National Institutes of Health
Office of Intramural Research
Office of Technology Transfer

Technology Transfer Community Newsletter

What a Year!

It's been over a year since the official reorganization of the NIH Technology Transfer Program. Hats off to the community for all of your hard work toward a smooth transition. Many attended extra meetings, served on committees, helped train staff, updated systems, learned new processes, improved communication, moved offices, and in general just adapted to changes throughout the year.

Take a look at just some of the work that was accomplished this year, despite all of the transition activities…

- Negotiated and executed 299 agreements
- Licensed 430 technologies NIH/FDA/CDC-wide
- Submitted and processed 313 Employee Invention Reports
- Managed 635 Patent Applications and 553 World-Wide Patents
- Executed 108 CRADAs
- Prepared 76 "Green Sheets"
- Submitted 2734 Request for Quotes to the Law Firms
- Docketed more than 10,000 Patent and Law Firm documents
- Posted 1,676 income items for a total of $137M in royalties
- Activated 170 users of NIH TechTracS
- Connected 10,082 staff to the OTT SharePoint site

Basically, "YOU ROCK". Here's to another successful year in the Technology Transfer Community.

"appreciate this moment, stop and look around you. be thankful for all you have and where you are because this time next year, nothing will be the same." –r.h.Sin

Technology Transfer Working Group (TTWG)

The Technology Transfer Working Group was formed by Dr. Gottesman, Deputy Director of Intramural Research, in the early part of 2015 to tackle the myriad of challenges presented by the reorganization of the Technology Transfer Program at the NIH. The membership of the working group changed as the community progressed through the reorganization, but included the following staff:

Anna Amar (NIH/NIDDK)
Susan Ano (NIH/NINDS)
Laurie Arrants (NIH/NINDS)
David Bradley (NIH/NIDCR)
Alan Deutch (NIH/NHLBI)
Claire Driscoll (NIH/NHGRI)
Steve Ferguson (NIH/OTT)
Ann Hammersla (NIH/OD)
Bonny Harbinger (NIH/OTT)
Deborah Kassilke (NIH/OTT)
Timothy Leahy (NIH/OTT)
Karen Maurey (NIH/NCI)
Michael Mowatt (NIH/NIAID)
Charles Niebylski (NIH/NIDDK)
Lili Portilla (NIH/NCATS)
Richard Rodriguez (NIH/NCI)
Karen Rogers (NIH/OTT)
Alice Welch (FDA/OC)
Mark Rohrbaugh (NIH/OD)
Jennifer Wong (NIH/NIMH)

With the anniversary of the reorganization behind us, the last official meeting of the TTWG was held on October 20, 2016. A big thanks to this group for all of their efforts to keep the ship sailing straight. Have no doubt as the community moves into the next year that existing and new working groups will help us navigate new challenges.

Service Now/Help Desk Tickets for NIH TechTracS or SharePoint

In our continuing efforts to better serve the NIH Tech Transfer Community, we would like to remind everyone of the requirement to open an NIH IT Help Desk ticket when needing access to or have questions concerning OTT SharePoint or NIH TechTracS.

As our community continues to expand, your emails, Lync messages, voicemails, and phone calls are no longer the most efficient means for requesting assistance.

Submitting NIH IT Help Desk tickets allows OTT the opportunity to prioritize all incoming requests, route requests to the appropriate OTT personnel, and provide timely and sequential resolutions to your requests, while offering the transparency of our efforts.

To submit a Request for Service go to:
itservicedesk.nih.gov/support/

Docket Reports Have Been Updated

We realized that the Docket Reports were losing their context in the post-reorg environment and the intended purpose wasn't clear. As a result, both sets of reports, the LPM and Supervisor versions have been updated. The new reports launched on Monday, October 31, 2016.

Purpose of the Reports
The reports were designed to be a tool to assist LPMs and Supervisors with managing patenting and licensing matters. The reports provide regular updated summaries of significant events and offer the LPMs the ability to summarize, identify priorities, and safely monitor their technologies.

Reports Schedule (Alternating Weeks)

Licensing Related Reports
- License Applications Summary
- License Application Actions
- CRADA Determination Status

Patenting Related Reports
- EIR and Waiver Review Report
- PCT, National Stage, and Regional Validation Filing Deadlines
- Actions and Work Orders

The Changes You'll See (Title, Format, and Intro)
The titles of the reports have been updated and now have a standardized title in the subject line. All reports begin with "DOCKET REPORT:" which is helpful, especially for those of you who utilize the folder options in Outlook.

The formats of the reports have been updated to be more cosmetically appealing. The fields have been reconfigured to align better with the fields and information in NIH TechTracS. The reconfigured reports are longer in length but they provide clearer information.

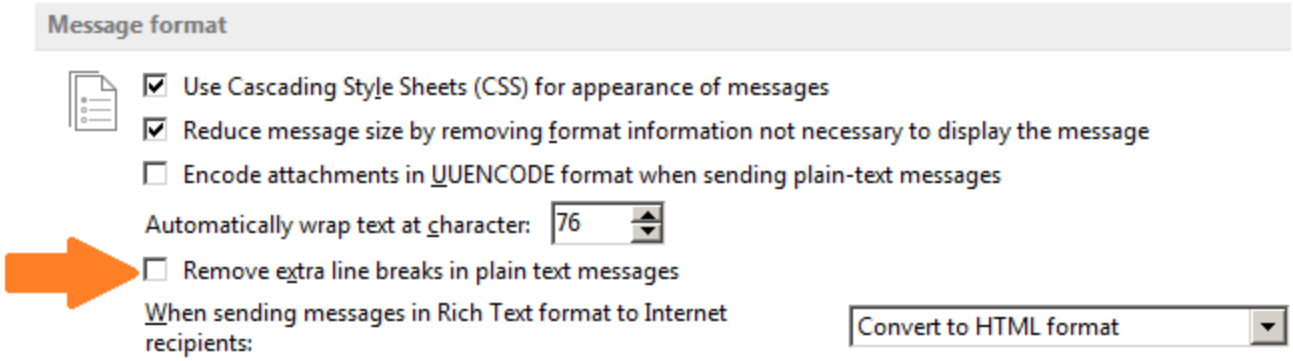
Each report contains a brief introductory statement that will provide guidance on the details included in the report.

Program Specialists
For those ICs or centers that utilize filing decision memos and have Program Specialists (PS) on staff, please remember to share the details of the memos with the PSs. Doing so will allow the PSs the opportunity to docket the details of those recommendations and filling authorizations accurately into TechTracS, while positively impacting the docket report containing **PCT, National Stage, and Regional Validation Filing Deadlines**.

OTT (Jill Roering and Karen Rogers) continues to work closely with PSs to aid them in understanding the strategic role each PS plays in managing patent activities in support of LPMs.

Informational Guides
Informational guidance has been developed for each type of the six docket reports. The guides will be posted on the SharePoint site under the **Training** section and in the **LPM** and **BC Manual**.

Are You Ready for the New Docket Reports?
Due to the new formatting of the docket reports, the settings in your Outlook may need to be changed in order to see the reports in their intended format. In order to confirm your settings, please select **File** in the upper right-hand corner of Outlook. Next you'll need to select **Options** and then **Mail**. Scroll down toward the bottom portion until you see **Message Format**. Look to see if **Remove extra line breaks in plain text messages** is *not* selected. In order to view the new format of the docket reports, this field should *not* be selected:



LPM Permissions Role in TechTracS

The LPM permissions role in NIH TechTracS is for the individual with the authority to negotiate licensing terms and make patent prosecution and maintenance decisions for the NIH's technologies.

This role provides the individual with the ability to issue new Actions, generate Task Order Request for Quotes (aka Work Orders), approve/reject Task Order Request for Quotes (estimates), and approve/reject Invoices for patent prosecution costs.

This role provides access to the fields and tables necessary to perform these licensing and patenting activities. These activities take place in the Action/Work Order, Invention, Technology, Patent, and License Application tables in NIH TechTracS. However, not all fields within these tables are available to this role.

Some tasks that cannot be performed by this permissions role include:

- administratively close license application records and patent application records;
- create CRADA records;
- add data associated with initial/additional publication of an abstract for a new patented invention or research material;
- add data into the License Application table that is associated with the prospective grant notices for an exclusive license;

- create a License Number;
- close out a license application and route the license application to the Royalty Administration Unit.

Requirements for USPTO Registration Number

Before Technology Transfer Staff can direct the contract Patent Law Firms to do any work, they must have a United States Patent and Trademark Office registration number and they must be identified in a letter to the law firms. A search for the registration number can be made on the USPTO web site (https://oedci.uspto.gov/OEDCI/practitionerSearch.jsp). To add a staff member to the notification letter, Technology Development Coordinators should send an e-mail with the USPTO registration number and staff name to Karen Rogers at RogersK@nih.gov.

For a staff member wishing to obtain a USPTO registration number, there are a number of educational requirements as well as an examination to be taken. Details about this can be found at: http://www.uspto.gov/about-us/organizational-offices/office-general-counsel/office-enrollment-and-discipline/becoming.html.

New License Compliance Checks Really Do Work

License negotiators are reminded to consult with the OTT Royalties Administration and Monitoring and Enforcement Units for company compliance prior to execution of new license agreements. Send an e-mail with the name of the company to Bruce Goldstein, Chief, Monitoring and Enforcement Unit, (goldsteb@mail.nih.gov) and Debbie Collins, Royalties Administrator, (collinsde@od.nih.gov) requesting clearance to proceed with a new license agreement.

Why? Licensees may have outstanding obligations to submit progress reports or royalties. Holding up execution of new agreements until licensees are in compliance gives the NIH the muscle we need to bring the licenses into compliance and collect the royalties that Institutes and Centers need.

IC Program Specialist Monthly Meetings

The next IC Program Specialist Meeting will be held on Wednesday, November 16th, at 2:00, in the OTT Conference Room B. Thanks to Mayra Alvarez (NCATS) for chairing. This is a great opportunity for you to ask questions in a welcoming environment and learn from OTT staff and each other. We encourage Program Specialists to come in person and network.

Technology Transfer Community Staff

Welcomes and moves…

Sidra Ahsan has joined NCI TTC as a Technology Transfer and Patenting Fellow. She received her Ph.D. in Cancer Biology from Wayne State University School of Medicine and Karmanos Cancer Institute in Detroit. The focus of her graduate training was molecular biology, targeted therapeutics, and genetics. After graduate school, Sidra joined a small biotech company, Advaita Bioinformatics, as a product manager of a pathway analysis tool, where she gained expertise in product development, marketing, and bioinformatics. She has also previously interned in the lab of Curtis Harris at NCI, where she worked on identification of cancer stem cell markers in non-small cell lung cancers.

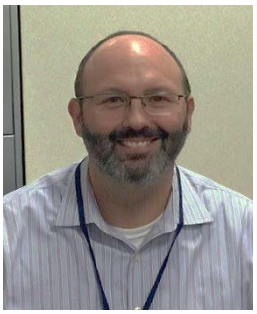
Anna Amar has joined the Office of the Director, DCTD, NCI as a Senior IP Advisor, where she will be working with Jason Cristofaro and Sherry Ansher's team on extramural tech transfer agreements such as those related to CTEP, MATCH, NCI Formulary (part of the Moonshot Initiative), ALK Lung Cancer Trial, etc. Anna has been at NIH for over 21 years. For the last 6+ years she was the Acting Deputy Director, Technology Advancement Office, NIDDK; the previous 7 years were spent in various roles (e.g., Acting Extramural Branch Chief) at the NIAID tech. transfer office (now known as TIPPO). Before taking up tech transfer, Anna spent 7 years in the Laboratory of Immunology, NIAID.

Anna received her B.S. (Hons) from Murdoch University, Australia, where she also undertook post-graduate training and was employed in the fields of immunology and molecular biology. While continuing her Ph.D. research at the Laboratory of Molecular Genetics, University of South Florida, she worked in the Immunoprameters Unit at All Children's Hospital.

Anna has served as the Chair of the TDTC and the TTWG, having previously chaired the TDTC Training WG, the NIAID Agreements for Clinical Trials WG, and participated in the TDTC Marketing WG, Research Tools WG and the Training & Education Subcommittee of the NIH Technology Transfer Policy Board.

Anna has been invited to speak at many BIO Conventions and AUTM meetings as well as other forums and has served on the AUTM Annual Program Planning Committee.

Dr. Wade Green has joined the NIAID TTIPO as a seasoned Team Lead. He is a technology transfer professional with nearly ten (10) years' experience in academic and federal technology transfer offices in positions of increasing responsibility. Wade holds a Ph.D. in Microbiology from the University of Chicago, and a B.S./M.S. in Microbiology from Michigan State University, East Lansing, MI. He is a registered Patent Agent with the USPTO and honorably served in the National Guard and United States Army. He is also a long standing member of AUTM and LES.



Phoebe Nguyen has joined the NIAID TTIPO as a paralegal. She has over 14 years of experience working as a patent paralegal and case coordinator at Northern Virginia law firms where she coordinated the administration of numerous patent interference proceedings, ranging from pre-interference matters to appeals to the Court of Appeals for the Federal Circuit ("CAFC"). Phoebe coordinated the timely preparation and filing of pleadings and evidentiary documents in complex proceedings before the Patent Trial and Appeal Board ("PTAB") and related appeals at the CAFC. Phoebe also coordinated the administration of ex parte patent prosecution, district court litigation, appeals, and foreign opposition proceedings. Additionally, Phoebe coordinated and executed patent portfolio monitoring strategies, including the generation of periodic reports relating to activities in complex foreign and domestic patent families. Phoebe graduated from Hanoi National University with a Bachelor of Laws (LLB) degree, and from Western Sydney University with a Master of Laws (LLM) degree.

Dr. Shane Peng is a new Technology Transfer Fellow for the NIAID team in Branch C. Before coming to TTIPO Shane worked with Princeton's Office of Technology Licensing. Additionally, she completed a postdoctoral fellowship in radiology from the University of Pennsylvania and a Ph.D. in Chemistry from Washington University in St. Louis.

Michael Salgaller, Ph.D. joined NCI TTC in August 2016 to lead TTC's newly created Invention Development and Marketing Unit. He has over 20 years of scientific and business experience in various life science sectors. He was a long-time industry executive who has held various positions in biotechnology and professional service firms. He was on the investment team of life sciences-based venture capital. Before that, as Vice President of Clinical and Research Affairs at Northwest Biotherapeutics, he led clinical and product development for their oncology pipeline. He began his career as a senior staff scientist at the NCI, with Steven Rosenberg, M.D., Ph.D. and a biotechnology training fellowship, with Jeff Schlom, Ph.D. He is an author of over 100 articles, presentations, and book chapters, and serves on the editorial boards of several journals. He is the author of "Biotechnology Entrepreneurship," and teaches a FAES course on the subject. He was elected to the Sigma Xi Research Honorary, as well as the Pi Delta Epsilon Journalism Honorary. Michael received his Ph.D. in Pathology from The Ohio State University.

Dr. Betty Tong has joined NIDDK TAO as a Senior Licensing and Patenting Manager. She manages patent portfolios and licensing activities for NIDDK and NIAAA. She began her federal technology transfer career at the NCI TTC in 2005, later joined the NIH Office of Technology Transfer in 2008. At OTT, she managed patent portfolios from a number of NIH ICs, and negotiated

license deals leading to FDA approved diagnostic kit, NephroCheck, as well as EMA approved orphan drug product, Glybera. Her work won the Federal Laboratory Consortium's Excellence in Technology Transfer award numerous times, at both regional and national level. She currently serves as the Vice Chair of the NIH tech transfer community's Exclusive Licensing Consulting Group.

Dr. Tong obtained her Ph.D. in Molecular Biology from the University of Pennsylvania, and conducted postdoctoral research at Harvard Medical School and MIT. She was a recipient of National Research Service Award. She is registered to practice before the USPTO.

Dr. Rosemary Walsh is now a member of NIDDK TAO serving as a Sr. Technology Development Specialist where she negotiates transactional agreements primarily for NIDDK's intramural scientists. Dr. Walsh's

initial experience with technology transfer began in NIAID TTIPO in 2004. She worked extensively with the investigators at the Vaccine Research Center on projects relating to therapies and vaccines directed to malaria, Ebola and Respiratory Syncytial Virus (RSV).

Dr. Walsh received her Ph.D in Biochemistry and Biophysics from the University of North Carolina at Chapel Hill. After a brief post-doc and NIEHS, she worked in the areas of technical service and product management for several biotech companies. She supported a diverse range of product lines that included cell lines, antibodies, reagents for DNA amplification and kits for the study of apoptosis and gene methylation.

Thanks for reading and staying informed.

Have ideas for the next issue? Please e-mail them to RogersK@nih.gov.