

About NIH

Capitalizing on Discovery

Technology Transfer

Technology transfer is essential to ensuring that the public has ongoing access to new and more effective health care products and procedures resulting from advances in medical research. Provisions of the Bayh-Dole Act (35 U.S.C. 200 et seq.) and the Federal Technology Transfer Act (15 U.S.C. 1501 et seq.) are intended to stimulate the commercialization of federally funded inventions by ensuring the transfer of federally funded technology to the private sector entity best suited to conduct the further research and development needed for potential commercialization and public health benefit. HHS has designated NIH as the lead agency for biomedical technology transfer and intellectual property (IP) policy matters affecting public health. The NIH [Office of Technology Transfer](#) (OTT) evaluates, protects, markets, licenses, monitors, and manages the wide range of intramural NIH and FDA discoveries and inventions; works with NIH's Office of Financial Management to manage the NIH Royalties Program; and takes the lead in developing technology transfer policies for NIH's intramural and extramural research programs.

Technology transfer policies, as they apply to extramural research, are administered by NIH OER and include principles, guidelines, and regulations related to invention reporting and intellectual property policy matters. [NIH extramural policies](#) are designed to enhance access to publications resulting from NIH-funded research (see *NIH Public Access Policy* below in this chapter); ensure appropriate sharing of data, tools, and research resources; and promote the transfer of technology (in the form of licenses and patents). All recipients of Federal grants or contracts must report details of inventions and patents that have been made through such awards. NIH OER administers the web-based Interagency "Edison" ([iEdison](#)) electronic reporting system through which inventions supported by more than 20 Federal research agencies can be reported through a single interface; approximately 500 grantee or contractor organizations are registered and using the system.

For the intramural research program, OTT reviews invention disclosures reported by the ICs and FDA; works with ICs/FDA to assess commercial and patent potential; oversees patent prosecution; negotiates licenses for commercial use in research and development; monitors licensing agreements with companies to ensure development compliance and royalty payment obligations; and administers the collection and distribution of royalties. Over the past decades, NIH has executed thousands of license agreements. In calendar year 2009, licensees reported nearly \$6 billion in sales of products covered by NIH licenses (see Table 2).

Table 2: Intramural Technology Transfer this Biennial

Activity	FY 2008	FY 2009
New U.S. patent applications filed	176	156
Patents Issued	88	110

Licenses Executed	259	215
Royalties Earned	\$ 97,200,000	\$91,200,000

NIH technology transfer activities include marketing and outreach to companies, coordinating inter- and intra-agency activities, and facilitating access to patented technology for NIH intramural and extramural research programs. The NIH [Pipeline to Partnerships \(P2P\)](#) searchable database, developed with the NIH [Small Business Innovative Research \(SBIR\) and Small Business Technology Transfer \(STTR\)](#) programs, encourages the development of technologies licensed from OTT or being developed by NIH SBIR/STTR awardees. P2P has expanded to include unique technologies from 158 companies as of November 2009. OTT also has launched the electronic [Product Showcase](#) to display technologies from NIH intramural research that were licensed to companies for commercial development and now are on the market. These products are used every day to detect, treat, or prevent disease or assist researchers as tools to explore ways to develop newer and more effective health care products and procedures. As of November 2009, there were 225 products in the Showcase database with new ones added regularly.

The National Library of Medicine

Through NLM, NIH provides the world's largest medical library, including electronic information services that deliver trillions of bytes of data to millions of users every day. The library collects materials in all areas of biomedicine and health care and plays a pivotal role in translating biomedical and behavioral research into practice. NLM collections stand at more than 12 million items—books, journals, technical reports, manuscripts, microfilms, photographs, and other forms of medical information. To maintain the currency of its collection, the library acquires publications from a wide variety of sources. Each year NLM reviews and processes approximately 25,000 monographic items for possible addition to the NLM collections, and acquires and licenses more than 22,000 print and electronic serial titles. Housed within the library is one of the world's finest medical history collections of old and rare medical works.

Far more than a physical facility, NLM also is responsible for PubMed[®]/MEDLINE[®], a database freely accessible on the Internet and that has more than 19 million journal article references and abstracts going back to 1948. The database draws on 5,300 of the world's leading biomedical journals published in the United States and more than 80 other countries. Links from PubMed references to full text articles in PubMed Central, NLM's digital archive of journal articles, or on publisher websites are now available for more than half of the 19 million references—and more than 86 percent of those published after 1999. MedlinePlus, a companion Web information service, is a goldmine of authoritative, up-to-date health information from all NIH components, other Federal agencies, and authoritative private organizations. It includes information about prescription and over-the-counter drugs, an illustrated medical encyclopedia, interactive patient tutorials, and the latest health news for health professionals and consumers alike, and gives easy access to medical journal articles. In FY 2008, high-quality consumer health information in more than 40 languages (beyond English and Spanish) was added to MedlinePlus to address the growing need for understandable information for non-English-speaking patients treated in hospitals and clinics across the United States. More than three billion searches of NLM online information resources are done each year by health professionals, scientists, librarians, and the public. (See also the sections on *Disease Registries, Databases, and Biomedical Information Systems* and on *Health Communication and Information Campaigns and Clearinghouses* in Chapter 3).

To manage its collection and maximize accessibility, NLM employs sophisticated cataloging and indexing schemes that in and of themselves are important tools for the Nation's network of medical libraries. These activities include maintaining and developing the online [NLM Classification](#), a scheme for the shelf

arrangement of medical literature in libraries, and [MeSH®](#), the library's controlled vocabulary thesaurus. MeSH® consists of descriptors in a hierarchical structure that permit searching at various levels of specificity. The MeSH® thesaurus is used for indexing articles for PubMed/MEDLINE.

The library virtually stands at the center of biomedical research—receiving, storing, disseminating, and connecting published research results, including articles deposited in response to the NIH Public Access Policy (see section below), with research data from laboratories and research centers around the world. NLM also supports, develops, and disseminates standard medical terminologies in the Unified Medical Language System. As the HHS coordinating body for clinical terminologies, NLM plays a leadership role in developing U.S. and international health data standards, including those related to electronic health records and the expansion of standards to cover genetic tests.

Public Access Policy

The [NIH Public Access Policy](#) ensures that the published peer-reviewed results of NIH-funded research are accessible to the public. In April 2008, the NIH mandatory Public Access Policy regarding peer-reviewed publications took effect. This policy replaced a voluntary practice that had been in place since May 2005. In accordance with the Consolidated Appropriations Act of 2008²⁴ and the Omnibus Appropriations Act of 2009,²⁵ the NIH Public Access Policy now requires the submission of peer-reviewed papers resulting from NIH-funded research to [PubMed Central](#) (PMC), a free, full-text, digital archive of biomedical, behavioral, and life sciences journal literature. These papers are made publicly available on PMC within 12 months of the official publication date. PMC and its international sites in the United Kingdom and Canada also support the public access policies of other U.S. and international funders of biomedical research.

The NIH Public Access Policy is off to a promising start, and NIH has made considerable progress toward full compliance. During the voluntary period (May 5, 2005, to December 31, 2007), NIH was able to collect only 19 percent of the target estimate of 80,000 papers per year arising from NIH funds. Based on publication data for July 2008 to June 2009, it is estimated that NIH now funds approximately 88,000 papers a year. Even with the higher target, NIH has received more than 60 percent of the papers published between July 2008 and October 2009.²⁶ These papers either are already available in PubMed Central or will be at the expiration of the typical 12-month embargo. This positive beginning to the requirement is due in large part to cooperation from NIH awardees and publishers. Since the policy became a requirement, the percentage of final published papers deposited directly by publishers has increased from 12 to 26 percent, and manuscripts submitted by authors have increased from 7 to 36 percent.

Through the Public Access Policy, NIH has been able to make tens of thousands of papers publicly available on PMC, which contains more than 1.9 million papers overall, most from publishers who have been participating in PMC since 2000. These papers are heavily accessed. On an average weekday, some 360,000 users retrieve more than 700,000 papers. These users include patients, doctors, educators, and scientists at universities and small businesses. Access to NIH-supported papers on PMC increases the likelihood that all of these groups will use the NIH investment in research to improve public health.

²⁴Division G, Title II, Section 218 of Pub. L. No. 110-161.

²⁵Division F Section 217 of Pub. L. No. 111-8.

²⁶The period from January 2008 to June 2008 is not reported, as papers published during these months were likely accepted for publication after the law creating the policy change was passed, but before the policy requirement took effect, and their rates are therefore possible to attribute to either policy condition.