

# Technology Development

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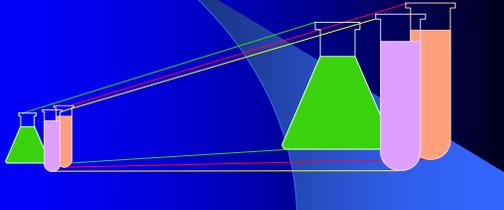
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# Technology Development

Or, How Tech Transfer Can Help You  
Expand Your Lab's Research



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## Introduction: What is "Technology Transfer?"

Translating intellectual property created by  
government or academia into a product or service

- Inventions, patents, and licenses
- Agreements with the private sector
- Other IP (copyright, trademark)



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## Why Bother Patenting Inventions?

- Provides incentive for private sector to invest
- Auxiliary means of publication
- Royalties encourage further research
  - Each inventor gets a percentage of any royalties collected on his/her inventions
  - Remainder of royalties gets plowed back to support further research

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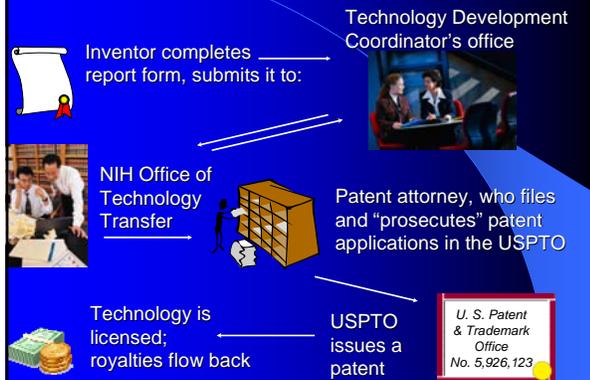
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## Inventions: Action Timeline



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## Why Do Agreements?



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## Why Do Agreements?

- Share information or research materials
- Collaborate on research (state/foreign government agencies, academia, or industry)
- Clarify expectations; avoid misunderstandings; preserve rights
- Encouraged in policy statements
  - NIH intramural:  
<http://www.nih.gov/news/irnews/guidelines.htm>
  - NIH grantees:  
[http://ot.od.nih.gov/policy/rt\\_guide\\_final.html](http://ot.od.nih.gov/policy/rt_guide_final.html)

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## Most Common Types Of Technology Transfer Agreements

- Confidential Disclosure Agreement (CDA)
- Material Transfer Agreement (MTA)
- Clinical Trial Agreement (CTA)
- Cooperative Research And Development Agreement (CRADA)
  - Materials-CRADA



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## Confidential Disclosure Agreement



- When: scientist wants to discuss a pending publication, invention, or confidential information with someone *outside* scientist's Institution
- Key terms in a typical CDA:
  - Identifies typically what is to be disclosed
  - Exclusions (e.g., stuff that becomes public)
  - Duty to mark "CONFIDENTIAL"
  - Duration of the secrecy; freedom to publish

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## Transfers of Research Materials



- MTA: Transfer of research materials
  - For *basic research* purposes only
    - normally no clinical uses are permitted
  - Providers may prohibit redistribution, or use of the materials for commercial gain (reselling, commercial screening, etc.)
  - No transfer of funds or other resources
  - May not be used to bypass “fair access,” ethics rules, or procurement laws

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## Transfers of Research Materials



### Special types of MTAs:

- Simple Letter Agreement  
[http://www.ott.nih.gov/forms\\_model\\_agreements/forms\\_model\\_agreements.html](http://www.ott.nih.gov/forms_model_agreements/forms_model_agreements.html)
- MTA for the Transfer of Model Organisms  
(Same URL as above)
- Uniform Biological Material Transfer Agreement  
[http://www.autm.net/aboutTT/aboutTT\\_umbta.cfm](http://www.autm.net/aboutTT/aboutTT_umbta.cfm)
- Human Embryonic Stem Cell transfers (NIH only)  
<http://stemcells.nih.gov/info/health.asp>

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## Clinical Trial Agreement (CTA)



- Authorizes transfer and use of materials in research using human subjects
- Assigns responsibilities for regulatory requirements
- Specifies who has rights to use data in regulatory filings
- Publication rights, other duties
- Otherwise like an MTA

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## Cooperative Research And Development Agreement (“CRADA”)

- A CRADA can:
  - ✓ Provide a collaborator with a license option to your inventions made during the CRADA
  - ✓ Permit a collaborator to provide PHS with funds to do collaborative research
  - ✓ Facilitate the exchange of significant material and/or FTE-ceiling-exempt personnel in support of collaborative research
- The cornerstone of any NIH CRADA is *actual collaboration*

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## CRADAs - Process

- CC PI approaches TDC with a specific Collaborator, or CC advertises for Collaborator
  - CC PI undergoes Conflict of Interest review
  - PI and Company scientists develop research plan, while TDC negotiates legal and funding terms with Company lawyers
  - Review of CRADA by PHS’s “CRADA Subcommittee”
  - Execution of CRADA by parties
- Estimated time: 4-8 months

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## Materials-CRADA

- When: Company transfers its proprietary or sole-source material in exchange for IP rights
    - No personnel or other material will be exchanged
    - Company does not “collaborate” in the research
    - One-year term
  - If Company agrees to use unmodified form, PHS approval is highly streamlined
  - If Company wants minor modifications, PHS approval is partially streamlined
- Estimated time: 4-8 weeks

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## CDA, MTA, CTA, CRADA terms

...have they ever made a difference in the "real world"?

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## "Real World" cases:

- University faculty member punished; publications delayed
  - Personally signed CDA with restrictive terms, manuscript which breached those terms was suppressed
- Scientist who signs MTA with company risks personal assets
  - "Indemnification" clause
- Scientists arrested and charged with theft of trade secrets
  - Took samples of materials from University without MTA or other permission
- Congress raised questions about NIH scientist who sent research materials abroad
  - Receiving party used the materials in human clinical trial in which patients died

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## What would you do if...?

- You plan to meet with a colleague in a company to discuss recent, unpublished results and explore interest in collaboration. She asks you to sign a document first.
- Discuss your situation with the Technology Development Coordinator (TDC)
  - Is there an invention to report?
  - Even if not, what about a CDA? MTA? Something else?
- May also need to check with Ethics
  - Determination/approval for official duty activity

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## What would you do if...?

- In your lab you have received materials from two different companies (for separate experiments). You would like to do a study combining the materials.
- Check with the TDC
  - Will seek permission for the combination study
    - New three-way agreement, or amendments to existing agreements

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## What would happen if ...?

- A scientist signs a company MTA without review or approval of his Institute's authorized official (*You* wouldn't do this, of course). The MTA says the company has a "paid up license" to inventions made with the material.
- The scientist reports an invention, which NIH publishes as available for licensing. The company comes to NIH with their MTA/paid-up license
- Check with TDC
  - MTA did not have authorized signature
  - Damage control

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## What would you do if...?

- You are working under a CRADA collaboration, and the research is progressing well
- The company expresses delight in working with someone with your talent and invites you to come in for a job interview. You are interested in pursuing the opportunity. Now what?
- Contact Ethics

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## Forms of Intellectual Property

- ✓ Patents
- Copyright ( © )
- Trade Secret
- Trademark ( ® , ™ )

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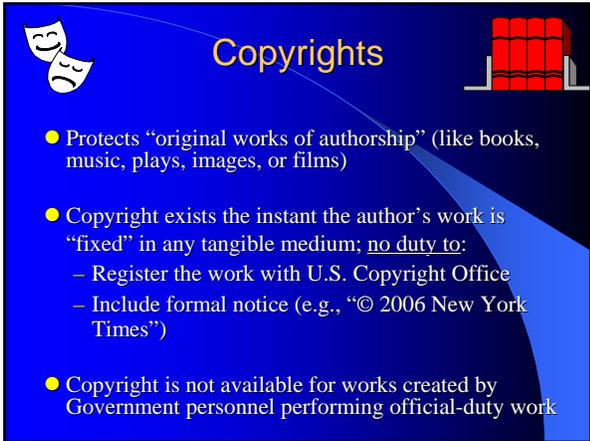
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## Copyrights

- Protects “original works of authorship” (like books, music, plays, images, or films)
- Copyright exists the instant the author’s work is “fixed” in any tangible medium; no duty to:
  - Register the work with U.S. Copyright Office
  - Include formal notice (e.g., “© 2006 New York Times”)
- Copyright is not available for works created by Government personnel performing official-duty work

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## Copyrights: Common Questions

- **What if a publisher asks me to assign my copyright?**
  - Inform the publisher that no copyright exists to be assigned
  - If work was written as official gov’t duty, no royalties allowed
- **What about “fair use?”**
  - “Fair use” is a last-ditch defense when caught copying
- **If I hire a contractor to write software, are there any copyright issues to consider?**
  - Yes: a contractor normally owns the copyright in their works, even under a government contract. Be sure your agreement requires delivery of exactly what you want, e.g., “right to redistribute”
  - Note that software can be *both* patented and copyrighted

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## Trade Secrets: Definition



- “Trade secret” is defined in over fifty ways (each State, DC, territory has its own twist)
- Generic definition has the following elements:
  - Information *having commercial value*
    - Results in profit or cost-savings
    - Expensive or difficult to replicate/reverse-engineer
  - That is *secret in fact*
  - Provided the owner *takes steps reasonable under the circumstances* to keep it secret

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## Owning a Trade Secret



- If the owner of info can prove it qualifies as a trade secret, the owner can get injunctions and/or damages
- Gov’t does not generate any trade secrets on its own, but can acquire them from private parties, and has a legal duty to protect confidentiality
  - Felony for federal employee to knowingly disclose one
- **Warning:** risk of insider trading may extend to grossly negligent “tipping off”

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## What is a Trademark?

- Definition: A trademark is any word, phrase, logo, symbol, shape, number, letter(s), color, sound, scent, or other device (or combination of these) *that serves to identify the source of specific goods or services, and to distinguish them from similar goods or services sold by others.*



Archer, Daniels & Midland



Singapore Airlines

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## Why might Government/academia care about trademarks?

- To identify and promote the Agency as a quality source of information, products, and services
- To provide certification that a seller of goods/services meets NIH standards for those goods/services
- To protect the reputation of the Agency
  - Misuse of Government information, logos, etc., to imply endorsement
  - Where copyright is unavailable to protect the integrity of Government-created materials



NCI Comprehensive Cancer Center



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## TDC Contact Information (case-specific questions)

**Kenneth Rose, Ph.D., Esq.**  
NCI Technology Transfer Branch  
6120 Executive Blvd., EPS Suite 450, Rockville  
Phone: (301) 496-0477  
Fax: (301) 402-2117  
[rosek@mail.nih.gov](mailto:rosek@mail.nih.gov)

**Elaine Ayres**  
Building 10, Room 6-1531, Bethesda  
Phone: (301) 594-3019  
Fax: (301) 402-0244  
[EAyres@nih.gov](mailto:EAyres@nih.gov)

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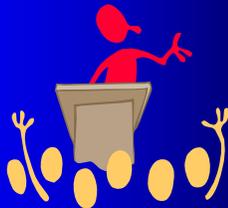
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Thank you for your attention



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