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NIH Launches Policy Aimed at Promoting Access to Products Stemming from NIH-Owned Inventions

Abby Rives, OSP

Broad access to the fruits of NIH's investments—whether in the form of data, results, or products—drives innovation. To advance this aim, NIH is launching a new policy to improve access to medical products developed from NIH-owned inventions.

This <u>policy</u> emphasizes the importance of proactive planning for patient access in the commercialization process for NIH-owned inventions. It applies to inventions that result from research conducted by NIH's own scientists within its Intramural Research Program. Organizations partnering with NIH through patent license agreements will provide the agency with plans describing the steps they will take to promote patient access to any new drug or medical device that results from the invention. These "access plans" will be submitted to NIH when an organization applies for a license, and the plans will be incorporated into the licenses granted by NIH.

NIH looks forward to working in collaboration with its licensing partners to promote the best public health outcomes for the American public. And the agency will continue to work with stakeholders and communities to promote effective implementation of this policy, building on the <u>public input</u> that informed its development.

NIH is committed to efforts that can improve the health of all Americans. This policy is one example of how NIH is working across the biomedical research enterprise to deliver on the Nation's investment in biomedical research.

Further information about the new policy, guidance, and other HHS Technology Transfer Policies and resources can be found on the NIH IRP Access Planning Policy webpage

Policies Pol

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on the NIH Technology Transfer website.

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Tech Transfer at the NIH Research Festival

Richelle Holnick, OTT

The NIH Research Festival is always a busy time for the NIH Technology Transfer Community!

OTT had a booth at the Resource Fair on the first day of the festival to talk with the community and make sure that researchers know how to access support from their tech transfer office, as well as share any trainings or fellowships available within the community.

"Are you an inventor?" is Steve Ferguson's opening line, and while usually he is met with a "no" he is quick to follow up with "you could be and not even know it". This is always a great way to chat with researchers and make sure they are aware that when a company or university reaches out to acquire research materials, they should work with their

Richelle Holnick (left) and Steve Ferguson (right) working NIH Tech Transfer's booth at the Festival

tech transfer office to draft an agreement and receive royalties! Fun fake money is given out with a QR code that goes to the <u>Resources for Inventors page</u>.

The Federal Laboratory Consortium (FLC) graciously sent inventor notebooks, pens, and luggage tags as giveaways. This certainly helped increase traffic to the booth! Steve and Richelle Holnick ran out of giveaways halfway through the event.

The poster sessions are another great tool to reach people during the Research Festival. This year, OTT had two posters, one on "NIH and the FLC" and one on "Careers in Technology Transfer and Business Development". The Office of Science Policy had one on the "NIH Intramural Research

Program Access Planning Policy".

Steve Ferguson also helped plan and facilitate the Patent Law, Industry, and Tech Transfer Scientific Interest Group's workshop, "From Postdoc to Paycheck".

Lastly, you may be looking for information on The Philip S. Chen Jr., Ph.D., Distinguished Lecture on Innovation and Technology Transfer as it is usually held during the Research Festival, however, it was paused for this year. We look forward to its return next year!



Workshop organizers and presenters, from left to right: Steve Ferguson, Ulisses Santamaria, Monica Ventura, Duong Nguyen, Linda Orzolek, and Harish Panth

Mukul Ranjan: 35 Years of Connection, Curiosity, and Global Impact

Dylan Drobish, NIAID

"Technology transfer is a contact sport." For Mukul Ranjan, this phrase isn't entirely a metaphor: It's been a guiding truth. Over more than three decades at the NIH, he demonstrated time and again that the business of moving science from bench to bedside depends as much on relationships, trust, and persistence as it does on legal frameworks and scientific breakthroughs. To make an impact, one has to be on the field, ready to engage, negotiate, and (at times) fight for what will ultimately benefit public health.

From Bench to Bridges

Mukul arrived at NIH as a postdoc in 1989 after completing his PhD in biochemistry at the University of Notre Dame. Those early years in the lab were devoted to the molecular mechanisms of gene regulation and the biology of oligodendrocytes in multiple sclerosis. But after six years, he



Mukul Ranjan

pivoted. A brief stint at the U.S. Patent Office exposed him to the power of intellectual property in shaping science's trajectory, and by 1997, he had begun his career in technology transfer at NHLBI, later moving to NIAID.

Looking back, he reflected that curiosity and opportunity propelled him: "I wasn't expecting anything," he said during our conversation, "so I was pleasantly surprised to find how much this work mattered and how much could be done."

Building Systems, Shaping Standards

Throughout his career, Mukul's imprint can be seen in the very systems and processes that today feel routine. He implemented Wellspring, the first comprehensive database for tracking agreements at NIAID, years before other NIH offices followed. He co-chaired TEAC, introducing new procedures and eliminating the rush filings that had once been common. Together with Maryann Puglielli he, developed agreement templates, standardized gift processes, and helped reorganize the office's structure for handling new inventions, into its now-integrated model.

"I was always looking for the gaps," he explained. Whether building the Product Development Team concept, streamlining TEAC workflows, or launching the "Stories of Success" initiative, Mukul saw technology transfer not as a static job but as an evolving ecosystem in need of constant refinement.

A Global Stage

Mukul's reach extended well beyond Bethesda. Representing NIH and NIAID internationally, he became a steady voice in global health and international research policy. His early recognition of the Nagoya Protocol as a challenge for biomedical research led to his leadership in raising awareness, including chairing the first AUTM session on it in 2023.

He was the lead negotiator in NIAID's designation as a WHO Collaborating Center in 2020, a milestone achieved by leveraging his deep well of relationships across NIH, HHS, and the State Department. During outbreaks—MERS, Zika, and most critically, COVID-19—he worked tirelessly to create standardized agreements that allowed samples to move quickly across borders to accelerate the development of diagnostics, therapeutics, and vaccines.

Convening Industry and Community

One of his proudest achievements was organizing the first NIH Industry Day in 2024. What began as a daunting task to unite NIH, industry, academia, and government stakeholders became a watershed moment in fostering collaboration, with more than 1,200 attendees.



His colleagues' reflections underscored his role as the glue that held the project together. "We needed someone to be the 'glue' and pay attention to the many details, and Mukul took on this task," said Dr. Amy Klion of NIAID.

That convening spirit carried throughout his career. As TTIPO's Senior Advisor from 2015 onward, he moved into a broader role connecting NIH with agencies, nonprofits, and international partners. "It allowed me to focus on projects that went beyond NIAID, to HHS, other government agencies, nonprofits, and international agencies like the WHO," he said, describing it as a turning point in his professional life. Mukul credits Mike Mowatt for allowing him the flexibility to step into this role.

A Lasting Legacy

Mukul's career is not easily summarized by a list of awards, though he has received many, including the NIAID Director's Award, the OD Honor Award, and the NIH Director's Award. His true legacy lies in the bridges he built—between scientists and policymakers, agencies and nations, and most of all, between the lab and the larger world that depends on its discoveries.



As someone newer to the field myself, I found our conversation both humbling and inspiring. In Mukul's words and example, the message is clear: technology transfer is indeed a contact sport—but it is also a human one, played best with curiosity, tenacity, and generosity.

Two Ways to Get Involved with the FLC

Richelle Holnick, OTT

There are two new ways to get involved with the Federal Laboratory Consortium (FLC)! First, if you are interested in speaking at a meeting, conference, or webinar, you can register yourself in the <u>FLC's T2 Speaker Directory</u>. This directory offers a comprehensive list of tech transfer professionals across a variety of agencies with different expertise. The professional development team can match you with speaking opportunities and others can search this directory to find a speaker. If you are interested, you can <u>create a profile</u> on the FLC website.

Secondly, are you a subject matter expert (SME) in intellectual property, agreements, marketing/business development, or administration/operations? The FLC is looking for SMEs to help build and refine the tech transfer training that they offer. SMEs will review outlines and content, provide feedback, and join a working session to finalize course materials. The commitment is as follows:



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- **Kickoff session (1 hour):** Introduction to the program, scope, and tools.
- **Feedback period (1–2 weeks):** Review and comment on content using our collaboration tool.
- Working session (90–120 minutes): Implement feedback and finalize outlines.
- **Follow-up review:** Provide final input before materials are published.

If you are interested, please reach out to education@federallabs.org to volunteer.

Order Now - FLC's 2026 Planner

The wait is almost over! The 2026 FLC Planner reviews are in, the selections have been made, and it will be ready to print and ship to a wall near you. Make sure to order this visual celebration of federal innovation in the form of a 14-month calendar. Take in all the captivating photos showcasing game-changing tech success stories from federal labs.

To order an FLC Planner — absolutely free, by the way — fill out this quick form.

Order by November 26th!



NIH: Inspiring Innovation in Biomedicine and Health

Richelle Holnick, OTT

NIH's Steven Ferguson and Michael Salgaller have co-written a chapter in the recently released book, *Science for a Better Tomorrow*. Their chapter, *The U.S. National Institutes of Health: Inspiring Innovation in Biomedicine and Health*, is an insightful read for anyone who is looking to better understand the NIH innovation ecosystem, from how to access technologies or funding, to how NIH collaborates with industry, and more.

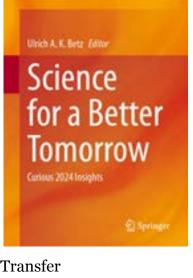
The full scope of the chapter includes:

- Introduction
- NIH Today
- Structure of the NIH Innovation Ecosystem
- NIH Innovation Keystone: Bayh-Dole and the Birth of Technology Transfer
- Accessing Technologies and Collaborations in the NIH Innovation Ecosystem
- Industry Collaborations in the NIH Innovation Ecosystem
- Licensing Technologies from the NIH Innovation Ecosystem
- Funding in the NIH Innovation Ecosystem
- Using NIH Basic and Clinical Research Assistance to Enhance Innovation
- · Contracting Opportunities with NIH and NIH-Funded Institutions
- Training and Education in the NIH Innovation Ecosystem
- NIH Innovation Ecosystem Has Spurred Biotechnology Industry Growth
- NIH Innovation Ecosystem: Results to Date

You can read the full chapter on our website: <u>The U.S. National Institutes of Health: Inspiring</u> Innovation in Biomedicine and Health.







NIH Tech Transfer On the Road

Richelle Holnick, OTT

Many representatives from NIH Tech Transfer have been out of the office attending events and speaking engagements this summer.

In July, OTT hosted a Scientific Vendor Expo on campus in conjunction with Life Science Exhibits. This brought in over 35 vendors and over 300 attendees. This was a great event that Life Science Exhibits made extra fun by having the attendees play Scienceopoly- they got a punch on their Scienceopoly board for each vendor that they talked to. This game gave them access to a free lunch, which was so successful that they ran out of meals!

September was especially busy. OTT's Steve Ferguson attended the Maryland Tech Council's Bio Innovation Conference, which brings together the region's top life science professionals with global industry leaders, venture capitalists, and innovative start-ups.



Steve Ferguson and Richelle Holnick at Scientific Vendor Expo

Next, Steve Ferguson and NCI Technology Analysis and Marketing Unit (TAMU)'s Joe Conrad both spoke at the BioTechX conference in Philadelphia, PA. Steve's panel was on "Partnering with NIH in the Rare Disease Landscape" and Joe's was on "Leveraging NIH as Your Commercialization Partner".



NIH Tech Transfer booth at BioHealth Capital Region Forum

Lastly, OTT's Tara Kirby, Steve Ferguson, and Richelle Holnick, along with NCI TAMU's Michael Salgaller, Joe Conrad, and Malek Kechrid exhibited at the BioHealth Capital Region Forum and Investment Conference from September 23-25, 2025. This was a great opportunity for NIH Tech Transfer to educate companies and investors on how NIH is a competitive and attractive partner.



ETT's "Year of Automation"

Terry Goodell, Sapient

This has been the year of ETT automation for OTT's Monitoring and Enforcement Unit (MEU), declared Charlene Maddox, Unit Chief of the MEU, in a recent OTT All-Hands meeting. She's not wrong – this year has seen a lot of automation across all of ETT, with some significant automations for MEU and the Royalties and Administration Unit (RAU).

Just this past month, a new Sentinel Rule was released called "Scheduled to Drop". This rule provides an email alert to the Licensing Compliance and Administration Unit (LCAU) (which is comprised of MEU and RAU), when a patent that is linked to an active license agreement has been scheduled to drop. Although one of the existing checklist items in the drop report is to inform any licensee, there aren't any instructions to inform LCAU. This new Sentinel Rule bridges this disconnect.

This past summer, multiple Sentinel Rules were implemented to send automated emails to appropriate licensee contacts when a Certificate of Destruction, Progress Report, Sales Report, or Final Report is coming due and/or is overdue for both NIH and CDC license agreements. This tremendously cuts down on the manual effort to remind licensees that an Agreement Report is to be submitted.

In addition to the enterprise and IC-specific reports, another point of automation for MEU is multiple new dashboards and reports that have been built for them, these include:

- **MEU License Expirations and Terminations**
- MEU Amendments Pending and Executed
- **MEU Progress Reports**
- **MEU Sales Reports**
- Monitoring Enforcement Officer Open Activities

These new dashboards and reports allow MEU to quickly find licenses that are about to expire or terminate, amendments that are pending or executed, etc. without manually going into each record and checking the dates. This automation brings significant time savings to the monitoring

enforcement officers.



Join the Licensing Executives Society at No Cost

Richelle Holnick, OTT

The NIH Institutional Membership in the Licensing Executives Society (LES) is now active and is available for you to join at no additional cost! This is a trial institutional membership that initially will run through May 11, 2026.

There are lots of excellent reasons for you to take advantage of LES membership, including receiving the results of the new life sciences royalty rate survey, access to the articles in *les Nouvelles*, and getting member discounted rates (often free) for various licensing-related training programs, workshops and conferences. As a bonus, there is also a very active local LES chapter here in DC.

So far, 65 people have joined the LES with this new Institutional Membership! To register now as a new LES member, please click <u>this link</u> and follow the provided instructions. If you experience any difficulties with registration, please let Steve Ferguson know.

A Collection of Terry-isms

Adam Dahl, Sapient

Terry Goodell always has the most interesting phrases to share as part of his IT work supporting NIH Tech Transfer. Here's a collection of some of our favorites.



Comings & Goings



Samuel J. Claxton has left his position as a Product Manager at OTT supporting the ETT project. Previously, Samuel was working on a project at HRSA as a Core Java software developer. He received a Masters of Science in Managing Information Technology (MSMIT), Masters of Business Administration (MBA), and a Bachelor's degree in Information Technology from Sullivan University. If you had any ongoing reporting work with Samuel, please reach out to ETT Support.



Senior Technology Transfer Specialist with NCI's Frederick Unit to move to the Department of Energy's Fermilab as Division Head of the Office of Partnership & Technology Transfer. Whitney is also the Chair of the Federal Laboratory Consortium. Before working in tech transfer, she was employed in industry as an engineer with Corning and was a fellow in the NCI Nanobiology program. Whitney holds a B.S. in mechanical engineering from Clemson University, and completed her M.S. and PhD in Mechanical Engineering at Johns Hopkins University.



Julianne "Annie" Morgan has finished her fellowship in NCI TTC's Technology Analysis and Marketing Unit (TAMU). Annie previously interned with TAMU twice during undergrad. She returned a third time to complete her capstone internship while pursuing her master's in biotechnology at Georgetown University which was awarded in May 2022. From her experiences working at NCI, Annie's interest in cancer biotechnology and working at the intersection of business and biotechnology grew. We wish Annie the best of luck on her next endeavor!



Tichele Newton has left NCI TTC where she served as a communications specialist beginning in January 2014. Michele was the first person to serve in such a role at NIH Technology Transfer. She was a member of TTC's TAMU leading communications to support their unique proactive marketing and outreach mission. She was a co-chair for the Annual NCI and Frederick National Laboratory Technology Showcase, and a co-chair for TTC's Communications Team. She was involved in several projects including the CAI Startup Challenges, FLC Awards, TTC's website platform migration and management of TTC's website and GovDelivery platforms. Michele has a degree in journalism and public relations. Prior to joining TTC, she worked at various technology companies in marketing and communications roles. She hopes that her next role will keep her connected to the biotech and entrepreneurship community.



Jarod Raedels has left his position as a developer supporting the NIH Technology Transfer website and ETT. He had joined OTT in 2020 and is now supporting another NIH contract.



Mukul Ranjan has reitred from NIH after 35 years of service. He was most recently a Senior Advisor for Innovation and Technology Transfer within NIAID TTIPO. Mukul arrived at NIH as a postdoc in 1989 after completing his PhD in biochemistry at the University of Notre Dame.