TECHNOLOGY TRANSFER COMMUNITY NEWSLETTER

November 2018

ETT System – Update

ETT Project Nearing Implementation Phase

David Vismer, Sapient

The procurement team for the new Enterprise Technology Transfer (ETT) System, led by Tim Leahy, is nearing the end of the acquisition process, having reviewed a number of proposals submitted by software vendors to provide the base ETT system. The team has done a detailed analysis of each proposed system to identify and document any gaps between the system capabilities and the requirements of the NIH technology transfer community that were identified in the requirements gathering process. This information is critical in preparing for the customization and implementation of the system. The team expects to award the contract and begin the implementation process in the 4th quarter of 2018.

Building on the work that has been done this year to document all the business processes, system needs and critical features of the new ETT system, the requirements team is continuing to move forward, documenting the related data and system interactions, to ensure that we can hit the ground running as soon as system implementation begins. The ETT project team recently completed documenting the patent application process, and the management of law firm tasks, and is currently working with specialists at the NIH in Technology Marketing, Royalties, Annuities, and Monitoring & Enforcement, to ensure that the system meets the unique and complex needs of the NIH technology transfer community.

If you have any questions about the project or would like to volunteer your time to share your expertise in our focus groups, please ask your supervisor to reach out to the ETT Project Governance Group for more information.

In This Issue

CRADA PI Eligibility Change

Staff Clinicians Eligible to be Considered PI on CRADA

Arlyn Garcia-Perez, Ph.D., NIH-OIR

We have modified the Sourcebook to contain the policy for the ability for certain Staff Clinicians to be considered to be PI on a CRADA. To confirm if a Staff Clinician has been approved by the DDICR, as required, to be Associate Research Physician or Senior Research Physician, the only two positions that may be PI on a CRADA, please contact Dr. Arlyn Garcia-Perez at OIR by email.

Please see: https://oir.nih.sourcebook

The specific paragraph:

> "In 2016, in order to more fully reflect the varied and vital roles that NIH physician-scientists have, such as providing highly specialized clinical care or leading complex patient-care teams to carry out complicated research trials, the IRP has created new position levels: Assistant Research Physician (PDF File), Associate Research Physician (PDF File), and Senior Research Physician (PDF File). The official NIH Intramural Professional Designation (IPD) will remain "Staff Clinician." The title of Associate Research Physician and Senior Research Physician must be approved centrally at OIR by the DDICR. Only appropriately OIR-sanctioned Associate Research Physicians and Senior Research Physicians may be considered for the role of PI in a CRADA (use the Clearance for Designation of a NIH Associate Research Physician or Senior Research Physician as NIH Principal Investigator for Cooperative Research and Development Agreement (PDF File))."

The direct link to the form is a fillable pdf at: https://oir.nih.personnel.clearance.form

T2 Rocks Out at Research Festival

Steve Ferguson, NIH-OTT

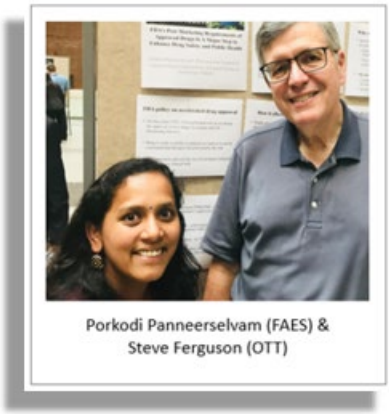
Though not actually listed as such in the NIH Research Festival Program, Wednesday, September 12th turned out to be "Technology Transfer Day" at the 2018 NIH Research Festival with 3 poster presentations and a symposium focused on this topic. Poster Session I that day included these presentations:

- "Careers in 2018 for NIH Scientists in Technology Transfer & Business Development" from Steve Ferguson and Jeff Thomas.
- "NIH scientists and the Federal Laboratory Consortium for Technology Transfer (FLC) in 2018" from Anna Amar, Steve Ferguson and Jack Pevenstein.
- "FDA's Post Marketing Requirements of Approved Drugs Is A Major Step to Enhance Drug Safety and Public Health" from Porkodi Panneerselvam, Fred Provorny and Steve Ferguson [A FAES Technology Transfer Capstone Student Project].


Anna Amar (NCI)

Immediately following these posters in the afternoon was a technology transfer-themed symposium entitled:

- "Technology Transfer: Successful Partnerships" organized and chaired by Sabarni Chatterjee which consisted of two parts:
  - "Role of Technology Transfer: Who We Are and What We Do" with presentations from Michael Salgaller, Sue Ano and Steve Ferguson.
  - "Panel on Technology Transfer Success Stories: Successful Collaborations and Partnerships" with presentations by NIH investigators Mitchell Ho, James Hodge and Malcolm Smith.


Porkodi Panneerselvam (FAES) & Steve Ferguson (OTT)

Miss out on the action? It's not too early to be thinking about your idea for a tech transfer poster or symposium at the 2019 Research Festival!


Jeff Thomas (NCI)


Left to right: Malcolm Smith (NCI), Michael Salgaller (NCI), Sue Ano (NINDS), Steve Ferguson (OD), Sabarni Chatterjee (NCI), Mitchell Ho (NCI), James Hodge (NCI)

"What is the attitude of private venture capital (VC) organizations to funding technologies licensed from NIH? Does NIH somehow facilitate any kind of information/contacts exchange with VCs?"

With focus on highly innovative but early development stage technologies, the NIH intramural programs are a natural match-up for early stage companies and the organizations that fund them. Although NIH is better known in the VC community for extramural academic grants that lead to university spinouts and SBIR and STTR company grants to further fund these companies, our intramural program is no lightweight. Data from the NEJM study, for example, seems to indicate that a disproportional higher rate of FDA-approved drugs and vaccines originate from IP from our own intramural institutes versus the better-known extramural academic grant programs.

Besides being a source of important new technologies, what else about intramural licensing and collaboration programs make them attractive to VCs and start-up companies? Unlike other organizations, for example, NIH will not be taking an ownership position in the company nor requiring a seat on the company board of directors. Other IP owned by our licensees can remain unencumbered at the company and the NIH will not be asking for downstream marketing or co-marketing rights for products. Collaborations of course are encouraged with intramural investigators but funding of the inventor's lab (sponsored research) is not required. Also, start-up template agreements (original and NCI 2.0) have been designed to speed up the overall process. Even paying product royalties for NIH intramural inventions has an upside as these funds go towards rewarding inventors and funding future discovery-generating research!

However, with these assets but a general lack of awareness in investment community about the intramural program, we still all need to do more to facilitate interactions with VCs and other private investors. It's a prime opportunity identified for us as part of the Heartbeat study of current NIH licensing efforts and could pay big public health and commercialization dividends in the future – so stay tuned!

Have your own licensing question or a discussion topic for an upcoming Licensing Forum session? Just ask Steve!

Steve Ferguson, NIH-OTT

License Audit Case Study

Bruce Goldstein, NIH-OTT and Richard Rodriguez, NIH-NCI

The PHS Model Licenses for commercial uses all allow the ICs to conduct an audit using a third-party accountant. For reviewing 5 years' worth of the records of one company, auditors typically charge between $35,000 and $45,000, and if affiliates, sublicensees, or substantial travel are involved, upwards of $60,000. If the auditor finds that the licensee underreported or underpaid royalties by at least 5%, our Models indicate that the licensee must include a reimbursement with the catch-up payment. Because audits require a large upfront payment and take substantial time to run, MEU does not recommend running audits until there is some basis for thinking a discrepancy is likely. The threshold has been at least $2 million in aggregate royalties, because even simple human error could result in a 5% short payment ($100,000), which would clearly exceed the cost of the audit. NCI recently completed settlement negotiations over a short payment discovered by an audit, an example which fleshes out what can be involved when invoking that right.

For at least six years, one of NCI's licensees had been selling two categories of diagnostics, one using an antibody and another using conjugated nucleic acid sequences, with great success. In 2015, MEU recommended to NCI to conduct an audit; NCI agreed, so we contracted with a company specializing in patent-license audits. The audit began in early 2016 and concluded five months later. The auditor found seven distinct failures in the reporting, in particular that the company had incorrectly calculated Net Sales, failed to report later-launched products covered by the patents, and even for those products being reported, failed to include all sales. The result was an underpayment roughly equal to what they had reported owing us, before assessing additional royalties for lateness. There was no evidence of bad faith, but the aggregate was surprisingly high.

The licensee did not dispute the facts found by the auditor, but not surprisingly, they began arguing every basis they could imagine to justify not paying us. They challenged how the patent claims should be construed in light of the prosecution, whether the patents contained enough species to support genus claims, how to interpret the deductions for Net Sales, whether sales to affiliates qualified as a sale at all, and whether they were owed a refund of most of the royalties they paid. With the unanimous agreement of NCI, MEU, OGC, and NCI's contract counsel that these arguments all lacked any serious merit, negotiations for restoring compliance stalled for 18 months. The impasse was so firm that the parties were on the cusp of hiring a mediator.

Failing to resolve a dispute like this would have forced NCI to terminate the license. When that happens, the short payment is referred to OFM, which in turn transfers the debt to the Treasury. Treasury has several tools to collect on debts, including the use of contract debt-collection companies, flagging the company and its affiliates in the GSA's "System of Award Management" (what used to be called the "Excluded Parties list") to preclude any future contracting – including with CMS – until the debt has been paid, and coordinating with the IRS. This route makes the dispute public, and as the licensee was not a small company, potentially could be high-profile. That outcome was unacceptable to both parties, but by itself did not move negotiations forward.

Continued

The logjam broke because of three key events. One was the licensee hired a new general counsel who was focused on finding business solutions rather than getting tied up in legal arguments. He offered to fly to DC just so that they and we could have lunch – no negotiating. The second was a chance meeting between Susan Rucker and one of the licensee's negotiators at a conference. In that setting, they could talk informally about the situation. Third, the Federal Circuit issued a decision that cast a cloud over some of NCI's patents.

We agreed to meet in person at NCI for up to four days of negotiations to find a solution. By the end of those meetings, we had a resolution acceptable to both parties; the licensee would pay the audit findings and also an estimate of sales for the next two years, distributed in installments over a ten-year period to maximize the inventors' share, and NCI would cede royalties on future sales above that estimate.

One key tool was face-to-face interactions, which are deeply undervalued in an age of convenient electronic communications, which fail to convey facial expression and vocal tone. Even phone and videoconferencing are less efficient because of the iterative nature of the conversation; you discuss something, end the call, determine a response, then set up the next one. Sitting in the same room forces immediate responses and counter-responses, dramatically saving time. Moreover, even when negotiations are on hold, conversations humanize the parties and help forge personal trust.

Audits are one of the few big "sticks" we have to ensure we collect the royalties we should be receiving. They are, however, expensive and time-consuming, and auditors cannot guarantee a short payment of at least 5% will be found. Even when the auditor does find one, companies frequently will refuse to pay some or all of it for one reason or another. And that is where the real work begins. Finally, close work amongst many NIH offices, but in particular, NCI TTC and OTT MEU and RAU, led to a highly successful outcome for the NCI. Such collaborations cannot be overstated.

TT Community Members

Comings & Goings

Retirements

Cristina Thalhammer-Reyero (NHLBI)

Cristina retired from Federal service in September 2018.

Karen Maurey (NCI)

Karen retired from Federal service in September 2018.

Chuck Duffney (OTT)

Chuck retired from Federal service in September 2018.

TT Community Staff Member Moves

Yun Mei (NIDCR)

Yun has moved to a new position in NIDCR's Scientific Review Branch.

Corrections & Clarifications

In a recent article "New Procedures for ELCG Review of Non-Complex PDs" we would like to acknowledge that the list of Meeting Participants was incomplete. The complete list of all participants is as follows:

Meeting Participants

Michael Gottesman (Organizer)
Mark Rohrbaugh (OD/OSP/TTIP)
Karen Rogers (OD/OIR/OTT)
Claire Driscoll (NHGRI)
David Bradley (NIDCR)
Charles Niebylski (NIDDK)
Richard Rodriguez (NCI)
Lili Portilla (NCATS)
Susan Ano (NINDS)
Charles Salahuddin (NIMH)
Alan Deutch (NHLBI)
Michael Mowatt (NIAID)

Please forward articles and newsletter suggestions to Ajoy Prabhu at aprabhu@od.nih.gov.