Research-Asset Assessment Study for Commonwealth of Virginia:

Phase II – Environmental Scan of University Technology Transfer, Commercialization and Industry Partnership Activities: Practices, Policies, Organization and Opportunities to Advance

> To: Virginia Research Investment Committee and State Council of Higher Education for Virginia

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A. Introduction

The State Council of Higher Education for the Commonwealth of Virginia (SCHEV), on behalf of the Virginia Research Investment Committee (VRIC), has launched a comprehensive study to assess the Commonwealth's research assets, including those at its public and private universities, federal research facilities and private sector companies. To assist with the analysis, SCHEV has retained TEConomy Partners, LLC. (TEConomy), which was formed in late 2015 as an independent company, transitioning the complete staff and capabilities of the Technology Partnership Practice (TPP) from the Battelle Memorial Institute. TEConomy has a proven track record in conducting rigorous and robust assessment studies of research and development (R&D) assets and overall innovation ecosystems in states, including Arkansas, Arizona, Connecticut, Georgia, Indiana, Iowa, New Hampshire, Ohio, and Utah, that inform the targeting of innovation-led growth opportunities found in a state as well as strategic actions to further innovation-based development.

Nearly a decade since the onset of the Great Recession of 2007-2009, the capability to innovate is fast becoming the most important determinant of economic growth for U.S. states and regions, reflecting the acceleration of a new economic era marked by increasing globalization, the fast pace of technological change, and the growing strength of developing nations in generating highly educated and skilled talent to compete for economic growth. The U.S. Council on Competitiveness in its report, *Innovate America*, put the issue succinctly: "We believe that the bar for innovation is rising. And, simply running in place will not be enough to sustain America's leadership in the 21st century...Today the forces of global economic integration and advances in technology are creating a different and more complex challenge."¹

At a time when innovation, talent and technology capabilities are the key driving forces for state and regional economies, the value of university research activities increasingly depends upon not just their size and excellence, but the ability to translate that university research base for advancing new product development, new company formation and industry cluster development. As the National Research Council in its 2013 report *Best Practices in State and Regional Innovation Initiatives: Competing in the 21st Century*, explains:

"A key factor in the rise of the United States as a technological power has been a long tradition of close ties and frequent collaboration between companies and a network of first-rate universities. Underlying the success of innovation clusters such as Silicon Valley, Route 128, and the Research Triangle of North Carolina are local universities with a longstanding mission of spurring economic development by developing technology with and transferring technology to local industry and stimulating the creation of new businesses in university-centered incubators and science parks. Technology-intensive companies commonly locate their operations near the best universities in particular fields of science and engineering in order to enable their internal research departments to work with "star" scientists and to recruit promising students."²

¹ Council on Competitiveness, Innovate America, December 2004, page 11.

² Charles Wessner, Editor, "Best Practices in State and Regional Innovation Initiatives: Competing in the 21st Century," National Research Council, 2013, page 49.

Indeed, an examination of numerous studies published in leading economic journals of the relationship between industry innovation and university research expenditures at the state and regional level concluded that "almost without exception, the research has found a relationship between the measure of innovation and university research performed in close proximity."³ According to a study prepared for the U.S. Small Business Administration, "Research universities and investment in research universities are major factors contributing to economic growth in the labor market areas in which the universities are situated."⁴

But the demands for technology transfer of university research are changing. As a 2017 report by the Association of Public and Land Grant Universities on *Technology Transfer Evolution* explains, "University leaders are increasingly responding to the needs of the innovation economy—and in particular their local economies—by including innovation, entrepreneurship, and "economic engagement" programming in their strategic planning processes." APLU continues by noting that: "In evolving toward broader participation in university economic engagement, technology transfer offices will develop deeper relationships with industry and other community partners; broaden their reach to areas such as education, technology development, and entrepreneurship; and integrate more closely with other supportive administrative functions such as industry contracting."⁵

APLU sets out four important themes around the changing nature of how universities go about the translation of university research activities:

- 1. Success in technology transfer should not be measured by revenue, but by contributions to economic prosperity. The emphasis needs to shift from transactional to relationship building; from revenue-generation to realizing translational potential of the technology.
- 2. Technology transfer must better integrate and align with the broader economic engagement efforts of the university. This approach will require the appropriate alignment of functions across the campus, including technology transfer, entrepreneurship, corporate partnerships, industry contracting, accelerator programs, advancement, alumni relations and other activities. The broader economic engagement enterprise should include a "concierge" service that helps external audiences connect with the right type of resource on campus, and that helps faculty identify appropriate resources matching their needs.
- 3. Strategic resource allocation for technology transfer, including funding and staffing, must take into account a broader scope of activities and expectations.
- 4. *Make the economic engagement story more explicit*. University leaders must communicate across the institution the value of economic and societal engagement, and underscore that

³ Paula Stephan, How Economics Shapes Science, Harvard University Press, 2012, page 214, citing studies from Adam Jaffe et al "Geographic Localization of Knowledge Sources as Evidenced by Patent Citations," Quarterly Journal of Economics, 108:576–98; Zoltan Acs, et al, "Real Effects of Academic Research," American Economic Review 83:363–67; Grant Black, The Geography of Small Firm Innovation, New York, Kluwer, and Corinne Autant-Bernard, "Science and Knowledge Flows," Research Policy 30:1069–78.

⁴ Bruce Kirchhoff, "The Influence of R&D Expenditures on New Firm Formation and Economic Growth," Maplewood, N.J.: BJK Associates, 2002.

⁵ Association of Public and Land Grant Universities, *Technology Transfer Evolution*, November 2017, pages 3-4

technology transfer – along with other parts of the innovation management enterprise – help the university achieve its engagement goals.

In light of the increasing importance of innovation for economic competitiveness and the heightened requirements for success in the translation of university research, it is imperative that the Virginia Research-Asset Assessment involve a close examination of current practices, policies and organization found across Virginia's universities not simply in technology transfer, but in the broader focus of translational research involving commercialization and industry partnerships. This Environmental Scan undertakes two important tasks:

- It assesses the practices, policies and organization of Virginia universities efforts in technology transfer, commercialization and industry partnering compared with emerging best practices
- It also identifies opportunities to advance the impact and value creation of university translational research activities to bolster the Commonwealth's economy statewide.

This effort involved site visits by the TEConomy project team with university staff leading technology transfer, industry sponsored research and university-based economic development to learn about:

- Specific practices, program activities, organization and approaches to deal terms
- Updates on recent performance and notable successes
- Key barriers and constraints

Following these site visits, the TEConomy project team reviewed specific university policies, templates and other formalized guidance to compare and contrast with emerging best practices.

B. Setting the Context of University Translational Research Activities Involving Technology Transfer, Commercialization and Industry Partnerships

University efforts to translate research were a limited and often ad hoc process until the passage of the Bayh-Dole Act in 1980.⁶ Bayh-Dole required universities to take responsibility for intellectual property developed with federal funds and initiated a broadened university role in patent activities and licensing given that federal funding comprises more than half of university research funding. More specifically, Bayh-Dole regulations set out the following responsibilities that all universities receiving federal funding must conform to:

- strict time-frames for disclosing subject inventions to government, for electing title to the invention, and for filing patent application
- university's licensees must be capable and reasonably diligent
- products sold in US must be substantially manufactured in US
- universities must *give preference* in licensing to small companies over large
- universities required to report on utilization of subject inventions
- government retains royalty-free, internal license, plus march-in rights

Adding to the approaches incorporated into university technology transfer practices are other federal requirements, particularly for managing conflicts-of-interest in receiving federal funding. Plus, many states placed their own requirements on technology transfer activities and often had state constitutional issues related to private use restrictions and benefits from public research activities.

Technology Transfer as the Passive Management of Intellectual Property

By the close of the 20th Century, technology transfer offices were a common organizational feature found at research universities in the U.S., typically reporting to the university's research administration leadership. For the most part, technology transfer activities commonly found at universities at the turn of the 21st Century involved **the passive management of intellectual property**. The key activities undertaken by technology transfer involved seeking disclosures of discoveries from research faculty before they are made public, determining whether to file for patent protection based on the novelty and potential market for the technology, and then seeking to license the intellectual property (to either an existing company or to create a new business, often led by the faculty or their graduate students) to pursue the development of a product, process, service or other intervention based on the discovery and its associated license. A common practice of technology transfer offices is to file relatively inexpensive provisional patents, and then partner with an industry sponsor who would become responsible for covering the far more expensive costs associated with filing for full patent protection.

⁶ David C. Mowery and Bhaven N. Sampat, "University Patent and Policy Debates" in the USA, 1925–1980," Industrial and Corporate Change, Volume 10, Issue 3, 1 August 2001, Pages 781–814

Emergence of Need for Technology Commercialization to Identify and Address the Demands of the Market Place for Translation of Technology

It soon became obvious across technology transfer offices that moving research discoveries into the marketplace is not a passive "pipeline" approach of protecting intellectual property and then handing off to industry through licensing. Instead the process of translation of research discoveries to the marketplace is a highly complex, interactive, and market-driven process that calls for enhancing research discoveries into technology solutions to meet the need(s) of customers in the marketplace. It involves a number of activities, such as assessing the technology and its potential markets against current products in the marketplace, e.g., technology and market assessments. It involves proof-of-concept of the viability of the technology, and optimizing its engineering and design to meet price points of the marketplace in order to enhance the potential for sales and growth. For successful start-ups, it involves identifying and recruiting the business and management team and securing the sources of investment or financing that will carry the product and/or firm through various stages of growth and development toward becoming an established company/product in domestic and global markets. In short, technology commercialization focuses on technology, proof-of-concept and technology development or scale-up capabilities, capital and talent.

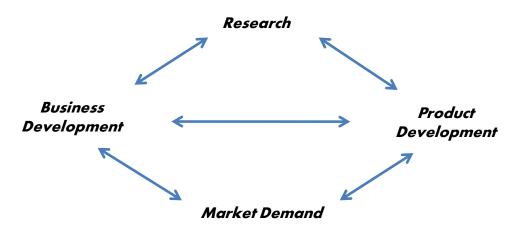


Figure 1: Market-Driven Process of Innovation and Technology Development

Over the last decade, emerging best practices across universities have been seeking to complement the passive function of technology transfer with more pro-active efforts of technology commercialization. Examples of approaches to ensure that companies will succeed in commercializing technology include the following:

- Providing access to proof-of-concept funding and networking resources to address the technical feasibility and explore in more depth the commercial viability of a technology
- Supporting recruitment and retention of staff with business experience to engage university researchers and to scout university laboratories for discoveries that may have commercial potential

- Offering prototyping facilities and services to produce engineering prototypes or to produce test runs for marketing or evaluation purposes
- Developing capacities related to drug development (e.g., high throughput screening, medicinal chemistry, etc.), clinical research, regulatory compliance, and related activities to advance prospective biological and life science discoveries and related technologies toward market introduction
- Creating mechanisms to help companies mature to "investment-grade status" i.e., they have a strong business plan, an experienced management team, a well-thought-out marketing strategy, etc.
- Encouraging strategic partnerships between large companies and start-ups

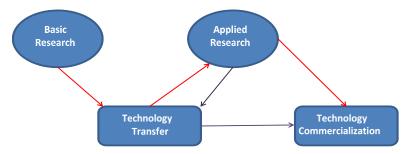
Consequently, technology commercialization must expand its focus beyond the research organization and look toward the commercial sector, including private investors, serial managerial talent, customer/patients, and more – prioritizing its capacities to understand and address solutions to real market needs, and beyond research which contributes to our knowledge base without attention to its translational potential.

Importance of Industry Collaborations in Applied Research to Advance University Technology Commercialization

At the same time, universities began to recognize that research generating intellectual property is not simply based on fundamental basic research, but also often requires industry collaborations to address the development of specific applications and solutions. The value proposition of university-industry collaborations is significant -- universities can offer their cutting-edge solutions based on research discoveries and expertise, while industry partners can bring their understanding of market needs and expertise and capabilities in product development.

The starting point for technology commercialization of university-industry collaborations in applied research solutions is different than for basic research innovations and so what is needed to move forward in terms of technology transfer activities can vary, as shown in Figure 2. In particular, a basic research discovery that has IP potential often needs additional applied research efforts to advance the discovery. For instance, a new research discovery of a key drug target still needs to go through drug development before it can be advanced as a new drug candidate for clinical testing. Similarly, a basic nanotechnology discovery of a new material or structure needs further applied research to develop more specific uses, which then need to go through prototyping and scale up.

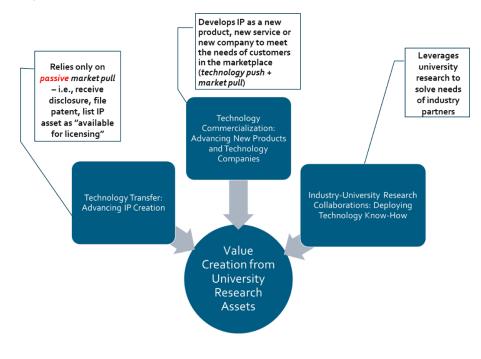
For applied research solutions drawing on industry-university collaboration, the starting point is focused on advancing an application or solution in response to a market need and often involves convergence of multiple technologies. As such, once the translational research is completed it becomes intellectual property that, from a technology transfer perspective, can then be disclosed, evaluated and assessed both from a market and technical perspective, protected through patents or copyrights, and ultimately transferred via a license (to an existing or startup company) of the intellectual property and know-how. If intellectual property, technology development, and market-based challenges are addressed successfully, it can then move into technology commercialization activities with an exclusive partner or number of non-exclusive partners for prototyping, scale-up, manufacturing, and product introduction and sales.

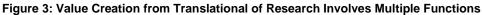




Multiple Paths to Drive Value Creation

As universities have considered ways in which they drive value creation from the translation of research a more sophisticated approach is taking form as set out in Figure 3. These three functions are often highly inter-dependent and often require trade-offs to generate value creation. For instance, a university may decide that an industry partnership is the best means to successfully translate technologies and may forego or reduce royalties in return for industry sponsored research activity. Or, a university may decide that a locally-based start-up can champion the technology more effectively and can generate the highest value over time, and so decide to take its returns in the form of equity that may not payout for many years rather than licensing the technology to an existing company, which may generate financial return more quickly. The overall gains in developing a startup, in terms of jobs, opportunities for student placement, industry sponsored research and ultimately equity payout, may be a longer-term win for the university, its students and its local economy.





C. Examining the Practices, Policies and Organization of Virginia Universities Across the Stages of Technology Transfer, Commercialization and Industry Partnerships

Building off the model of value creation from the translation of research, the TEConomy project team organized its assessment by considering each stage of possible value creation – technology transfer, technology commercialization and industry research collaboration. Each stage has associated with it specific outcomes that are measurable as set out in Figure 4.

Figure 4: Specific Stages and Outcomes Associated with University-related Technology Transfer, Technology Commercialization and Industry Research Collaborations

	Technology Transfer		Technology Commercialization	Industry Research Collaboration	
Stage	Discovery to IP Creation	Translational Research	Licensing and New Firm Formation	Pre-Competitive Research	Applied Research
Outcomes	 Invention Disclosure Research collaboration Advance to next stage, or return to inventor 	 Market assessment Proof-of-concept Intellectual property (patent, copyright, trade secret, open access, etc.) Fail and start again 	 "Investment grade" ready technologies Pro-active advancement of start- ups Licenses are signed with existing companies 	 Industry consortium Open innovation partnerships with industry, NGOs, others 	 Individual company specific application or technology solution

In the sections that follow TEConomy sets out emerging best practices for each stage of the research translation and how existing Virginia universities stack up. Before walking through that assessment, some general observations are in order to provide a high-level overview:

- All Virginia research-oriented universities have processes in place for management of intellectual property (IP) but wide variance in resources, operations and priorities exist.
- Technology transfer policies at Virginia universities appear fairly consistent with national best
 practices in terms of how to handle intellectual property, conflict of interest and faculty incentives.
 Still a major uncertainty for Virginia public research universities is what are the goals the
 Commonwealth seeks from technology transfer short-term revenue maximization from IP
 management or longer-term value creation for advancing the state's economic development.
- Virginia universities are typically using university-affiliated, independent non-profit 501(c)(3)
 organizations for handling IP management. This addresses restrictions placed on Virginia's public
 research universities as public-sector entities in having the flexibility to structure deals and to retain
 the expertise to guide IP management.
- Tech commercialization strategies typically involve a range from start-up development to licensing to research collaborations with existing companies, though the level of focus and resources applied to these strategies vary significantly across Virginia's public research institutions.

- Some universities offer IP on a royalty-free basis to industry research partners to encourage more sponsored research activity.
- Overall, the smaller research universities have critical mass issues that may affect their tech commercialization potential.

As the findings below detail, while there are clear commonalities across activities found in technology transfer, technology commercialization and industry collaboration across Virginia universities, there is also a wide diversity of practices and resources brought to bear on university technology transfer.

Stage One: Discovery to IP Creation

At the stage of discovery to IP creation, several key practices need to be in place to ensure sustained generation of invention disclosures that can be developed into intellectual property to begin the technology transfer process:

- Intellectual property policies that set out the rules, pathways and incentives for moving research discoveries to the stage of intellectual property
- Institutional culture and engagement of faculty to pursue innovation and entrepreneurship from research efforts
- Initial assessment of the potential commercial market and technical feasibility of the invention and follow-on invention management
- Strategies for intellectual property management
- I. Intellectual property policies The starting point for a successful institutional approach to technology transfer is an institutional intellectual property or technology transfer policy which:
 - Clearly aligns with institutional requirements set forth in the Bayh-Dole Act
 - Creates timely and consistent guidelines for the disclosure, protection and management of inventions
 - Sets forth the ways in which researchers engage with and benefit from the technology transfer process.
 - Addresses other policies or organizational frameworks which can be critical to success including conflict of interest policies and faculty tenure and promotion policies.

Observations/Assessments of Virginia Practices:

- Most Virginia institutions have well-developed and up-to-date intellectual property policies and procedures which are well-aligned with Bayh-Dole requirements.
- Royalty sharing with inventors at Virginia universities appears to range from 33-50% consistent with national best practices.
- Virginia's public research universities are caught between conflicting goals of short-term "revenue maximization" versus "value creation" and economic development-oriented goals for the Commonwealth that focus on efforts to create and support start-up companies, that support growth of existing companies, and that attract outside companies to establish basic

and translational research partnerships and broader operations in Virginia. The University of Virginia appears to be the only technology commercialization program that does not support its operations from retaining a portion of licensing revenue each year.

- Conflict of interest policies appear to be consistent with federal and state requirements and most universities report that these policies are working well. Most importantly, Virginia universities recognize the importance of managing conflicts (rather than forbidding them) in order to facilitate technology transfer and commercialization.
- Most Virginia universities have policies that encourage consideration of engagement and impact in technology transfer and commercialization in the tenure and promotion process.
- Some universities noted concern that Virginia's financial interest disclosure policy may serve as a disincentive for some to engage in startup or industry research activities focused on advancing their research toward commercialization.

Recommended Improvements:

- Clarify that state policy and goals for university technology transfer and commercialization do not include revenue maximization – and develop a funding mechanism for technology commercialization activities that does not rely on funds derived from a portion of earned licensing revenue.
- 2. Set out clear metrics for measuring value creation that may include revenue generation but which include other measures as well. Such measures could include numbers of startups formed; number of commercialization licenses or similar agreements; examples of regulatory milestones achieved by products under development in startups or licensees; amount and source of investment capital raised by startups; evidence of valuation increases in university startups based on institutional investors or other external sources; amounts of square footage occupied, jobs, average salaries, local and state taxes paid, and related economic indicators based on startup activities; and others. In setting out these metrics, it is important to have common definitions and to the greatest extent possible those definitions used by the Association of University Technology Managers should be deployed.
- 3. Consider creating a revised approach to conflict of interest management and Virginia's financial disclosure requirements that explicitly states that individual inventors' royalty and equity interests received as a result of commercialization success are per se allowable and exempt from public disclosure provided they are included in the individual's annual disclosure of conflicts of interest submitted on his/her respective campus.
- II. Institutional culture towards innovation and entrepreneurship from research efforts An institutional culture enabling successful innovation and entrepreneurship is also required for generating faculty, post-doc and graduate student interest in pursuing IP creation from research discoveries. Engagement in the technology transfer and later stage commercialization process needs to be taught, coached, facilitated and celebrated. It is important to hold regular seminars, networking events and outreach to the entire community of researchers in academic institutions.

Observations/Assessments of Virginia Practices:

• Most Virginia universities are active in faculty engagement to raise an understanding of technology transfer. These activities typically include seminars, orientation for new faculty recruits, and training in IP and related business development skills. Still, few universities are

engaged in pro-active prospecting for inventions through ongoing contact with individual investigators in their labs.

- Many Virginia universities now have innovator-of-the-year recognition awards; entrepreneurship events; and related innovation culture-building special events and awareness.
- A number of universities are offering elective, for-credit courses in innovation, designthinking, business planning, venture capital, patent law, and other areas designed to ensure that graduates have more opportunities to include innovation and entrepreneurship in their academic programs.

Recommended Improvements:

- 4. Create shared regional and/or statewide programs for entrepreneurial training, business plan competitions, and start-up company residencies for graduate students/post-docs. As feasible, include "invention prospecting" initiatives within the scope of these programs by providing proactive "invention prospecting" interactions between technology transfer experts and academic researchers.
- 5. Consider statewide recognition and award initiatives with high value financial and publicity benefits for inventors, teams, startup companies, and products achieving significant milestones and impacts in the marketplace.
- 6. Annual or bi-annual regional or statewide innovation showcases and pitch events should be offered to get more Virginia university researchers engaged and, as importantly, to announce to prospective industry and investor partners that Virginia universities are "open for business."
- Revive the Virginia Innovation Partnerships (VIP) program funded in 2013 by the Department of Commerce I6 program – designed to create a statewide resource for funding market- and industry-driven proof-of-concept projects. This could be accomplished by utilizing the program infrastructure developed and managed by the University of Virginia during the I6 projects.
- III. Initial assessment of potential commercial market and technical feasibility and overall invention management Mature technology transfer practices bring both in-house and outside expertise together to generate the needed assessment of inventions by technical, market and business savvy experts in order to help guide decisions whether to file patents, to identify specific feasibility questions, and to suggest likely paths to market, whether as a license or as a new start-up. This assessment is a critical part of the management of inventions, which also needs to address having specific timelines on go/no-go decisions.

Observations/Assessments of Virginia Practices:

• Virginia's technology commercialization offices tend to be thinly staffed and resourced, but staff appear knowledgeable regarding the basic components of invention assessment, intellectual property management, marketing, negotiating licensing, and related aspects of technology transfer. Basic technology transfer business processes appear to be in place.

- What is not consistent is the access to outside experts who can bring technical, market and business savvy advice on how to assess an invention. This creates a haves and have-not world within technology transfer across Virginia's research universities.
- Smaller institutions appear interested and committed to providing effective technology commercialization and translational research initiatives, but are constrained by their lack of resources and by the lack of critical mass in prospective deal flow needed to leverage more effective impacts and outcomes from their technology commercialization efforts.
- The use of established procedures and timeframes for making "go/no-go" decisions on filing of IP is uneven. Only a handful of Virginia universities have language in their IP policies that has specific timeframes. Others either have more vague standards of "reasonableness" or do not address at all.

Recommended Improvements:

- 8. Technology transfer offices in Virginia should enhance their efforts to create and share standard invention management and translational research/commercialization process maps (with as much specificity as feasible regarding time frames for key decisions, key decision makers, contact information, and related details).
- 9. Universities should develop criteria (with time frames) for offering to release invention disclosures to the inventor(s) in cases where it is not prepared to invest in patenting, marketing or licensing the invention which is the subject of the invention disclosure.
- IV. Strategies for intellectual property management Intellectual property (IP) strategy and management is an increasingly complex and expensive component of effective technology commercialization and translational research initiatives. Key questions in developing an effective IP strategy focus on whether to file, when to file, how to manage the significant costs involved in building patent estates, and strategies for managing increasingly common occurrences involving multiple co-inventors from multiple research institutions and companies.

Observations/Assessments of Virginia Practices:

- Virginia universities tend to leave patent filing and strategy decisions to professional technology transfer staff, which enables more timely decision-making and allows the university to negotiate in good faith with industry partners.
- Virginia universities are typically using university-affiliated, independent non-profit 501(c)(3) organizations for handling IP management. These university-affiliated, independent non-profits enable universities in Virginia more flexiblity on structuring deals, engaging formal industry guidance on managing IP and retaining specific legal and other management consulting services with expertise in IP management than would be allowed the universities themselves given state constitutional and procurement restrictions.
- A concern raised about the structure of having to use university-affiliated, independent nonprofit 501(c)(3) organizations for handling IP management is that it has created uncertainty about whether Virginia universities can make use of the sovereign immunity protection

grated to states in copyright and patent lawsuits by the U.S. Supreme Court's decision in *Florida Prepaid Postsecondary Educ. Expense Board v. College Savings Bank.*

- With one or two exceptions, Virginia universities tend not to invest in speculative filing of full utility or international patent applications unless a licensee is identified to take responsibility for patent costs. In some cases, this is likely a solid strategy; in others (especially for very early stage, long-term translational projects), this may be less appropriate. Few universities seem to have systematic processes in place to seek external industry, market, and patent strategy input to assist in making these complex and financially sensitive decisions.
- Some Virginia universities which have industry-member research centers turn over the patent strategy and financial responsibility for seeking and managing IP to industry members and typically allow members to obtain royalty-free non-exclusive licenses in return for covering such costs.

Recommended Improvements:

- 10. Ensure that university technology commercialization offices have mechanisms for seeking and considering external expert input in formulating and managing their strategies for seeking IP protection.
- 11. Create budget lines to allow university technology commercialization offices to pursue more "at-risk" patent filings, including full utility patents and international patents, where careful vetting and opportunity analysis indicates that such investment is justified.
- 12. Include patent strategy expertise and criteria for industry advisory boards, boards of directors, and other expert bodies advising technology commercialization offices.
- 13. Examine how to address the concern of ensuring Virginia public research universities can make use of the sovereign immunity defense in protecting their IP claims, which are available to public research universities in other states.

Stage Two: Market-Driven Translational Research

At the stage of translational research, key practices shift the focus from the more passive management of technology transfer to more pro-active technology commercialization efforts. The importance of the translational research stage is growing as the "valley of death" between intellectual property creation and new product introduction has widened in the last decade. These practices include:

- Establishing market-driven translational research approaches
- Pursuing strategies for commercialization
- University proof-of-concept funding to de-risk technologies
- Engaging innovation partners

I. Establishing market-driven guidance to translate research through commercialization – At the stage of going from invention to intellectual property creation, it is important to get the input of technical, market and business savvy experts on whether to pursue patenting. For the translational research stage of moving IP through commercialization, the need is to better activate this market guidance to inform the commercialization approaches for translating university research discoveries. Across universities, there is a growing use of entrepreneurs-in-residence (EIR) to provide this more engaged and intensive approach to help inform commercialization efforts. EIRs are experienced entrepreneurs who are retained by the technology transfer offices to advise and assist faculty and students as they explore the commercial viability for research discoveries and inventions. The effective use of EIRs goes well beyond just the commercial assessment of technologies and the coaching of faculty and students. EIRs are particularly effective in prospecting for inventions by walking the halls of research facilities to learn about the expertise of researchers in the labs and what research questions are being addressed to determine if they may have significant commercial relevancy – so offer a better way to bring out inventions than simply relying on faculty themselves. Plus, EIRs can often be a resource for networking with the larger investment and entrepreneurial community in a focused and value-added manner, and so increase the prospects of successfully commercializing a univerity technology and forming a new start-up company or collaboration with an existing venture.

An even more intensive process of market-driven efforts to translate research through commercialization is establishing very rigorous and market-facing approaches to screening earlystage inventions with active industry guidance informing key milestones for commercialization. This type of effort is now found at many larger universities in the life sciences through what is known as Coulter-type translational research processes due to the initial pioneering of such efforts by the Wallace H. Coulter Foundation.

Observations/Assessments of Virginia Practices:

- Entrepreneur-in-residence (EIR) initiatives are used by some, but not all of Virginia's research universities. For those Virginia universities using EIRs, most are very limited efforts with just one or two EIRs covering the entire research enterprise
- The University of Virginia has in place a Coulter Center that is one of the nation's top performing centers and is now endowed at \$20 million, enabling it to sustain its efforts going forward. This Coulter Center is primarily focused on life sciences technologies that bring together engineering and clinical teams and so is very medical device-oriented.

Recommended Improvements:

- 14. Explore and pursue funding opportunities to develop capacities throughout Virginia's universities to engage with business, customer, patient, regulatory, and related issues critical in advancing the commercialization of university research inventions.
- 15. Develop mechanisms to identify networks of alumni, community members, and related expert stakeholders willing to partner with technology commercialization offices in translational research and early stage technology de-risking initiatives.
- **III.** Establishing University Proof-of-Concept Funding to De-Risk Technology A growing tool among universities seeking to move inventions closer to the market and facilitate licensing and start-ups is

undertaking proof-of-concept funding to de-risk new technologies and demonstrate their commercial value. A proof-of-concept project will answer critical experimental questions that will help to validate a technology for commercial applications. The recent APLU report on Technology Transfer Evolution notes that proof-of-concept funding is one of the growing practices that are enabling the success of technology transfer efforts. One of the leading efforts noted by APLU is at the University of Colorado-Boulder, which reports that over the past 10 years it has funded 100 commercially promising projects that have translated into 32 licensing agreements and 31 start-ups that went on to reach \$313 million in follow-on investment. So, clearly a well-run proof-of-concept fund program can pay off.

Observations/Assessments of Virginia Practices:

- Internal proof-of-concept funding programs for Virginia universities are quite limited, with UVA making the most use of this effort, but only for life sciences. VCU also has limited funding for proof-of-concept, which again goes largely to life sciences.
- State sources for proof-of-concept are very important, but limited. The CIT Commonwealth Research Commercialization Fund provides roughly \$1.4 million in proof-of-concept funding across all Virginia universities that over the past two years has funded a total of 26 projects, or an average of 13 per year. The Virginia Biosciences Health Research Corporation (the "Catalyst") is another state source of proof-of-concept funding, though limited to the life sciences, and requires two universities to work together with a commercial venture. Over the last two years, VBHRC has provided approximately \$2.85 million annually for what it calls its translational research grants with 6 to 7 projects funded annually.
- Another source of proof-of-concept funding is through the Federal Small Business Innovation Research (SBIR) program, but this requires that the university technology be spun out into its own company or have a partnership with a private company. So SBIRs are not a substitute for internal proof-of-concept funding.
- All Virginia university technology transfer offices interviewed have expressed that increasing the pool of proof-of-concept funding is a top priority and one that should be available without having to "pay to play" through matching fund requirements which disadvantage smaller research universities.

Recommended Improvements:

16. Every Virginia research university – from the most well-resourced to the least developed in terms of technology commercialization capacities - identified the need for more proof-of-concept and translational resources. It is possible to do this across all universities in Virginia through a more collaborative approach as was done through the Virginia Innovation Partnership (VIP) grant awarded by the U.S. Economic Development Administration that involved nearly all of Virginia's research universities and was managed by UVA, Virginia Tech and SRI International. This effort targeted support for 20 proof-of-concept projects annually through a competitive RFP process, supported by a mentoring network of private sector experts and linked to venture investors, including a major annual event to pitch those projects that supported forming new company start-ups. The results of the Virginia Innovation Partnership were very promising – 147 proof-of-concept ideas submitted from 12 Virginia universities, with 36 projects funded and completed, 21 patents filed and 2 trade

secrets established, and 12 new start-ups formed, who raised \$4.3 million over the 2012-2014 period of the grant. An effort should be undertaken to learn from this experience and seek additional resources and funding to re-start a similar initiative that is used to create a national brand around this Virginia capability – effectively advertising to the industry and investment communities that Virginia's innovation pipeline is more substantially de-risked and investment worthy than is typically found in universities in the US.

IV. Engagement with innovation partners to promote translational research - Institutional cultures where innovation and commercialization thrive are those which include opportunities and incentives for scientists, engineers and others creating new knowledge to engage with and be mentored by seasoned entrepreneurs. It is critical for universities, their researchers, and their technology commercialization professionals to become more market-or industry-facing so each step of the invention and innovation management process is more likely calibrated to address real market needs with the lowest possible risk for both institutional and external investors.

Observations/Assessments of Virginia Practices:

- Advisory committees at some universities have expert members external to the universities who assist university staff in assessing newly disclosed innovations, in planning business and technology development strategies, in identifying market opportunities, and in monitoring progress during the translational research process.
- Effective alumni networking is not typically found at Virginia research universities. One of the more effective alumni networking efforts, though, is found at the University of Virginia, which is open to sharing their network with other universities in Virginia.
- The university technology commercialization offices in Virginia all operate via a 501(c)(3) structure which means they all have a Board of Directors. There are examples of universities utilizing these Boards to connect and engage with high value industry, investor, and entrepreneurial talent.
- Many universities have in place NSF funded Industry-University Collaborative Research Centers (IUCRCs) that link industry consortiums to university faculty in specific technology fields. These IUCRCs are tapping the market and technical expertise of their industry members to better inform their commercialization efforts. There is a strong interest across Virginia technology transfer offices in developing relationships and extending networks of industry to provide needed market and technical expertise in shaping commercialization efforts.

Recommended Improvements:

17. The Boards of the non-profit corporations administering the technology commercialization function at each university in Virginia should be expanded to maximize engagement by representatives of business, industry, entrepreneurs and investors which align well with the respective university's research and economic development focus.

- 18. Develop a shared network of Virginia university alumni with specific technology area domain expertise, market knowledge and entrepreneurial management skills that all universities can tap. Feature showcase events for this alumni network at different locations across the Commonwealth that represent technologies being advanced across multiple universities.
- 19. Consider development of regional technology commercialization resource centers in areas where a shared resource could be particularly useful in creating a critical mass of deal flow, translational research networks and resources, investor and partnership development initiatives, and technology development and deployment initiatives focusing on regional economic development priorities and industry clusters. A pilot initiative in Norfolk serving Old Dominion University, Norfolk State University, and the Eastern Virginia Medical School is suggested due to the proximity of these institutions, their expressed desire to explore mechanisms to partner more effectively in technology commercialization and in innovation and entrepreneurship, and their shared focus on leveraging innovation and research assets to help drive economic development in their region.

Stage Three: Licensing and New Firm Creation

At the stage of licensing and new firm creation, among the key components of university technology transfer practice are:

- Possessing transactional excellence
- Having entrepreneurial support programs and networks
- Creating new sources of seed capital funding
- I. Advancing transactional excellence in Virginia's university technology transfer offices Effective and high impact value creation in technology commercialization requires the ability to create winwin transactions between universities where IP is created and de-risked, and private sector partners willing to advance product development. These transactions include licenses, options, sponsored research agreements, startup company agreements, testing and analysis agreements, and core facility user agreements.

Excellence in transactional capabilities includes an awareness of what constitutes fair and reasonable market-based term sheets and valuations, and a consistent focus on effective negotiations and on managing transaction time and costs. Possessing transactional excellence creates the ability to foster a robust entrepreneurial ecosystem where research institutions and their external partners can work effectively together on win-win deals – and with a high likelihood that the parties will continue to want to work together on additional deals going forward.

Observations/Assessments of Virginia Practices:

 Virginia's university technology commercialization offices reported that they have developed or are considering the development of template or standardized agreements and term sheets. Some expressed an interest in express license (a license where the standard agreement, including financial terms, is 100% prenegotiated) for startup companies. There did not appear to be a consistent approach to posting standard agreements, term sheets, or related document on websites or otherwise in proactively making them available to prospective investors or licensees.

- Most Virginia universities seem to approach the most common technology commercialization transactions licenses, options, and sponsored research agreements in a way which corresponds with standard and "best" practices in top performing technology commercialization offices both nationally and globally. Terms of these transactions may include up-front license fees, equity stakes, royalties, reimbursement of patent costs, due diligence or development milestone requirements and/or payments, and related provisions. The typical approach is to use different approaches, based on good faith and reasonable negotiations, to construct commercialization agreements which are fair to all parties, which maximize the potential for commercial success, and which strike a proper balance among incentives, obligations, and rewards for both parties.
- Still, many universities in Virginia do not have an approach to setting deal terms that are predictable, while ensuring milestones are met. An often-used phrase was we are flexible in working with our faculty start-ups, which means a lot of uncertainty for these companies. The consulting team was told by several university technology commercialization offices that they were involved or considering efforts to standardize the equity percentage requested in license agreements with startup companies.

Recommended Improvements:

- 20. Pursue efforts to further standardize term sheets and boilerplate agreements and post examples of these standardized terms on university-related websites. Efforts are underway across Virginia's universities to create common templates and this is a very promising development that needs to be vetted with industry and venture capital representatives before it is finalized.
- 21. Through mechanisms like a revitalized Virginia Innovation Partnership and/or regional consortium of universities, Virginia universities should be encouraged to share their knowledge and access to expertise available to them via industry advisory boards, board members of technology commercialization 501(c)(3) organizations, alumni networks, and specialized consulting resources to provide confirmation, reassurance and reinforcement of the objective and high-quality approach to transactions undertaken by technology transfer offices in Virginia.
- II. Entrepreneurial Support Programs and Networks Start-up companies should be a major focus of technology commercialization initiatives in the Commonwealth of Virginia. They can be the best vehicle to champion and accelerate the commercialization of university innovations because their survival and eventual return on investment depends on the core technology they have licensed. Start-up companies can also provide much more significant and long-term economic development impact than licensing technology to existing industry that may likely be located outside of Virginia creating high value returns in the form of investment, new jobs, tax generation, corporate engagement, improved quality of life, and many other areas. However, despite their many advantages, startup companies are high risk, resource-intensive and long-term initiatives that are challenging for even the best-resourced and most experienced university technology

commercialization offices to manage and to succeed. Broader community-based, entrepreneurial support programs and networks are critical in creating innovation ecosystems which can support, nurture and guide these startups.

Observations/Assessments of Virginia Practices:

 Nearly all of Virginia's universities are working closely with local and regional entities such as economic development agencies, entrepreneurial support not-for-profits, incubators/accelerators, business school faculty and students, angel networks, alumni councils and related groups to build and nurture entrepreneurial ecosystems to facilitate the launch of startup companies and to invest, mentor and support the companies as they begin to grow.

Recommended Improvements:

- 22. Startup acceleration programs are critical factors in increasing the number, success, and rate of growth of startup companies in Virginia. Accelerators involve facilities, core labs and equipment, proof-of-concept and seed investment capital, access to shared services, management talent, and related resources. A strategic plan should be developed identifying milestones and criteria for launching, growing, and supporting accelerator programs so that all Virginia universities have access and engagement with the programs and facilities.
- 23. Business schools are increasingly interested in incorporating major classroom and experiential educational activities in areas related to technology assessment, business planning and finance, company formation and management, and venture capital investments. More mutually beneficial linkages should be established involving technology commercialization offices and business schools.
- III. Create new sources of seed capital funding to launch more startups across the Commonwealth Early stage capital as new technology ventures are being formed is a critical component of all successful entrepreneurial ecosystems. However, many on the front lines of university technology commercialization report that early stage capital is the hardest money to find – and yet the most critical given its essential nature in technology maturation, prototype development, company formation, and management recruitment. Many of the more robust entrepreneurial ecosystems have sources of early stage capital that involve university organized/sponsored funds, philanthropic seed funds, state supported funds, or other similar and cooperative approaches to creating and deploying such funds.

Observations/Assessments of Virginia Practices:

 University-based seed funds are not widespread across Virginia. Both UVA and Virginia Tech do have active seed funds underway. While statewide resources are helpful, these university-based seed funds are demonstrating that regionally-focused efforts are more aligned with advancing university technologies.

Recommended Improvements:

- 24. A "how-to" implementation strategy should be developed and shared with all Virginia universities advising them on the organization and management of university-affiliated seed funds.
- 25. University technology transfer offices should be encouraged to develop networks and creative approaches to partnering with philanthropic organizations, angel networks, alumni networks, and others willing to provide seed investment capital in support of launching early stage startup companies.
- 26. Create more sources of seed funding targeted to advancing university start-ups. Various options exist for doing this – ranging from infusing more capital into existing entities; to matching locally raised and locally managed seed funds affiliated with universities (such as Virginia Tech and the University of Virginia); to exploring new mechanisms for raising, managing and deploying such funding. Criteria for investing from these funds should be extremely risk-tolerant and focused on emerging technology opportunities coming out of the university commercialization activities.

Stage 4: Applied Research Collaborations with Industry Partners

Encouraging more engagement between Virginia universities and industry needs to be embraced as a key component of technology transfer. Virginia industry has a generally low level of own-source funding of research, so engagement with the expertise and facilities found at universities can offer a more cost-effective means of bringing new innovations into commercial development.

Similar to more traditional university technology transfer, this stage of applied research collaborations with industry partners needs to find ways to streamline and reduce the transactional costs of working together, while also finding more effective means to drive collaborations. Key practices include:

- Promoting a more business-friendly and pro-active strategic approach to sponsored research with industry partners
- Engaging start-ups to become strong partners in sponsored research
- Establishing university-industry research consortia and where feasible, develop initiatives to support aggressive pursuit of federally funded university-industry research centers and consortia
- I. Promote a more business-friendly and pro-active strategic approach to sponsored research with industry partners— There is a growing recognition that a barrier to industry partnerships for universities is the time needed to negotiate terms and conditions for sponsored industry partnerships. Perceptions of lengthy and uncertain transaction times, misunderstandings surrounding negotiating positions and strategies, and a lack of consistency from one negotiation to the next are often cited by both industry contacts and university personnel as factors which may be inhibiting opportunities to increase the number and dollar amount of industry-sponsored research agreements. Further, there are many terms and conditions required by academic institutions which their industry collaborators may not understand such as right-to-publish clauses, governing law clauses, intellectual property ownership and management clauses, indemnity clauses, and others. Development and sharing of standard agreements and/or term sheets can address many of these

challenges and create a more fertile environment for growing research partnerships between academic institutions and industry.

Increasingly major corporations are seeking university partnerships to engage in more sustained research collaborations, which often tap student engagement and interactions with emerging technology ventures. Master research agreements are a more traditional way to engage corporations in a sustained and often interdisciplinary range of research projects. Increasingly, major corporations are establishing corporate innovation centers close to their university partners to pursue more strategic research and development activities.

Observations/Assessments of Virginia Practices:

- Efforts are underway at many Virginia universities to actively standardize and share agreements and term sheets. These efforts are, for the most part, being coordinated among various campus offices (including technology commercialization office, sponsored research, general counsel, etc.) with a view toward enhancing the institution's capacity to speak with a unified and coordinated voice as it negotiates transactions with industry partners.
- Virginia universities tend to offer their corporate research partners options to license intellectual property owned by the institution. They will pre-negotiate royalty rates for such licenses where required by the corporate partner and where allowed under applicable tax regulations; in other cases, options are granted on terms which are fair and reasonable and which will be negotiated at the time the option is exercised.
- The use of master research agreements is more common at larger research universities, and tends to be focused on areas of strong translational research competencies. Nearly all of these master research agreements are with companies outside of Virginia.
- Virginia universities do not have a tradition of strong strategic business development units which aggressively market core research and innovation strengths to prospective research sponsors, such as found at Georgia Tech or Penn State. Virginia Tech is putting in place this capacity as part of its efforts to redesign its technology transfer approaches to be more industry focused.

Recommended Improvements:

- 27. Each Virginia university, at a minimum, should develop and market standard term sheets for sponsored research, FAQ pages, boilerplate research agreements, and other tools and information sources designed to "demystify" the process for industry in developing collaborative research agreements with universities. Even more impactful would be to have common templates for industry sponsored research used by all Virginia research institutions, including master agreements, which have been vetted with industry representatives.
- 28. To promote the wider university strengths found across Virginia and raise Virginia's ability to compete for master agreement relationships with industry, consider creating "multi-university access" to master agreement relationships negotiated by individual Virginia universities. This unique collaborative approach can work best by having a

primary university that maintains the overall relationship, but reaches out to other universities around specific needs of the company that are beyond their research capabilities. An effort in this regard is currently being developed with multi-university collaboration with MITRE, who manages a number of Federal Funded Research and Development Centers, spurred by MITRE's interest in broadening its access to university research expertise as it serves its national security clients.

- 29. A key complement to opening up master agreements for use by other Virginia research universities is the development of a portal for industry seeking to identify university research and innovation resources and utilize this mechanism to identify and catalyze applications among universities (either solo application or in collaboration with other campuses) in Virginia for competitive industry center or consortium grants.
- 30. Create research business development initiatives on Virginia campuses designed to identify and communicate about core areas of strength and capacity in research and innovation, and to market those capacities and opportunities to prospective industry research funders. These efforts should be especially targeted to identifying strengths, facilities, and key competencies which align with key industry sectors in Virginia.
- 31. Address the growing expectation by industry that when a company is solely funding research it should be the beneficiary of any intellectual property generated. This has led to a growing effort across universities to advance predictable and streamlined processes for industry to take ownership of intellectual property from sponsored research with universities, and for straight-forward contracting processes. For instance, the University of Minnesota, through an approach called Minnesota Innovation Partnerships, or MN-IP, allows a company sponsoring research at the university to pre-pay a fee and receive an exclusive worldwide license at a set royalty rate. The University of Minnesota noted that in its first four years the program resulted in 83 partnerships to develop products and services across industries like composite materials, pharmaceuticals and medical devices, with partnering companies ranging from small local startups to large multinationals. Penn State has gone further by allowing the company sponsoring the research an option to request ownership of Intellectual Property (IP) resulting from the sponsored project, if all the Penn State researchers involved in the project agree to release the IP.

1. Engage start-up companies to become the next generation of industry research funders for the originating university.

Observations/Assessments of Virginia Practices:

- Efforts by Virginia's universities to engage with their startup companies after they are launched and begin to progress toward the marketplace appear to occur on a case-by-case or sporadic basis, but there was no evidence of a proactive, strategic approach to build and nurture these follow-on relationships.
- Virginia's conflict of interest rules require disclosure and public listing of financial interests which state employees, including research faculty, may have with for-profit entities. There were concerns expressed about the degree of disclosure and publicity which is required and the possibility that this serves to inhibit some faculty from

pursuing close research or related relationships with startup companies in which they hold a significant financial interest.

Recommended Improvements:

- 32. A strategic research business development approach should also focus Virginia universities on becoming and remaining the "research partner of choice" for startup companies launched by Virginia universities. This should include both streamlined agreements and favorable terms for sponsored research with university start-ups. The success and rate of growth of university startups can be advanced by maintaining close research and development relationships between the companies and the universities from which they emanated. Further, as these companies grow and achieve critical business development and financing milestones, they can become the next generation of key corporate partners with universities funding research, hiring faculty as consultants, providing internships to students, recruiting university graduates into their workforce, engaging in open innovation all of which create a robust innovation ecosystem and a "sticky environment" in which these companies are more likely to remain as they grow.
- 33. Consideration should be given to developing new, or revising existing, public policy relative to conflict of interest and financial interest disclosures to ensure that a proper equilibrium is reached between necessary conflict of interest management, on the one hand, and incentives for innovation-based economic development, on the other.
- 2. Establish university-industry research consortia and where feasible, develop initiatives to support aggressive pursuit of federally funded university-industry research centers and consortia A best practice at many universities in terms of advancing innovation-based economic development has been the creation of university-industry research centers or consortia. These range from federally funded, strategic programs such as the NSF ERC and I/UCRC programs, or research center and consortium initiatives funded via other federal agencies such as NIH, the Department of Energy, and others. These vehicles create excellent funding streams; valuable opportunities to enhance academic and research reputations and relationships; and most importantly, critical partnerships to catalyze research and development initiatives, and innovation transfer initiatives, around areas that are critical to economic development impacts in business, industry, startups, and regions.

Observations/Assessments of Virginia Practices:

Virginia universities – both large and small – have been making wide use of smaller
 I/UCRC programs to engage industry partners, but have not been particularly successful in attracting large, federally funded research centers and consortia.

Recommended Improvements:

34. Virginia universities should consider collaborative efforts in areas of strong overlap in research competencies – such as cyber and cyber-physical security, system of systems

engineering and niche areas of life sciences – to pursue multi-university collaborations with industry for larger center grants. Having access to funding for program coordination of this effort would be a very helpful means to facilitate this type of effort.

D. Summary for Advancing University Technology Transfer Practices

The TEConomy team review of university technology practices across all research universities in Virginia finds significant similarities in technology transfer-related policies, involving IP management, faculty incentives and conflict of interest. For the most part, these policies are consistent with national best practices.

Another similarity is the structure for IP management across research universities in Virginia, where university-affiliated, independent 501(c)(3) organizations are used to manage IP. This arises primarily due to the constitutional restrictions that would limit the flexibility in deal terms for Virginia universities, especially in the formation of university spin-out technology ventures.

Where differences arise is in the actual practices and resources brought to bear on advancing university technology transfer. This is not unexpected given the size differences in research activity across Virginia's universities, but is one that should be addressed as Virginia builds more collaborative strengths across its research universities in order for them to be more competitive in pursuing large federal research centers and in collaborating with industry.

Across the stages of technology transfer, commercialization and industry collaborations, TEConomy has set out 34 recommendations for improving practices. This significant number of recommended improvements in practice point to the breadth and complexity found in modern technology transfer practices that now go well beyond simply managing the process of disclosure and creation of IP that industry then licenses.

One major theme that emerges from this review of technology transfer policies across universities is the many opportunities for increased collaborations in technology transfer practices and resources across Virginia's universities, including activities such as:

- Established common templates and deal terms across Virginia universities that are vetted with industry and venture capital representatives.
- Sharing of access to alumni and other experts with knowledge of specific markets and technologies
- Multi-university access to "master agreement" relationships
- Use of shared entrepreneurs-in-residence
- Shared programs for entrepreneurial training, competitions, etc. for graduate students/postdocs

• Create a shared market-driven "translational research"/commercialization mechanism accessible to all universities across technology fields – "Coulter process for all technologies"

There have been past efforts, such as the Virginia Innovation Partnership, and unfolding efforts, such as the multi-university collaboration with MITRE and advancement of standard agreements, which should be encouraged and advanced.

Perhaps the most powerful recommendation though is the focus on what are the goals of university technology transfer. A strong public policy statement of the focus on value creation to advance economic development, rather than revenue maximization, would provide clarity for Virginia universities to pursue more aggressively market-driven translational research and industry partnerships.