NATIONAL CANCER INSTITUTE

What should SS/SCs know about technology transfer?

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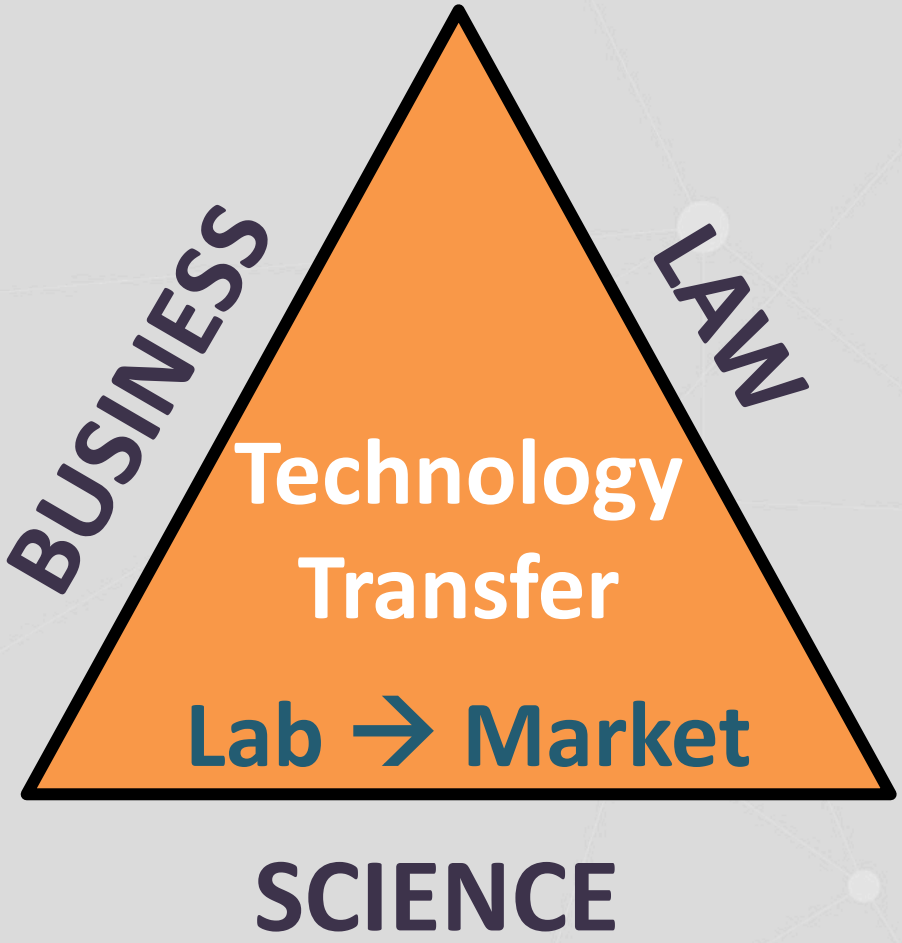
NCI Technology Transfer Center (TTC)

What is Technology Transfer?

Tech transfer is the process of transferring knowledge and materials from one organization to another to promote further development and commercialization of technology.

Activities may include:

- Sharing materials and information
- Protecting technologies through patents and copyrights
- Licensing technologies to further develop and commercialize them
- Developing partnerships and collaborations to advance scientific research and development
- Partnering with academic, industrial, and economic development organizations to foster economic growth



What We Do

- TTC manages technology transfer (TT) for intramural and extramural investigators
- Each lab has a Technology Transfer Manager (TTM) assigned to it (do you know who your lab's TTM is?)
- Find your TTM:
  - Click here if you are CCR
  - Click here if you are DCEG

When Should Your Lab Interact with TTC?

- **Intramural labs work on many different types of projects. TTC is here to help you find and use the right technology transfer tool for your job.**

Practical Examples

1. **When you want to send or receive materials and/or data**
   - Material Transfer Agreement (MTA)
   - Data Transfer Agreement (DTA)
2. **When you have an invention to report (…if you're unsure, contact your TTM)**
   - Employee Invention Report (EIR) (timing is important!)
   - Patenting
   - Licensing
3. **When you want to collaborate with an outside (or inside) party to develop a technology**
   - Confidential Disclosure Agreement (CDA)
   - Collaboration Agreement (CA)
   - Cooperative Research and Development Agreement (CRADA)
4. **When you want to run a clinical trial**
   - Clinical Trial Agreement (CTA)
   - Clinical CRADA

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MTA: Material Transfer Agreement

Purpose: To specify the transfer and use of research materials

- May control materials and information
- Generally prohibits human use
- Frequently used in academic collaborations

What Causes a Transfer to Need "Special Attention"

- **NIH providing any material directly obtained from humans: identified, coded or unlinked**
  - Tissue, organs, blood, gametes, embryos, fetal tissue, waste
  - Extracted or subcomponent parts including whole genomic DNA, plasma, protein fractions, fractionated cells
- **NIH providing derivatives only if identified or NIH has access to the code**
  - Human cell lines, recombinant DNA clones of human genes
  - Isolated infectious agents from humans
- **Any material which will be provided by NCI and used by an outside party in human subjects research**

Human Material Transfers

- **Human MTA's require IRB approval or OHSRP exemption**
  - IRB protocol gets amended
- **Determine if material is directly obtained from humans or derivative that is identified and coded**
- **If patient is deceased, OHSRP or IRB approval not required**
- **Notify protocol specialist for IRB approval and NCI TTC for MTA negotiations**

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Collaboration Agreement vs. Cooperative Research and Development Agreement (CRADA)

Purpose: To permit collaboration wherein a two-way exchange of starting materials, starting information, resulting data and/or resulting materials will take place

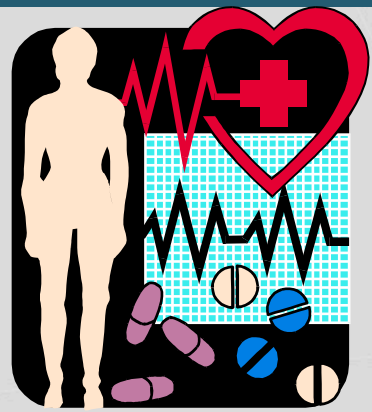
- **Combined terms of a CDA and MTA**
- **Exchange of new material created during the collaboration is also addressed**
- **No $$ exchange**
- **No license option**

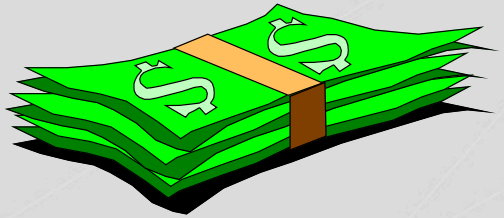
- Agreement to conduct specified R&D by a Federal laboratory and a non-Federal party

- **Federal laboratory may provide**
  - **Personnel**
  - **Services**
  - **Facilities, equipment, IP or other resources**
- **Collaborator may provide**
  - **Same as above &**
  - **$$ Funds**
- **Exclusive license option to collaborator, to inventions made by a Federal laboratory employee(s)**

Advantages of a Collab or CRADA for the NIH

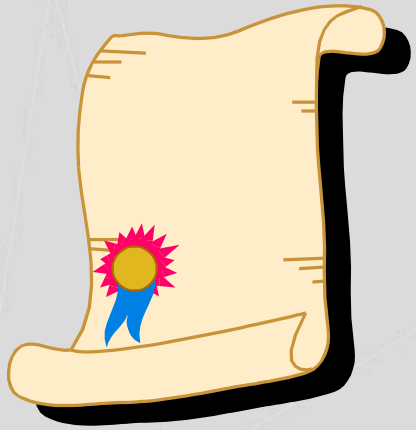
- Access to scientific, regulatory, & commercial development expertise
- Access to unique reagents and resources
- Funds for research project (CRADA)
- Satisfaction of participating in development of research results into commercial product
- New Inventions





Advantages of a Collab or CRADA for a University or Company

- Access to unique reagents and resources
- Access to scientific and regulatory expertise
- Exclusive license option to inventions made by a Federal laboratory employee(s) (CRADA)



What you Need to Think About First

- Is a CRADA really necessary? Appropriate?
- Who is the Collaborator?
- What are the goals and concerns of the Parties?
  - Is this more appropriately a contract?
  - Can it simply be a Clinical Trial Agreement (CTA)?
  - Or an MTA or Collaboration Agreement?
- Always begin CRADA with a Conflict of Interest (COI) (Ethics Review)

TTC Timing Goals for Executing An Agreement

- **MTAs and CDAs: 1 – 2 Weeks**
- **Collaboration Agreements: 1 – 2 Months**
- **CTAs: Average 3 Months**
- **CRADAs: Average 6 Months**

NCI TTC

- We are here to work with you and ensure your interests are protected
- Important to build good relationship with your tech transfer manager (TTM) as they will understand your science and goals and make sure your interests are protected

What can you do?

- Contact TTC to transfer materials and confidential information
- Report inventions 3 months before public disclosure
- Maintain your research notebooks in a manner that supports patenting
- Update TTC about scientific projects related to patent-pending technologies
- Forward licensing leads or inquiries from commercial entities
- Talk with us about ways to promote development of your inventions and ideas or to facilitate research collaborations

SS/SC Interest & Discussion

TT-Training Resources

- FAES Courses & TT Certificate
  - *Advanced education coursework (at cost) at NIH*
- **Technology Transfer University (TTU)**
  - *Free TT training every Spring*
  - ***Duration:*** *Half day or one day each week for ~2 months*
- TT CRTA Fellowship
  - *Paid fellowship for post-docs interested in Marketing/Invention Development or Negotiation track*
  - ***Duration:*** *Same as NCI CRTA*
- Technology Transfer Ambassadors Program (TTAP)
  - *Free training for post-docs seeking to enhance their current research activities with hands-on training in biomedical invention development and commercialization*
  - ***Duration:*** *1 year (approximately 5-8 hours per week). Post-docs remain in the lab during this time.*
- Transition to Industry Fellowship (T2I)
  - *Paid fellowship for post-docs interested in entrepreneurship and industry-focused research training*
  - ***Duration:*** *2 years (80% in lab, 20% in TT/SBIR)*
- **Intramural I-Corps Program**
  - *Intramural scientists work in teams with TTMs to advance their focus beyond the lab and accelerate tech development through market research.*
  - ***Duration:*** *4 weeks (10-15 hours per week spread across teams of 3-4)*

Contact Information

Technology Transfer Center (TTC)

Email: ncitechtransfer@mail.nih.gov

Website: https://techtransfer.cancer.gov/

Find your Technology Transfer Manager (TTM):

- Click here if you are CCR
- Click here if you are DCEG

- **Shady Grove**

9609 Medical Center Drive
Room 1E-530, MSC 9702
Rockville, MD 20850
Phone: 240-276-5530

- **Frederick**

8490 Progress Drive
Riverside 5, Suite 400
Frederick, MD 21701
Phone: 301-624-8775

Leidos Biomedical Research Inc.

IP and Strategic Agreements
ATRF E-3100
Frederick, MD 21702
Phone: 301-846-6308

Thank you!

Any questions?

Additional Slides

CTA vs. Clinical Trial CRADA

- **Clinical Trial CRADA**
  - Allows funding to come into NCI
  - Provides the Collaborator with an exclusive option to elect a nonexclusive or exclusive license on IP developed from the CRADA research
  - Can encompass both preclinical and clinical research
  - Can take longer to approve than a CTA because it is reviewed by multiple offices and approved at the NIH level
- **CTA**
  - Collaborator cannot provide funding and Collaborator does not receive an option to a license on inventions
  - Essentially, this is a drug supply agreement, i.e., the Collaborator provides CCR with an agent to run a trial
  - Can be executed more quickly because the agreement is handled at the Institute level

Who Signs Agreements? TTC Can Help!

For these unmodified NCI/NIH models	
Agreement	**Who Signs?**
NCI model CDAs	Lab Branch Chief
Simple Letter Agreements (SLAs)	Lab Branch Chief
Material Transfer Agreements for the Transfer of Organisms (MTA-TO)	Lab Branch Chief

SEND TO TTC	
Agreement	**Who Signs?**
Collaboration Agreements and modified CDAs and MTAs	TTC
Human Material MTAs	TTC and CCR Director
Clinical Trial Agreements	CCR Director
CRADAs	NCI Deputy Director, and clearance from Ethics and NIH

To Patent or Not to Patent: It's a Business Decision!

Discoveries	Research Tools	Inventions
Identify a biochemical pathway	Transgenic mouse Cell line Plasmid	Novel compounds for inhibiting pathway
Mathematical relationships *License*	Software	New diagnostic test
Publish	**Publish** **License for commercial use** **MTA for academic research**	**Patent** **Publish** **License for product development and sales**

To Patent or Not to Patent: It's a Business Decision!

- We are here to support the research mission of NIH scientists
- Sometimes this research leads to "discoveries" that should be published (and not patented)
- Other times the research creates research tools which can be licensed for commercial uses without patenting
- Patenting is used very selectively, to provide a means to incentivize a company to further invest in developing a product (such as a novel compound which can be used as a drug)

- If you aren't certain whether or not to report an invention, please contact me for assistance

A Day in the Life of a Technology Transfer Manager (TTM) in NCI