses KU resources or is part of a collaboration with faculty
- Generally does not own if created/invented as part of course work

Sponsored Research – agreements with sponsors can include terms & conditions applying to IP

- Federal sponsors – generally Bayh Dole requirements
- Non-Federal – can grant licenses/ownership, share revenue, etc.
  - Industry-sponsored clinical trials, may grant sponsor ownership
  - Basic & applied research, less likely to grant ownership
  - BUT… Universities will not generally agree to restrict publication or use of results
- These terms can show up in MTAs, DUAs, etc. as well

Tech Transfer Process

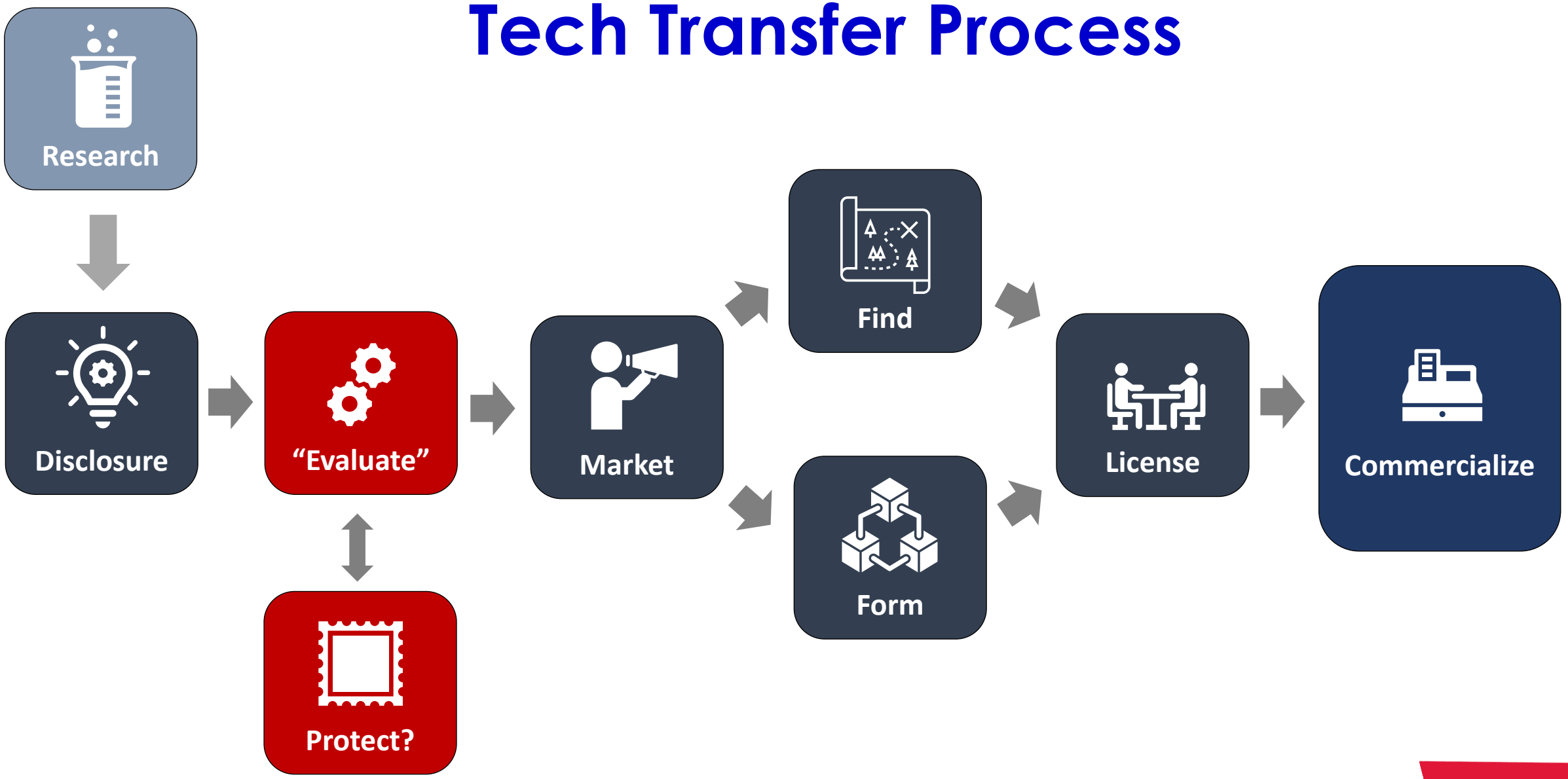


What can jeopardize obtaining patent rights for an invention?

Disclosing the invention to the public prior to filing a patent application

- This includes presentations at conferences & academic publications
- Also includes theses and dissertations since they are made "publicly available" even if no one reads them
  - What is considered "public" is very broad
- In the US rights may still be available if the patent application is filed within 12m of the date made public, ex-US most likely a no-go

Tech Transfer Process



Does “Intellectual Property” only mean patents?

Utility Patents – Protect inventions - process, method, machine, device, article of manufacture, or a composition of matter. With certain limitations, most thing "made by humans" may be patentable.

- Doesn’t give you the right to use invention; gives a right to exclude others.

Copyrights – Protect original works of authorship - writings, photographs, songs, etc. Copyright protects form of expression not subject matter or idea expressed.

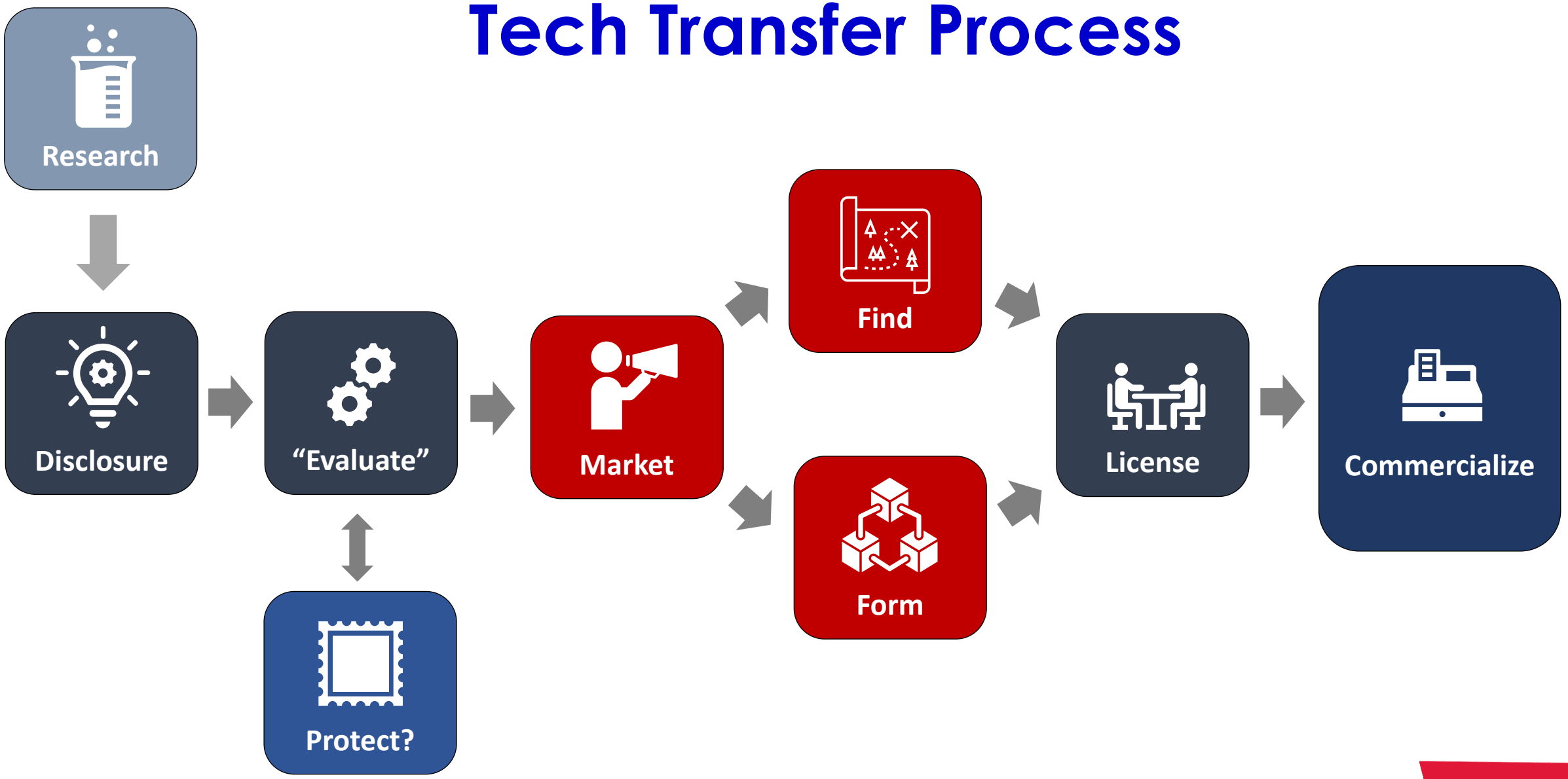
- Software (code) is subject to copyright protection like other written works.
- Databases can be subject to copyright in certain cases.

Trademarks - Provides protection for the name, word, symbol, color, etc. of a product or service that is used in commerce.

- Helps differentiate products or services from one another

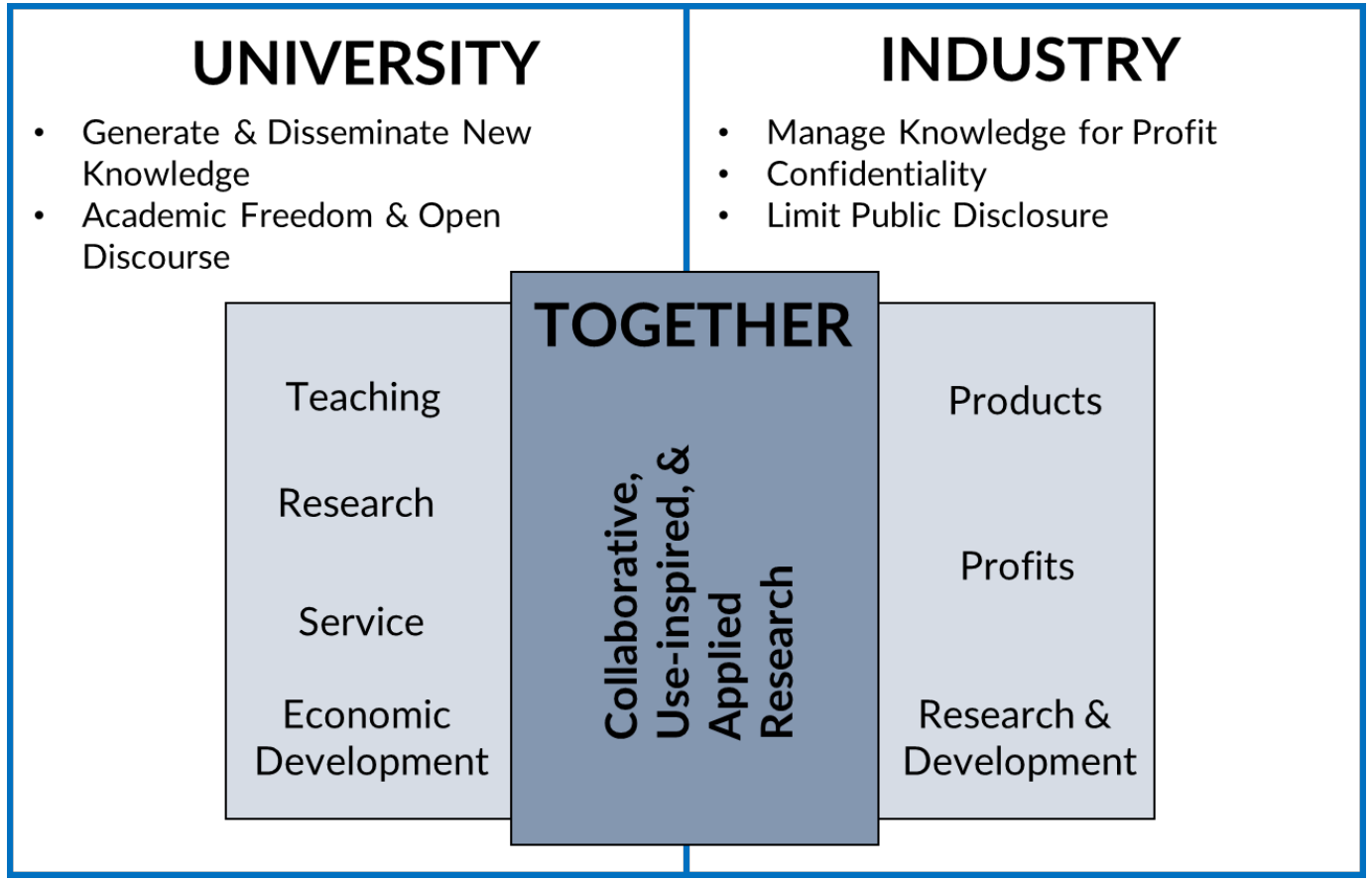
Other Types – Trade secrets, Plant Patents, Design Patents, Data…

Tech Transfer Process



Industry & Academia

Different missions; but working together



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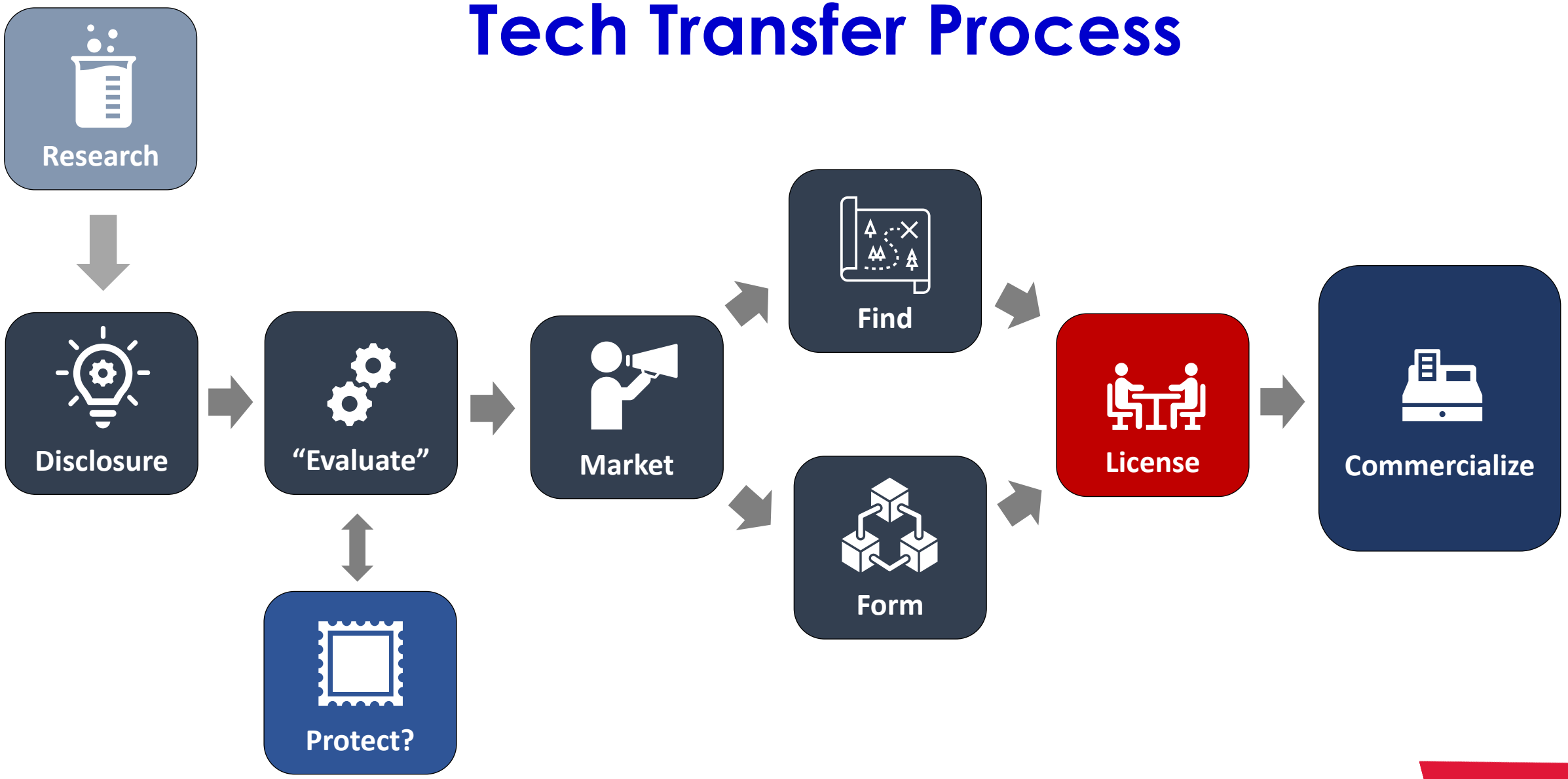
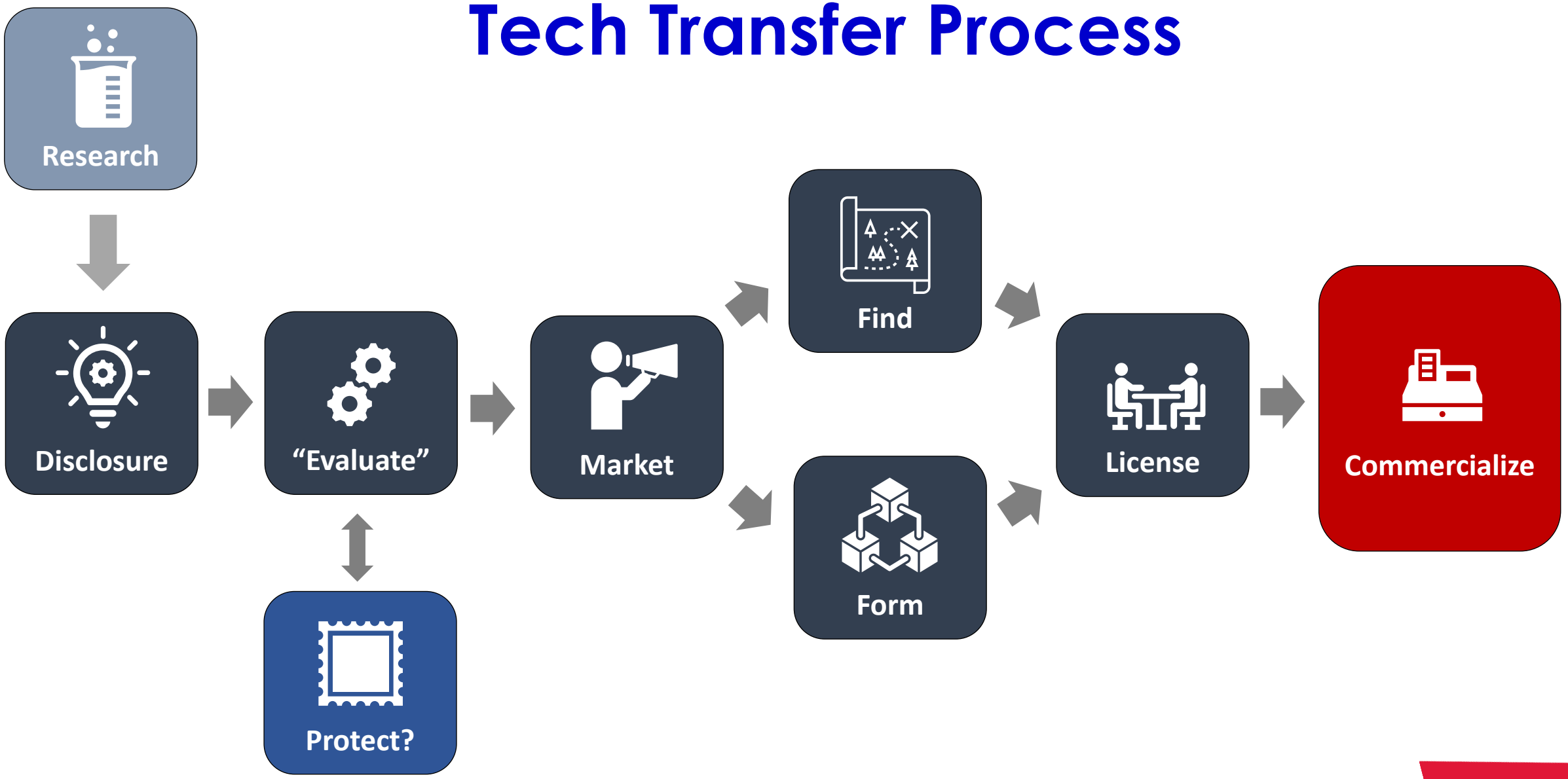


University concerns in licensing IP

- **Primary Goal: Making the technology available to the public**
- Requires Licensee to be diligent in development – verified through milestones
- Fair commercial return to university, but timing and form can be tailored
- Licensee is expected to pay associated patent costs and bear risks of doing business (indemnification, insurance, IP enforcement, etc.)
- Limit potential interference with ongoing/future research
  - Preserve right to publish & practice inventions

Tech Transfer Process



How revenue gets shared @KU

Follows the KU IP & Tech Transfer Policies

Revenue Distribution Formula	
33 1/3 %	Inventor(s)/Contributor(s)
33 1/3 %	KU Center for Research (L) or KU Research Institute (KUMC)
33 1/3 %	Department/Center - 67% retained as Departmental/Center general funds 33% returned to the Inventor to a research account designated for the inventor's research expenses. Upon resignation or termination of employment of the Inventor from the University of Kansas, this share will revert to Departmental/Center general funds

A Note of Equity - An inventor/contributor may receive Founder's equity and also receive the inventor's/contributor's share of revenue under the IP policy from the licensing of KU IP to that company.

How do you define success?

- Number of patents? Licenses?
- Number of startup companies?
- Revenue generation?
- Jobs created?
- Products sold?

IMPACT – All of the above and more

Part 3 -
Tech Transfer at KU

KU | Center for Technology Commercialization

Supporting Innovation for All KU

KU Center for Technology Commercialization

What is KUCTC:

- A "One University" office serving researchers at all our campuses; We add value to KU by
    1. Identifying, **reviewing, and protecting, intellectual property** resulting from research
    2. Negotiating licenses for KU intellectual property
    3. Collaborating with innovation ecosystem partners to support startup endeavors and industry engagement.

Who is KUCTC:

- 7 team members – Executive Director, Licensing Team x 2, Operations/Finance Team x 3, Patent Manager
- 3 PhDs, 1 JD
- Reports through David Vranicar, CFO & VC for Tech Commercialization; Board is mix of KU-L & KUMC

When to contact KUCTC:

- When you have made a **discovery, invention, or some other innovation** that could have use outside of the university
- When you have a creative solution for challenge or problem common to your field or industry
- Before you publish or present your potential discovery or innovation

Why contact KUCTC:

- We're a good starting point - provide **guidance to our researchers** regarding intellectual property protection, commercialization activities, and can make connections to other resources at KU

What does KUCTC do?

Key Roles

- Scouts for research results with potential IP for disclosure
- Reviews new invention disclosures & protects KU IP
  - Provides feedback and recommendations to our researchers
  - Work with our researchers to formulate next steps (IP protection, commercialization, partnerships, etc.).
- Negotiates licenses and other agreements related to KU IP

We Also

- Educate researchers about IP, TT, & entrepreneurship
- Market KU IP
- Support the development of start-up companies based on KU IP
- Monitor existing licenses for compliance
- Ensure compliance with Federal or research sponsor guidelines for IP
- Partner with others in the KU innovation ecosystem

What about our CTSA partners?

Most Universities and Academic Medical Centers will have an office like KUCTC

- In a pinch contact your legal or research administration offices

KUCTC (KU & KUMC) - https://research.ku.edu/innovation-commercialization

Children's Mercy Hospital - https://www.childrensmercy.org/about-us/center-for-pediatric-innovation/

Kansas State University - https://www.k-state.edu/research/industry/innovation-partners/

UMKC - https://ors.umkc.edu/services/commercialization

Kansas City University - https://www.kansascity.edu/research

Saint Luke's - https://www.saintlukeskc.org/office-research-services#

Thank you!

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Learn more about Innovation & Commercialization at KU