Licensing Process and Policies

Licensing Process

• **Find the specific technology to license.** You can find technologies available for licensing in TTC’s online database of Available Technologies, from the database maintained by the NIH Office of Technology Transfer, or by discussions with a TTC Invention Development and Marketing Specialist (link sends e-mail). Preliminary discussions may then lead to detailed discussions with the researcher/inventor and a Technology Transfer Manager, and these discussions can be covered by a Confidential Disclosure Agreement (CDA) executed by the TTM. (TTM's manage intellectual property for any given laboratory at NIH). A CDA also may be obtained through the TTM if you want to obtain a copy of an unpublished patent application that covers the technology of interest.

• **Submit a License Application:** If you want to license an NIH invention, an Application For License is completed and submitted to a Technology Transfer Manager at the NCI TTC. This application serves as the primary basis for licensing decisions. It provides the TTC with information about the potential licensee, the type of license desired, some of the terms desired and the potential licensee's plans for development and/or commercialization of the invention. Also, if the applicant desires a license with some form of exclusivity, the completed application provides TTC with the applicant's justification for an exclusive license. Note: Confidential commercial or financial information provided in a license application is exempt from disclosure under the Freedom of Information Act (FOIA) (5 USC 552(b)).

• **Review of the License Application:** After reviewing the license application, TTC determines if the applicant's proposal is consistent with the licensing strategy developed for the invention and whether the grant of the license would benefit the public and be consistent with the interests of the Federal government.

  If the applicant has requested a nonexclusive license and a favorable determination has been made upon the application by NCI Licensing and Patenting Managers, then negotiations will begin as appropriate.

  If the you have applied for an exclusive or partially exclusive license, TTC will publish a notice in the Federal Register, as required by law, and after a 15 day period to receive comments on the proposed grant of an exclusive or partially-exclusive license, the TTC will re-evaluate the application and all public comments to make a final determination regarding the license. The criteria to be considered in evaluating exclusive license applications (37 CFR §404.7) include whether:
  
  ◦ Exclusive licensing serves the best interests of the public;
Practical application of the invention is not likely to be achieved under a nonexclusive license;
An exclusive or partially exclusive license is a reasonable and necessary incentive to promote the investment of risk capital to bring the invention to practical application;
Exclusive or partially exclusive license terms and conditions are not broader than necessary;
Exclusive licensing will not lessen competition;
Preference for "equally as likely" small business.

Licensing Policies

Starting October 1, 2015, the NCI Technology Transfer Center has authority for licensing, patents, and co-development agreements, including the lead responsibility for licensing intramural and extramural intellectual property for NCI and nine other ICs.

The NIH Office of Technology Transfer has policy-related duties, including the following:
• Serving as the focal point for NIH comment (through the NIH Office of Legislative and Policy Analysis) on legislative proposals regarding technology transfer and intellectual property policy; and
• Serving as coordinator for any updates to the Public Health Service Technology Transfer Manual.

Additionally, OTT makes determinations on behalf of NIH related to certain inventorship rights, including:
• Waiver of rights for an NIH invention to the employee inventor (EIW);
• Waiver of rights for a grantee/contractor subject invention to the inventor;
• Waiver of the US manufacturing requirement; and
• Assignment of title to a grantee/contractor subject invention to third parties.

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Source
URL: https://techtransfer.cancer.gov/partnering-with-nih/licensingagreements/licensing-policies