The Office of Technology Transfer (OTT) is the central National Institutes of Health (NIH) office responsible for the management of inventions from NIH and the Food and Drug Administration (FDA) intramural research activities and for the development of technology transfer policy for NIH intramural and extramural research activities. Implementation responsibilities are shared among the OTT, the Office of Extramural Research (OER), and the Institutes and Centers (ICs). At the end of Fiscal Year 2005 (FY05), OTT was staffed by 57 Government full-time employees (FTEs), 10 contractors, one Intramural Research Training Award (IRTA) Fellow, and one American Association for the Advancement of Science (AAAS) Fellow.

Office of the Director, OTT

The Office of the Director provides advice to the NIH Director, other Department of Health and Human Services (HHS) agency heads, and Public Health Service (PHS) component ICs on general matters of technology transfer, including Cooperative Research and Development Agreements (CRADAs), patenting, license agreements, Material Transfer Agreements (MTAs), and associated policies involving intramural and extramural technology transfer activities. The Office is involved with numerous global, HHS, and NIH-wide issues involving intellectual property, innovation, and technology transfer. These activities include model or agency-wide agreements for the transfer of materials, issues raised by members of Congress and public interest groups, CRADAs, and inter- and intra-governmental technology transfer issues. Additionally, the Office staff gives presentations and meets with companies and non-profit institutions worldwide to facilitate public-private partnerships and to provide information on NIH technology transfer activities. This outreach also involves sharing policies and practices with Government and non-profit organizations to advance the development of technology transfer infrastructure.

In FY05, representatives from the Director's Office attended or presented at national and international meetings, including: World Health Organization (WHO); Council on Governmental Relations (COGR); Organization for Economic Cooperation and Development (OECD); Biotechnology Industry Organization (BIO); Association of University Technology Managers (AUTM); Pan American Health Organization (PAHO); Center for Strategic and International Studies (CSIS); Federal Laboratory Consortium for Technology Transfer (FLC); American Association of Pharmaceutical Scientists (AAPS); Licensing Executives Society (LES); Scottish Enterprise International Forum; WHO Commission on Intellectual Property; WHO Department of Vaccines and Biologicals Strategic Advisory Group of Experts (SAGE); BIO Forum 2005; Maryland BIO Forum; Chinese Biopharmaceutical Association; U.S. Healthcare Forum; ALSSA (Analytical & Life Science Systems Association) 2005 Senior Management Conference; and The Netherlands' Conference on Dutch/EU and US Initiatives.
The Office received a multitude of international visitors and represented HHS and NIH at international conferences around the globe. Representatives from the office were invited by the Irish Minister of Enterprise, Trade and Employment to meet with Ireland's scientific and academic institutions, technology transfer professionals, and biotechnology and medical device companies. International visitors to OTT included representatives from the UK, France, Sweden, India, Hungary, Germany, Japan, Columbia, and Ireland.

The Office also represented NIH at foreign embassy receptions and sessions on technology transfer, including those held at the Embassies of Finland, Ireland, Sweden, and Canada.

OTT undertook a comprehensive analysis of its portfolio and the needs and capabilities of emerging economies and entered into an on-going dialogue with regional institutions, international organizations and private foundations. As a result, OTT has identified a niche of technology transfer opportunities for technologies related to diseases such as HIV/AIDS, pertussis, malaria, dengue, childhood diarrhea (rotavirus), meningitis, typhoid fever, cancer, and diabetes. In FY05, more than 15 license agreements were completed with public and private institutions in India, Mexico, Brazil, China, Korea, Egypt, and South Africa.

In partnership with technology transfer offices at several U.S. universities, OTT developed a database of technologies available from these institutions pertaining to neglected diseases. This database should be an important resource for technology managers of universities and research centers in developing countries and institutions interested in licensing technologies related to the treatment, prevention and diagnosis of neglected diseases. It is available presently on the OTT website although discussions are underway with other potential hosts. The expectation is that other U.S. universities with technologies related to neglected diseases will eventually join this initiative.

In FY05, OTT's International Training Program included a representative from the Chinese Academy of Sciences and a commercialization manager from the Council for Scientific Industrial Research (CSIR) of South Africa. In addition, the Office conducted on-site training sessions for representatives from Ghana, Zambia, India, Brazil, Japan, and Korea. OTT staff participated in intellectual property management workshops in Mexico, Argentina, China, Croatia, and Hungary.

The Office initiated a new program for advancing the research infrastructure of Minority Educating Institutions (MEIs) and establishing a framework that promotes capacity building and sustainability such that it fuels new research enterprises. This is a joint initiative with the Kauffman Foundation for Entrepreneurship, the Oak Ridge Associated Universities, the National Science Foundation, the American Association for the Advancement of Science, Florida State University, and Florida A&M. The initial objective is to deliver a cost-effective and efficient process (toolkit) for managing intellectual assets, transforming research to commercialization, and positioning the MEIs to advance their science and engineering technology portfolios. As part of this initiative, the Office participated in the 6th Annual Congressional Forum for Historically Black
Colleges and Universities, the White House Initiative on Historically Black Colleges and Universities, and the National Sponsored Programs Administrators Alliance of Historically Black Colleges and Universities. Additionally, the Deputy Director has been invited to serve as Federal Liaison to the Board of Advisors for Jackson State University College of Science, Engineering and Technology.

The marketing group coordinates and conducts marketing activities, including evaluating technologies, identifying potential markets for technologies, and disseminating current technology transfer information. The marketing group promoted NIH technology transfer through the OTT web site, exhibits and presentations at technology shows, an e-mail newsletter, dissemination of promotional materials, and a targeted marketing program.

The marketing and management of the vast and varied portfolio of intramural inventions is a critical aspect in translating scientific discoveries into products that can benefit public health. OTT has established a Knowledge Management (KM) system called TechMatch. The system is composed of software, hardware, and databases to enable marketing and licensing staff to bring meaning and relevancy to large sets of scientific, technical, and legal documents using one single KM interface to access real-time information relevant to the NIH and FDA intramural inventions. The marketing group focused its immediate efforts on leveraging this text mining software and developed TechMatch to improve the marketing and management of NIH intellectual property assets. In its initial year, the project succeeded in text mining the following data sources: TechTracS (the OTT database of NIH and FDA patent, licensing and CRADA activities), the U.S. Patent and Trademark Office database, Medline, science news wires, and NIH CRISP (Computer Retrieval of Information on Scientific Projects).

The marketing group developed an interactive Marketing CD to partly replace and supplement OTT's printed marketing materials. The inclusion of a full and comprehensive set of information and the placement of appropriate links to the OTT website has made the CD a stand-alone informational piece. Additionally, a catalogue of NIH medical engineering technologies available for licensing was developed and used to promote these technologies to companies and investor groups.

A new avenue of promoting NIH's inventions was opened up through our relationship with the Federal Laboratory Consortium (FLC). Abstracts of three NIH technology licensing opportunities were published in the FLC monthly newsletter, NewsLink, which has a readership of approximately 7,000.

The marketing group nominated two groups of NIH inventors for the mid-Atlantic Federal Lab Consortium Inventor awards. Both groups won and were presented with the awards at the FLC annual meeting. These same two groups of inventors were nominated for the annual Intellectual Property Owners Association Inventor of the Year award. While neither group received the top award, both reached the Top Five status. Based on nominations from the National Heart, Lung and Blood Institute (NHLBI), the mid-Atlantic Federal Lab Consortium presented awards to two NHBLI scientists for their inventive contributions.
Division of Technology Development and Transfer (DTDT)

This Division has the primary responsibility for overseeing all OTT program activities related to the reporting of intramural inventions, assessing the commercial and patent potential of the technologies, securing patent protection for commercially viable technologies, negotiating licenses for commercial research, development, and sale as well as the monitoring and enforcement of those agreements. Included in these patent and licensing responsibilities are industrial outreach as well as inter- and intra-agency coordination activities, coordination and support of collaborative research activities, and coordination and resolution of national and international patent and licensing issues relating to NIH extra- and intramural programs. DTDT is organized into five branches: Cancer, Infectious Diseases and Medical Engineering, General Medicine, Monitoring and Enforcement. In addition there is a Technology Transfer Service Center.

DTDT reported the following statistics for NIH technology transfer activities for FY05 (the numbers include FDA technologies unless otherwise indicated):

<table>
<thead>
<tr>
<th>Category</th>
<th>Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Invention Disclosures Received</td>
<td>388</td>
</tr>
<tr>
<td>New U.S. Patent Applications Filed</td>
<td>186</td>
</tr>
<tr>
<td>Issued Patents</td>
<td>66</td>
</tr>
<tr>
<td>Executed Licenses</td>
<td>313</td>
</tr>
<tr>
<td>Royalties (in millions)</td>
<td>$98.2</td>
</tr>
<tr>
<td>Executed CRADAs (NIH Only)</td>
<td>80</td>
</tr>
<tr>
<td>Standard</td>
<td>39</td>
</tr>
<tr>
<td>Material</td>
<td>41</td>
</tr>
</tbody>
</table>

Of the 313 licenses executed during the fiscal year, new agreements were finalized with 18 foreign countries, including Hong Kong, Japan, Germany, Brazil, the Netherlands, China, Canada, France, Israel, South Korea, the United Kingdom, India, Switzerland, Egypt, South Africa, Italy, Belgium, and Australia.

Some of the NIH technologies licensed this fiscal year included: mouse model of human osteoarthritis, in vitro diagnostic and/or prognostic uses for extra-cellular cAMP-dependent auto-antibodies in human cancer, recombinant immunotherapeutic pox virus-based vaccines for use in the prevention and/or treatment of cancer in humans, therapeutics using BL22 or HA22 for CD-22-expressing hematologic malignancies, development of a peptide vaccine containing melanoma cancer antigen gp100 in conjunction with BMS-663515 for the treatment of melanoma in humans, and multivalent rotavirus vaccine technology based on bovine-human reassortants. The Division also concluded Interference settlement agreements with Merck, GlaxoSmithKline, and DKFZ (the German Cancer Institute) regarding the human papillomavirus vaccine that allowed the parties to move forward with the development of the vaccine.

The Monitoring and Enforcement Branch monitors the status of executed licenses; reviews, reports, and attempts to resolve potential infringement of NIH intellectual
property. The Branch also resolves disputes with licensees regarding non-payment and other issues that may result in amending licenses. During the fiscal year, 313 new licenses were executed while 74 licenses were terminated and 91 licenses expired, resulting in a net increase of 148 licenses and a total of over 1300 licenses to track and monitor. Branch activities resulted in the collection of $361,057 from audits, $4,947,024 from collections, and $2,588,494 from new licenses, for a total of $7,896,575.

The Technology Transfer Service Center provides a variety of services to the ICs, including review of Employee Invention Reports and patent annuity payments, and administration of TechTracS, the OTT proprietary database. In addition, OTT executed a Memorandum of Understanding (MOU) with the National Institute of Mental Health (NIMH) for the Center to serve as its Competitive Service Center. The Center will provide a full range of technology transfer services that would otherwise be managed by the Institute. The Center also initiated reviews of the NIMH portfolio in preparation for a new marketing campaign.

OTT utilizes proprietary software named TechTracS (i.e. Technology Tracking System) to record, facilitate, and coordinate many office functions (e.g. docketing, work-flow, and records management). The Technology Transfer Service Center continues to manage substantial enhancements to TechTracS, which this fiscal year included: adding a new Monitoring Module for tracking post-license execution activities, adding Congressional Data and Congressional District information to facilitate congressional information requests, a new 4D Client implementation of the NIH Passport security requirements, updating the Extramural Waiver module and importation of older data, importing the NIH National Enterprise Directory (NED) numbers of many NIH inventors to enable cross referencing with other NIH databases, and numerous other enhancements to the Patent, Technology, and Invention tables to enhance interface and user productivity.

DTDT staff hosted three technology transfer training lectures for the entire NIH technology transfer community, coordinated and taught two Foundation for Advanced Education in the Sciences (FAES) courses entitled “Technology Transfer” and “Biomedical Business Development for Scientists” and served on both the PHS Technology Transfer Policy Board (TTPB) Training and Education Subcommittee and the Technology Development Coordinators (TDC) Training Working Group, and hosted the “NIH On-Line Technology Transfer Training” module on the OTT Web-site.

DTDT staff also co-chaired the “Technology Transfer Task Force” for the Greater Washington Board of Trade and provided support and mentoring for their “Virtual Incubator” Program. Two technologies submitted by NIH OTT were selected by the Virtual Incubator for further development.

Division of Policy (DOP)

OTT serves as the lead office within NIH for developing policies and procedures related to technology transfer and intellectual property matters. The Division of Policy provides much of the resources for these activities. Among the activities performed within the
DOP, many are aimed at crafting and communicating policies that enhance the translation of early-stage technologies into practical applications that, directly or indirectly, support the improvement of public health. These roles include assisting offices and programs across the government, including HHS and its component agencies on issues concerning health-related technology transfer matters and providing advice and expertise on a range of issues related to associated intellectual property. DOP also supports technology transfer and development activities by offering training, and by acting as liaison between components of the NIH and a variety of outside organizations. Furthermore, the DOP provides HHS and NIH representation within interagency, intergovernmental, and international fora. The DOP also hosts the Cooperative Research and Development Agreement (CRADA) Administrator and Coordinator, who facilitate implementation and management of CRADAs across NIH.

DOP was involved in a trans-NIH working group to advance the NIH Rapid Access to Interventional Development (RAID) program, a major initiative of the NIH Roadmap. The working group helped to establish agreements to transfer materials between applicants and NIH.

The Division of Policy spearheaded a pilot feasibility study for developing new measures of technology transfer outcomes. These new metrics focus on the manner and extent to which products utilizing licensed NIH or FDA intramural technologies are meeting the NIH mission of advancing research to ultimately improve public health. More specifically, the evaluation involved developing a menu of tools and metrics that can be used to measure the impact of NIH and FDA technologies on public health and biomedical research. The evaluation also assessed the usefulness of the final metrics, recommended new measurement tools, and identified data sources necessary for application of the proposed new metrics to value the effectiveness of NIH based technologies from the bench to the bedside.

The DOP also has provided policy-related assistance in connection with various technology transfer and intellectual property related matters before the legislative and executive branches. More specifically, the DOP provided policy-related support through NIH's Office of the Director and Office of the General Counsel (OGC) to the U.S. Department of Justice in connection with a variety of patent litigations that affect public health, including cases relating to patent infringement research exemptions (Merck KGaA v. Integra Lifesciences I, Ltd., No. 03-1237) and the patentability of diagnostic methods (Laboratory Corp. of Am. v. Metabolite Labs, Inc., No. 04-607). Similarly, through OGC and NIH's Office of the Director, the DOP provided policy related comments to the U.S. Patent and Trademark Office (PTO) on the following: patent interference practice before the PTO's Board of Patent Appeals and Interferences; restriction practice; the PTO's implementing regulations to the Cooperative Research and Technology Enhancement (CREATE) Act; and the PTOs written description guidelines.

The CRADA Administrator has formed a CRADA Policy Working Group that has proposed a revised CRADA Subcommittee charter, updated the Conflict of Interest and Fair Access Survey (COIFAS) form, and started reviewing the PHS Technology Transfer
Manual Chapters on CRADAs for any proposed changes. She also has formed a working group to clarify which extramural scientists may serve as the Primary Principal Investigator on CRADAs.

In FY05, DOP processed and reviewed 45 standard CRADAs, 50 Material-CRADAs, 107 extramural waiver requests, and helped the extramural program of the National Institute on Aging negotiate Material Transfer Agreements (MTAs) with foreign entities. The OTT FOIA coordinator is part of the Division of Policy and has responded to numerous FOIA requests.

Finally, the DOP, working through the NIH Office of Legislative Policy and Analysis (OLPA), served as a resource for the development of NIH input on a variety of legislative initiatives that relate to technology transfer, intellectual property policy, and associated operational issues. Similarly, the DOP has helped HHS respond to Congressional inquiries by, for example, collecting data and providing suggestions on technology transfer and intellectual property policy matters affecting public health and academic research.

Division of Administrative Management (DAM)

This Division is responsible for the internal policy development, guidance, and conduct of administrative and management functions within OTT, including financial management; human resource management; administrative training; travel; purchase and maintenance of equipment and supplies; acquisition and management of space; contracts and interagency agreements; database management; and records and forms management. DAM is also responsible for the post-license agreement administration tasks related to royalty collection through the NIH Office of Financial Management (OFM), recoupment of patent costs from licensees, receipt of annual progress reports, and assistance in audits of licensees. In FY05, NIH collected $98.2 million in royalty payments from 841 license agreements or amendments from a total of over 1,300 active licenses.

In June 2004, the HHS Office of Inspector General began a year-long audit of NIH royalty processes and collections, reviewing all payments received in FY 2002, 2003 and 2004. As a result of their initial findings, the auditors determined they only needed to perform an in-depth review on a small sample of the payments and associated license agreements. While its investigation is complete, the OIG had not submitted a report on its findings and recommendations to the Director, OTT, by the end of the fiscal year.

DAM improved liaison activities and reporting procedures to the Office of Financial Management (OFM), which resulted in Royalties being distributed to Institutes and Centers in less than half the time than in previous years, 20 days as compared to two to four months. Additionally, the implementation of paperless processing of post-license agreements and notices has significantly reduced the effort needed to distribute documents to licensees, NIH Technology Development Coordinators (TDCs), and the OFM and greatly improved communication within the NIH technology transfer community.
DAM oversaw the hiring of 11 new FTEs, 18 contractors, and three IRTA fellows for OTT. Additionally, DAM processed 15 interns from the ICs, educational institutions, and foreign countries. The Division also succeeded in the recruitment and placement of two interns from the NIH STRIDE career development program. The interns have been placed in positions within DAM and the Division of Policy. Administratively, the office received more than 1,300 visitors and processed more than 480 non-patent prosecution related invoices, 114 training and registration fee requests, and 161 travel orders. The information technology personnel reviewed two NIH-wide IT policies, provided IT and TechTracS support to 129 people, and were involved in the re-design and development of the OTT website.

DAM supported the multi-award contract to law firms for patent prosecution of NIH and FDA inventions. In FY05, the group managed 14 law firm contracts and authorized 3,285 orders. Initially, $30M was obligated on the orders for patent prosecution. During the fiscal year, DAM staff reduced the obligations to $21M as a result of careful review of orders, invoices, action items, matching obligations to expenses, and reducing the obligations as necessary. There was a net increase of 11% in patent prosecution obligations for FY05.

In an effort to reduce the number of prior year unliquidated law firm orders, DAM personnel reviewed all prior year open orders and closed, reduced and/or paid more than 1,000 orders that resulted in reducing IC prior year obligations by nearly $3.4M. DAM has instituted a quarterly review of all open orders to ensure the efficient and effective de-obligation of funds, as necessary.

During FY05, DAM processed almost 400 invoices and authorized nearly $3M for 121 Record of Call Orders to pay U.S. maintenance and foreign annuities patent fees.
Articles authored by OTT personnel


Posters presented by OTT personnel

Zhang Y, Balakrishnan K, "How to Find Licensees without Breaking the Bank," AUTM Annual Meeting, Phoenix, AZ, February 2005

Finley, S, "NIMH Technology Transfer," 9th Annual NIMH IRP Scientific Retreat, September 2005

Select presentations by OTT personnel

Tumor Selective Inactivators of O-6-Alkylguanine-DNA Alkyltransferase for Improving Chemotherapy, Southeast Expo, October 2004


Technology Transfer: the NIH Experience, Technology Transfer: The U.S. Experience, Italy's Case, and the Future Conference, Venice, Italy, October 2004

TT with Institutions in Less Developed Countries, WHO IP Commission, Bethesda, MD, October 2004

Products, Partners & Public Health: Commercialization of New Technologies from NIH, Presentation, TEDCO/Neuroscience@NIH Technology Partnering Showcase, Gaithersburg MD, October, 2004

Products, Partners & Public Health: Commercialization of New Technologies from NIH, Presentation, Johns Hopkins Lab2IPO Course, Baltimore, MD, October, 2004

B2B Marketing and Technology Transfer, Presentation, Licensing Executive Society Annual Meeting, Boston, MA, October 2004

Improving Public Health through PPPs, Scottish Enterprise, Baltimore, MD, November 2004

‘Of Mice & Meri’: NIH Perspectives On Research Tools, Presentations, Research Tool Forum, Nagoya University & Kyoto University, Nagoya & Kyoto, Japan, November 2004

NIH TT: Collaboration to Add Value to New Technologies, Enterprise Ireland, Ireland, November 2004

PPP: Balancing Public and Private Partner Needs, American College of Neuropsychopharmacologists, Puerto Rico, December 2004

NIH Technology Transfer: An Overview, the NIH Clinical Center's IPPCR (Introduction to the Principles and Practice of Clinical Research) course, January 2005


Facilitating Public Policy Goals in License Agreements, Presentation, Duke University Conference on IP and Public Policy, Durham, NC, February, 2005


Products, Partners & Public Health: Commercialization of New Technologies From NIH, Presentation, Pfizer Strategic Alliance Meeting, Groton, CT, March, 2004

Licensing Technologies from NIH, Presentation at the Swedish-American Entrepreneurial Days 2005, Rockville, MD, April 2005

NIH Technology Transfer, USPTO Visiting Scholars Program, Alexandria, VA, April 2005


National Institutes of Health Technology Transfer Activities in China, Presentation, Burrill/Perkins Coie BIO Conference, Philadelphia, PA, June 2005

Products, Partners & Public Health: Commercialization of New Technologies from NIH, Presentation, Italy Economic Development BIO Conference, Philadelphia, PA, June 2005

Why is Intellectual Property Important? and How to Recognize Commercialization Value in Your Research, RCMI Principal Investigators' Meeting, NIH, September 2005

Outreach and Communications Challenge in Technology Transfer, Session Chair, Federal Laboratory Consortium Mid-Atlantic Meeting, Cumberland, MD, September 2005

Disruptive Technology Transfer and NIH: The Case of Taxus Express ™, Presentation, Technology Transfer Society Annual Meeting, Kansas City, MO, September 2005

Trade Shows

Southeast Technology Expo, Research Triangle Park, NC

TEDCO/Neuroscience@NIH Technology Partnering Showcase, Gaithersburg MD
2004 LES Annual Meeting Tech Fair, Boston, MA

American Association of Pharmaceutical Scientists, Annual Meeting 2004, Baltimore MD

MD BioForum 2004, Rockville MD

Mid-Atlantic BIO/MED Conference and Exhibition, Baltimore MD

Mid-Atlantic Venture Association (MAVA)/Greater Washington Board of Trade, Potomac Conference, College Park MD

AUTM 2005 Annual Meeting/Networking Fair & Technology Exchange, Phoenix AZ

Drug Discovery Technology 2005, Boston MA

Awards received by OTT personnel

NIH Director's Mentoring Award (1)

NIH Merit Awards (3)

NIH Technology Transfer Training and Seminars

734 NIH employees completed the mandatory internet-based Technology Transfer Training modules

‘Optimizing Patent Claims for Licensing’

‘Inequitable Conduct in Bio/Pharma Applications: The New/Old Plagué’

‘FDA Regulation of in vitro Diagnostic Devices’

“The National Venture Capital Association and its Medical Industry Group, and its Role in Addressing the Unique Needs of its Members Investing in the Life Sciences Industry”

‘Working with OTT's Outside Law Firms’

“Vaccine Technology Transfer to the Developing World - 1895 to 2005”

“LabCorp v. Metabolite and the Grokster cases pending before the Supreme Court”

“Patentability of New Uses for Old Diagnostic Methods: Can you Patent a Natural Phenomenon?”

“Things I Wish I Knew While I was at OTT that I Only Learned after I Left”

‘Principles of Win/Win Negotiating’

‘Resources for Evaluating Biotechnology Inventions’

‘Interim PTO Rules for Adoption of the Cooperative Research and Technology Enhancement (‘CREATE’) Act’

‘Overview of the Freedom of Information Act at the NIH’

‘Proper Care and Feeding of Paper and Electronic Laboratory Notebooks’

‘Recent Changes to 35 USC §103(c) and New USPTO Fees’

‘Inequitable Conduct in Bio/Pharma Applications: The New/Old Plague?’

“An Overview of USPTO Interference Procedures’

‘Policies, Procedures, Structure, etc. of NHLBI’s Technology Transfer Office’

‘Policies, Procedures, Structure, etc. of NIAID’s Technology Transfer Office’

‘Inventorship and Ownership Rights Determinations involving PHS Employees’

‘Dealing with Problems in Patent Prosecution before the USPTO’

‘Information Disclosure Statements as seen by the Federal Circuit and the USPTO’