

Technology Transfer Basics

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What is Technology Transfer?

- Process of transferring knowledge and/or materials from one organization to another to promote the further development and commercialization of technology

What Activities are involved in Technology Transfer?

- Sharing materials and information
- Protecting technologies through patents
 - NIH does not copy right work of NIH employees
- Licensing technologies to further develop and commercialize the technologies
- Developing partnerships and collaborations to advance scientific research and development
- Partnering with academic, industrial and economic development organizations to foster economic growth

Advantages for 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

Advantages for 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)

Technology transfer is a TEAM effort

CCR Scientists

Conduct cancer research

NCI TTC

Evaluate inventions and manage invention reporting.

Work with scientists to select best agreement type; negotiate agreements

Match NCI discoveries with partners, and facilitate collaborations

Manage patenting through contract law firms

Manage licensing via NIH licensing specialists

Manage license monitoring, auditing and enforcement

Other NIH Offices

Office of Budget and Finance

Office of General Counsel

Office of Human Subjects Research Protection

NCI Ethics

Types of Translational Agreements

Type of Agreement	Description
Confidential Disclosure Agreement (CDA)	<ul style="list-style-type: none">• Protects the exchange of confidential information between two or more parties
Material Transfer Agreement (MTA)	<ul style="list-style-type: none">• Send and receive research materials• NOT FOR USE IN HUMANS
Human MTA	<ul style="list-style-type: none">• Requires IRB approval or exemption
Collaboration Agreements	<ul style="list-style-type: none">• Joint research project with universities, non-profit organizations or industry
Clinical Trial Agreement (CTA)	<ul style="list-style-type: none">• Receive investigational drug for the conduct of clinical trials
Cooperative Research and Development Agreements (CRADAs)	<ul style="list-style-type: none">• Collaborative research project, often with industry• NCI can receive funds <u>but not provide funds directly to CRADA collaborator</u>

CDA/NDA: Confidential Disclosure Agreement

- Purpose: to specify the treatment of proprietary information and protect confidentiality
- Controls information (vs. materials)
- One-way or two-way exchange
- Often 1st step in collaboration
- Though PHS policy is open access to results of federally-funded research, a CDA is required in certain situations:
 - Industry: need to protect trade secrets

When to Put a CDA in Place:

- CRADA discussions and negotiations
- Discussions involving unpublished data, research results
- Product development
- Patent filing
- Grant submissions

Essential Elements of a CDA

- Definition of the Parties
- Definition of Confidential Information
- Purpose of Disclosure
- Obligations of disclosing party
 - Duty to disclose information defined
- Obligations of receiving party
 - Duty not to disclose and not to use the information for other than stated purpose
- Exclusions from Confidential Information
- Duration

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

Essential Elements of an MTA

- Identity of the Parties
- Define the Material
- Ownership of the Material by the Provider
- Set out the use of the Material by the Recipient (non-commercial)
- NOT FOR USE IN HUMANS
- No further distribution

Human Material Transfers

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

CA: Collaboration Agreement

- Purpose: to permit collaboration of a two-way exchange of starting materials, starting information, resulting data and/or resulting materials
- Combined terms of a CDA and MTA
- Exchange of new material created during the collaboration is also addressed
- No \$ exchange
- No license option

CTA: Clinical Trial Agreement

- Purpose: to specify the transfer and use of material into NIH for research in Human Subjects
- Investigational drug, biologic or device
- No funding from the outside party
- No first option to a license

Essential Elements of a CTA

- Drug or Device Supply
- Data Sharing
- Regulatory Issues and Monitoring
- Handling of Identifiable Private Information

What is a CRADA?

- 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
 - Personnel
 - Services
 - Facilities, equipment, IP or other resources
 - Funds

Who enters into CRADAs?

Agreement between a Federal government laboratory and ...

- Industrial organizations
- Public and private foundations
- Nonprofit organizations including Universities
- Units of state and local government

Why do the Parties Select the CRADA Mechanism

For NIH:

- May receive funds for research project
- May provide confidentiality for research results – five years after development (15 USC 3710(c)(7)(B))

For Collaborator:

- Exclusive license option to inventions made by a Federal laboratory employee(s)

What Policies Govern CRADAs?

- Consistent with missions of the Federal laboratory
- NIH CRADA policies
 - Not general funding for NIH lab
 - Focused CRADA research plan
 - Scientific communication and dissemination of research results
 - Intellectual contribution by NIH and Collaborator
 - Conflict of interest review for NIH

CRADA Elements: Research Plan

- Term
- Scientific background
- Capabilities of the parties
- Workscope
- Responsibilities of each of the Parties
- IP and other related agreements

CRADA Elements: Staffing, Funding and Materials/Equipment

- List the specifics for specific CRADA
 - Number of person years per year
 - Payment schedule and instructions
 - Listing of materials and equipment exchanged
- Standard provisions in CRADA
- No funds from Government to Collaborator
 - No permanent staff supported with Collaborator funds; freedom to participate in other activities
 - Funds and equipment

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

TTC Timing Goals for Executing An Agreement

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

Who Signs Agreements?

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

NCI TTC FY17 Metrics

- \$113 M NCI Total Royalties

CDAs	524
CRADAs	46
CTAs	19
MTAs	1402
NCI Issued Patents	53

NIH Office of Technology Transfer: <https://www.ott.nih.gov/>

NCI TCC: <https://techtransfer.cancer.gov/>



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