

**Technology Transfer
at the
National Cancer Institute:
Priming the Innovation Pump**

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“Critical to [NCI’s] ultimate success will be the collaborations and partnerships necessary to further scientific discovery, to translate that discovery into the development of better prevention, detection and treatment methods, and to deliver that progress to all who are in need.

Andrew C. von Eschenbach, M.D.

Director, National Cancer Institute

(www.nci.nih.gov/directorscorner/welcome)



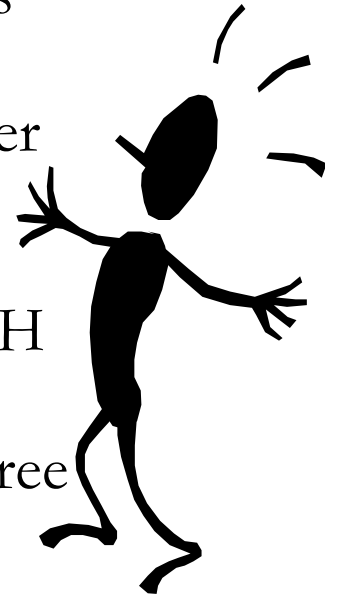
Technology Transfer at the NCI: Working Definitions.

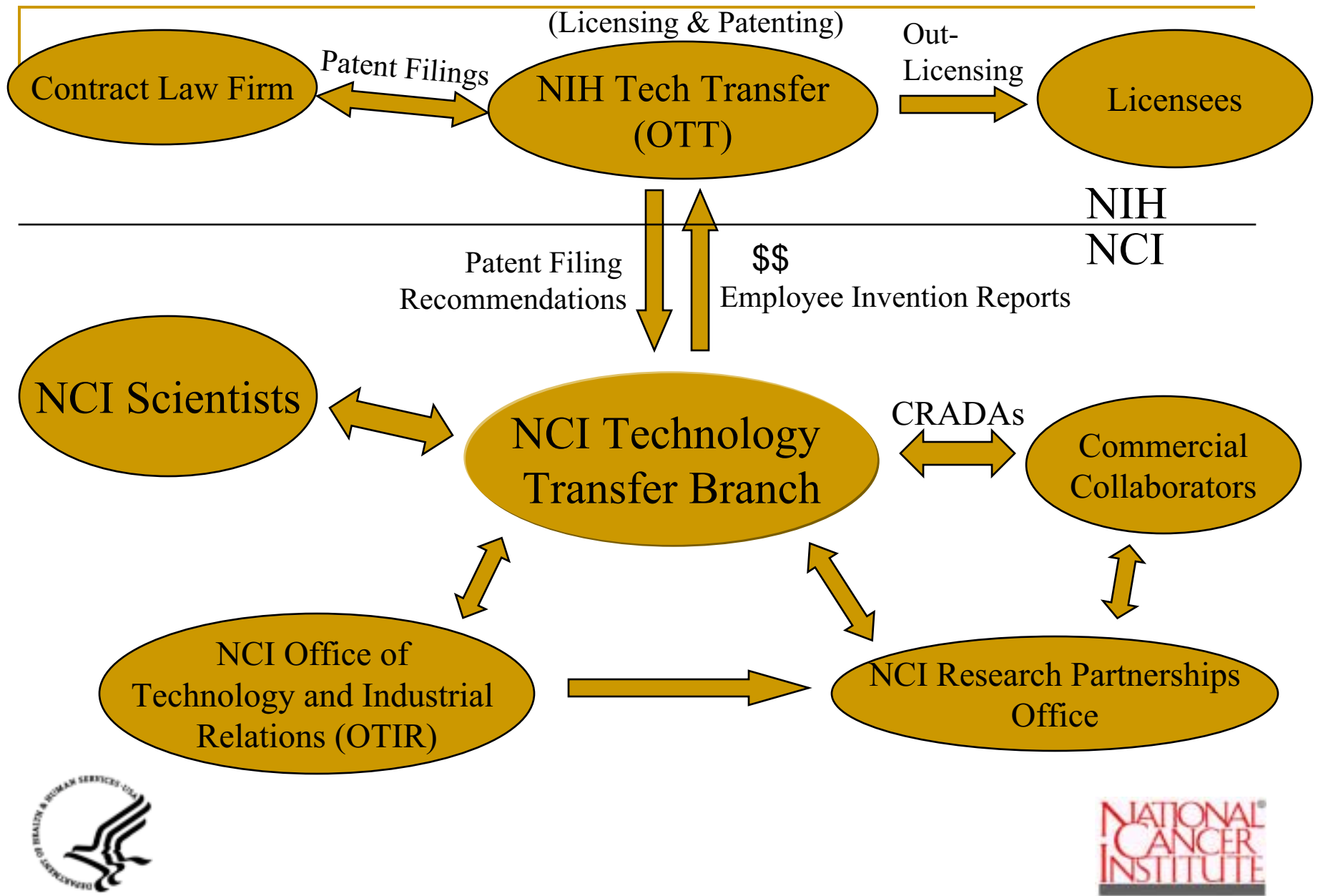
- › Implement the terms of the Bayh-Dole and Stevenson-Wydler Acts of 1980 and the Federal Technology Transfer Act of 1986 to *further the public good by appropriate transfer and commercialization of technologies created with government resources.*
- › Transfer knowledge in the form of intellectual property to public companies, universities and nonprofit institutions.



NCI's Technology Transfer Branch

- › 50 scientists, attorneys, former PTO examiners, business administrators, marketing specialists, and support staff
- › Manages ~250 active CRADAs and a wide range of other transactional agreements with industrial and academic partners
- › Serves as competitive service center for eleven other NIH institutes
- › Ensure that NCI's technology development activities agree with Federal statutes and regulations, and NIH policy.
- › Review employee invention reports and patentability reports, and approve filing of domestic and foreign patent applications by contract law firms through NIH's Office of Technology Transfer (OTT).





NCI's Transactional Agreements

Cooperative research and development agreements (CRADAs) for collaborative research on commercializable technologies;

Material Transfer Agreements (MTAs) for exchange of research materials;

Clinical trial agreements (CTAs) for preclinical and clinical studies of the safety and efficacy of new pharmaceuticals; and

Confidential disclosure agreements (CDAs) for exchange of confidential information.



What is a CRADA?

- › **CRADA** = **C**ooperative **R**esearch **A**nd **D**evelopment **A**greement
- › Authorized by the Federal Technology Transfer Act of 1986 (“FTTA”) and National Technology Transfer & Advancement Act of 1995 (“Morella Bill”)
- › Requires intellectual collaboration between Government scientist and (usually) company.
- › Collaborator gains access to technology, data and expertise, as well as option to future IP rights
- › **Funding** may be received by government



The CRADA Process

1. Find or select a partner
2. Draft a research plan (“**RP**”) to define Scope of proposed research
3. Negotiate agreement
4. Obtain approvals and carry out RP



CRADA Advantages

- › Provides collaborator option to IP rights in advance
- › Proprietary information held confidential
- › Government retains “use license”.
- › Government Scientists retain freedom to publish.



NIH Technology Transfer Policies

- › Minimize publication barriers and delays
- › Avoid patenting of ‘research tools’ such as cell lines, reagents, and animal models
- › Facilitate transfer of government technologies to the public



NEGOTIATION OF CRADA (Government License)

7.4 License in Collaborator Inventions.

Pursuant to 15 U.S.C. 3710a(b)(2), for inventions made solely by Collaborator employees under this CRADA, pursuant to Article 6.2, the Collaborator grants to PHS a **nonexclusive, nontransferable, irrevocable, paid-up license to practice the invention or have the invention practiced throughout the world by or on behalf of the Government for research or other Government purposes.**



Success!

- › ~42 CRADAs implemented by NCI in FY '02.
- › In FY03 NCI scientists collaborated with industry and other partners under 185 active CRADAs.
- › More information and Email notification available at <http://ttb.nci.nih.gov/cradaopp.html>



Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) Inventions:

Conforming with the Bayh-Dole Act



SBIR/STTR Funding has Three Phases

- › **Phase I** establishes technical/scientific merit and feasibility of proposed R/**R&D efforts**.
- › **Phase II** continues **R&D efforts** initiated in Phase I. Funding based on the results of Phase I, scientific and technical merit, and **commercial potential** of technology
 - £ **Commercialization Plan Required**
- › **Phase III**: During Phase III, the small business pursues commercialization with non-SBIR/STTR funds (either Federal or non-Federal).



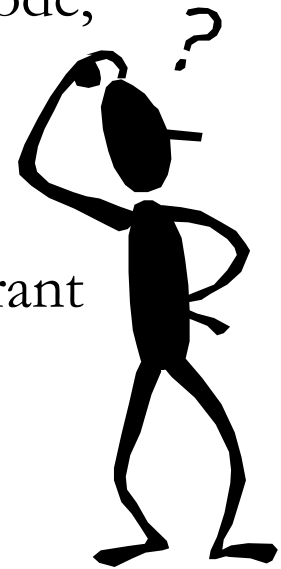
Main Provisions of the Bayh-Dole Act

- › Title of Federally supported inventions vests with the grantee/contractor organization
- › Grantee/contractors must demonstrate progress toward transfer of the technology
- › Requires acknowledgment of the government's involvement and license
 - £ Government use license
 - £ Federal support clause in the patent
- › Provides incentive to inventors and more rapid development and commercialization
- › Applicable to ALL U.S. Government funded grantees and contractors: Domestic and Foreign



What is an Invention (per Bayh-Dole)?

- › Standard patent rights clauses (37 CFR Section 401. 14)
 - £ (a) Definitions
 - › (1) **Invention** means any invention or discovery which is or may be patentable or otherwise protectable under Title 35 of the United States Code, ...
 - › (2) **Subject invention** means any invention of the contractor conceived or first actually reduced to practice in the performance of work under this grant or contract,...
 - › Does not include copyrightable materials, e.g. books
 - › Includes software; deemed patentable as of late '90s



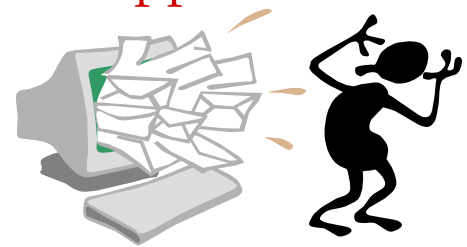
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Invention Reporting Requirements of SBIR Grantee/Contractors

Administrative Requirements (per 37CFR, 401.14)

- › Implement Employee Agreements ð **as needed**
- › Disclose Each Invention ð **within 60 days**
- › Resolve Election or Waive of Title ð **within 2 years**
- › File Patent ð **within 1 yr. of election**
- › Provide License to the Govt. ð **upon title election**
- › Indicate Govt. Support on Patent ð **with patent appl.**
- › Product Manufacturing in U.S. ð **required**
- › Report on Invention Utilization ð **annually**
- › Final Invention Report ð **at award close out**



Technology Transfer at the NCI Natural Products Branch

<http://dtp.nci.nih.gov>



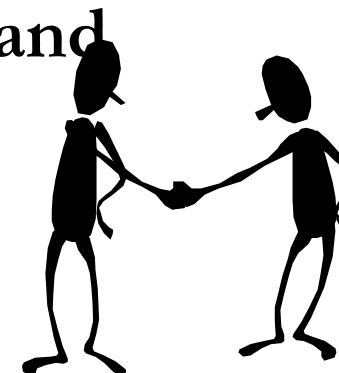
Natural Products Branch Activities

- › Collects crude natural product materials world wide for extraction and screening in the **NCI cancer cell line screen**
- › Collects large quantities of raw materials to produce sufficient quantities of active agents selected for preclinical and clinical evaluation.
- › Responsible for NCI's Open Repository Program and Active Repository Program, which provide materials to outside organizations under **Material Transfer Agreements**
- › Collaborates with qualified research organizations in source countries through the signing of a **Memorandum of Understanding** for screening natural product extracts for anti tumor activity, and the pre clinical and clinical development of active agents



NCI LETTER OF COLLECTION: BENEFIT-SHARING

§ Licensees of patented drugs required to negotiate agreements for collaboration and compensation with Source Country Organizations.

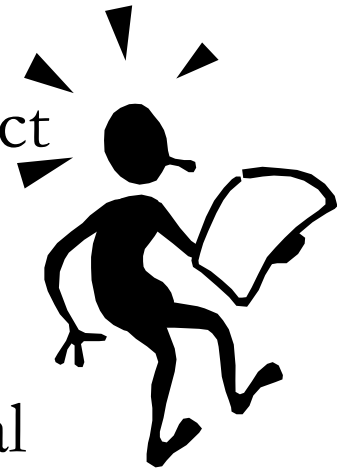


§ Licensees must use Source Country resources as first source of materials for drug production subject to mutually agreeable terms.



NPB's Material Transfer Agreement

- › Stipulates terms of access of source country to samples and confidential information in Active Repository
- › Allows source country access to crude extract materials from that country
- › NCI retains title to IP rights in materials
- › If material obtained under LOC, commercial licensees required to address mutual concerns of source country and NIH



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