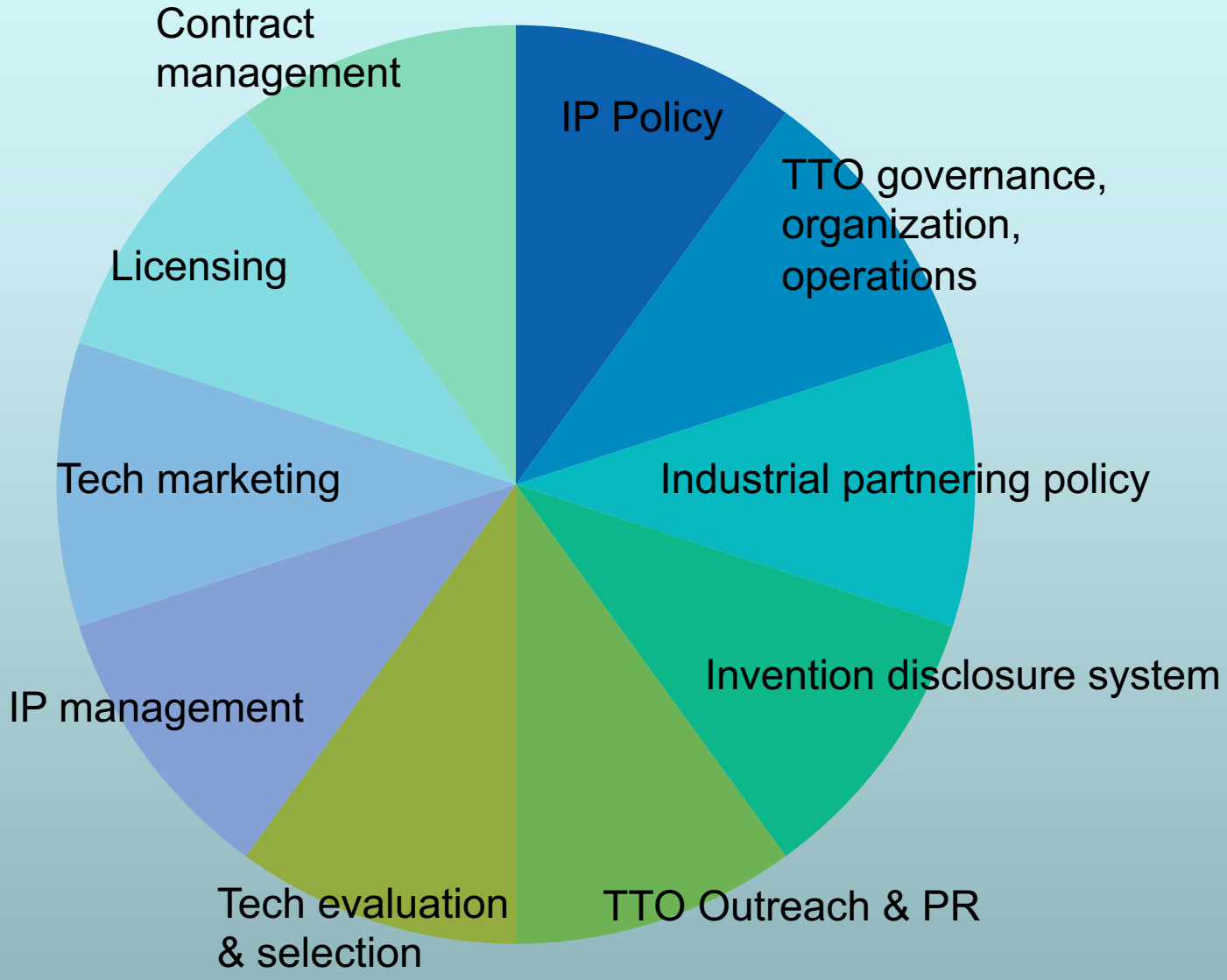
Guidebook of IP/Technology Transfer

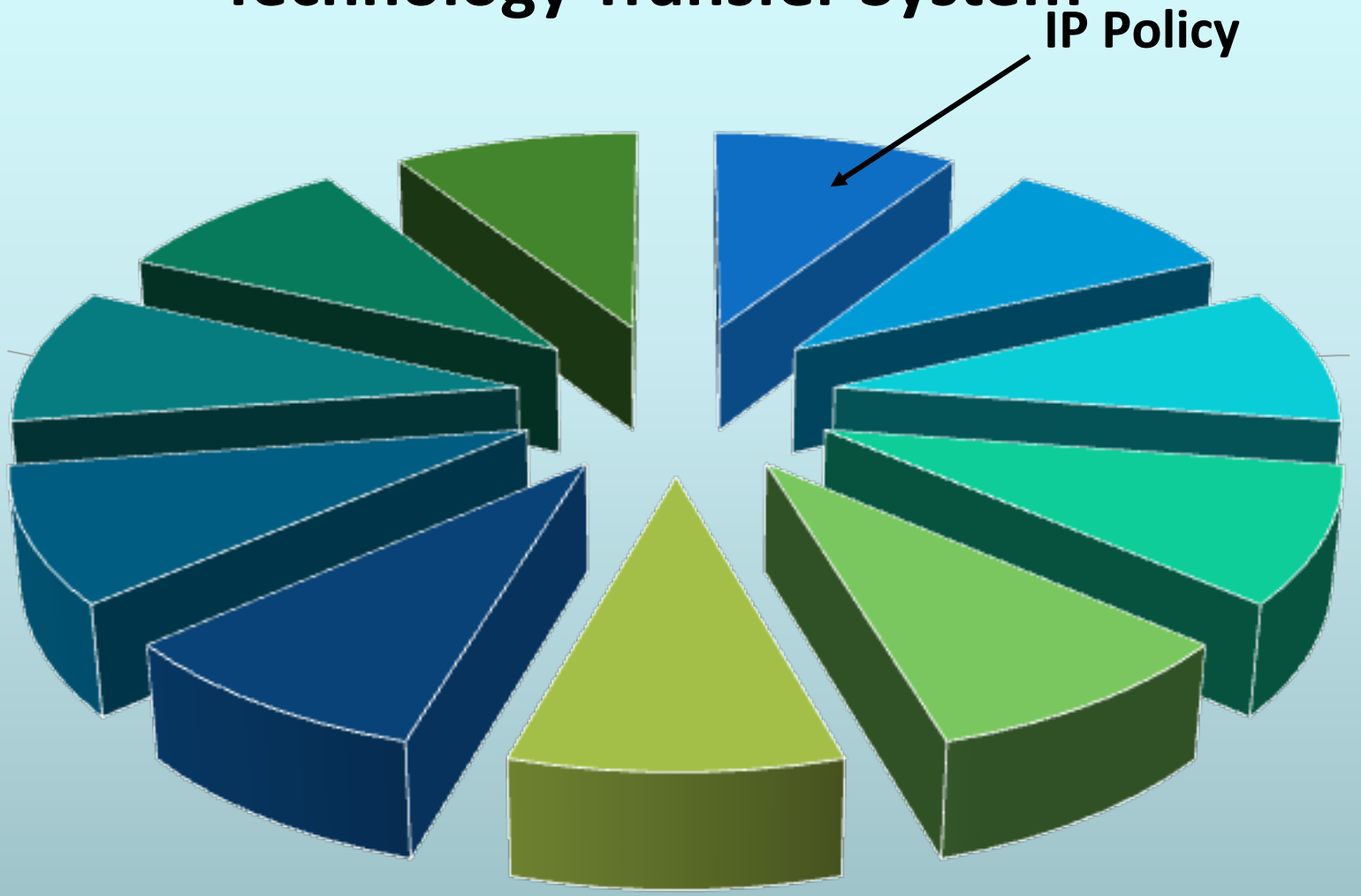
Track 4
Technology Transfer Managers & Directors

Topic 4.1.1
Institutional IP Policy Overview

Technology Transfer system



Technology Transfer System



Key IP Policy Topics

- Rationale for IP-based transfer/commercialization of invention/creation by non-profit research institution
- National legal context
- IP and academic freedom
- Scope
  - personnel covered, “institutional duties” umbrella
  - IP types
- Ownership of IP
- IP and external entities
  - research collaborators/partners
  - sponsored research contracts
  - technical services
- IP and teaching, scholarly works

Key IP Policy Topics

- Rights/obligations of inventors/creators and institution
- IP management
  - disclosure, confidentiality & publications
- Benefit sharing
  - Incentive for inventors/creators
  - Institution's share
    - Institutional stakeholders
- Funding the IP-transfer function
- Decision-making hierarchy
- Arm's-length management of IP-transfer functions
- IP Governance vs IP Operations

  (policy-making vs transactions management)

Key IP Policy Topics

- IP commercialization
  - license vs sale
  - exclusive vs non-exclusive license
  - duty of diligence and “shelving” invention/creation
- Entrepreneurship
  - faculty, staff involvement
- Equity in Institution “spin-offs”

The Mission of the Public Sector Research Institute (PSRI)

- Teach existing knowledge to the next generation

  While helping them transition from adolescents to adults

- To discover new knowledge and disseminate it broadly

  While training the next generation of researchers

- To care for patients

  While advancing the state of the art of medical care

- To be a source of economic development

  Without conflicting the previous three elements of the Mission!

The PSRI's IP policy must be entirely consistent with the mission of the institution

Whether the role of the institution, as defined by its mission, is primarily:

- disseminator of knowledge through teaching and publication,
- generator of research,
- technology transfer engine,
- promoter of economic development through education and service
  and/or through technology transfer,

Institutional IP policy should be drafted, enacted, and implemented in a manner consistent with the mission.

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PSRI IP Policy

- A well-crafted IP Policy, in alignment with the institutional mission will bring efficiency and clarity to IP management,
- All components of the policy, including IP ownership, patenting, confidentiality, and disclosure are written into the policy.
- Moreover, the intellectual property will serve the mission in a way that strengthens the institution's credibility, reputation, and public image.

Importance of IP Policy

- PSRI are important sources of new technology
  - They are good at addressing local needs and industries
- For years, translation/transfer of that research to the corporate sector was haphazard, at best
- In U.S., government owned any patents invented with Federal Funding
  - Absolutely terrible at it (only licensed 4% of its patents)
    - Would only grant non-exclusive licenses
      - No incentive to make pioneering investment to prove viability of embryonic inventions
    - Separated
      - The inventor, at the university
      - From the invention, owned by the government

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Why Are Universities Engines of Innovation?

- Faculty are inherently entrepreneurial
  - Have to "sell" their research programs to funding agencies
  - Have to "sell" their courses to students
  - Can "have their cake and eat it too" via "day per week" consulting rules
- Graduate students are at a stage in their life where they can take risks
  - Used to working all hours
  - Great carriers of the technology from the university to industry
- Universities can't commercialize their technologies: they need commercial partners (licensees)
  - Funding runs out the closer things get to the market
  - Not their mission
  - Tend to make paradigm-changing discoveries

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PSRI IP Policy

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Mechanisms of IP Policy Implementation

Mechanisms of IP Policy Implementation

- Establishing rules and procedures for capturing, managing, and transferring IP
- Signature authority
- Managing IP issues arising in research activity
- Multiparty collaboration and joint IP ownership management

Establishing rules and procedures for capturing, managing, and transferring IP

- Unambiguous IP Policy rules on ownership by institution

  Inventions made in the course of institutional duties by employees or those with research or teaching appointments

- Publicize these Policy rules widely

  faculty/staff handbook

  website

  seminars

Mechanisms of IP Policy Implementation

Establishing rules and procedures for capturing, managing, and transferring IP

- Unambiguous IP Policy rules on ownership by institution
- Apply these rules equally,

  fairly,

  consistently
- Caution! **Do Not create an IP Police State!**

  (be careful with policy obligations to disclose and punishments for breach)

Mechanisms of IP Policy Implementation

Establishing rules and procedures for capturing, managing, and transferring IP

- Unambiguous IP Policy rules on ownership by institution
- Employment agreements (signed, if possible)
- Invention disclosure obligations
- Effective invention disclosure system implemented by TTO
- Promote good notebook-keeping practices among researchers

Establishing rules and procedures for capturing, managing, and transferring IP

- TTO evaluates invention disclosures in reasonable time (define the period)
- TTO communicates with inventors in timely manner
- Decision made logically & efficiently:

  TTO to pursue IP/tech transfer or

  return rights to inventor
- TTO manages IP protection process

  In-house prior art, patent drafting

  external service provider

Mechanisms of IP Policy Implementation

Establishing rules and procedures for capturing, managing, and transferring IP

- TTO collaborates with inventor(s) to market technology to find potential licensees
- TTO and inventor(s) cooperate on interaction with potential licensees
- TTO negotiates license contract with licensee (inventor involved behind the scene)

Signature Authority (for agreements)

- Institution approves template agreements
- TTO negotiates agreements
  - NDA (Non-Disclosure or Confidentiality)
    - MTA (Material Transfer)
      - Option
        - License
- Who signs the Agreement?
  - TTO Director
    - Vice President
      - Institution's Lawyer

Managing IP issues arising in research activity

- Research vs Technical Services
- Research: PI directs work,

  IP ownership = inventorship

  "But for" clause limits university's use of IP
- Technical Services: Company directs work

  IP ownership = company
- Confidentiality vs publishing

  all university research results are publishable

  (doesn't include Technical Service data)

Managing IP issues arising in research activity

- Managing jointly-owned IP (joint inventorship)
- University management of company's trade secrets and confidential information
- Personnel exchanges and its effect on IP ownership
- Equipment sharing and its effect on IP ownership
- "Background IP" and its effect on research collaboration

Multiparty collaboration and joint IP ownership management

- Multiparty collaboration best structured by contract
- Clarity of: IP ownership & disposition
- IP ownership → inventorship (this is optimal!)
- IP disposition → serves interests of parties (align with all institutional IP Policies)
- Parties need an IP decision-making process (committee? managing partner?)

The optimal engagement:

- Confidentiality Agreement
- Material Transfer Agreement
- Research contract with standard IP ownership
- License Agreement

  (with option on certain future inventions)
- Consulting Agreement (faculty & company)

The optimal engagement:

- Research contract with standard IP ownership terms:

  IP disposition gives company certain rights in IP made under research contract

  automatic inclusion in existing license (if invention under umbrella of licensed patents)

  option under pre-negotiated license terms

  "NERF" (non-exclusive, royalty-free)

  right-of-first-refusal

The optimal engagement:

- License Agreement

  (with option on certain future inventions)

- Future inventions by inventors of licensed technology

  within patent umbrella → flows to license

  outside patent umbrella → new license

- License explicitly linked to Research Contract

IP Policy: Miscellaneous Topics

Conflict of interest/commitment

- Essential for successful, sustainable IP-based technology transfer
- Maintains essential (non-commercial) character of university/public research agency
- Protects basic mission of education, research, academics
- Honor system & transparency the basis
- No violation of personnel obligations under institution's policy guidelines
- Enforcement by administration/faculty (not TTO)
- Not too restrictive to prohibit participation in proper IP commercialization

IP Policy: Miscellaneous Topics

Biological Material ("Bioproperty")

- Whole plants and animals
- Individuals & collections
- Parts of plants and animals
- Microbes
- Cell lines
- DNA
- biomolecules

IP Policy: Miscellaneous Topics

Biological Material

- Tangible property (not IP)
- Falls under personal property law
- IP and personal property entirely separate law

  (some overlap, e.g., plants)
- Bailment law (transfers right to possess, not own)

  presumes possessor is owner, unless
  owner has transferred right of possession, or
  the material has been lost, or stolen
- All materials coming in or going out

  should have an MTA (a bailment)

IP Policy: Miscellaneous Topics

National laws on biodiversity

- National laws on biodiversity supersede institutional IP and biological property policies
- Some materials fall under biodiversity law (wild, listed species, other)
- Collection, use, and transfer of some biological materials restricted by national law
- Be aware of national biodiversity law implications

IP Policy: Miscellaneous Topics

National laws on traditional knowledge (TK)

- National laws on TK supersede institutional IP policies
- Be aware of national TK law and its rules
- Inventors must acknowledge use of TK in inventing (on invention disclosure form)
- Managing inventions using TK must comply with national TK law

WIPO IP Policy Template & Guidelines

IP Policy Template

- Presumes IP-based transfer of invention/creation is a basic goal
- Provides a framework to develop/improve institutional IP policy
- Sufficient format and structure for policy document
- Informed choices rather than directives
- Offers specific language & structure
- Presents a range of policy selections
- Includes basic, ancillary documents

WIPO IP Policy Template & Guidelines

IP Policy Guidelines

- Rationale for IP-based transfer
- Explanations for key policy decision points
- Offers arguments, “pros & cons” of policy choices
- Provides global examples
- Presents resources for further investigation

Purpose of the IP Policy (from the WIPO IP Policy Template)

- The IP Policy intends the widespread dissemination and use of Institution Inventions and Creative Works. It seeks to encourage an environment where useful Inventions/Creative Works made by Institution Personnel in the course of their Institution Duties, are used in ways which assure that the maximum benefit can accrue to the Inventors/Creators, the Institution, and society-at-large.

- The IP Policy ensures the legal protection, effective disposition, and Commercialization of useful Institution Inventions and Creative Works, while at the same time not interfering with the traditions of education and scholarship, academic freedom, open and timely publications, freedom of inquiry, university sovereignty, and the university mission of serving the public interest.

Purpose of the IP Policy (from the WIPO IP Policy Template)

- The IP Policy sets out the Institution's position regarding ownership and use of IP (respecting binding/applying legal rules and ownership regimes and IP management), the recognition and reward for the Inventors/Creators, and the obligations, roles, rights, and responsibilities of all parties. It also sets out the rules of the Institution for cooperation with industrial and other organizations and provides guidelines on the sharing of benefits arising from the development, use and Commercialization of IP.

- Such cooperating institutions include government agencies, philanthropic organizations, non-governmental organizations (NGOs), other higher education institutions, private investors and individuals across the globe.

Ownership of IP

Only four options for ownership:

- The Professor ("Professor's Privilege")
- The Institution
- The Sponsor of the research (Government, Company)
- Public domain (No one owns)

US and UK moved to institutional ownership from government ownership in 1980's

this now the international norm

Most institutions have exemptions

- Students (except if supported on grants)
- No significant use of institution's funds, resources, facilities and personnel

Professors Privilege

Drawbacks:

- Disenfranchises faculty who can't afford to pay for patents
- Professors generally aren't good businessman

  the TTO provides the business expertise
- Multiple inventors is complicated

  Is it appropriate for university laboratories to become private CRO's for professors?

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Types of IP Generated by Academic Institutions

- Patents
- Utility models
- Industrial designs
- Copyright
- Literary works

  (Course-ware, Computer software, Video, Multimedia)
- Geographical indications
- Trade and service marks
- Plant Breeder's Rights (new plant varieties)
- Trade secrets

Benefits of Institutional Ownership

- Establishes clear title to IP generated by the institution's faculty
- Essential for collaborative research with industry
  - Many international funding arrangements will require it too
- Allows institution to create an IP management office
  - Develop expertise
  - Apply consistent policies and valuations
  - Provide funds for patenting

Some IP Ownership Issues

- Retain right to practice IP licensed to others
- "Shop right" to IP owned by faculty and brought to the institution

Nine IP Policy Points to Consider

(Endorsed by AUTM)

Developed by 11 U.S. universities and AAMC, led by Stanford

1. Reserve right to practice inventions
2. Encourage use of idea
3. Minimize licensing improvements
4. Manage conflicts of interest
5. Ensure broad access to research materials
6. Carefully consider enforcement
7. Understand export regulations
8. Be mindful of working with patent aggregators
9. Consider “carve outs” for unmet needs

Point 1: Reserve Right to Use

- Internal use ensures that your inventor can continue their work
- Request that other universities and government agencies can use it as well
- Helps prevent an idea from being ignored
- Allows broad research community to check data, reproduce results, and guarantee integrity of research results

Point 2: Encourage Use

- Ideas that are licensed but not developed do not serve society
- Cost of removing research ideas from the community is more than the value of the idea
- Early stage ideas may be capable of addressing needs in multiple markets, use promotes working on all ideas in parallel when possible

Point 3: Minimize Licensing Improvements

- Licenses that contain rights to improvements decrease the ability of a faculty research lab to receive other funding
- Value of each idea is diminished, especially for platform technologies
- May inadvertently license rights to faculty not compensated by the license

Point 4: Manage Conflicts

- Conflicts of interest and commitment cannot be avoided but can be managed
- Open discussion of potential conflicts inhibits misunderstandings

Point 5: Access to Research Tools

- Research tools helped create the idea itself
- Critical to the ability of the scientific community to reproduce the results
- Tools may lead to other discoveries in the field

Point 6: Carefully Consider Enforcement

- Goal of university is to promote technology use
- Enforcement means telling someone they cannot use your idea (without a license, if one is available)

Point 7: Export Control

- Government regulations may limit the ability to take technology out of the country or have researchers who are not citizens work on the project
  - More complex than export of tangible items

Point 8: Patent Aggregators

- Also called non-practicing entities (NPE), or patent “trolls”
- ‘Value add’ aggregators pool patents to promote use by others and increase freedom to practice
- “Trolls” use patents to extract payments and are less interested in use
- Current US debate on IP reform is vigorous on these points

Point 9: Consider the Underserved

- Emerging markets have less ability to pay for patented technologies
- Include provisions that permit use in neglected areas

  Patients

  Geography

  Agriculture

  See "PIPRA" , *Public Intellectual Property Resource for Agriculture*

  http://www.pipra.org/en/page/Default/index

Scope of the IP Policy (from WIPO IP Policy Template)

This IP Policy applies to all Institution Personnel, unless there are written contract clauses that stipulate otherwise, and which have been approved by the Senior Authorized Officer of the Institution.

- Institution Personnel includes Employees, anyone with a Research or Teaching Appointment, anyone with a Visiting Researcher or Visiting Scholar Appointment, or Adjunct Faculty.

  (Note: any non-employee that carries out work related to research, educational, or outreach activity of the Institution (not including facilities maintenance, repair, or construction), except work under a signed contract with the Institution, must as a prerequisite of such work, hold a formal Appointment .

OPTIONAL

- Institution Personnel also includes: any person who, under contract with the Institution, is engaged as a consultant, or on secondment to the Institution; and
- Students (Not recommended)

Institution Ownership of IP (from WIPO IP Policy Template)

- Ownership of IP in Inventions or Creative Works invented/created by Institution Personnel in the course of carrying out their Institution Duties or with Substantial Use of Institution resources, vests in the Institution [unless otherwise agreed in contracts signed between the Institution and relevant third parties

- Ownership of IP in Inventions or Creative Works IP invented/created by Institution Personnel outside the course of carrying out their Institution Duties and with no Substantial Use of Institution resources, vests in the Inventor/Creator.

Institution Ownership of IP (from WIPO IP Policy Template)

- **Institution Duties** means all those activities required of an individual by the Institution in the conduct of their institutional employment, appointment, or other formal affiliation with the Institution.

- **Substantial Use** means unreimbursed use of the Institution's resources or facilities (including but not limited to laboratories, design studios, pilot plants, workshops, or computational facilities), equipment, human resources **[including supervision?],** or funding. Substantial Use does not include routine use of libraries and office space [option: elaborate what does not constitute Substantial Use].

Institution Ownership of IP (from WIPO IP Policy Template)

- **Invention** means a product or a process that provides, in general, a new way of doing something, or offers a new technical solution to a problem. It involves a new composition, device, process, or method. A patentable invention is a novel, useful, and nonobvious improvement of a process, machine, or product that satisfies the statutory criteria of patentability. See also **Patentable Invention.**

- **Creative Work** means any non-patentable intellectual creation potentially subject to a form of IP .

External Partners, Sponsored Research, Technical Services

- The primary issue:

  Ownership/control of IP that arises in research and technical work, and in collaboration with other parties

- Sound IP management and effective technology transfer requires clear and solid rules for IP ownership under these conditions
- Most outside entities expect the institution to have predictable rules of IP ownership and prefer institutional ownership rather than ownership by individuals at the institution
- Losing control (ownership) of IP made by institution persons or at institution means losing control of IP and its benefits for the institution

External Partners, Sponsored Research, Technical Services

Research

Intellectually exploratory work, designed and led by a Principal Investigator.

- The institution owns IP that arises

Technical Services

Not intellectually exploratory, no PI, routine testing and analysis, technician-level management

- The client owns the results of the technical services.
- However, if institution staff make inventions of the method (unless provided by client) or equipment belongs to the institution.

IP ownership under Research contracts

- Some institutions grant ownership to funders

  (i.e. "sell" their IP)

  but, this is highly problematic and not recommended
- A much preferable policy:

  Ownership directly tied to inventorship

This maintains the linkage of inventor-to-invention and respects the value of intellectual contribution over money (an underlying tenet of university technology transfer)

IP ownership under Research contracts

A preferable policy

Ownership directly tied to inventorship

- Inventions solely made by institution personnel

  Solely owned by the institution (no exceptions!)
- Inventions solely made by funder's personnel

  Solely owned by the funder
- Inventions jointly made by institution & funder personnel

  Jointly owned by institution & funder

IP ownership under Research contracts

A preferable policy

Ownership directly tied to inventorship

- Respects the university's basic principle of the primacy of intellectuality – not mercantilism
- Maintains the key linkage between inventor and invention – another key attribute of the university
- Preserves the focus on technology rather than money

IP ownership vs Commercial Use Rights:

responding to industry's concerns

Industry's view: we paid for the work to be done, we should own the IP

Institution's view: you paid for the work (and data), but not for invention

(the creative mind of the inventor is not for sale; and would cost much more than the cost of the research, if it were)

The underlying needs of each party:

- Industry needs commercial use rights
- Institution needs to own to protect its mission and long-term interests

IP ownership vs Commercial Use Rights:

responding to industry's concerns

The Resolution:

- Institution retains ownership of IP made by its faculty and staff….. but,
- Grants company funding research all the rights it needs to profitably commercialize that IP

(e.g., Exclusive, world-wide, all fields)

IP ownership under Research contracts

- Need to respect national laws and regulations
- Government funding may come with IP ownership conditions
- IP Ownership (or serious conditions) requests by industry & commodity associations with political weight

IP ownership and Faculty Consulting

- Is consulting for outside entities acceptable?
- Can be a good idea and ethically acceptable

  but, not if it subverts the institution's rightful IP ownership

- Consulting activities can never cause faculty or staff to act contrary to their obligations to the institution under the IP Policy

IP ownership under Research contracts

- The preferable policy

  Ownership directly tied to inventorship

This allows the institution to participate in designing IP utilization schemes with collaborators:

- Philianthropic consortia

  Wheat Rust Initiative

  Public IP Resource for Agriculture (PIPRA)

Protecting Academic Standards

- Freedom to keep working in the field
- Freedom to publish

  Licensee/Research sponsor gets rights to review publications for:

    Confidential information

      May require it be removed before publication

    Patentable material

      30 days to review

      30 days to correct

Protecting Societal Interests

- Preference for local companies
  - Reward taxpayer funding of the institution
  - Economic development
- Global health considerations
- Export controls

Copyright Policy

- "Professor's Privilege"

  Faculty own scholarly works

- University owns copyright related to sponsored research
- Corporate sponsor may own results as "work for hire" if permitted

Ownership and Use of Data

- Who owns data?
  - Professor
  - Institution
- Who is responsible for managing it?
  - Promote or protect access
- Human subjects information may have special considerations
- How long must you keep it?

Policy: Data Use

- Open dissemination of research
- Accessibility for continued work
- Diligent development of products or return rights to university
- Maximize *use* of the IP
- University must uphold obligations from sponsors and to inventors

Academic Freedom & Protection of IP

(from WIPO IP Policy Template)

The Institution acknowledges that academic freedom is integral to the public good and the mission of the Institution and thus, the unfettered right of Institution Personnel to publish, is absolute.

In parallel with inviolable academic freedom and right to publish, the Institution acknowledges that, in certain situations, serving the public good and the interest of the Institution by making Institution Inventions and Creations available to the public through the Commercialization process, can best be accomplished if such Inventions and Creations are protected by IP.

Academic Freedom & Protection of IP

(from WIPO IP Policy Template)

Furthermore, the Institution also acknowledges that financial and other rewards that may be attained through the process of making Inventions and Creations available to the public through Commercialization can incentivize Personnel, improve Invention and Creation, and improve the ability of the Institution to accomplish its mission, and fund further research, thus supporting sustainability.

The Institution hereby commits to: 1) not limit Personnel's right to publish, and 2) strongly encourage Institution Inventors, Creators, and other Personnel to avoid loss of IP rights caused by premature publication prior to taking steps for IP protection.

Patent Assignment agreements

- Consider national laws and tradition

  For example, in the U.S., unless there is a contract that dictates otherwise, the inventor is the owner of the patent

- Therefore, it's essential that the institution take active steps to require personnel to agree (preferably in writing) to assign their ownership rights in patentable inventions to the institution

Note: this is a routine practice in industry

Copyright Assignment agreements

- Consider national laws and tradition

  For example, in the U.S., unless there is a contract that dictates otherwise, the employer is the owner of the copyright

- Copyright assignment complicated by the academic tradition in which faculty own their own texts, authored works, and educational materials (e.g., syllabi, etc.)

Patent Assignment agreements

How to obtain signed Patent Assignment Agreements

- The ideal: a Patent Assignment Agreement signed and archived for each faculty, staff, and appointee prior to doing any work at the institution.
- This is difficult given the numbers of faculty, staff, and appointees coming and going from work at the institution

Patent Assignment agreements

Some approaches to obtaining signed Patent Assignment Agreements

- Require signature at time of hiring for all new hires/appointments
- Require departments to obtain signed agreement from all faculty and staff
- Designate the office responsible for collecting and recording all agreements; track down agreements for all
- Passive implementation: promulgate the policy requirements widely; state that cashing the first check or receiving appointment letter is tantamount to agreement to assign
- Require Assignment Agreement at time of invention disclosure

Track 4
Technology Transfer Managers & Directors

Topic 4.1.1
Institutional IP Policy Overview

Thank you