

# Technology Development

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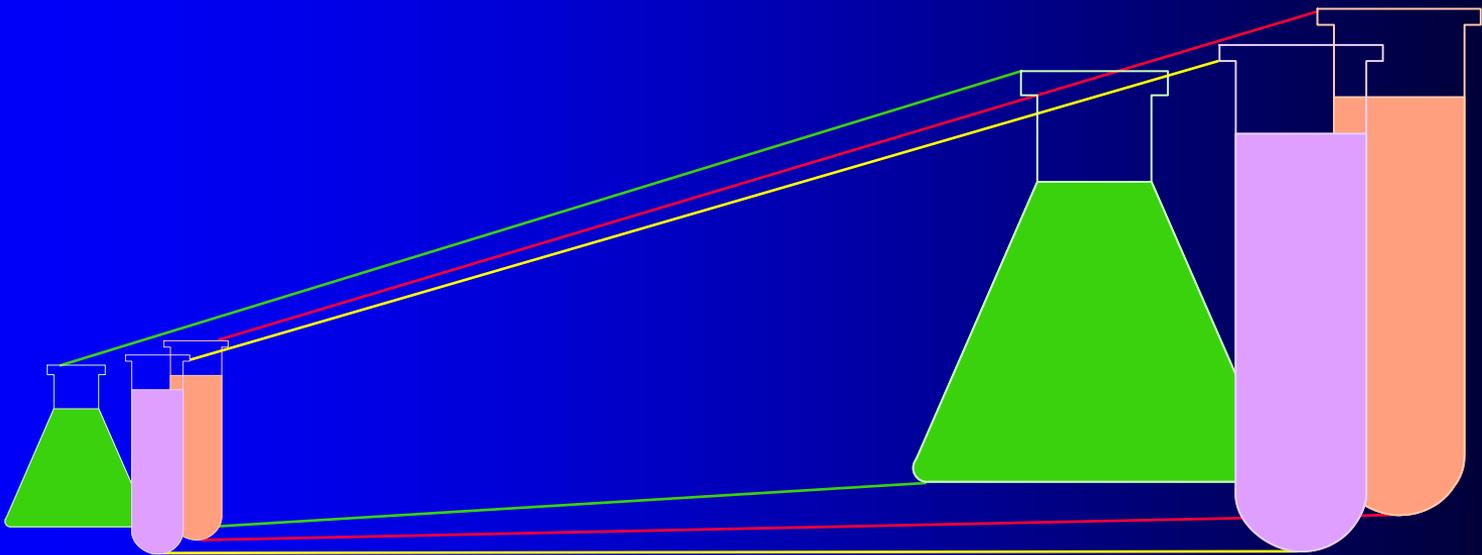
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# Technology Development

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



# 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)



# Why Bother Patenting Inventions?

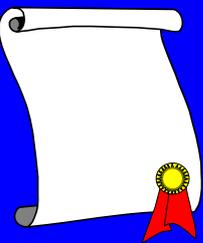
- \* Provides incentive for private sector to invest
- \* Auxiliary means of publication
- \* Royalties encourage further research
  - Each inventor gets a percentage of any royalties collected on his/her inventions
  - Remainder of royalties gets plowed back to support further research

# Inventions: Action Timeline

Technology Development Coordinator's office



Inventor completes report form, submits it to:



NIH Office of Technology Transfer



Patent attorney, who files and "prosecutes" patent applications in the USPTO

Technology is licensed; royalties flow back



USPTO issues a patent



# Why Do Agreements?



# 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://ott.od.nih.gov/policy/rt\\_guide\\_final.html](http://ott.od.nih.gov/policy/rt_guide_final.html)

# 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



# 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:

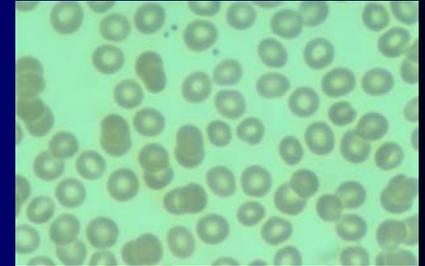
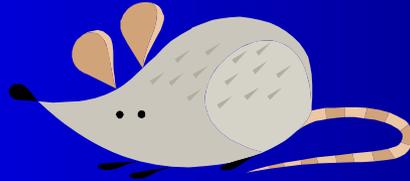
- Identifies topically what is to be disclosed
- Exclusions (e.g., stuff that becomes public)
- Duty to mark "CONFIDENTIAL"
- Duration of the secrecy; freedom to publish

# 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

# 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)

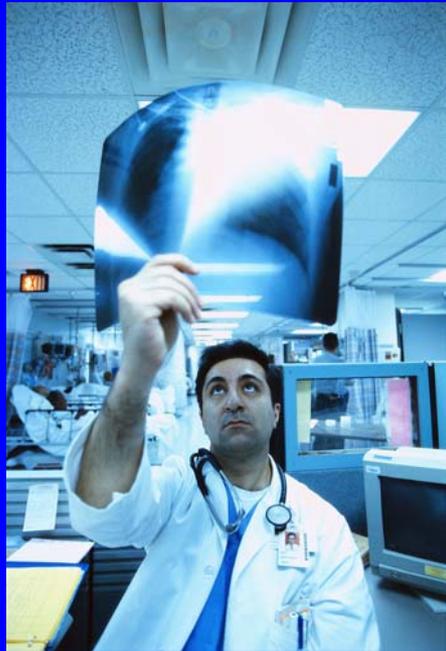
- Uniform Biological Material Transfer Agreement

[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>

# 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

# 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*

# 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

# 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

CDA, MTA, CTA, CRADA terms

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

# “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

# 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

# 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

# What would happen if ...?

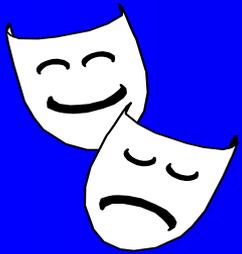
- \* A scientist signs a company MTA without review or approval of his Institute's authorized official (You wouldn't do this, of course). The MTA says the company has a "paid up license" to inventions made with the material.
- \* The scientist reports an invention, which NIH publishes as available for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

# What would you do if...?

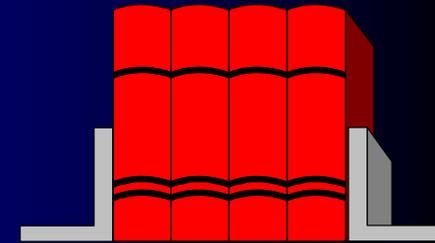
- \* You are working under a CRADA collaboration, and the research is progressing well
- \* The company expresses delight in working with someone with your talent and invites you to come in for a job interview. You are interested in pursuing the opportunity. Now what?
- \* Contact Ethics

# Forms of Intellectual Property

- \* *Patents*
- \* Copyright (copyright symbol )
- \* Trade Secret
- \* Trademark (reg. symbol , trademark symbol)



# 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

# 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

# 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

# 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”

# 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

# Why might Government/academia care about trademarks?

- \* To provide certification that a seller of goods/services meets NIH standards for those goods/services
- \* To identify and promote the Agency as a quality source of information, products, and services
- \* To protect the reputation of the Agency
  - Misuse of Government information, logo 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)

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Thank you for your attention

