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Standardized four-phase process leads to influx of industry partnerships

The Office of Innovation and Industry Alliances at Moffitt Cancer Center in Tampa, FL, recently announced a three-year deal with Incyte Corp. in Wilmington, DE, to fund three new oncology research programs. This latest agreement capped off a roughly two-year span where the Innovation Office has reaped some $35 million in funding from industry partnerships with such companies as Forma Therapeutics, Celgene Corp., Biotheranostics, Signal Genetics, Lion Biotechnologies, and Bristol-Myers Squibb.

“Negotiating industry alliances [is] a great way to support the research mission of an academic institution,” says Latanya Scott, PhD, senior industry alliance development manager. “The current state of federal funding has created a squeeze on faculty in terms of them being able to do the research that they are driven to do and that will move the needle of innovation in the United States. While industry alliances won’t replace federally funded or foundation-funded grants, they can provide an additional source of revenue to support faculty members along that path of innovation.”

The foundation of the Innovation Office’s success in increasing collaboration between industry and Moffitt researchers is a standardized four-phase process. “The benefit of a standardized process is that it communicates the same information to everyone in the office, including new full-time staff and temporary staff such as interns,” says Jarett Rieger, Esq, MBA, senior director of the Innovation Office. “As a result, the work product is of high value and is consistent regardless of who produced it. A standardized process is particularly important as your office grows if you want to achieve consistency from anyone working on a project.”

In addition, using a four-phase approach helps keep both sides in the alliance partnership accountable and on track, says Scott. “You always know where you are going and what your goal is. If you are able to orient yourself as to where you are in the process at any given moment, then you can say, ‘This has gotten off track. Here is what

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we need to do to prod the company,’ or ‘Here’s what we need to do to prod ourselves to get back on track and keep the momentum going.’”

The basics of the four-phase process are as follows (also see process implementation tips, p. 3):

**Phase 1: Concept**

In the concept phase, potential sponsors, Moffitt investigators, and/or the Innovation Office can seek out industry alliances, says Ruan Cox, PhD, industry alliance development associate. “With one of our partners, for example, their head of pharmacology and toxicology learned about a Moffitt investigator’s proprietary patent-protected platform at a meeting and wanted to explore the idea of collaborating.”

Once the initial idea is broached, the Innovation Office fulfills two important functions in this phase:

1. **Assessing partner suitability.** “The critical work of the concept phase is vetting new potential partners,” says Rieger. “Our focus is the quality of deals, not the quantity. So in the concept phase, we look to select the partners that will provide the greatest value and benefit to the organization.”

The Innovation Office developed a scoring sheet to analyze each potential partner across seven dimensions. “The scoring is necessary because we want a research collaboration vs. a fee-for-service agreement where appropriate,” says Cox. “The company should partner with the investigator. So we are building relationships, not just business transactions, and these factors set the stage for those relationships.”

The seven dimensions are:

* The partner’s level of interest. “Are we talking to salespeople, associates, or C-level executives?” explains Rieger.
* The link to Moffitt’s scientific priorities and initiatives, particularly the partner’s stance on scientific publications. “As an academic institution, it is critical that our faculty members continue to publish, so we try to pick partners that can allow our faculty members to publish,” points out Rieger.
* Access to early-stage technologies and technical expertise.
* The likelihood that the partnership can lead to peer-reviewed funding. “We want our investigators to profit from grant applications due to the work being done here,” says Cox.
* The financial viability of the potential partner.
* How much revenue the company generates on a yearly basis.
* The deal size in terms of potential funding for Moffitt.

Boiling it down, “fit and need are probably the best indicators of whether a company will be a good collaborator,” says Cox. “If the company’s needs and our needs fit, then chances are we can make a good collaboration around it. For example, one partner has a deep drug pipeline, and their expertise in a particular space is well-respected. Here at Moffitt, we have top-notch investigators who are working with heme malignancies and blood cancers, so we felt like it was a good fit.”

2. **Developing a blueprint for collaboration.** “The concept phase also involves discovery on both sides that leads to a collaborative framework. Basically, this is taking a step back and asking, ‘What’s involved? What’s included in the work?’” says Scott. “For example, will we have a scientific committee made up of members from both the company and...”
Industry alliances: 6 strategies for success

The four-phase process for creating industry alliances developed by the Office of Innovation and Industry Alliances at Moffitt Cancer Center in Tampa, FL, seems simple enough. However, TTOs can maximize results by implementing these strategies:

- **Structure your process even further.** Moffitt is developing detailed checklists to guide staff through each of the four phases; says Jarett Rieger, Esq, MBA, senior director of the Innovation Office. “Multiple steps need to be completed in each phase. These checklists help us ensure that no step is overlooked or not completed properly, then we bring in new staff.” (See Budget Phase checklist, p 4.)

  The checklists improve efficiency and consistency, adds Ruan Cox, PhD, industry alliance development associate. “We want to produce the same work product at each phase of the negotiations with each potential partner, no matter which staff member is doing the work.”

  In addition, “knowing when an industry alliance is in the concept phase, the research plan phase, the budget phase, or the contract phase is not always straightforward,” points out Cox. “The checklists help us to make clear, objective decisions about when to move onto the next phase. They also help us to keep accurate records of what we’ve accomplished and when we’ve communicated with either a company or an internal entity that we need information from.”

  The Innovation Office also plans to use the checklists as a quality assurance tool, says Rieger. “After deals are completed, we’ll review a certain number of them, going through the checklists to make sure that all the steps were completed. If a step was overlooked or not completed properly, then we can use that as a training opportunity for the staff member.”

- **Put someone on point but avoid arbitrary timelines.**

  Industry alliances are hard to implement, says Latanya Scott, PhD, senior industry alliance development manager. “If they weren’t, everyone would be doing them left and right. To be successful, you have to have someone spearheading alliance development.”

  To fulfill that role, the Innovation Office has a dedicated industry alliances unit with two full-time staff members. While these staff members drive alliances toward the contract signing, “there is no real timeline for completing an industry alliance,” notes Cox. “The large-scale collaborations may take about a year to nail down, but other alliances have been completed in as short as a few months.”

- **Use interns wisely.**

  Interns don’t participate in any parts of the process that require building a long-term relationship with a company, says Scott. “Interns are by nature transient, so you have to give them work that doesn’t require them to be around for the long haul to develop that relationship and grow the discussion.”

  What Moffitt interns do instead is work on business intelligence. “For example, in the concept phase, the interns will do a lot of the scoring that determines whether a company is compatible as a potential partner,” she explains. “So they will look at: Is the company a good fit? Are they financially stable and sound? Are they focused? Are they a powerhouse in this area, making them a good partner for us?”

  Then in the contract phase, the interns will work on an executive summary document for research leadership and people who are involved in signing the agreement, says Scott. “We provide a good breakdown of the salient, key points in the contract so they don’t have to read all of the legalese. This summary package includes such information as how this relationship started, how the negotiations went, key financial terms, and Moffitt’s key obligations.”

- **Strengthen faculty relationships.**

  Developing a strong relationship of trust and confidence with the faculty members is a prerequisite for successful industry alliances, says Rieger. “Absent that strong connection with the faculty members, these partnerships will not come to fruition. Faculty members are the key opinion leaders. They understand the science, and they understand the unmet need — what the value is to the company. So they are key in terms of selling the value proposition to the company.”

  However, a strong partnership doesn’t mean simply deferring to the faculty members, he stresses. “It means having a relationship where the faculty members understand their role, stay within ‘their lane,’ and remain engaged throughout the process. If you are too firm and you put numerous restrictions on the faculty members, they are not going to work with you. On the other hand, if you don’t provide some framework for the faculty members, it is going to be incredibly difficult to complete a deal that is structured in a way that is beneficial for the organization.”

  Moffitt’s framework is that faculty members must defer to the Innovation Office on business terms, says Rieger. “If the issue of any business terms comes up, the faculty members shouldn’t try to tackle that or to assume what the institution’s response would be. Instead, we ask them to put it to our office.”

  Having that good relationship with faculty “is about credibility plain and simple,” says Rieger. “We have to establish credibility with the faculty members so that when we share the ‘best practice’ with them, they respect us and listen. Without that credibility, you are dead in the water.”

  That credibility, adds Scott, is typically built over time by engineering successful deals and bringing funding to faculty research labs. “If you have proved... continued on next page
Strategies for success continued

yourself to be successful, faculty members will come to you again when new opportunities present themselves down the road,” says Scott. “You will be the go-to player in this whole process. Faculty members won’t imagine going anywhere else because they can count on your team to get them what they need and help them reach their long-term goal.”

• Be a team player with internal partners.

“Internally, our industry alliances team is very collaborative,” says Cox. “We don’t do everything by ourselves. We work as a team with other internal entities such as research administration, the investigators, the Office of Sponsored Research, and corporate compliance. For example, Moffitt’s leadership recently presented us with an internal Spirit of Moffitt Award to recognize our efforts in forging new industry alliances. The recipients of the award included 26 people from within our office and across our organization. Teamwork is crucial to these alliances, says Cox. “Being a team player involves being transparent and knowing exactly what your strengths are. You need to reach out to those in your organization who can fill that void for where your strengths aren’t.”

• Don’t sign it and forget it.

The four-phase process takes Moffitt to the contract signing, notes Rieger. “Where the rubber meets the road is in implementation. You don’t want to lose sight of post-execution and what that entails.” Moffitt has developed an alliance management function to oversee contract implementation, says Rieger. “We put a line item into the budget for alliance management so we would have the cash to support that critical function through these partnerships.”

The alliance management team includes project managers who, for example, are responsible for scheduling meetings, taking notes and minutes, making sure that deadlines for deliverables are met, and ensuring that Moffitt collects payments on time. “This team provides incredible value to our partners because there are dedicated individuals to make sure that the relationship runs smoothly, and there is always a point of contact if the partner has any questions or concerns,” says Rieger.

The alliance management group reports to research administration, remaining independent of both the Innovation Office and faculty members’ labs. “We designed this function so it’s not handled by a management assistant that reports to a faculty member,” he says. “This function requires a different skill set than most management assistants have. In addition, management assistants might not give this responsibility a high priority since they have a million other competing priorities.”

“What we do on this side in our Innovation Office is only half the battle,” agrees Scott. “Once the deal is signed, someone needs to keep everyone focused because things can still fall apart. For example, your academic investigators might get upset because they are not getting what they thought they would get out of the relationship. On the flip side, the company might get upset because they are not getting what they anticipated. If you have someone there actively managing the relationship -- making sure all parties are meeting obligations and goals, and being the person that everyone can come to when issues crop up -- it results in a better relationship overall and then increases the likelihood of you expanding or continuing the relationship down the road.”

Critical items in the budget phase: Checklist

Principal steps involved in putting together a budget for an industry alliance in the Office of Innovation and Industry Alliances at Moffitt Cancer Center include the following:

☑ Identify core facilities that may be involved in the budget.
☑ Distribute the research plan and protocol to make sure that the core facilities are providing adequate quotes.
☑ Set up an initial teleconference with the principal investigator to discuss the budget and the percent effort for the personnel.
☑ Develop a budget for all materials and supplies.
☑ Talk to the grant administrators and the Office of Sponsored Research to make sure they are providing accurate salaries for the personnel so that budgets can be aligned.
☑ Develop budget justifications that justify exactly why these people/pieces are being added to the budget and exactly why Moffitt need these funds.
☑ Make sure the investigator approves these budget justifications, as well as approves of the budget.
☑ Make sure the Office of Sponsored Research and grant administrators approve the budget.
☑ Make sure the company approves that the budget and that the budget justifications meet its needs.

Source: Ruan Cox, PhD, industry alliance development associate, Moffitt Cancer Center.
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and Moffitt to review all the research and have constant dialogue about the project and the larger-scale goals that might need to be amended over time?"

With some deals, for example, “we held several preliminary meetings to discuss both the business and the scientific sides of a potential collaboration,” says Cox. “Then the Innovation Office drafted a concept document envisioning the collaboration as a multi-investigator/multi-project collaboration centered on the highest priority indications of interest, and using their proprietary drugs as a focal point of the research.”

A concept document is most important for a larger-scale relationship, involving significant dollars or perhaps many different labs with many different PIs working on somewhat related but not overlapping projects, stresses Scott. “In that type of situation, we go through the formal concept phase and work on a concept document.”

However, this part of the concept phase sometimes bleeds into or overlaps a little bit with the research plan phase (Phase 2), notes Scott. “The distinguishing factor is the size and scope of the relationship. If a relationship is very focused in nature (e.g., one or several principal investigators working on one type of project), we sometimes won’t create a formal concept document because both parties come into it knowing what they want to focus on. We’ll jump directly into the research plan phase.”

Phase 2: Research plan

In the research plan phase, the Innovation Office leads the development of a statement of work that is mutually aligned for Moffitt investigators and the company. “The goal is to develop a succinct project description that clearly defines the roles and responsibilities of both parties,” says Rieger.

“That is easier said than done. In my experience, many research plans are too detailed. They throw in the kitchen sink, and they are aspirational in nature,” he points out. “So our job is to work with the parties to make sure that they specify the scope of the project. We want to make sure that a plan has well-defined, realistic milestones. In addition, the responsibilities and the studies contemplated in the research plan should not overlap with any other relationships that the organization may have.”

This phase requires significant dialogue from both sides regarding the research plan and protocol, says Cox. “For example, during this phase of one of our deals, we had several conference call-based project discussions about which projects were going to be selected. Then once the company chose the projects, we went forward with building the scope of the partnership. In addition to discussing what the milestones would be in the research plans, we talked about how those milestones would be achieved and other key criteria such as when go/no-go decisions need to be made.”

Phase 3: Budget

The budget phase involves preparing -- and getting both internal and external approval for -- a budget that details Moffitt’s costs for performing the research. “We prepare the budget after the research plan is finalized so we understand the scope of the project and can cost it out,” says Rieger.

“The most important aspect of the budget phase from the academic side is to make sure you are in good communication with all of the research project’s relevant stakeholders and parties (e.g., investigators, grant administrators, and Moffitt’s Office of Sponsored Research),” says Scott. “Internally everyone needs to be on the same page about what it will take to do the project, and who is doing what.” (Note: The grant administrators and the OSR, which focuses on helping researchers obtain and manage research grants, have access to relevant salary information and other key data.)

This internal communication is key to ensuring all of the costs are covered, says Scott. “You don’t want to get most of the way through the budget preparation process and then figure out, for example, ‘Oh, the percent effort we are considering giving this faculty member or this staff member might not be enough because there’s this other portion of work that wasn’t incorporated into the calculation.’”

Budget development is often time-intensive because budgets need to be justifiable, says Rieger. “It’s critical to fully understand all of the costs -- and to be able to walk the partner through the budget and explain where all the costs come from.”

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“To sell the notion of the company funding the idea, you need to demonstrate the value of the research project to the company,” agrees Scott. “Then the budget discussion is not as challenging. Companies are less likely to think the price tag is too high if the value of the data and the value of the faculty member’s expertise are both clear.”

**Phase 4: Contract**

The contract phase is fairly straightforward, says Scott. “You have gone through the first three phases, and everyone is invested in the whole process and wants to get the contract done. So it’s really just protecting the best interests of your institution but being flexible and creative enough to make both sides as happy as possible.”

The Innovation Office defers to the company “as to whether they wish to use their agreement template or our template,” says Rieger. “Then the research plan and budget are incorporated into the contract.”

During this phase, the Innovation Office focuses on key provisions in the contract “that could have the biggest impact on our ability to do research,” notes Rieger. “For example, it is critically important that Moffitt has the ability to access any data generated by the company and to be able to use it for research and publication purposes, so we ensure that ability is included in contract. We closely scrutinize those important provisions in the contract that could have an impact on our research mission.”

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**New model of industry collaboration relies on systematic start-up creation**

A new model of industry-academia collaboration being applied by a pharmaceutical giant is very rapidly turning university innovations into start-up companies — and in many cases just as quickly shutting the start-up down if the technology fails to reach early milestones. And it’s launching these test beds for early-stage discoveries outside traditional technology transfer operations.

Interestingly, the tech transfer exec at one school where the drug company-sponsored program is in place says it actually fixes some of the frustrations with traditional tech transfer. Indeed, she says it’s the “most brilliant” program she’s ever experienced. Even better, other universities should be able to replicate the successful program fairly easily.

The novel arrangement accelerates research commercialization through systematic “NewCo” formation. In place since 2011, the GlaxoSmithKline plc program partners the drugmaker with academic institutions in what it calls “Discovery Partnerships with Academia,” or DPAC.

Part of the DPAC model involves a separate partnership between GSK and California-based venture capital firm Avalon Ventures, which invests in the start-ups alongside GSK and helps move them forward. Avalon finds the technology, provides management, and ensures the fledgling companies meet their milestones. If the start-ups hit their milestones and appear to hold real promise for the drug maker, GSK then pays Avalon an acquisition fee up to a maximum of $50 million.

For its part, GSK provides most of the initial investment — up to $10 million — to establish and fund the start-ups, and also lends its expertise in drug development and clinical testing, which is often lacking in NewCos, notes Carolyn Buser-Doepner, PhD, who heads the DPAC initiative for GSK. The NewCos are each located within the affiliated incubator of COI Pharmaceuticals, based in La Jolla, CA.

“Why does this make sense?” she asks. “It’s almost too obvious. Universities have academics who are very focused on their disease of interest. Pharma has the expertise to develop medicines. Combine the two with one end goal.”

The program actually comes in several flavors, she adds. “Often we see science that is a little bit too early,” she explains. “We can engage in a pre-DPAC, basically a smaller collaboration that may lead to a full collaboration.” There’s also the Discovery Fast-Track Challenge, in which an investigator can apply for a high-throughput screen at

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GSK. “If everything goes well,” Buser-Doepner adds, “our goal is to push that into a full DPAC collaboration.”

Avalon plays a key role, notes Jay Lichter, PhD, CEO and president at COI. “This is a financial instrument, there’s no question about that,” he says. “It’s all about company creation.” Avalon is always the first institutional investor in the NewCos, he explains; COI, shorthand for “community of innovation,” is where they gestate. There are about a dozen companies under the umbrella right now, Lichter reports, and eight of them are GSK-related.

After Avalon identifies a novel innovation for potential creation of a new company, GSK and Avalon jointly perform due diligence. Avalon establishes the NewCo, negotiates all licenses for it, and launches product development. “We give it a name,” Lichter says, “and a little bit of a brand.” The initial infrastructure, staffing and oversight are provided by COI, he adds, in careful collaboration with GSK scientists. There are pre-set terms for investment and acquisition by GSK at the clinical candidate stage.

**A hybrid approach**

All the individual pieces are familiar to research management professionals, but the overall structure may not be. “The DPAC model is very different from most types of industry-academic interactions,” Buser-Doepner says. “The structure of a DPAC agreement is a hybrid between an academic collaboration and licensing agreement.”

That means, she explains, that prior to signing, DPAC scientists and the academic principal investigator “work closely to develop a detailed, scientific workplan with key inflection points for the identification of a clinical candidate.” During the first phase of the collaboration, GSK provides “stepwise funding” to reach the next inflection point. Once a clinical candidate is identified, GSK provides milestone payments as the asset moves from a clinical candidate through clinical trials and to regulatory approval of a commercial medicine.

“A unique and important aspect of the deal structure is that when milestones are not met and the DPAC program is closed,” she adds, “lead molecules are offered [back] to the academic institution, which is then free to work with others on them.” That way, she says, “no research sits on the back burner, and each idea is given every opportunity to develop into a new medicine.”

Often the academic-focused preclinical sponsorship agreement and the licensing-focused clinical/commercial agreement are handled by different groups at a university, she notes, “and that can be challenging to negotiate within the existing organizational structures. But that’s definitely not an insurmountable challenge. We now have several prestigious DPAC agreements in place with top U.S. institutions, and we’ve received much positive feedback on our responsiveness in driving our part of the science in these collaborations.” Indeed, she adds, “the model is going so well that we already have two candidate-selected molecules from the first 10 DPAC agreements.”

**‘Almost too good to be true’**

That success impresses Ida Deichaite, PhD, director of industry relations at the University of California-San Diego’s Moores Cancer Center. Her take on the DPAC program? “There’s no downside for us,” she enthuses. “For us, it’s a tremendous win situation. It’s almost too good to be true.”

Deichaite’s regard for the program stems from her frustration with traditional tech transfer. “In academia, we license,” she says. “But we lose control and participate as a consultant. That’s not good enough. This program addressed that 100%.” Indeed, she explains that “the real issue with NewCos is not the funding, it’s losing the scientific expert. Instead of having the person who’s best positioned to navigate the technology’s commercialization, we lose that person. We need that person badly.”

What else do you need? “First, get buy-in from all stakeholders,” Deichaite advises. One way to boost that effort, she notes, is pointing out that “this is a unique educational opportunity for our postdocs and scientists. It’s hands-on education for our researchers. A key is communicating that value to all stakeholders.”

**Others look to adopt similar model**

The DPAC model’s benefits for the pharma company aren’t hard to decipher. Malcolm Skingle, BSc, PhD, director of academic liaison at GSK, notes that “in the last 20 or 30 years, the pharmaceutical industry has consolidated -- it’s merged, downsized and grown again. So academia is constantly looking

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for new contacts. You build a relationship and then the person moves on, and overall you have fewer partners that you try to work with.” On the other hand, the pharma companies that are still around when the dust settles “are reaching out more to academia than they ever have before,” he adds. “There are some quite innovative models now.”

They need academic partners to refill their flagging pipelines, and they are also increasingly interested in getting involved earlier in a drug’s development -- the stage universities focus on.

Other pharma companies are taking a look at the model, Skingle reports. “We have received interest from other companies, so certainly others are considering it,” he says, also noting that the collaborative structure could work for any type of technology, so even schools without drug discovery research could adapt it to their specific industry focus. “In fact, we have been contacted by companies outside of pharma as to how DPac works,” he reports. “The most important thing is to have buy-in from the top of your organization.”

He adds: “The academics who have been engaged in the DPac programs have all been delighted with our openness in trying to work together to get new medicines to the clinic. Having said that, there will always be a place for straight licensing and start-up activities. We need lots of different types of academic-industry activity to develop new medicines.”

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To match industry needs, university applies ‘lean’ principles to labs and faculty

The “lean start-up” is all the rage in tech circles, and it made an impression on Dan Langford, manager of industry partnerships at University of Nevada Reno and its Desert Research Institute. But with no incubator and not much focus on start-ups at UNR-DRI, it struck Langford that lean principles could also be applied earlier in the research commercialization process in the institute’s labs.

Just as start-ups in the lean movement are urged to engage with customers early on and iterate their products in response to customer reactions and feedback, researchers at the institute are now being encouraged to engage with industry before their ideas are fully formed, letting potential future users help shape their discoveries.

“The idea of ‘lean start-up’ is you go out and do customer discovery to validate your business model,” says Langford. “When you think about it, that’s kind of obvious. You can also do that with an individual. We apply “lean” methodologies to expertise rather than to technology, and basically treat a researcher and his or her lab as a company.”

Indeed, Langford adds, UNR has adapted elements from the “lean” school, SRI International, and the National Science Foundation’s Innovation Corps -- but it “applies them in a very different way.” Rather than focus on start-ups and validated technologies, “the aim is to have the inventors or other champion engaged from the idea stage throughout the development and commercialization process,” he says. “In the longer term, that also means that the disclosures you get are already validated and likely come with a licensee attached.”

One approach borrowed from I-Corps is a development team built around each project; the I-Corps team includes two tech people and a business person. Langford’s shop took that team idea and added an MBA student as a business intern. “By adding that position, we offload the work required by the principal investigator and the entrepreneur,” Langford notes. “They don’t have to do all the market research legwork, and that makes it easier to get the job done.” The business intern is also the project manager and, Langford notes, “is responsible for maintaining momentum -- as some researchers can be easily distracted.”

Each Innovation Team consists of:

• The PI, of course. The lead researcher is “expected to champion their technology and expertise and provide high-level technical guidance,” Langford explains, as well as “taking the lead in presentations to industry.”

• The Technical Lead is a graduate student or post-doc with a working knowledge of the relevant technical field. They’re responsible for working...
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with business interns to develop marketing materials and identify and evaluate potential industry partners.

- An industry mentor, usually a volunteer member of the local entrepreneurial or business community.

Industry Engagement Programs

Borrowing from the approaches used at both SRI and I-Corps, Langford calls his particular mix of their disciplines simply “Industry Engagement Programs.”

There are three, he explains, each targeting a different stage of commercialization:

- **Strategic Research Program.** Here researcher expertise is defined, then used to engage industry for feedback on specific needs.

- **IP Development Program.** Industry feedback is sought for a specific invention to generate a technology development strategy focused on maximizing industry uptake.

- **Impact Program.** Once an invention is validated, this program helps the researcher develop a business plan or marketing strategy with the goal of starting a company or licensing a technology.

The first program takes traditional lean start-up tools and uses them at the lab level, not the start-up level. “In my experience, researchers don’t often talk to the potential users of their technologies,” Langford explains. “They do research because they can get funding for it, and they’re often not motivated by the real-world impact of their innovations. We basically get them out of the lab and get them talking to their customers.”

The ideal outcome of that is research plans that better recognize relevant industries’ needs. If those plans guide researchers’ work, they should be more successful in commercializing their discoveries, Langford reasons.

That technology validation approach is what Langford is referring to when he talks about treating labs like start-ups. “The similarities are quite significant,” he says. “The head of the lab is out there raising money, putting a team together and building expertise within that team. The only difference is it isn’t a real company.” His approach to engaging researchers in the very early stages of commercialization “is very different from what most do,” he adds. “Most TTOs wait for a disclosure to hit their desks. We get involved before they even have an idea about what research projects they’re going to take.”

The second of Langford’s three programs -- the IP Development Program -- is introduced after a disclosure is received. “The technology is generally not in a format that’s ready for licensing, because of a gap in the data or a particular form of prototype that’s missing,” Langford explains. The program helps the researcher and the innovation team to “talk to their constituents, the industry bodies that might actually use the technology,” he says. “They’ll tell us what additional work needs to be done and what particular types of data are needed. Then the researcher knows what he or she needs to do.”

The impact program, he adds, is “the familiar bit that every TTO does,” Langford comments -- patenting inventions, developing business plans for spin-outs, or crafting a marketing strategy for licensing.

The progression from one program to another is linear, but an inventor can come in at any stage -- and at any level of sophistication about the commercialization process. “Depending on where they are in the development process, we apply the programs in different ways,” Langford reports. “We don’t have cohorts of teams going through. Each person’s placement depends on what he or she comes to us with.” Ideally, the three programs should lead from one to the next, he adds, “but unfortunately that perfect world doesn’t exist.”

Here’s a for-instance: “Say we get a disclosure,” he says. “We do a patentability check and determine that the inventor is motivated. We may put her in the IP Development Program. That can be a very quick process. Or we may identify that the researcher has everything she needs, so she may go straight into the last phase, the Impact Program, where we focus on trying to license the technology [or] start a business. Or sometimes they come to us with a disclosure that’s not patentable and we suggest going through the Strategic Research Program, so they know how to come to us better next time with a more complete technology and disclosure.”

Is it working?

How will Langford know if the three-tiered approach using lean principles is working? For UNR-DRI it’s all about local economic development, and that’s hard to wrap a metric around. “We do have metrics,” Langford says, but he’s not looking to merely compile a large collection of patents or disclo-
sures. “We’ve convinced our school’s management that all those numbers can be faked or fudged. If we’re judged on patents, we can drop patents all day long. So we focus on quality patents.”

And that, he emphasizes, is where the notion of champions -- borrowed from the SRI approach -- comes into play. “Having a champion is key,” he states. “A champion can be anyone, although we’d expect it would be the inventor or, secondarily, a PhD student working on the technology who picks it up and wants to start a business. Occasionally the champion is an outside entrepreneur. We don’t mind who it is, as long as there’s someone there to drive it forward.”

Pushback from faculty who prefer the traditional model hasn’t been a problem. “It’s their choice. If they don’t want to do it, no one makes them do it,” Langford says. “We explain that we’re not trying to influence academic freedom associated with research at all. But we want them to understand what the end user will do with the technology. We’re trying to increase the impact of their work, and still encourage traditional research.”

The refocus on identifying industry needs as a research driver is still a work in progress. “Long-term, we don’t know how this will work out,” he concedes. “If you teach a researcher to engage at an early stage, when it comes to the point of disclosure, he or she already has a licensee, so your job’s done. That’s the Holy Grail. Those people will come back in two years with a licensee they’ve been working with the whole time. That’s a major plus.”

Langford adds: “Some are concerned about pushback stemming from telling researchers how to research. But many researchers are becoming more willing to take guidance from industry. We are successful if a researcher walks away more comfortable pitching to a business executive. That’s a big win.”

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**Lean principles continued from p. 9**

More universities are getting comfortable with deeper, more integrated forms of sponsored research as they attempt to improve industry relationships and move more IP to market. But industry-sponsored research programs must be careful not to violate certain tax rules that these arrangements can violate -- such as restrictions on the use of publicly funded buildings by for-profit entities. Without attention to detail in constructing these agreements, the severe consequences of violating the tax rules could outstrip by far any gains made by the sponsored research office (SRO).

The biggest area of concern is the clash between sponsorship and the tax-exempt bond issues that most 501(c)3 organizations use for capital improvements such as university buildings, says Tom Wintner, JD, a partner at the law firm of Edwards Wildman in Boston who has extensive experience with IP litigation and other legal issues involving universities. The bonds and the earned interest are not taxed, which makes them quite attractive and gives universities an advantage in the marketplace, Wintner explains. “They have to be careful, though, that the money they are raising does not go to so-called private business uses,” he explains. “Instead, money must be used for the purpose and the mission of the institution.”

The tax issue can arise unexpectedly, Wintner says. If a university wants to build a new laboratory for $100 million, for instance, it issues that amount in bonds to investors. Once completed, the lab might be used for a few years by faculty, staff and students. But then a biochemist strikes up a relationship with a pharmaceutical company that spurs an offer to fund cancer research at the lab.

“Now you have a researcher working in a facility that was financed with tax-exempt bonds but they’re doing something that could constitute private use,” Wintner says. “So the question becomes how you can fulfill your agreement with this company and also comply with IRS tax law. That is not always so easy.”

**The 5% rule**

A key determinant of compliance with the IRS requirements is known as the “5% rule,” he explains. This rule of thumb says that 5% of the bond funds -- or 5% of the lab in this example -- can go toward private use without triggering problems with the IRS, Wintner says.

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**Tax-exempt bond status could be jeopardized, with huge costs**

**With closer ties in sponsored research agreements, ignore tax issues at your peril**
“There’s always a little bit of a safe harbor built in because the IRS realizes there may be some minimal private use that should not invalidate everything else that happens in the building,” he says. How to measure that 5% is not detailed by the IRS. The 5% could be a measure of floor space, annual revenue, or other factors that represent a percentage of the funds coming from the bonds.

The IRS has provided two more safe harbors for sponsored work in a bond-funded facility, Wintner adds. Both apply only to “basic research,” which the IRS defines as “original investigation for the advancement of science and technology, not having a specific commercial objective.”

“The intricacies of that definition can be debated, but there are some things that are obviously not basic research,” Wintner says. “A company can’t give the university a bunch of compounds for clinical testing. That’s not basic research. It has to be so broad that it is something like research on cancer in general or maybe a particular type.”

Sponsored research agreements that involve more specific research that has an easy connection to the commercial market cannot be performed in a publicly funded building. If the research does meet the IRS definition of basic research, Wintner explains, the two safe harbors provide protection when structuring the deal:

- Any license or use of the resulting technology must be on the same terms that the university would permit use by a non-sponsoring party. It must be an arms-length transaction at a typical price, determined at the time the technology is available for use. That means the deal cannot spell out the terms of a purchase price or licensing arrangement up front. “To take advantage of the safe harbor, you actually can’t include any terms with respect to price until the time that you actually develop some technology you might want to license,” Wintner explains. “That’s to avoid some sort of sweetheart deal with the sponsor.” If the sponsor wants to spell out the purchase or licensing terms in advance, that is permissible if the deal specifies that the work will be performed in a privately funded facility.

- Or, the patent remains with the university and the sponsor can get no more than a non-exclusive, royalty-free license. The university would be permitted to license the technology to competitors or other interested parties. This safe harbor is used less by corporate sponsors and more by the government and charitable foundations that are not as interested in an exclusive use of the patent. “Your classic pharma company would try to take advantage of harbor number one and wait to see what the research yields. If it is valuable and you want an exclusive license, you have to pay for it,” he explains. “The law is designed so that you don’t have the inside track because you provided sponsorship.”

**Big risks in non-compliance**

The risk of non-compliance lies with the university, not the sponsor, so sponsored research offices must be careful to structure the deals properly with the aid of legal counsel, Wintner says. Otherwise, the scenario could play out like this: The university obtains $100 million in bond financing, and then five years down the road it enters into a sponsored research agreement. Three years after that, the IRS audits the bonds and finds that the agreement doesn’t fit into either of the safe harbors and is well over the 5% threshold of use in the publicly funded building. The IRS then sends a bill to every single one of the bondholders asking for tax on the bond’s interest because the university’s action retroactively cancels the tax-exempt status of the bonds.

“You can only imagine how big a bill that might be. The bondholders never pay that amount, however, because the closing agreement typically requires the university to indemnify them for the bonds being, essentially, mischaracterized,” Wintner explains. “So the university all of a sudden is on the hook for what could be millions of dollars of interest on bonds that were mischaracterized.”

When the university knows early on that complying with the IRS rules in a new research facility, for instance, will be difficult, it might opt for equity financing for the building rather than bond financing, Wintner says. The common ways of doing that are for the sponsor to pay for the building outright or for the university to use its endowment funds. Under those scenarios there are no concerns about complying with the IRS rules on publicly funded facilities.

**Communicate with CFO**

Research managers may not be the final word on decisions related to these IRS issues, Wintner notes. More often, it is the chief financial officer (CFO) who makes the key decisions because they deal with the tax issues related to the cost of the
building. But it’s up to research staff to bring a potential sponsorship arrangement to the CFO’s attention.

Research and tech transfer leaders “have the relationship with the companies, so one of the tricky things is the communication between the different offices,” Wintner says. “The tech transfer office is the one that understands these agreements and the potential benefits that come from them, but ultimately it’s the CFO who is responsible for the tax-exempt status of the bonds and the promises they made in years past to get the building built in the first place.”

Any sponsorship proposal should first be vetted for tax law violations, but the sponsored research office usually has no idea about what buildings were publicly funded or even what the safe harbors are, says Christine Reuther, JD, a shareholder with the law firm of McCausland Keen & Buckman in Radnor, PA. In her experience with handling matters on behalf of university clients, she finds that they do a poor job of segregating the tax-exempt bond funds. Research leaders must rely on the CFO and legal counsel, who may also have to research the building’s finance history and current allocation for private use.

“Blowing your bond exemption is not a common occurrence but it ought to be on your radar as a due diligence item,” she says. “[You] should be building bridges with finance, legal counsel, and facilities management now, so that when the question comes up they are ready to work with you.”

Reuther says it’s critical to assess the tax compliance issue early in any discussion about sponsored research. If you wait until the discussions are far along and everyone is excited to move forward, there may be a tendency to give short shrift to possible tax problems. For instance, the parties may rely on the 5% safe harbor and just hope or assume that the sponsored research will stay under that threshold.

“If the university has good controls in place to inventory the buildings that are subject to bond financing restrictions, and if the [research] office is diligent about checking that inventory before proceeding with sponsorship, you’re not going to have a problem,” she says. “If you don’t have those controls that provide ready answers, you have to be very careful because you don’t know if you may or may not be creating a bond issue for the university.”

GA Tech’s compliance process

The risk is well recognized at the Georgia Tech Applied Research Corporation (GTARC), on the campus of the Georgia Institute of Technology in Atlanta, says Kevin Wozniak, executive director for industry engagement. GTARC had $700 million in research expenditures in 2013, and $80 million of that was directly sponsored by companies. That figure climbs to about $100 million with the inclusion of federal government money that went to private companies and then was subcontracted to Georgia Tech, Wozniak explains.

The university entered into research contracts with about 600 companies last year, and has been doing so for years, he says -- and each of those agreements carries the potential for violating the laws regarding publicly funded buildings.

“There is quite a bit of effort put into understanding the revenue procedures that financed the buildings, where the debt is at, and understanding what research can be done where and how,” Wozniak says. “We’re always looking to see if the agreements falls within one of the safe harbors provided under the law. We do spend quite a bit of time managing those contracts.”

GTARC employs a bond compliance group on campus to review sponsored research agreements and the limitations on the use of certain buildings. GTARC representatives work alongside others from the university’s legal affairs and financial affairs offices. The group monitors research grants even after the initial vetting when the agreement is made, ensuring that restricted usage doesn’t creep in once the sponsored research program is established.

“Our campus is embedded in the city of Atlanta, so there are many buildings that are mixed use and there are different models for how the bonds are financed,” Wozniak says. “There is plenty for the bond compliance group to monitor.”

GTARC has not had any allegations of violating the tax laws with sponsored research, but Wozniak attributes that to the formalized review process by the bond compliance group. The risk, he says, is very real and especially with Georgia Tech’s volume of sponsored research.

“It is certainly something that becomes a point of conversation with sponsors, particularly with those that are not used to sponsoring research at universities,” Wozniak says. “The revenue procedures and how we fund our buildings is a con-

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constraint, but it helps lead to a bigger discussion about the types of collaborations that universities and industry engage in, and each party’s goals. We look at [ensuring compliance] less as a way of losing sponsorships and more as an opportunity for meaningful discussions.”

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Tax issues continued from p. 12

As government funding sources have tightened in the past few years, universities nationwide have sought ways to “increase engagement with local, national, and international companies in sponsored research,” says Zev Sunleaf, executive director of the University of Iowa Research Foundation in Iowa City. However, that engagement has been slow to develop. The University of Minnesota, for example, experienced five to six years in a row of “pretty much flat growth in industry-sponsored research even though a number of Fortune 500 companies are headquartered in the Minneapolis-St. Paul area,” points out Jay Schrankler, executive director of the Office for Technology Commercialization in St. Paul.

As most research offices have too-often seen, for many companies intellectual property terms in a research agreement are a barrier to a deal, suggests Lisa Lorenzen, PhD, executive director of the Iowa State University (ISU) Research Foundation in Ames. “Reducing the commercialization risk for companies should make them more open to engaging in sponsored research,” she comments.

In March, Iowa and ISU jointly announced that both universities would tackle the IP issue by offering for-profit companies an exclusive licensing option for research sponsorships. The new option is modeled after Minnesota Innovation Partnerships (MN-IP), a program launched by U Minnesota to “attract more companies to do research here by eliminating or lowering that barrier of IP concerns,” says Schrankler.

Minnesota designed its program based on the results of multiple interviews with industry, and reaction has been “very positive,” he states. “Under MN-IP, we signed more than 40 agreements in a year, and a number of big companies have done master research agreements in the program.”

Both Iowa and ISU are already talking to companies that are interested in executing deals. However, reaction “has honestly been mixed,” says Lorenzen. “Some companies seem pretty excited. However, others have done enough research that they know the type of research they do here typically doesn’t have a lot of IP potential,” she explains. “For those companies, I hope this new option can open their eyes to other types of research that they could do here now because there isn’t that risk. But evolving the kinds of research they can do will take time.”

How it works

Here’s how the exclusive licensing option works:

1. An upfront fee. “Basically the sponsor is paying a small upfront fee that guarantees a back-end fixed set of fees,” explains Sunleaf. That initial fee is the greater of 10% of the total cost of the research or $15,000.

2. A fixed royalty rate. On the back end, the royalty rate for licensed IP is 1% of total net sales in any year where sales exceed $20 million. Putting the threshold at $20 million “gives companies a chance to generate sales before they have to start paying a royalty rate,” says Schrankler. “So they get some cost recovery from their development work.” In addition, the fixed 1% rate allows TTOs to “incentivize research, yet share if we have a big winner,” says Lorenzen.

3. Ownership determined by invention. “If our principal investigators (PIs) alone invent a technology, we own the IP. If people from both the University of Iowa and the company invent a technology, the IP would be jointly owned,” notes Sunleaf. “So in that respect, there’s no difference from standard licensing.”

4. License guarantee. “Should there ever be an invention that comes out of the research, the company gets an automatic exclusive license to it, and the company does the patent prosecution,” says Schrankler.

5. Limited availability. The exclusive licensing option “doesn’t work in as many cases as the old tried-and-true licensing option,” says Sunleaf. “This only relates to research that is wholly fund-continued on page 14
Industry-sponsored research management is often associated with full F&A [facilities and administrative] rates paid by a single sponsor. For example, it doesn’t relate to federally funded research or research where there is income or sponsorship coming from multiple groups.”

The exclusive licensing research option “is an additional tool to use where it makes sense,” says Sunleaf. “Option No. 1 is still the standard licensing method of ‘negotiate appropriate terms after the technology is developed.’ However, in some cases this new option is available. So we’ve added to our capabilities.” (For the specifics of the policy language, see box below.)

Will it work on your campus?

Research offices that want to implement a similar program should take these steps:

- Calculate the potential benefits. Royalty rates are dependent on the type of technology. With a commodity chemical, for example, 1% actually...

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**Exclusive License Option for Sponsored Research Agreements**

The University of Iowa provides the following options on intellectual property rights for for-profit entities that would like to sponsor research at the university. Both options below share the following characteristics:

- The University of Iowa and inventors retain the right to use any intellectual property developed for research and teaching.
- Sponsor retains rights, free of charge, to use data arising from sponsored research even if there are no patentable inventions; and
- The decision whether to offer a sponsor Option 1 or Option 2 begins with the University of Iowa principal investigator.

**Option 1: Standard**

This option is the traditional approach to IP rights in industry-sponsored research agreements.

- The laws of inventorship determine ownership;
- No upfront fees for a one-year option;
- No pre-set license terms; and
- Sponsor and UI negotiate in good faith for commercial rights to UI IP created under the agreement once IP has been developed.

**Option 2: Exclusive License at fixed rates**

The UI offers this option to remove uncertainty for sponsors regarding future financial obligations.

- The laws of inventorship determine ownership;
- Sponsor pre-pays a non-refundable Option fee of the greater of 10% of total cost of sponsored research agreement or $15,000. (The fee is calculated based on the entire project budget including standard University F&A costs that must be paid at the full federal research F&A rate. The fee is applied based on funds obligated in the agreement. If the sponsor pays the $15,000 amount because the initial obligation of funds is <$150,000, the sponsor will not be charged the 10% on future obligations until after the $150,000 threshold in obligated funds is reached);
- The full amount of the fee will be due within 30 days of billing. Failure to pay the fee will result in the revocation of Option 2 and implementation of Option 1;
- Sponsor may execute an exclusive, perpetual, worldwide license for rights to all inventions (patentable or not), and software arising from and funded by the sponsored research project at its option:
  - Under a license, Sponsor pays 1% royalties on net sales of licensed intellectual property (IP) when sales using IP exceed $20 million;
  - There are no annual minimums or other technology commercialization fees, time limits or milestones as part of the license;
  - Sponsor is free to sublicense/cross-license inventions as part of the license;
  - Sponsor fully manages and directs all patenting activities, including choosing patent counsel (while collaborating with the University on patent claims), and directly pays all costs associated with patent prosecution under the license;
- University-owned background IP is not automatically included; however, UI will consider licensing background IP;
- Option 2 is not available for research awards from government, non-profit, or other types of non-commercial sponsors or awards for public service or testing; and
- Option 2 is contingent on the sponsor paying the full costs of research performed under the sponsored research agreement.

**Distribution policy for Option 2 Fee:**

- 25% to PI’s lab
- 15% to PI’s Department
- 15% to PI’s College
- 20% to OVPR
- 25% to UIRF

Any royalties received as part of 1% of nets sales will be distributed as specified in the UI Intellectual Property Policy.

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Source: University of Iowa
would be a high royalty rate, notes Schrankler. However, on a standard license for IP that was developed under someone else’s funding, royalty rates often run from 3% to 10% depending on multiple factors, adds Sunleaf.

So an obvious question is: Will universities lose money by doing this because they are giving up significant royalty income? To assess the viability of this approach, “we looked at the history of sponsored research here and asked ourselves: How much royalty income ever came out of patents from industry-sponsored research?” says Schrankler.

“The answer was a few million dollars a year over a 20-year period,” he says. “It was such a small amount that it wasn’t worth the price of turning companies away. Our evaluation showed that the risk of losing a lot of money on potential hits was low, and the upside -- getting the upfront money and bringing in more research -- was much bigger.”

Similarly, ISU found that its royalty income from commercializing industry-sponsored technologies was “pretty low,” says Lorenzen. “The truth was that most of our industry-sponsored research did not lead to patented and commercialized technologies. Most of it just led to know-how and information.”

To equal its current licensing of industry-sponsored research, “the upfront 10% fee set by Minnesota was a number that seemed to make sense,” says Lorenzen. “It is high enough that they take it seriously, but hopefully it is not high enough to be a burden to industry.”

• Don’t include background IP. “Typically background IP is federally funded,” says Schrankler. “You can’t predetermine royalty rates under the Bayh-Dole Act, so companies have to license background IP separately under different terms.”

• Check tax laws for public buildings. “In many states, paying the fee upfront prior to the awarding of any license is potentially problematic. It has to do with publicly bonded buildings and how much of the upfront rates fall into this public-use issue,” says Schrankler.

“Minnesota is unique because its publicly bonded buildings are all pooled at the state level, providing a lot of overhead. Typically you can’t do more than 10% of the value of the building in public use.”

Still, universities that have avoided this option due to the public-use issue should consider the fact that “you are probably never going to hit that overhead anyway,” he notes. “However, at the end of the day, universities have to do what is right for them in their community and their situation. It may not work for every university.”

• Bring in the university’s key players. One essential step in developing this type of program is “figuring out who at the university should be involved,” says Sunleaf. “You have to get everyone on board and have the key groups review the different options, address critical questions, and approve the new template agreements and other documentation required to make the program run smoothly. In our case, we developed a partnership between the Office for the Vice President of Research, the Office of General Counsel, and the Division of Sponsored Programs.”

Executive leadership also has a role to play in establishing this type of option, adds Lorenzen. “A priority of ISU President Steven Leath since he took office in January 2012 has been to make sure we are supportive of industry -- with the right policies and procedures in place to be friendly and open to working with them.”

• Give PIs the option to refuse. “The PI has the first choice as to whether this option is on the table,” says Sunleaf. “If they say, ‘This is the type of research I don’t want to do this with,’ we don’t make that offer.”

“The faculty members have to be able to opt out if they don’t like the terms. They have to have control,” agrees Schrankler.

• Don’t skip due diligence. Due diligence is a must to ensure that the exclusive licensing option “doesn’t overlap with any other funding mechanisms (e.g., National Science Foundation or National Institutes of Health) that would prevent you from making this offer,” says Sunleaf. “It really has to be encapsulated projects.”

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For Further Information...

- Iowa State University Flexible Solutions program: http://www.industry.iastate.edu/flexiblesolutions.html.
IP-related barriers continued from p. 15

- **Align internal processes.** Don’t “underestimate the internal behind-the-scenes processes that need to be considered,” suggests Lorenzen. “Who is going to bill this new option for you? Who is going to distribute monies? When the researchers submit their information to the university about the project, there probably is no box to check on the form about this new option. There needs to be. You have to have your internal processes set up to manage it.”

  The ISU Office of Intellectual Property and Technology Transfer handles research contract negotiations as well as tech transfer. “So all of the new implementation fell within our office,” says Lorenzen. However, some universities might need to coordinate changes across more than one office or group, she adds.

  One example of a change that ISU made relates to treating the upfront 10% payment as royalty income, says Lorenzen. “We identify it as royalty income, but it is going to be shared back right away -- not shared back once or twice a year like a typical TTO. So we’ve had to implement a new internal process in our office for how to manage those funds.”

- **Educate your campus.** Reaction from PIs has been generally positive, says Sunleaf. “Researchers look at anything that decreases the amount of time to obtain their funding as a good thing. In many cases, there is the tried and true response, ‘I don’t think anything will come out of this. I just want money for my research.’ Very few of them have been concerned about the downstream royalties.”

Even so, be prepared to provide good communication and education, says Sunleaf. “Among the PIs, there has been some confusion as to what this program relates to. For example, people have said, ‘These are just licensing terms for anything.’ Of course, it’s not. So you have to do some teaching to implement the program.”

  “Even describing the option in clear, simple terms, a lot of people will misunderstand it,” says Lorenzen. “So you’re going to spend a lot of time explaining why you are doing this and what it really does.”

- **Share ideas for partnerships.** Lowering the barriers to industry involvement in university research is not one-size-fits-all, so research managers need to have multiple options in their toolkits, suggests Schrankler. “The Washington, DC-based University-Industry Demonstration Partnership, which is run by the National Academy of Sciences, is a great organization for sharing ideas to have better partnerships between universities and industry.”

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**Coming in future issues...**

Critical issues in negotiating international industry collaboration agreements • Why researchers may balk at these sponsorship deal terms • Best practices for dealing with incoming and departing faculty with ongoing sponsorship agreements • Free marketing that promotes industry partners helps cement lasting relationships

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