Final Report of the Committee for the Review of Proposals to Ohio's Third Frontier Program, 2014-2015: Innovation Platform Program 2014

Committee for the Review of Proposals to Ohio's Third Frontier Program, 2014-2015

Aeronautics and Space Engineering Board

Division on Engineering and Physical Sciences

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Acknowledgments

This report has been reviewed in draft form by A. Thomas Young, Lockheed Martin (retired) in accordance with procedures approved by the Report Review Committee of the National Research Council. The purpose of this independent review is to provide candid and critical comments that will assist the institution in making its published report as sound as possible and to ensure that the report meets institutional standards for objectivity, evidence, and responsiveness to the study charge. The review comments and draft manuscript remain confidential to protect the integrity of the deliberative process.

Although Mr. Young provided constructive comments and suggestions, he was not asked to endorse the conclusions or recommendations, nor did he see the final draft of the report before its release. Responsibility for the final content of this report rests entirely with the authoring committee and the institution.

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October 8, 2014

David Goodman
Director
Ohio Development Services Agency
77 S. High Street
Columbus, OH 43215-6130

Dear Mr. Goodman:

This letter details the work and transmits the final report of the Committee for the Review of Proposals to Ohio's Third Frontier Program, 2014-2015, for proposals submitted to the 2014 Innovation Platform Program (IPP). This activity was supported by a contract from the Ohio Development Services Agency (ODSA) with the National Academy of Sciences and was performed under the auspices of the National Research Council's (NRC's) Aeronautics and Space Engineering Board (ASEB). The NRC is committed to providing elected leaders, policy makers, and the public with expert advice based on sound scientific evidence. For this study, the committee appointed to conduct the review was asked not only to exercise scientific judgment, but also to focus on commercial viability as a key consideration. This is the twelfth year the NRC has reviewed proposals for the State of Ohio.

Program Objectives

As stated in the IPP's request for proposals (RFP), a major goal of the Ohio Third Frontier (OTF) is to "catalyze collaborations in technology commercialization, innovation, and product development between the State's colleges and universities and Ohio industry."[1] The specific purpose of the IPP is "to support commercial partnerships involving an Innovation Platform at a single Ohio college, university or other not-for-profit research institutions, and Ohio for-profit companies. Partnerships are to be formed to further the near-term (within 3 to 5 years of the start of the Project Period) commercialization of product innovation, next generation products and new products."[2] Critical to grasping the program's objectives is an understanding of what is meant by "Innovation Platform." The RFP defines an Innovation Platform as

> An already existing capacity that incorporates unique technology capabilities and strengths, talent, equipment, facilities, engaged industry partners, a track record of research commercialization and innovation, intellectual property and other resources in a particular technology area that collectively can serve as a vehicle for significant, industry-defined and directed opportunities through the development and

[1] Ohio Third Frontier Innovation Platform Program Fiscal Year 2014 Request for Proposals (RFP), available at http://development.ohio.gov/files/otf/2014_IPP_RFP_Final.pdf, p. 5.
[2] Ohio Third Frontier Innovation Platform Program Fiscal Year 2014 Request for Proposals (RFP), p. 5.

commercialization of new products and innovations. To be considered a Platform Technology, there must be multiple applications to commercial products that are capable of being developed by independent Ohio for-profit companies.[3]

The RFP also outlines several key objectives of the program:

- To support existing Innovation Platforms at Ohio colleges, universities or not-for-profit research institutions that will serve specifically defined near-term commercialization objectives of 3 or more non-related Ohio for-profit companies;
- To support Innovation Platforms that will develop and launch new products, innovations or services into the commercial market within 3 to 5 years of the Project start date among all of those 3 or more non-related Ohio for-profit companies;
- To kick-start the long-term, sustained use of the Innovation Platform by multiple Ohio industry partners; and
- To support Innovation Platforms that will create wealth and employment opportunities within Ohio.[4]

Scope of Engagement

For the 2014 IPP, a total of 9 proposals were submitted and evaluated by the committee. Proposals spanned, but did not include all of, the ten technology areas identified in the program's RFP: advanced materials related to advanced polymers, ceramics, composites, carbon fibers and nanotubes, and specialty metals and alloys; aeropropulsion power management; fuel cells and energy storage; medical technology related to imaging, surgical instruments/equipment, implant devices and regenerative medicine; software applications for business and healthcare; sensing and automation technologies; situational awareness and surveillance systems; solar photovoltaics; agribusiness and food processing; shale (see Table 1).

This report provides the committee's assessment of all of the received proposals. The committee recommends that the Third Frontier Commission (TFC) consider funding 5 of the 9 proposals. Two of the proposals should be funded without additional conditions, one with minor conditions, and the remaining two should be funded based on conditions that must be met to receive additional funding. The recommended proposals make a strong case that they would achieve the goals and purpose of the IPP. The total amount of State funding recommended is $11,394,128. The amounts of state funds requested by the recommended proposals are as follows:

Cleveland Clinic Rodent Imaging Center (Cleveland Clinic)	$2,999,936
Akron Functional Materials Center (University of Akron)	$3,000,000
Smart Sensor System Design, Development, and Commercialization (University of Akron)	$1,744,192 (see conditions)
The OHIO Shale Platform (Ohio University)	$1,450,000 (see conditions)
Carbon Nanomaterials Based Platform Technology (Ohio State University)	$2,200,000 (see conditions)

[3] Ohio Third Frontier Innovation Platform Program Fiscal Year 2014 Request for Proposals (RFP), p. 5.
[4] Ohio Third Frontier Innovation Platform Program Fiscal Year 2014 Request for Proposals (RFP), p. 6.

Evaluation Methodology

Committee members were recruited based on their familiarity with the subject areas of the letters of intent submitted to the IPP and for their experience with business practices, technology transfer, venture capital, and economic development. The committee was chaired by T.S. Sudarshan, president and CEO of Materials Modifications, Inc. The committee comprises a combination of working engineers, academics, and business executives; one member is also a member of the National Academy of Engineering, and another is a member of the National Academy of Sciences. The committee roster appears on page v, and biographical sketches of the committee members can be found in Appendix E.

Based on criteria and proposal requirements specified in the RFP, ASEB staff developed an evaluation worksheet (see the section "Evaluation Criteria and Key Differentiators," below) to help guide the initial evaluation of the proposals. ASEB staff also developed a definition sheet of critical terms and key criteria, again based on the RFP (see Appendix D). Committee members were then assigned on average 3 to 4 proposals each to evaluate. For each proposal, committee members were designated as primary or secondary reviewers for the purposes of guiding committee discussions at the first meeting. Each proposal was evaluated in-depth by at least three committee members before the committee's first meeting.

The committee held its first meeting on July 22, 2014. Early at this meeting, the committee heard a presentation from ODSA staff and held a discussion regarding the IPP's objectives, requirements, and criteria, seeking clarification from ODSA as needed. The committee then discussed all 9 proposals in detail.

TABLE 1 Innovation Platform Program Proposal Technology Areas

Proposal	AM	APM	FCES	MT	SABH	SAT	SASS	PV	AFP	SH
14-301	X									
14-305										X
14-306	X			X						
14-311	X									
14-312	X		X							
14-317						X				
14-319				X						
14-320				X						
14-322				X						
Total	4		1	4		1				1

NOTE: AM, Advanced Materials; APM, Aeropropulsion Power Management; FCES, Fuel Cells and Energy Storage; MT, Medical Technology; SABH, Software Applications for Business and Healthcare; SAT, Sensing and Automation Technologies; SASS, Situational Awareness and Surveillance Systems; PV, Solar Photovoltaics; AFP, Agribusiness and Food Processing; SH, Shale.

The committee also developed a list of follow-up questions that addressed areas of concern for each of these 9 proposals. These questions were sent to ODSA, who forwarded them to the lead

applicants prior to the second meeting. Applicant teams were instructed to provide written answers approximately 2 weeks before the committee's second meeting.

The committee held its second meeting on September 8-9, 2014, and at the request of ODSA interviewed all 9 applicant teams. Each applicant team was given 45 minutes to address additional questions from the committee. Each session was conducted in true "interview" format; no presentation materials were allowed unless requested by the committee. In addition, as needed, the committee met with the lead applicant separate from the clients for the individual proposals.

The committee also followed-up the interviews with requests for clarifying information from some of the teams, which they usually provided the same day as the interviews, and in some cases this information was vital to determining the proposal's ability to meet the requirements of the IPP. The committee was determined to arrive at an informed judgment of the proposals and a key factor was equitably gathering as much information as possible from the teams and to ensure that they had as much opportunity as possible to clarify their responses. This question, interview, and follow-up phase proved vital, as some vital information was obtained from the teams that had not been included in their original proposals. However, in some cases, information was not provided even after repeated requests.

Following the interviews, the committee held an in-depth discussion on each of the 9 proposals and, through consensus, determined which proposals best satisfied the requirements of the RFP and their respective rank-order.

Evaluation Criteria and Key Differentiators

The IPP's RFP details the evaluation criteria utilized by the committee. The evaluation worksheet generated by ASEB staff to guide the committee's initial evaluation of the proposals groups most of these criteria into five broad sections (see Appendix C). Below are several of the individual criteria from the worksheet, rewritten and paraphrased here as questions to illustrate their overall breadth.

- *Technical Merit and Plan.* Can the technical challenges be met? Are the project goals and objectives realistic? How will these be met? Are there significant risk factors? Does the proposal align with the definition of a platform? Does the proposal include a plan for beyond the 3-year time period?
- *Commercialization Strategy.* What are the specific value propositions of the different commercial applications? Is sufficient evidence provided to support the contention that the market values these benefits? Has the Innovation Platform already achieved at least proof of principle? What are the competitive advantages of the IPP's technologies or products over existing and alternative technologies? Does the team understand the total resource requirements for achieving market entry and full commercialization, the type of knowledge that must be produced at the identified positioning stage, and who will likely be the funding providers for the market entry stage?
- *Performance Goals.* What is the project's impact on Ohio in job creation, personal wealth, new sales of products, and follow-on investment? Does the proposal contain a realistic forecast of the economic impacts of the Innovation Platform (for 3 and 5 years after start of project)? How successful was the performance of the team on related prior OTF grants?
- *Experience and Qualifications.* Do the lead applicant and clients have the direct experience needed to perform both the technical and commercial work being proposed? Who are the key personnel (technical director and commercialization director)? Do they have the required skills and experience to serve in their capacities?
- *Budget and Cost Share.* Is the budget justified in a detailed narrative with the appropriate forms? Is it adequate to meet proposal goals? Is the cost share necessary and reasonable? Is the cost share in the form of cash? Are letters of commitment provided, and are they sufficiently detailed, including an explanation of cost share commitment?

During the course of the study, the committee prepared an Overview Table (see Appendix A) to summarize how well each proposal satisfied the evaluation criteria in each of the above groups. On the chart, "E" and the color green indicate that the proposal *exceeds* the RFP requirements, "M" and the color yellow indicate that the proposal *meets* the RFP requirements, and "D" and the color red indicates that the proposal *does not meet* the RFP requirements. The committee stresses that understanding the context of these determinations is somewhat critical. In some cases, a relatively strong proposal may have "does not meet" grades in several areas due to a single problem that relates across each of the areas, whereas another proposal could have an equivalent number of areas with "does not meet" grades, yet be a much weaker proposal, due to the number of failures in the individual areas.

The committee also generated Table 2 to illustrate how the proposals measured against several key RFP criteria relating to the budget and cost share and economic impacts of the proposals. The RFP includes the following two provisions:

> 1. It is required that a super majority, or more, of Ohio Third Frontier Funds remain with the Lead Applicant to support the Innovation Platform's work for its Clients as well as on collaborative projects for the platform's Clients, the Ohio for-profit companies.[5]
> 2. Proposals must have a minimum of 50% of the cash Cost Share contributed by the Client Ohio for-profit companies. Strong Proposals will have a super majority of cash Cost Share contributed by the Client Ohio for-profit companies as evidence of their commitment to the value of the technology platform. Teams with strong commercialization structures are required. Any commercialization that results must benefit Ohio through investment, sales, job creation and/or business capitalization.[6]

TABLE 2 Comparison of Original Proposals' Key Budget and Economic Impact Numbers

	Budget and Cost Share			Economic Impacts			
				Jobs (Year 3)			
#	Cost Share Ratio	State Funds to Lead (%)*	Cost Share from Clients (%)	For-Profit	Non-Profit	Total	Revenue (Year 3) (million$)
14-301	1.00	80.00	60.00	40	10	50	$15.00
14-305	1.00	100.00	50.00	26	0	26	$13.51
14-306	1.00	85.00	63.31	16	11	27	$6.80
14-311	1.00	72.75	85.96	27	5	32	$4.90
14-312	1.19	88.29	52.64	32	10	42	$33.48
14-317	1.02	55.26	58.06	38	2	40	$63.92
14-319	1.14	56.75	44.12	17	4	21	$26.50
14-320	1.03	50.29	50.54	10	2	12	$22.00
14-322	1.04	79.99	51.23	10	2	12	$56.00

NOTE: *RFP requires a supermajority.

[5] Ohio Third Frontier Innovation Platform Program Fiscal Year 2014 Request for Proposals (RFP), p. 7.
[6] Ohio Third Frontier Innovation Platform Program Fiscal Year 2014 Request for Proposals (RFP), p. 8.

Recommendations

The committee recommends that the Third Frontier Commission consider funding 5 proposals that make a strong case for achieving the goals and purposes of the Innovation Platform Program (see Table 3). In terms of the evaluation criteria presented in the RFP, the strengths of these proposals far outweigh whatever weaknesses may be present. Detailed reviews of all 9 proposals appear in Appendix B. For the benefit of the TFC, the committee has rank-ordered the proposals in terms of their relative merit and compliance with the RFP.

Three of these five proposals are recommended with caveats: 14-317 warrants consideration for funding only if the Bendix element is removed from the proposal; 14-305 warrants consideration for funding to clearly demonstrate that many materials challenges can be overcome in the construction of a working prototype for field testing; 14-301 warrants consideration for funding after the removal of funding for the bio-nanocomposites and the structural foam funding and based upon conditions outlined in the summary.

TABLE 3 Proposals Recommended for Funding Consideration

Rank	Proposal	Title (Lead Applicant)
1	14-322	Cleveland Clinic Rodent Imaging Center (Cleveland Clinic)
2	14-306	Akron Functional Materials Center (University of Akron)
3	14-317	Smart Sensor System Design, Development, and Commercialization (University of Akron)
4	14-305	The OHIO Shale Platform (Ohio University)
5	14-301	Carbon Nanomaterials Based Platform Technology (Ohio State University)

The first two proposals (Cleveland Clinic Rodent Imaging Center, and Akron Functional Materials Center) are recommended for full state funding. The Smart Sensor System Design, Development, and Commercialization proposal is recommended for funding minus the state funding of $264,000 for Bendix. The other two recommended proposals include conditions.

The OHIO Shale Platform

The committee recommends that this proposal be considered for funds with conditions. In view of the significant uncertainties related to the selection and performance of materials of construction, the committee believes that this key barrier has to be overcome. As a result, the committee has reduced the funding to first provide the demonstration and testing of the piece of equipment and no funding beyond that amount. Furthermore, the committee recommends that the disbursement of state funds be made in tranches corresponding to the successful completion of project milestones as follows:

Project Milestone	OTF		Cost Share		Total
Pilot Unit Design	$250,000		$250,000		$500,000
Pilot Unit Fabrication *	$600,000		$600,000		$1,200,000
Pilot Unit Field Demonstration	$600,000		$600,000		$1,200,000
Total	**$1,450,000**		**$1,450,000**		**$2,900,000**

NOTE: * Including solving the materials of construction issue.

Carbon Nanomaterials Based Platform Technology

The committee recommends that this proposal be considered for funds under the Ohio Third Frontier Innovation Platform Program, except that the structural foam and bio-nanocomposites components of the proposal should be eliminated, reducing the State expenditures by $800,000. The committee recommends that the maximum amount of Ohio funding be limited to $2.2 million.

The 5 recommended proposals are summarized as follows:

(Rank 1) *Cleveland Clinic Rodent Imaging Center (14-322)* seeks to establish the Cleveland Clinic Rodent Imaging Center (CCRIC), a comprehensive rodent MRI-based translational sciences center. The main goals of this proposal are the purchase, installation, and multiple application development of a rodent MRI facility, that when combined with client company (Image IQ, ChanTest, Renovo Biosciences, Juventas Therapeutics, Renovo Neural) capabilities, will constitute the commercialization of an integrated platform of rodent MRI imaging, image analysis, image validation services, MRI-based translatable biomarker discovery, and MRI-biomarker-based drug discovery efforts. Based on a memorandum of understanding (MOU) between the Cleveland Clinic Foundation (CCF) and Case Western Reserve University (CWRU), the new rodent MRI instrument will be included in the small animal Imaging Research Core of the Case Center for Imaging Research (CCIR). Thus, CCRIC will benefit from the organizational, scientific, and business management experience of CCIR towards the desired expansion and commercialization of the rodent MRI-based platform.

(Rank 2) *Akron Functional Materials Center (14-306)* seeks to optimize multi-component materials. The Akron Functional Materials Center (AFMC) platform is a centralized knowledge and technology resource infrastructure consisting of an integrated collection of facilities, instruments, and advanced characterization and imaging tools that empower researchers and innovators with generic or customized materials design, processing methods, and optimization and testing-validation. The client companies for this proposal include Austen BioInnovation Institute in Akron, Lubrizol Corp, PolyOne Corporation, and SNS Nano Fiber Technology, LLC. In each case, client companies are seeking

- Testing and optimization support of efforts to leverage existing materials and supply chains to accelerate commercialization of novel medical devices that address unmet needs and provide a competitive advantage, combined with
- Integrated clinical utility and regulatory assessment focused upon managing and accelerating the approval and commercialization processes.

(Rank 3) *Smart Sensor System Design, Development, and Commercialization (14-317)* seeks to utilize the sensor platform established at the University of Akron by means of partnerships with the engineering Research Center (ERC) and specific sub groups of the following entities: Wright Center for Sensor Systems Engineering (WCSSE-UA), the Center for Advanced Vehicles and Energy Systems (CAVES), the Timken Engineered Surfaces Laboratory (TESL), the Center for Surface Engineering and Lubrication Research (CSELR), the National Center for Education and Research on Corrosion and Materials Performance (NCERCAMP), the Institute for Biomedical Engineering Research (IBER), and CenTire, an NSF-funded tire center. The objective is to develop sensor solutions for three client companies in the areas of (a) automobiles (b) power grids, and (c) HVAC systems.

(Rank 4) *The OHIO Shale Platform (14-305)* seeks to expand the capabilities of Ohio University's (OHIO) existing innovation platform for shale wastewater treatment/management to meet the increasing commercial needs for water management and re-use in unconventional oil/gas development, thus reducing wellhead development costs and mitigating water disposal issues. The technology platform is expected to facilitate collaboration among Ohio-based companies to address commercialization issues by providing wastewater treatment technologies and envisioned applications – such as heavy oil recovery, brown grease conversion and animal feeding operations wastewater treatment – an expedited development pathway to market entry. Ohio University states that it has already developed a technology platform utilizing supercritical water (SCW) processing to treat wastewater from shale wells and has successfully demonstrated the technology at the lab scale.

(Rank 5) Carbon Nanomaterials Based Platform Technology (14-301) seeks to develop a group of new foam, coating and composite products for industrial applications using well-established innovative carbon nanomaterials and the associated processing platform. Over the past 15 years, OSU has established an IPP with research and development and processing capabilities in carbon nanomaterials. This infrastructure at OSU will be utilized to work with industry and has previously supported product improvement for Ohio companies including the client companies on this proposal. This proposal seeks to use the IPP at OSU to develop and commercialize new products and technologies in several areas using OSU's Carbon Based Nanomaterials Technology Platform: (1) NIL will scale-up and commercialize the surface functionalization of carbon nanoparticles for high strength nanopapers, (2) Owens Corning will commercialize insulation foams using benign blowing agents to meet the Montreal Protocol requirement; (3) OMNOVA will also develop conductive carbon nanopapers and coatings for EMI shielding; (4) GDC and Emc2 will developed biocomposites for automotive applications. The project can be divided into five major research thrusts including: Insulation and Structural Foams, Thermosets with In-Mold Coatings (IMC), Thermoplastics with IMC, Bio-nanocomposites, and New Product Innovations. The ultimate end-users of the products of this project will be the automotive and wind energy industries.

All of the remaining 4 proposals scored substantially lower than the 5 proposals listed above *when ranked against the criteria and requirements specified in the IPP's RFP*, and they are not recommended for consideration under the current year's program. This does not necessarily mean that the proposals lack merit or should not be funded as part of some other program sponsored by the TFC, the State of Ohio, or the federal government. They may also improve their proposals and resubmit to the IPP in the future, which some past proposal teams have done with success. In the past, all proposal teams have been offered individual extensive debriefings in order to help them improve their proposals (or, in the case of selected teams, to provide any additional information that they might benefit from). Not all have taken advantage of this offer. Significant additional support has also been provided by ODSA personnel on the intricacies and requirements of the proposal writing process through a bidders' conference as well as individual calls and meetings with ODSA personnel on clarifications related to the specific submission of the IPP proposal. The specific strengths and weaknesses of all the IPP proposals are included in the individual reviews in Appendix B.

The committee also wishes to mention an additional overarching issue: because regulatory approval of biomedical products by the Food and Drug Administration (FDA) requires several years or more, the committee does not think that the IPP RFP-required timeline for delivery of jobs and revenues at years 3 and 5 is realistic for most medical proposals *unless they have already initiated discussions with the FDA and charted a course of action to get the necessary regulatory approval*.

The committee wishes to thank the State of Ohio for the opportunity to review these proposals and to provide its recommendations as to which of the proposals best meet the requirements set forth in the IPP's RFP.

Sincerely,

T.S. Sudarshan, *Chair*
Committee for the Review of Proposals to Ohio's Third Frontier Program, 2014-2015

cc: Michael H. Moloney, *Director, Aeronautics and Space Engineering Board*

Appendixes

A Overview Table
B Individual Summary Evaluations
C Evaluation Worksheet
D Innovation Platform Program Definitions, Goals, and Critical Criteria
E Biographical Sketches of Committee Members and Staff

Appendix A
Overview Table

This table was prepared by the Committee for the Review of Proposals to Ohio's Third Frontier Program, 2014-2015 to summarize how well each proposal satisfied the evaluation criteria of the Request for Proposals (RFP) for the 2014 Ohio Third Frontier Innovation Platform Program.

Key	
E	Exceeds Requirements of the RFP
M	Meets Requirements of the RFP
D	Does Not Meet Requirements of the RFP

Proposal (Lead Applicant)			**Technical Merit and Plan**	**Commercialization Strategy**	**Performance Goals**	**Experience and Qualifications**	**Budget and Cost Share**
Recommended		RANK					
14-322	Cleveland Clinic Rodent Imaging Center (Cleveland Clinic)	**1**	**E**	**E**	**M**	**E**	**M**
14-306	Akron Functional Materials Center (University of Akron)	**2**	**M**	**M**	**M**	**E**	**M**
14-317	Smart Sensor System Design, Development, and Commercialization (University of Akron)	**3**	**M**	**M**	**M**	**M**	**M**
14-305	The OHIO Shale Platform (Ohio University)	**4**	**M**	**M**	**M**	**M**	**M**
14-301	Carbon Nanomaterials Based Platform Technology (Ohio State University)	**5**	**M**	**M**	**M**	**M**	**M**
Not Recommended							
14-311	Materials Manufacturing Technology Hub (National Composites Center)		**M**	**D**	**D**	**M**	**M**
14-312	Scalable Nanomanufacturing of Functional Films (University of Akron)		**D**	**M**	**D**	**E**	**M**
14-319	Endovascular Technology Innovation Center (Cleveland Clinic)		**M**	**D**	**D**	**M**	**D**
14-320	Gene Reprogramming Therapeutics (Cleveland Clinic)		**D**	**D**	**D**	**D**	**D**

Appendix B
Individual Summary Evaluations

Summary evaluations of the 9 proposals to the 2014 Ohio Third Frontier Innovation Platform Program (OTF IPP) are given below. Proposals were evaluated according to criteria given in the Request for Proposals (RFP).

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OTF IPP 14-322
Cleveland Clinic Rodent Imaging Center (CCRIC)
Cleveland Clinic

Proposal Summary:

Proposed Budget		
	State Funds	Cost Share
Operating Funds	$1,377,216	$2,466,082
Capital Funds	$1,622,720	$657,304
Subtotal	$2,999,936	$3,123,386
TOTAL	$6,123,322	

This proposal seeks funds to establish the Cleveland Clinic Rodent Imaging Center (CCRIC), a comprehensive rodent MRI-based translational sciences center. The main goals of this proposal are the purchase, installation, and multiple application development of a rodent MRI facility, that when combined with client company (Image IQ, ChanTest, Renovo Biosciences, Juventas Therapeutics, Renovo Neural) capabilities, will constitute the commercialization of an integrated platform of rodent MRI imaging, image analysis, image validation services, MRI-based translatable biomarker discovery, and MRI-biomarker-based drug discovery efforts. Based on a memorandum of understanding (MOU) between the Cleveland Clinic Foundation (CCF) and Case Western Reserve University (CWRU), the new rodent MRI instrument will be included in the small animal imaging research core of the Case Center for Imaging Research (CCIR). Thus, CCRIC will benefit from the organizational, scientific, and business management experience of CCIR toward the desired expansion and commercialization of the rodent MRI-based platform.

Detailed Review:

- **Technical Merit and Plan**

The Cleveland Clinic (CC) proposes to leverage its well established clinical MRI center, along with internal and client company-provided expertise in rodent animal models of disease, novel drug discovery technology, and MRI image analysis methods, to develop a comprehensive non-clinical rodent MRI imaging center, CCRIC. The CCRIC platform proposal focuses on the purchase and installation (into CC-provided laboratory space) of a new Biospec® 7T/20 rodent MRI instrument and development of multiple rodent imaging capabilities, including anatomical imaging, diffusion tensor imaging, short echo time imaging, relaxation imaging, arterial spin labeling, dynamic contrast enhanced imaging, functional MRI, and magnetic resonance spectroscopy. Once fully developed and validated, these rodent MRI capabilities will be used to discover, optimize/validate, and exploit translatable imaging biomarkers to support preclinical drug discovery and development, focusing on rodent models of CNS disease. As a result of the MOU between CCF and CWRU, CCRIC's plans to install the instrument and establish/validate multiple rodent MRI applications within the first year of the grant period are realistic and support the applicants' first and subsequent year's projected revenue stream. Once the rodent MRI capabilities are fully developed in collaboration with CCIR, CCRIC is likely to attract academic users interested in conducting rodent imaging studies supported by federal grant funds with expected expansion of MRI imaging and image validation services delivery to client companies and new industrial customers. The CCRIC is also expected to attract pharmaceutical and biotechnology company clients. Based on these considerations, CCRIC, in collaboration with CCIR appears to be an established innovation platform poised to conduct late-stage development and commercialization of rodent MRI and image validation services. The proposal exceeds the requirements of the RFP on Technical Merit and Plan.

- **Commercialization Strategy**

Rodent MRI imaging services, in conjunction with the existing and OTF-funded capabilities of the five Ohio-based client companies (Image IQ, ChanTest, Renovo Biosciences, Juventas Therapeutics, Renovo

Neural), form the key elements of the commercialization plan. CCRIC may act as a contract research organization that provides rodent MRI imaging, image validation, and rodent behavior models directly to academic and industrial clients. Alternatively, CCRIC's client companies may subcontract rodent MRI instrument time to CCRIC or lease the instrument to conduct industry-contracted studies as part of their overall research and development of rodent MRI biomarkers of human CNS disease. Intellectual property focused on drug discovery technology (ChanTest) and potential therapies for stroke and multiple sclerosis appears to be well managed. Currently, there is no CCRIC-generated intellectual property (IP) associated with rodent MRI and image validation services. Cleveland Clinic's strong presence in clinical imaging, along with the planned collaboration and coordination with CCIR, demonstrates the feasibility of successfully running and commercializing a rodent MRI facility as part of CCRIC. The proposal exceeds the RFP for Commercialization Strategy.

- **Performance Goals**

Completing the development and validation of multiple rodent MRI capabilities within the first year of the grant period will be a critical success factor for achieving the performance goals of CCRIC and the client companies throughout the subsequent 3-5 years. Given the collaboration between CCRIC and CWRU's small animal Imaging Research Core of CCIR, the performance metrics (job creation and projected revenue streams) for CCRIC are reasonable. Client company performance metrics based on established efforts to identify and use translatable rodent MRI biomarkers for multiple sclerosis and stroke drug discovery efforts are also reasonable. CCRIC's rodent MRI platform (when consolidated with the existing core imaging center at CCIR) has a high probability of being an engine for growth and sustainability because the discovery and successful implementation of translatable imaging biomarkers for neurodegenerative diseases represents a significant unmet medical and commercial need. The proposal meets the requirements of the RFP on Performance Goals.

- **Experience and Qualifications**

Dr. Bruce Trapp, chair of the Department of Neurosciences, Lerner Research Institute, Cleveland Clinic Foundation, and Dr. Geoffrey Vince, chair of the Department of Biomedical Engineering, Lerner Research Institute, Cleveland Clinic Foundation, principal and co-principal investigators, respectively, are highly respected and established investigators representing internationally recognized centers of excellence in neuroscience and clinical imaging. Moreover, the client companies collaborating with CCRIC have proven track records of productivity and commercial success. The consolidation of the new rodent MRI facility within the umbrella of CCIR (directed by Dr. Chris Flask) provides solid evidence of an innovative platform with core technologies that are ready for late-stage development and commercialization. The proposal exceeds the requirements of the RFP on Experience and Qualifications.

- **Budget and Cost Share**

The budget for the proposal is well organized and realistic. ImageIQ, ChanTest, Renovo Biosciences, Juventas, and Renovo Neural have committed $300,000, $300,000, $485,448, $228,000, and $286,700, respectively, which, when added to the $1,523,238 in cost share provided by CC, amounts to $3,123,386 in total cost share. The proposal meets the requirements of the RFP on Budget and Cost Share.

Summary and Recommendation:

Based on the proposal and subsequent applicant interview, CCRIC, client companies, and CCIR provided evidence of an established innovative platform that will use OTF funds to collaborate with client companies to finalize technical development and initiate commercialization of rodent imaging services. This prerequisite of an established innovative platform is critical to predicting technical and commercial

success, along with a tangible economic impact in the State of Ohio. Building a new rodent MRI facility in collaboration and cooperation with the well-established small animal imaging core of CCIR, will relieve the bottleneck of available rodent MRI instrument time needed to support the establishment of pre-clinical imaging biomarkers and the discovery and development of novel drugs for CNS diseases. Academic investigators in CC and CCRIC's client companies will certainly utilize this facility and it is likely to attract and sustain an expanded market derived from large pharmaceutical companies and biotechnology organizations. Given these conclusions, the committee recommends that this proposal be considered for funds under the Ohio Third Frontier Innovation Platform Program.

OTF IPP 14-306
Akron Functional Materials Center
University of Akron

Proposal Summary:

Proposed Budget		
	State Funds	Cost Share
Operating Funds	$2,600,000	$2,752,047
Capital Funds	$400,000	$250,000
Subtotal	$3,000,000	$3,002,047
TOTAL	$6,002,047	

This proposal seeks to optimize multi-component materials. The Akron Functional Materials Center (AFMC) platform is a centralized knowledge and technology resource infrastructure consisting of an integrated collection of facilities, instruments, and advanced characterization and imaging tools that empower researchers and innovators with generic or customized materials design, processing methods, and optimization and testing validation. The client companies for this proposal include Austen BioInnovation Institute in Akron, Lubrizol Corporation, PolyOne Corporation, Viscus Biologics, and SNS NanoFiber Technology, LLC. In each case, client companies are seeking:

- Testing and optimization support of efforts to leverage existing materials and supply chains to accelerate commercialization of novel medical devices that address unmet needs and provide a competitive advantage, combined with
- Integrated clinical utility and regulatory assessment focused upon managing and accelerating the approval and commercialization processes.

Detailed Review:

- **Technical Merit and Plan**

The team clearly defined the problem faced by each of their clients. They also discussed the portion of the AFMC capability/platform/technology that is relevant to assisting each of the firms in optimizing multi-component materials for a variety of their specific target medical device/material applications.

- PolyOne is synthesizing and formulating radiopaque (RO) resins that are optically transparent using chemical modification of the polymer and additive chemical backbones and dispersion of nanoscale inorganic additives into the formulation. The role of the AFMC will be to characterize the RO dispersion using its computer-aided tomography and X-ray equipment, feeding results back to PolyOne to guide reformulation efforts.
- Lubrizol is synthesizing various novel, non-fouling polymer materials, upon which strong patent protection is expected. Lubrizol is planning to prepare numerous additional materials to help optimize the surface properties while maintaining the bulk physical and mechanical properties required for targeted medical device applications. In an iterative work program, AFMC will provide surface analysis of these novel materials and develop new surface analysis methods to evaluate non-fouling characteristics for melt-processed materials.
- Viscus Biologics will perform advanced development, design, manufacturing, and commercialization tasks related to the development efforts for universal mat and xenograft-polymer combination products, building upon AFMC's (Becker) IP portfolio in degradable polymers and functionalization methods to enhance existing materials. AFMC will design functionalization strategies and polymer deposition methods and develop methodologies that mechanically reinforce the materials as well as facilitate the attachment of proteins or peptides to decellularized xenograft tissue.

- SNS NanoFiber will leverage AFMC experience and knowledge to scale up their electrospinning process to make AFMC-developed and -patented nanofiber materials on a commercial scale. The AFMC will utilize novel chemistries that facilitate the attachment of proteins or peptides to nanofiber mats and meshes currently being produced and sold by SNS NanoFiber. SNS NanoFiber will optimize the process for fiber diameter, yield, and productivity.

The AFMC platform proposes to add new capacity—a solvent-based R2R manufacturing line that will enable material formulation for Viscus Biologics and the SNS NanoFiber. This capacity investment will expand AFMC capabilities and will support increasing the scope and client base for AFMC.

Each of the client efforts is building upon and extending existing products and materials. Technical risks appear to be well understood and manageable. The proposal meets the requirements of the RFP on Technical Merit and Plan.

- **Commercialization Strategy**

Each component of the proposal (and its respective partner) addresses real and significant problems. If solved, there appears to be potentially large market demand for cost effective products/materials. The commercialization strategy builds upon the tools, techniques, and methodologies already developed at AFMC to accelerate the new product-development process and support that is required for the Food and Drug Administration's 510(k) application to succeed within the target window for this grant program.

The market analysis provides a good discussion of the overall U.S. and global markets for the relevant product classes. Targeted markets offer strong potential sales volumes. The company clients are well positioned in the marketplace. The project's initial target products build upon existing product lines/materials. Assuming technical success, market entry is virtually assured, and confidence exists for taking significant market share. Each client has identified target products for concentration, and if successful, the solutions would be relatively easily integrated into many additional applications.

All of the clients plan to go to market with existing customers and relationships. The approaches are sound, and the committee does not expect to see significant impediments emerge. The large companies are well positioned to support the marketing and production for market entry. The two smaller companies provided strong assurance of adequate support from their parent company/investor.

The proposal meets the requirements of the RFP on Commercialization Strategy.

- **Performance Goals**

Performance goals are very conservative, based on the identified opportunities. Revenue estimates for all clients total $6.8 million in Year 3 and $19.8 million in Year 5. Employment projections include 27 jobs in Year 3 (16 for-profit, 11 not-for-profit) and 41 jobs in Year 5 (34 for profit, 7 not for profit). Follow-on investment values are not addressed in any concrete detail beyond general statements that investment will be required if the products are successful.

The proposal meets the requirements of the RFP on Performance Goals.

- **Experience and Qualifications**

The team is very good, with strong individuals in each of the partner organizations. The commercialization clients either have experience in launching new products into global markets or have established customers with track records in this arena.

The proposal exceeds the requirements of the RFP on Experience and Qualifications.

- **Budget and Cost Share**

AFMC is requesting $3,000,000. Total match is $3,002,047, meeting the 1:1 requirement. At 85% the platform receives state funds well in excess of the supermajority requirement. Clients provide more than 50% of the match at 63.31%. The proposal meets the requirements of the RFP on Budget and Cost Share.

Summary and Recommendation:

The technical goals appear achievable, the work plan well thought out, and the commercialization plan reasonable. This proposal builds upon and enhances a core competitive strength of Ohio, the University of Akron, and the client companies. The regulatory path is manageable in the project timeframe. Given these conclusions, the committee recommends that this proposal be considered for funds under the Ohio Third Frontier Innovation Platform Program.

OTF IPP 14-317
Smart Sensor System Design, Development, and Commercialization
University of Akron

Proposal Summary:

Proposed Budget		
	State Funds	Cost Share
Operating Funds	$1,975,692	$2,016,705
Capital Funds	$32,500	$32,500
Subtotal	$2,008,192	$2,049,205
TOTAL	$4,057,397	

The proposal seeks to utilize the sensor platform established at the University of Akron (UA) by means of partnerships with the Engineering Research Center (ERC) and specific subgroups of the following entities: Wright Center for Sensor Systems Engineering (WCSSE-UA), the Center for Advanced Vehicles and Energy Systems (CAVES), the Timken Engineered Surfaces Laboratory (TESL), the Center for Surface Engineering and Lubrication Research (CSELR), the National Center for Education and Research on Corrosion and Materials Performance (NCERCAMP), the Institute for Biomedical Engineering Research (IBER), and CenTire, an NSF-funded tire center. The objective is to develop sensor solutions for three client companies in the areas of (1) automobiles (2) power grids, and (3) HVAC systems

Detailed Review:

- **Technical Merit and Plan**

The sensor platform at University of Akron proposes to provide custom sensor solutions for three client companies with specific and diverse needs. University of Akron is the only academic institution that has a commercial license for the use of Cadence in designing integrated circuits for commercial purposes, and UA has harsh-environment testing capabilities suitable for developing and testing custom application-specific integrated-circuit (ASIC) sensors. For the client Bendix, the UA platform will develop, manufacture, and install an advanced unified brake sensor system for commercial vehicles. The end product will be packaged into an integrated circuit that will have the capability to withstand the harsh conditions demanded by this application. Bendix has not articulated an immediate need for the product, and had no clear expectation for bringing a product to market in the OTF time frame. Potentially, Bendix could work with the UA sensors laboratory independent of OTF if there was sufficient internal interest within Bendix. The visual sensor solution strategy seems prone to error and variability, and there has been no assessment of failure rates. Retrofitting existing commercial vehicles will be a challenging proposition. The use of visual sensors to address push rod failures is a high-risk strategy for monitoring push rods for commercial vehicles. Also, with modern commercial vehicles moving away from the use of push rods, the implementation of the technology will be challenging. Finally, Bendix expects the first product to be developed in a 10-year period, which is well outside the time frame of the RFP and hence does not meet the RFP requirements.

For the client Exacter, the UA platform will develop, commercialize, manufacture, and market a smart sensor platform for electric grid outage mitigation. Different monitoring opportunities are listed: transformer/breaker bushing, substation area monitor, insulator contamination, conductor damage, station battery degradation, underground vault, electrical cabinet, and transmission structure. These applications are different enough so that different sensors are required. Multiple sensors packaged in an integrated circuit (IC) format will be developed to evaluate power grid failure. The specifications, operations, and integration details have been better developed for some of the modules, but are not uniformly clear. The end product will be a specially engineered IC capable of withstanding a wide range of environmental conditions. There will be 10 sensor modules of which 5 will be brought online as products within the 3-

year time frame. The client seems on track to meet this goal. Exacter has two test beds: one is with AEP in Ohio, and the other is Florida power.

For the client Jacco, the UA platform will develop, manufacture, and market an HVAC sensor-harvester-controller mechatronics system to regulate airflow and improve system efficiency. An IC for energy harvesting will be developed. The objective is to increase efficiency by placing a turbine in the air stream exiting the outside heat exchanger, extracting energy from the flow. The proposers have not clarified this issue sufficiently, particularly the size of the unit for which this strategy becomes attractive. The system will be retrofitted into existing HVAC systems and integrated into new HVAC systems.

On Technical Merit and Plan, the proposal meets the RFP requirements for clients Exacter and Jacco and does not meet the requirements for the client Bendix.

- **Commercialization Strategy**

The commercialization strategy is realistic for clients Exacter and Jacco. Exacter has developed sensor technologies in partner for insulator monitoring and has tested and demonstrated that it is operable in the commercial space with stringent commercial manufacturing guidelines. The job creation numbers are low for the projected market opportunity. Primary revenue will be sales of the sensor, which is targeted at $500 per sensing modality. While Bendix has internal capital and Exacter proposes to raise capital through current product sales, at the time of the evaluation of the proposal Jacco has not identified a need to raise capital. However, there may be a need to increase capacity to sustain product development after the IPP period.

The commercialization strategy for client Bendix was especially weak, as there was insufficient market analysis. Additionally, based on client statements during the interview phase of the proposal review, it is expected that the time to commercialization for the intelligent sensor technology is 10 years, which is outside the scope of the RFP. Additionally, based on client statements, if the push rod technologies for commercial vehicles are in the process of being phased out, there appears to be limited commercial value in having an intelligent push rod brake system sensor.

The power grid management sensors for client Exacter shows more promise. There is a clear ability to achieve the time to market in 2 years. The idea of Jacco using sensor-controlled energy harvesting in HVAC systems is quite promising, although there has been little initial modeling work to establish proof of feasibility. Retrofitting existing HVAC systems, which is one of the proposed methods of revenue generation, is feasible in the OTF timeline, as is product generation at the end of year 3. However, demonstrating market entry at the end of the project period seems unlikely.

Exacter and Jacco meet the requirements of the RFP on Commercialization Strategy. Bendix will not meet this RFP requirement because commercialization seems unlikely to happen in the 3-year time frame.

- **Performance Goals**

The objective of this proposal is to utilize the unique ASIC-based sensor development capabilities at the UA–ERC sensor development platform to create custom sensor solutions for 3 client companies that have specific needs in the area of harsh environment sensors.

For Bendix, the objective will be to develop an electronic system to monitor the health conditions of the brake system in trucks and report those conditions to the central control unit. The performance goals are broadly defined as sensor development, testing and packaging. The proposers do not provide details that clearly establish the performance goals for this client. A number of key features of the visual test

technology including the camera and laser type need finalization, hence at the current point there is an absence of proof of feasibility prototype. For client Exacter, the objective will be to design a panel of sensors with versatile capabilities for monitoring the power grid to enhance its efficiency. The details on the performance and failure modes of the sensors are well defined, so is the integration of the multiple sensors into the hardware. The objective for Jacco is the design of an energy harvesting sensor chip for existing HVAC systems that can be implemented into new HVAC systems. The operation capability of such a sensor device will be unique as the energy harvesting mechanism is intuitive. Because it is also easy to implement, it is feasible to expect a product by the third year.

Bendix will not meet this RFP requirement because the product idea and evolution is still in the research stage and will need to be proven out to meet several metrics before it can be commercialized which is unlikely to happen in the 3-year time frame. The proposal meets the requirements of the RFP on Performance Goals for Exacter and Jacco. It does not meet the requirements for Bendix.

- **Experience and Qualifications**

All the partners in this proposal are well-qualified. The technical leads Drs. Garcia, Ida, and Sozer have expertise in ASIC based sensor design. Only two of the client companies, Bendix and Exacter, are represented in the leadership team. The proposal meets the requirements of the RFP on Experience and Qualifications.

- **Budget and Cost Share**

The committee recommends the elimination of Bendix as the third client. Because there is a 1:1 cost share with state funds for Bendix, elimination of Bendix will reduce the state funds and cost share by $264,000 each. Hence the total budget reduction will be $528,000. The original percentage of state funds going to the Lead Applicant was 55%, and with the elimination of Bendix the percentage increases to 64%. With the reduction in the budget, the proposal better meets the requirements of the RFP on Budget and Cost Share.

Summary and Recommendation:

The proposal targets developing three different ASIC based sensor solutions for designing rugged sensors for client companies with varied needs. With the first client; Bendix, the UA-ERC platform seeks to design an intelligent visual sensor system for identifying brake failure by monitoring the push rod. The need for such a technology seems weak and may be difficult to commercialize. This was also noted by the client in their interview, where a 10-year time period to commercialization for this specific product was indicated. The 10-year platform to market timeline is well outside the OTF RFP requirements. The second sensor solution that the UA-ERC platform seeks to develop is with the company Exacter for designing a panel of sensors that would monitor the power grids for designing smart grids. The opportunity for sensor implementation in this area is immense. There will be significant value associated with developing such sensor systems. The client has already identified two test beds, with AEP and Florida Power, and has implemented the insulator sensor module. Exacter has a high probability of success. The UA-ERC platform proposes to develop a sensor with Jacco for harvesting energy that can be retrofitted to existing HVAC systems and can be integrated into newly designed HVAC systems. Technically the idea is innovative and exciting, and there is a significant market opportunity for energy-harvesting devices. The client has a good appreciation of the technical capabilities and the commercialization strategy.

The committee suggests pursuing the smart grid and energy harvesting applications and recommends that the intelligent brake application be removed from the platform. The committee recommends that this proposal be considered for funds by the Ohio Third Frontier Innovation Platform Program if Bendix is

eliminated, reducing the budget by $528,000 (reducing the state funds by $264,000, resulting in a state contribution of $1,744,192).

OTF IPP 14-305
The OHIO Shale Platform
Ohio University

Proposal Summary:

Proposed Budget		
	State Funds	Cost Share
Operating Funds	$2,396,000	$1,430,000
Capital Funds	$84,000	$1,050,000
Subtotal	$2,480,000	$2,480,000
TOTAL	$4,960,000	

The project seeks to expand the capabilities of Ohio University's (OHIO) existing innovation platform for shale wastewater treatment/management to meet the increasing commercial needs for water management and re-use in unconventional oil/gas development, thus reducing wellhead development costs and mitigating water disposal issues. The technology platform is expected to facilitate collaboration among Ohio-based companies to address commercialization issues by providing wastewater treatment technologies and envisioned applications – such as heavy oil recovery, brown grease conversion and animal feeding operations wastewater treatment – an expedited development pathway to market entry. Ohio University states that it has already developed a technology platform utilizing supercritical water (SCW) processing to treat wastewater from shale wells and has successfully demonstrated the technology at the laboratory prototype scale.

The primary focus of OTF funds from this award is to design and build a pilot-scale test facility and establish field demonstration test sites for new shale wastewater treatment/management technologies. The platform is expected to concentrate the resources necessary to scale new shale wastewater treatment and management technologies from the demonstration phase (lab- and bench-scale) to market entry (pilot and field demonstrations).

The OHIO Shale Platform is a collaborative effort between Ohio University and five commercial clients including: RF Advanced Technologies Group, Babcock and Wilcox, Utility Technologies International Incorporated, Steel Warehouse and Watershed Management. RF Advanced Technologies Group has already formed an Ohio LLC and is positioned to start a wholly-owned subsidiary located in Ohio within two years of kickoff to serve as an operational hub for meeting the Ohio shale industry's water treatment needs.

Detailed Review:

- **Technical Merit and Plan**

The project contemplates experiments to determine and evaluate shale wastewater and precipitated solids properties at critical condition to support design of a pilot-scale process to demonstrate a supercritical-based wastewater treatment technology. This will be followed by the identification of potential locations for a pilot-scale unit and demonstration field trials leading to the fabrication of the commercial-scale pilot unit. The pilot unit will then be relocated to shale testing sites in Ohio and will be operated for treating fracking wastewater, producing a reusable water product and recovery of potentially recyclable salt products. With the experience gained from successful operation of the pilot plant unit, a preliminary design package for a commercial-scale shale wastewater treatment process will be developed including refined cost estimates, plant layout, and instrumentation diagrams.

The committee believes that some aspects of the proposed process are noteworthy, such as the proposed use of ohmic electrical heating of the produced salt water as a means of heating the water to a supercritical state. However, the committee strongly believes that the major technical challenge to be overcome for technical success is the highly corrosive nature of supercritical waste water containing

highly variable levels of salt and other ionic compounds, and the as-yet unspecified materials of construction for the supercritical reactor. This was confirmed by Babcock and Wilcox, who stated that their current supercritical water processes require highly purified water to avoid corrosion issues. **The committee strongly recommends that the issue of corrosion and materials of construction be identified and solved as soon as possible using the laboratory and bench-scale process equipment before all of the requested funding is released, contingent on the satisfactory identification of a solution to this problem, as outlined in the Summary and Recommendations below.** With this proviso, the proposal meets the requirements of the RFP on Technical Merit and Plan.

- **Commercialization Strategy**

Market entry is anticipated to occur during the project's second year through the development of a detailed business plan. In addition, a funding strategy for the commercialization organization will be developed including identifying private and government funding sources to support market entry. RF Advanced Technologies Group, one of the project's commercial clients, will establish a wholly owned Ohio-based subsidiary to commercialize the proposed shale wastewater treatment technology and provide a wastewater treatment service to the shale industry.

The platform's wastewater treatment technologies have several commercial applications with shorter-term opportunities from interested industry partners beyond shale, including brown grease conversion, heavy oil recovery, and CAFOs. The proposal states that most clients of the IPP are interested in multiple applications of the technology. The proposal meets the requirements of the RFP on Commercialization Strategy.

- **Performance Goals**

The specific performance goals and commercialization metrics appear to meet the RFP requirements and are achievable within the three year time frame, if the materials-of-construction issue can be solved. The ability to process wastewater on site to permit re-use rather than disposal would be of significant economic return to Ohio and elsewhere using the supercritical water process.

The pilot demonstration of the technology is critical for commercial success. Year 1 performance goals focus on the design and commissioning of the pilot plant. Year 2 goals focus on the design of a commercial system, identification of additional applications and market entry. Year 3 goals focus on completing the testing of the additional platform applications. In terms of commercialization metrics, the platform is expected to create 87 jobs in 5 years with an average salary of $71,000 and generate $56 million in new product sales.

Project Milestones: The project team expects pilot unit fabrication by month 7 (Milestone E), pilot unit field demonstration underway by month 12 (Milestone G), licensure by month 18, and commercial product launch within 24 months.

The proposal meets the requirements of the RFP on Performance Goals.

- **Experience and Qualifications**

Members of the project team have several project-related areas of expertise including shale wastewater treatment (associate director), energy (coal, natural gas, biofuels), environmental and business development. Although the specific domain expertise in shale wastewater treatment of all the members of the management members does not appear to be deep, the relevant background and experience of the project's clients provides the assurance that the team will be able to accomplish the stated technology

development and commercialization goals. The proposal meets the requirements of the RFP on Experience and Qualifications.

- **Budget and Cost Share**

The proposal's budget meets the 1:1 cost share requirement. It should be noted, however, that not all of the cost share is discretionary and unallocated as $1M in cash (40% of the $2.48M cost share) is being provided by one of the project's partners (RF Advanced Technology Group) to support the development of the pilot plant unit. All of the cost share is firmly committed as evidenced by commitments letters provided by well-established project partners. Additionally, 100% of the state funds will go to the lead institution thus satisfying the RFP supermajority requirement. The proposal meets the requirements of the RFP on Budget and Cost Share.

Summary and Recommendation:

The technology platform described in the proposal is established and the funding will be used to expand its capabilities by creating a pilot-scale test unit that will lead to the design of a package for a commercial-scale shale wastewater treatment process. The further development of the technology platform supported by the assistance of well-established industry operators as project partners will provide the state of Ohio with jobs and additional sources of revenue. It is also worth noting that the project partners will be the initial licensees of the technology from Ohio, thus increasing the likelihood of a successful market entry and commercialization effort.

The committee recommends that this proposal be considered for funds under the Ohio Third Frontier Innovation Platform Program with conditions. In view of the significant uncertainties related to the selection and performance of materials of construction, the committee believes that this key barrier has to be overcome. As a result, the committee has reduced the funding to first provide the demonstration and testing of the piece of equipment and no funding beyond that amount. Furthermore, the committee recommends that the disbursement of state funds be made in tranches corresponding to the successful completion of project milestones as follows:

Project Milestone	OTF		Cost Share		Total
Pilot Unit Design	$250,000		$250,000		$500,000
Pilot Unit Fabrication *	$600,000		$600,000		$1,200,000
Pilot Unit Field Demonstration	$600,000		$600,000		$1,200,000
Total	**$1,450,000**		**$1,450,000**		**$2,900,000**

NOTE: * Including solving the materials of construction issue.

OTF IPP 14-301
Carbon Nanomaterials Based Platform Technology
Ohio State University

Proposal Summary:

Proposed Budget		
	State Funds	Cost Share
Operating Funds	$2,836,000	$3,000,000
Capital Funds	$164,000	$0
Subtotal	$3,000,000	$3,000,000
TOTAL	$6,000,000	

The Ohio State University (OSU) seeks to lead a collaboration with client companies Owens Corning, OMNOVA Solutions, GDC, Engineering Mechanics Corporation of Columbus (Emc2), Nanomaterial Innovation Ltd (NIL), CK Technologies and Honda of Americas. The team seeks to develop a group of new foam, coating and composite products for industrial applications using well-established innovative carbon nanomaterials and the associated processing platform. OSU has established an IPP with research and development and processing capabilities in carbon nanomaterials. This infrastructure at OSU will be utilized to work with industry and has previously supported product improvement for Ohio companies including the client companies on this proposal. This proposal seeks to use the IPP at OSU to develop and commercialize new products and technologies in several areas using OSU's Carbon Based Nanomaterials Technology Platform: (1) NIL will scale-up and commercialize the surface functionalization of carbon nanoparticles for high strength nanopapers, (2) Owens Corning will commercialize insulation foams using benign blowing agents to meet the Montreal Protocol requirement; 3) OMNOVA will also develop conductive carbon nanopapers and coatings for EMI shielding; (4) GDC and Emc2 will developed biocomposites for automotive applications. The project can be divided into five major research thrusts including: Insulation and Structural Foams, Thermosets with In-Mold Coatings (IMC), Thermoplastics with IMC, Bio-nanocomposites, and New Product Innovations. The ultimate end-users of the products of the proposed project will be the automotive and wind energy industries.

Detailed Review:

- **Technical Merit and Plan**

The plan for the proposed research and development is generally clear. Two major research and development thrusts involve scaling up the production of carbon nanoparticles to make insulation foam, and nanopapers for in-mold coatings. These two program elements are recommended for further consideration.

Extruded Foams: The efforts on foam extrusion materials are clear. The applications for foams were divided into two key areas: insulation and structural foams.

Insulation Foams: A key product area is insulation foams with dispersed nanoparticles using benign CO2 blowing agents (as opposed to fluorocarbons with significant environmental impacts). The proposal noted a performance target of R5/inch of foam and that polystyrene matrix CO2 blowing agent and additives did not meet this target. The proposal claims that the addition of the carbon nanoparticles can make up for the substitution of fluorocarbons with CO2. However, insufficient preliminary test data was provided demonstrating that this performance target could be met. The metric of R5/inch of foam with CO2 blowing agent and a specified vol% of nanoparticle reinforcement at neutral cost to existing foam with HFC blowing agent should be demonstrably met at month 12 of the program. **If this metric cannot be met at month 12, the state should cease funding the proposal.**

In-Mold Coatings: The use of in-mold coatings for thermosets and thermoplastics and the potential outcomes in terms of added functionality for composites (surface durability and wear resistance, cosmetic

coatings, gas diffusion coatings, EMI shielding etc.) is clear. The key goal here is to produce thin papers or films, and them to integrate these coatings into molds for large throughput injection molding or other processes. The in-mold coatings would then improve properties of the fabricated part. Benefits and cost savings in composite processing derived from the application of these materials is expected. It was difficult to extrapolate these documented savings, which were quoted as savings by part for an unknown part of unknown dimensions (table B.3).

Structural foams and bio-nanocomposites should be eliminated from the program based on the comments below.

Structural Foams: Another product area is structural foam, where it is suggested that the addition of carbon nanoparticles may lead to higher strength and compression fatigue resistant foam. Insufficient preliminary test data was provided to substantiate the strength / modulus / fatigue augmentation resulting from dispersion of nanoparticles at the proposed particle volume fractions. The nanoparticles will introduce inclusions that degrade fatigue resistance, especially in tensile bending which is commonplace in wind turbine blades. The proposal team was asked to clarify this both at the interview and in a follow-up request sent after the interview and did not provide sufficient data at either opportunity. Based on these oversights on critically important mechanical properties, the structural foam component does NOT meet the requirements of the RFP.

Bio-nanocomposites: The bio-nanocomposites component of this work has not been explained in sufficient detail to enable the assessment of technology benefits, mechanical properties, and the potential success of biocomposites products or processes. These sections of the proposal are vague and seem to be an afterthought. Based on this lack of justification, it is not recommended that this task area be funded.

The proposal tasks on insulation foam and IMC meet the requirements of the RFP on Technical Merit and Plan. However, the bio-nanocomposites component does NOT meet the requirements of the RFP and should be eliminated from the program.

- **Commercialization Strategy**

Insulation foam and in-mold coatings (IMC) using nanopapers are expected to be sold primarily into the automotive markets. Additional applications for the nanopaper-based products are EMI shielding and increased surface durability. The clients companies are broad-based, and Owens Corning is a significant competitor in the extruded foam business, which provides a commercialization path that is a key to a successful outcome. The proposal meets the requirements of the RFP on Commercialization Strategy for insulation foam and IMC.

- **Performance Goals**

Within 3-5 years, the team seeks to create 40+ high-paying new jobs. After 3 years, this Innovation Product Platform is projected to be supported by the participating Ohio companies and federal funding agencies, under the leadership of several Ohio companies including Owens Corning and OMNOVA Solutions. It should be noted that NIL is a start-up company and does not qualify as a client company and is tightly coupled with OSU researchers. GDC and Emc2 are associated with the bio-nanocomposites tasks, which are not recommended for further consideration. OSU has a clear IP strategy including patents and provisional patents for some of the technologies under consideration in this program. The proposal tasks on insulation foam and nano-papers meet the requirements of the RFP on Performance Goals.

- **Experience and Qualifications**

The proposers have assembled a highly qualified team of university researchers and industrial engineers/scientists to carry out the proposed effort. The proposal meets the requirements of the RFP on Experience and Qualifications.

- **Budget and Cost Share**

The budget is reasonable in scope for the work being performed. However, one point in the cost share is not clear. OMNOVA will purchase $104,000 worth of equipment and it will reside at OMNOVA. Team members will be charged a fee to use this equipment at the end of the program. This fee should only be charged for consumables and not to recover capital cost.

It is not recommended that the bio-nanocomposites or the structural foam activities move forward. This means that the Budget Form 2C (GDC) state-funded expenditures (State $200,000) and Form 2D Engineering Mechanics (State $200,000) should both be eliminated. In addition, the committee estimates that approximately $400,000 going to the Lead Applicant is for these activities and should also be eliminated for a total reduction in State funds of $800,000. This reduction also makes the proposal consistent with the RFP's requirement of a 1:1 Cost Share ratio.

Summary and Recommendation:

The committee recommends that this proposal be considered for funds under the Ohio Third Frontier Innovation Platform Program, except that the structural foam and bio-nanocomposites components of the proposal should be eliminated. The committee recommends that the maximum amount of Ohio funding be limited to $2.2 million.

OTF IPP 14-311
Materials Manufacturing Technology Hub
National Composites Center

Proposal Overview:

Proposed Budget		
	State Funds	Cost Share
Operating Funds	$2,587,000	$1,437,051
Capital Funds	$125,000	$1,274,949
Subtotal	$2,712,000	$2,712,000
TOTAL	$5,424,000	

The National Composites Center (NCC) seeks to introduce new processing and manufacturing practices in order to commercialize products and services primarily in the area of reclaimed carbon fiber products to meet the needs of Ohio-based high-tech manufacturers in a number of industries. This will be achieved by incorporating reclaimed carbon fiber into traditional composite processes, as well as recycling for thermoplastic composites.

The platform seeks to produce reclaimed carbon fiber, in partnership with Argonne National Laboratory. They have surpassed the demonstration phase and are working on products and processes for commercial applications to benefit the following potential end users: Airbus, Adisco, Nanosperse, Cannon, GrafTech, Honda, Atlas, and Argonne. Argonne has developed a preliminary carbon fiber reclamation process and is relocating a 20 lb/hour reclamation furnace to NCC in Ohio in support of the program.

The Materials Manufacturing Technology Hub (MMaTH) will focus on innovative processing solutions with light-weight and recyclable materials. These process solutions are aimed at the following potential end users: Airbus, Siemens, Adisco, Gosiger, Lord Corp, RTI, Techsolve, and EWI.

This project also plans to develop nano-enhanced prepreg for commercial aircraft use by Airbus, which will be produced by Renegade Materials. The target for this prepreg sub-project is to develop an electrically conductive product for incorporation into composite aircraft wings as lightning strike protection.

Detailed Review:

- **Technical Merit and Plan**

The carbon fiber reclamation process to be used in this project was developed at Argonne National Laboratory and will be furthered at NCC. End-of-life carbon fiber from aircraft, automotive, and other industries will be incorporated into intermediary material formats.

A 12-inch-wide continuous carbon nanotube paper production line will be modified for this project to produce wet-laid nonwoven mats incorporating reclaimed carbon fiber. Dry-laid nonwoven mats are being produced using a combination of air-laying and carding techniques; they will explore incorporating reclaimed carbon fiber into the process. The NCC's current rapid fiber preforming process will be modified to incorporate reclaimed carbon fiber. Finally, reclaimed carbon fiber will be incorporated into fiber-reinforced thermoplastic pellets.

The NCC will collaborate with client companies to determine applications where their carbon fiber reclamation process can produce a product, recycle an end-of-life material, or potentially improve a material and/or reduce cost. The proposal meets the requirements of the RFP on Technical Merit and Plan.

- **Commercialization Strategy**

The commercialization strategy for this project involves incorporating the reclaimed carbon fiber technology to various products at four primary client companies. Reclaimed carbon fiber is in the demonstration phase for a number of products and processes; the demonstration phase was proven by Argonne National Laboratory.

The proposal identifies thermal insulation for photovoltaic applications as one of the more developed opportunities, which should lead to early revenue and profitability. GrafTech will lead this suite of products, focusing on thermal insulation for photovoltaic materials, as well as reinforcement to extend life of graphite electrodes, and reinforcement for semi-structural automotive components. Atlas will focus on bringing composite fastener products to market. Adisco will focus on a product for the CNC machining industry. There is collaboration with Airbus to recycle end-of-life carbon fiber materials. Finally, Renegade Materials is working on a carbon fiber reinforced polymer wing skin for aircraft. This sub-project does not involve recycled carbon fiber and seems relatively unrelated to the rest of the proposed project.

There are some challenges and risks documented in the proposal regarding commercialization of a recycled carbon fiber process, such as cost, complexity of the end-of-life composite recycle stream, sales approach, and educating the industry. There are also a number of significant risks that were observed by the committee. Primarily, little to no attention had been paid to environmental processing issues, EPA and OSHA requirements, and disposal of hazardous materials. In addition, there was no clear path to commercialization and revenue generation within the proposal period of 3 years. The proposal stated that $35 million would be needed to bring reclaimed carbon fiber products and K-Column technologies to market, yet a strong argument on the methodology to enable this to happen was lacking.

One of the largest potential end users, Airbus, stated that the materials certification process would likely not occur for 5-6 years, which is outside the 3-year timeline for the IPP program. Airbus indicated that the company produces 250 metric tons of waste carbon fiber annually. However, the company also indicated that it would not ship waste carbon fiber overseas for recycling, and in a follow-up response, the company indicated that the 250 metric tons is all produced in Europe and therefore would not be shipped to the United States for recycling. There are domestic U.S. aircraft manufacturers such as Boeing, Lockheed Martin, and Northrop Grumman, that all use carbon fiber in their aircraft in the United States and are therefore more appropriate clients, but they were not part of this proposal. The Argonne 20 lb/hour reclamation furnace is also too small to be used for the industrial-sized quantities of material that were discussed in the proposal.

Finally, there were three opportunities (proposal, follow-up questions, and interviews and interview follow-up clarifications) provided for the team to demonstrate a revenue/profit model—but the committee could not identify any clear path to sales and profitability within 3-5 years. <u>This proposal does not meet the requirements of the RFP on Commercialization Strategy.</u>

- **Performance Goals**

The proposal was weak in terms of detailing new revenue sources with any specificity, as well as any detail related to wealth creation, beyond the impacts implied from the job creation figures. Regarding job creation, a great majority of the expected results mentioned in the proposal are unrelated to client companies—most jobs are to be created via people trained at MMaTH. These trained students are to be hired by outside companies. In other words, jobs created outside of the client companies are more "indirect" because they are not within the control of the participants in this proposal. While the job

creation numbers are impressive on the surface, the lead and client companies are not in a position to assure results. The proposal does not meet the requirements of the RFP on Performance Goals.

- **Experience and Qualifications**

Lisa Novelli as CEO and president of NCC will have overall responsibility for this project, supported by Jessica Ravine as vice president of engineering. Based on the narrative of their backgrounds, they seem to have the relevant background to execute their roles. For both Ms. Novelli and Ms. Ravine, there is little mention of previous specific roles, titles, companies, or institutions regarding past employment. The principals at the client companies have much better documented and relevant backgrounds. They seem well qualified to execute their respective roles relative to this proposal. The proposal meets the requirements of the RFP on Experience and Qualifications.

- **Budget and Cost Share**

The ratio of cost share to state funds for this project is 1:1, the use of state funds for indirect operating cost is 11.9% of the operating costs subtotal, and 72.8% of total funds will go to the lead applicant. The budget narrative clearly explains the financial details for each of the client companies. There are a number of client companies that are providing cost share without receiving any state funds. The proposal meets the requirements of the RFP on Budget and Cost Share.

Summary and Recommendation:

The "green" component of this proposal is admirable, and carbon fiber is an important material in a number of areas within the manufacturing sector. That said, at this time, this proposal is focused on a solution that is a technology "push," rather than market "pull," as confirmed by Ms. Novelli at the interviews. In other words, because there is no clear market demand for this technology, and given that there is no compelling cost/benefit advantage, this would not be a promising approach to demonstrate revenue within the 3 years as required by the IPP. There are a number of disjointed technologies and companies involved in the proposal. There is a lack of a well-defined strategy demonstrating a clear path to commercialization with a realistic projection of revenues and profits within the timelines dictated by this program. Major innovations described in this proposal appear to require significant time and money to develop; the IPP program is designed for technologies that are far enough along that the path forward to commercialization is relatively well-defined. The proposal was lacking in these critical areas. The committee was thus not convinced that there would be meaningful commercial progress supported by revenue within 3-5 years.

Financially, the proposal was lacking in two areas. First, there was insufficient detail provided regarding the funding gap between OTF funds and the funds required to reach commercialization. Second, there was a lack of detail regarding revenue and profitability. The committee could not get a clear picture of the product, the buyer, the price, the profit margin, competing products, volumes, etc. While the proposal team made a case that end-of-life carbon fiber materials must be dealt with at some time in the future, this proposal did not demonstrate that they have a viable solution that could be successful within the proposal period of 3-5 years. The committee does not recommend that this proposal be considered for funds under the Ohio Third Frontier Innovation Platform Program.

OTF IPP 14-312
Scalable Nanomanufacturing of Functional Films
University of Akron

Proposal Summary:

Proposed Budget		
	State Funds	Cost Share
Operating Funds	$2,535,749	$3,301,596
Capital Funds	$464,000	$260,000
Subtotal	$2,999,749	$3,561,596
TOTAL	$6,561,345	

The platform is narrowly defined as the University of Akron's (UA's) Electromagnetic Processing Roll to Roll (R2R) Manufacturing Platform designed to use electric, magnetic, and thermal gradient fields to organize and orient minor phases (polymers, nanoparticles, copolymer phases) in the thickness direction of a flexible film at demonstration commercial scale. Their platform is, in fact, a broader complex of skills, tools, technologies, and techniques associated with the development and use of this first-of-a-kind commercial-scale unit.

The UA proposes to work with four client companies (Kraton Polymers U.S. LLC; PolyOne Corporation; Stratum Energy Systems, LLC; and FLEXcon Company, Inc.) to combine this platform with two "novel commercialization polymer platform technologies" developed by client companies to pursue a targeted subset of a wide range of unique potential applications (Novel Functional block copolymers from Kraton, Inc., and a polyimide class of polymers from PolyOne). Stratum is an end-user client for battery and fuel-cell applications, and FLEXcon is a client for the commercial film-manufacturing technology. The Stratum project and metrics is dependent on its vendor relationship with Ecospinners, a manufacturer of electric bicycles.

The goal is to develop commercial-scale R2R solutions that enhance the performance of films and membranes. The team has identified seven interrelated technical problems and potential early commercial application areas based on these two commercialization platforms that require enhancement of the through thickness morphology to design oriented domains that enable more efficient flow through the film/membrane of water molecules, ions, or electrons or phonons (heat)—without sacrificing other properties.

Detailed Review:

- **Technical Merit and Plan**

The problem statement summarizes some of the research and sample runs demonstrating proof of concept that the proposed approach offers significant opportunity in a number of potential applications. The committee is concerned that the project may be trying to address too many problems at the same time. The team makes a case that the interrelationships are such as to be mutually supporting lines of inquiry for developing a manufacturing solution and that a rigorous stage gated process will be used to quickly eliminate dead ends. Ultimately they have three primary project goals to support the following:

1. Kraton, in the development and commercialization of Z-oriented Nexar films;
2. PolyOne, in the development and commercialization of Z-oriented conductive polyimide resins and films; and
3. Stratum, in the development and commercialization of Z-oriented membranes for fuel cells and membranes for batteries.

The proposal team's discussion of the detailed technical plan raised a number of questions that were addressed in their formal response to questions. In particular, they provided some clarity concerning

properties of the target solutions with competing products, as well as a detailed explanation of the Stratum/Ecospinners project that is so critical to achieving the project's job performance metrics. The technical discussion addressed some of the constraints and issues with which the team will have to contend while developing a viable manufacturing process for film with the target properties.

Their case for success in the timeframe is based on the fact that they are starting with existing commercial or demonstration-phase material families and are building on demonstrated proofs of concept that the final products' thickness characteristics are tunable using the electric, magnetic, and thermal gradient-field technologies. These technology tools have been built into their commercial-scale R2R platform, which is to be the test bed for this project.

Overall objectives focus on enhancing performance, reducing cost, and producing specific materials for each potential application. In response to questions, the team provided concrete targets for performance and cost metrics. Despite proof of concept in the laboratory, the team was unable to show evidence that progress toward these goals was being delivered on the R2R demonstration machine.

With this many products, and the relatively early stage of demonstration, the committee questioned whether the team can meet the technical timeline requirements to have commercial solutions within the grant's 3-5-year window. Some of the product areas are more complex than others. The team has to prove that the R2R solution works, optimize the solution for each of a wide variety of very different products, and then develop a commercial-scale solution for transition to each client. Initially, the research machine could potentially produce limited volumes, but cannot be used as a production machine for any length of time for any client. The committee is concerned that the team greatly underestimated the challenges associated with the jump from research to commercial deployment in the timeframe required, especially for such a diverse range of targeted products.

<u>The proposal does not meet the requirements of the RFP on Technical Merit and Plan.</u>

- **Commercialization Strategy**

The market analysis provides useful discussion of the overall U.S. and global market for relevant product classes, and provides context for the overall opportunity. Follow-up questioning provided more insight into the size of the opportunity for each client in the seven target markets.

The proposal does a credible job in defining the generic value proposition for each target application, as well as exploring future potential in additional market applications.

The proposal team claims that this platform is a new dimension in polymer film technology and that this will provide sustained competitive advantage for Ohio and client companies. Follow-up questions produced a discussion of the competitive landscape and why the clients expect to have sustained competitive advantage in their target markets.

The targeted markets offer high potential growth and sales volumes. The company clients are players in the marketplace and are internationally competitive. The project's initial targets are to enhance existing products or new products already entering the marketplace. Assuming technical success, market entry would be virtually assured.

The team's responses to questions helped clarify how each client plans to manage the manufacturing transition from the research phase to commercial deployment. Longer-term success requires that each client develop or outsource its own manufacturing solution based on the UA core design. The committee was not convinced that the technical solution could be achieved in a timely fashion.

The proposal meets the requirements of the RFP on Commercialization Strategy.

- **Performance Goals**

In response to the committee's written questions, UA provided a more complete discussion of platform sustainability. The primary focus was on licensing of the R2R enhancement technologies to both the commercialization partners and more broadly to equipment manufacturers.

The performance goals are not unreasonable, based on the identified opportunity. However, if the technical solution is not completed in a timely manner, then the sales and employment projections cannot be met. Further, except for the Stratum/Ecospinners project, little detail is provided in support of the estimates. If the technical project were successful, the revenue estimates would be strong with over $33 million in sales projected for Year 3 and over $100 million in Year 5. Kraton dominates sales projections with $25 million in 3 years (75%) and $69 million in 5 years (68%).

Employment projections would be much more modest because production would primarily take place in existing Ohio facilities. Indeed, most of the new for-profit jobs would come from Stratum and their electric bicycle client, Ecospinners (29 out of 31 in Year 3 and 47 out of 54 in Year 5). Kraton only projects 2 new jobs in 3 years and 4 new jobs in 5 years.

Follow-on investment values are not addressed in any concrete detail beyond general statements that investment will be required if the products are successful. No firm commitments are made.

The proposal does not meet the requirements of the RFP on Performance Goals.

- **Experience and Qualifications**

The team is very good, with strong individuals in each of the partner organizations. The commercialization clients have great experience in launching new products into global markets.

The proposal exceeds the requirements of the RFP on Experience and Qualifications.

- **Budget and Cost Share**

UA is requesting $2,999,749. Total match is $3,561,596, well exceeding 1:1 match. At 88.29% the platform would receive state funds well in excess of the supermajority requirement. Clients provide more than 50% of the match at 52.64%. The budget and cost share appear to be compliant with the grant requirements, therefore, the proposal meets the requirements of the RFP on Budget and Cost Share.

Summary and Recommendation:

The committee concludes that the technical goals for developing such a diverse range of targeted problems and solutions will not be achieved during the timeframe of this program. Therefore, it is the committee's conclusion that both the commercialization and performance goals could not be met as well, because these are dependent on successfully meeting the technical goals. The committee concludes that the technology has broad potential applications in the future, but the team needs to invest more effort in demonstrating that the z-optimization goals can be achieved on the research machine for any particular application before a specific commercialization project can be funded. The committee does not recommend that this proposal be considered for funds under the Ohio Third Frontier Innovation Platform Program.

OTF IPP 14-319
Endovascular Technology Innovation Center (ETIC)
Cleveland Clinic

Proposal Overview:

Proposed Budget		
	State Funds	Cost Share
Operating Funds	$2,828,135	$3,228,417
Capital Funds	$0	$0
Subtotal	$2,828,135	$3,228,417
TOTAL	$6,056,552	

The Intra-Operative Positioning System (IOPS), which is currently being developed by Cleveland Clinic's Endovascular Technology Center (ETIC) for use in minimally invasive surgeries, will address serious issues of fluoroscopic radiation exposure to patients and clinicians, as well as improve the accuracy and consistency of vascular surgical procedures. The IOPS platform technology is comprised of four components: (1) the IOPS, a 3D-based GPS-like navigation positioning system; (2) sensor-equipped endovascular devices; (3) surgical planning software applications; and (4) surgical training systems. Because the surgical planning and training software systems are to be used for training surgeons, in general, and are not requirements for use of the intra-operative component, efforts to develop and commercialize the IOPS and its sensor-equipped guide wires and catheters are the proposal's first priorities.

The project described in this proposal is focused on achieving the technology improvements, testing and validations, and manufacturing optimizations that will make the IOPS and its sensor-equipped guide wires and catheters ready for commercialization, and its specific goals are (1) for the IOPS, conversion of the prototype to manufacturable equipment for use in the proposed clinical trials and subsequent 510(k) submission; (2) for the electromagnetic sensor-equipped endovascular devices, improvement of the fabrication process to increase the yields associated with electrically functional sensors, sterilization, and packaging processes and validation; (3) for the software planning, software applications, speed-optimization of the prototypes for stent-vessel interactions and structuring of their use by multiple users while maintaining HIPAA compliance; and (4) for the surgical training systems, effectiveness validation of the IOPS console, sensor-equipped instruments, and a 3D-printed model of the patients' vasculature that is already used by ETIC to pre-operatively simulate each case in the ongoing institutional review board-approved clinical evaluation.

Cleveland Clinic, the lead applicant, plans to work with four client companies: Cleveland Endovascular Navigation Systems (CENS) to market and sell the IOPS; STERIS Corporation for sterilization of endovascular devices; ImageIQ to correlate and standardize ETIC's software prototypes with the fluoroscopy system; and, as clarified by the project team at the in-person meeting, Parker Hannifin for manufacture of the required conductive-path-enabled endovascular catheters.

Detailed Review:

- **Technical Merit and Plan**

While X-ray based fluoroscopy is the current standard of imaging used to perform endovascular repairs, it provides an extremely limited form of visualization, showing bones and metal but not arteries. To visualize arteries, contrast dyes, which are toxic to the kidneys and only provide momentary visualization, must be used. When fluoroscopy is used for imaging, patients and caregivers are being irradiated with ionizing radiation, which has both acute risks (like that of skin damage) and long-term risks (like that of cancer). With complex endovascular devices, precise placement is critical, and so fluoroscopy is used even more heavily than in simpler procedures to attempt to compensate for the inherent limitations of the imaging technology.

At the demonstrating phase of development, the ETIC's IOPS platform technology is very innovative and aligns with the RFP's definition of a platform because it has achieved proof of principle, the IOPS and its sensor-enabled endovascular device add-ons have been developed as reliable prototypes, and it has the potential to be used for multiple applications, both short- and long-term. The technical work objectives and plan include (1) upgrading three aspects of the IOPS, 3D visualization, spatial accuracy, and tracked device interfaces; (2) improvement and finalization of manufacturing techniques for the sensor-enabled endovascular devices, including testing, packaging creation, and development and production of more complex sensor-equipped devices; (3) surgeons' testing of the surgical planning software in various procedures with a combination of instruments, virtual reality renderings, and physical 3D-printed models, use of those tools in a clinical trial and clinical evaluations, and later optimization and development of those prototypes into a system for commercialization; and (4) building a large collection of models and data sets (3D-printed models and associated mathematical models) as teaching examples and an IOPS console for demonstration to and training of vascular surgeons, and later addition of simulation modules based on ETIC's endovascular visualization software and vessel-device interaction models.

Positive aspects of the proposal are that (1) the IOPS approach achieved better image results versus those yielded by the fluoroscopic approach currently used (clearly shown in Figure 4 of the proposal); (2) the problem of producing fragile sensors was included as well as the specific steps to make sensors that were more stable and produced in greater yield; (3) the challenge of distortion from the presence of the metal C-arm in the magnetic field and the ETIC's approach to overcome that challenge by developing specifications for and verifying spatial accuracy were described; and (4) additional devices, ureteric stents, intravascular ultrasound probe, validation of radiation planning software produced by MIM Software, which can be developed for use with the IOPS, support the platform's sustainability.

The first intraoperative product planned for Phase 1 market entry is the IOPS with sensor-equipped guide wires and sensor-equipped catheters. ETIC has acquired data using a research angiography system in preparation for the clinical study. IOPS system design conforms to all required standards, such as IEC 60601-1 for electrical safety and IEC 60601-1-2 for electromagnetic interference. Further, the first Food and Drug Administration 510(k) application will not contain any marketing claims such as reduced fluoroscopic dose, decreased procedure time, or improved clinical outcomes; however, clinical studies will continue to collect data for marketing proof of these claims. With a non-significant risk of Class 2 classification based on ISO 14971, the July 28, 2014, 510(k) guidance update as background, and St. Jude's Mediguide navigational computer system and sensor-equipped wire and catheter as predicates, completion of the clinical evaluation and 510(k) submission on Phase 1 is planned by quarter 6 of the grant. <u>The proposal meets the requirements of the RFP on Technical Merit and Plan.</u>

- **Commercialization Strategy**

If 510(k) approval for the IOPS with sensor-equipped guide wires and sensor-equipped catheters is granted as quickly as expected; its Phase 1 market entry is planned for quarter 9 of the grant. However, CENS, the company that will market and sell the IOPS, is not funded and up and running yet, and no specific plans for market entry are presented.

The specific value propositions of the IOPS (reducing fluoroscopy radiation, increasing clinical efficiency, and savings of costs for healthcare), the rationale for its pricing, and its competitive advantages over the electromagnetic tracking systems for surgical guidance offered by other companies are also stated. During the interview meeting, the project team emphasized the enthusiasm of key opinion leaders not associated with the Cleveland Clinic for the IOPS as well as the significant market forecast for its use. However, it is well known that often the medical community takes a long time to embrace "breakthrough" medical technologies. Thus, despite the proposal's stated concerns about the risk of

patient's and clinician's exposure to ionizing radiation and the goal of minimizing the complexity of endovascular procedures, the committee believes that the project team is too optimistic about the amount of time it will take until the broader medical community' is willing to buy and use the IOPS when it is launched**.** Furthermore, the commercial success of the proposal is highly dependent on the success of the client company CENS. Since this company is a gestating startup and not an established company, and Series A funding from investors will be difficult to obtain because its products are at such an early a stage of development, there are significant concerns that CENS will not be up and running soon enough to commercialize the IOPS in the RFP-required timeframe. The proposal does not meet the requirements of the RFP on Commercialization Strategy.

- **Performance Goals**

The proposal itself and the project team at the in-person meeting did not state when Series A funding to start and staff CENS would be obtained. They also did not provide a business plan for market entry, including marketing, sales, a strong case for rapid adoption of a new approach to electromagnetic tracking systems for guidance, and a convincing scheme for achievement of reimbursement approval. With CENS providing most of the jobs forecasted and the sensor-equipped add-ons producing the majority of revenues projected, but with no strategy for selling them described, the committee is very skeptical about whether the team will be able to deliver the jobs and revenues forecasted in the RFP-required timeframe. The proposal does not meet the requirements of the RFP on Performance Goals.

- **Experience and Qualifications**

Matt Eagleton, M.D., and Karl West, M.S., leaders of the ETIC, and Jeffrey Yanof, Ph.D, the Senior Principal for Biomedical Engineering at the ETIC, are well qualified for the roles described. However, no biographical information was provided for the people at STERIS, ImageIQ, or Parker Hannifin who will be directly involved in the project. That IMARC will support the regulatory effort, Cleveland Clinic Innovations will manage IP, and William Fuller, a future candidate for CEO of CENS, has extensive business development experience are positive points. Sub-contractors that will support ETIC in the development of the sensor-equipped endovascular devices are Northern Digital (sensors), Yokowo (wires), and LogiSync (auto-detection of instrument type for IOPS's use with a much wider variety of sensor-equipped instruments), and Hileman to support CENS's commercialization effort. The proposal meets the requirements of the RFP on Experience and Qualifications.

- **Budget and Cost Share**

The ratio of cost share to state funds for this project is 1:14, and 56.75% of OTF funding will go to the lead applicant, which is below the supermajority requirement. Use of funds from Ohio and the clients' cost shares are described clearly, and the proposed cost share related to the difference between the Cleveland Clinic's indirect cost rate and the Department of Health and Human Services' indirect cost rate of 57% and is an adjustment allowed by the RFP's guidelines. When questioned in-person about Hileman's role as a client in the proposal, the project team indicated that while Hileman is a sub-contractor and not a client, Parker Hannifin is a client; however, the client list in the proposal shows Hileman as a client and includes a budget for Hileman, but the proposal does not list Parker Hannifin as a client and does not include a budget for Parker Hannifin. The proposal does not meet the requirements of the RFP on Budget and Cost Share.

Summary and Recommendation:

The IOPS technology platform is a very innovative approach to image-guided, minimally invasive surgery, and the proposed timeline to achieve the technical development objectives seems realistic.

However, a key problem with this proposal is that it does not include any specific information about how a successful launch of the IOPS and its associated sensor-equipped wires and sensors will be accomplished. It also does not indicate how those products will be marketed and sold to achieve the RFP-required revenues at the end of Years 3 and 5. At the same time, because the IOPS technology represents a "breakthrough" approach for surgical guidance, the committee strongly encourages the IOPS team and its collaborators to apply for OTF funding when 510(k) approvals for the IOPS and its sensor-equipped devices have been achieved and CENS has received Series A funding and is staffed appropriately. The committee does not recommend that this proposal be considered for funds under the Ohio Third Frontier Innovation Platform Program.

OTF IPP 14-320
Gene Reprogramming Therapeutics
Cleveland Clinic

Proposal Summary:

Proposed Budget		
	State Funds	Cost Share
Operating Funds	$2,999,520	$3,091,354
Capital Funds	$0	$0
Subtotal	$2,999,520	$3,091,354
TOTAL	$6,090,874	

The proposed Gene Reprogramming Therapeutics (GRT) technology platform will commercialize novel epigenetic therapeutics and companion diagnostics for precision clinical applications in multiple biomedical domains, including regenerative, oncology, and general internal medicine. The goal is to achieve FDA approval and market entry for the technology platform in the disease indication of myeloproliferative neoplasm (MPN) within 3 years and for definitive progress toward FDA-approval in three other disease indications during the timeframe.

Cleveland Clinic (lead) plans to work with three client companies: NectAu, CompDx, and Pivot Drug, Inc. Pivot Drug is a start-up therapeutic company commercializing novel non-cytotoxic epigenetic therapeutics. CompDx is a startup diagnostic company commercializing companion biomarkers for precision clinical application of epigenetic therapeutics. NectAu is a startup nanotechnology company that will commercialize a novel nanolinker technology that allows linking a tissue-targeting peptide onto off-the-shelf drugs.

Detailed Review:

- **Technical Merit and Plan**

Although regenerative medicine is listed as the first priority for the platform, it is not clear that the area is a focus of the platform, because it is not discussed in detail. Oncological and internal medicine applications are described in more detail, and both therapeutic products and diagnostic assays are planned for both patient populations. Further, the description of a nanotechnology-based linker that may have applications in multiple medical areas is limited.

The lead product of the platform will be a new drug that consists of an orally delivered combination of decitabine and tetrahydrouridine. A clinical trial is already underway in a sickle cell population for phase 1 study of this lead product, and the results of this study will allow the initiation of phase 2 and three trials for the drug in a population of patients with MPN. In addition, companion biomarkers will be developed and validated in these same trials. Thus, the first commercial products will be the target drug for MPN treatment and associated diagnostic assays.

Further work is also described that is not expected to result in direct economic impact during the project period, but will rather lead to job creation and additional revenue beyond the project term. This work includes proof-of-concept clinical trials for both p53-mutated/deleted advanced solid tumor malignancy and high-risk uveal melanoma, ongoing clinical trials in sickle cell disease, and the development of nano-linked, erythroid-lineage targeted LSD1 inhibitor-erythropoietin mimetic peptide for Investigational New Drug-enabling studies.

The principle investigator has completed significant preclinical work and some clinical work using the target drug in MPN and sickle cell populations. The proposal outlines the strategy for completion of additional trials for both the MPN and sickle cell populations, although at the interview, the team stated that the details of these trials are still being finalized. The details for the work to be completed in the areas

of the companion biomarkers and the nano-linking technology were not well described in the proposal nor clarified in the interview. The proposal does not meet the requirements of the RFP on Technical Merit and Plan.

- **Commercialization Strategy**

The PI has one U.S. patent that covers the oral formulation of the combination drug, there is one issued patent related to in vitro stem cell expansion, and two other provisional patents are listed in the proposal, one for the nano-linking technology and another for a diagnostic for uveal cancer prognosis. The first issued patent has been licensed to one of the client companies.

The first goal of the platform is listed in the proposal as "achieving FDA approval and market entry for the technology platform in at least one disease indication within 3 years," which requires FDA approval of the lead drug for the MPN disease population or the diagnostics based on the associated biomarkers. Although significant preclinical and preliminary clinical work has been done, FDA approval times can be difficult to predict, and it is not clear that the timeline for New Drug Application submission and FDA approval of these products can be achieved. Market entry will not happen until some finite time after FDA approval, further extending the timeline. An additional concern is a competitor in this arena, Astex Pharmaceuticals, which has already begun a clinical trial with a very similar drug in a similar patient population. This established pharmaceutical competitor will be further along in generating the clinical data required for the FDA approval process and has longstanding experience in marketing and distribution of drugs, which may lead to a significant commercialization advantage.

Furthermore, the RFP states that an Ohio client must have the complete wherewithal to commercialize in Ohio in 3 to 5 years the resulting products, next-gen products, and product innovations for the platform. Because each of the clients are newly formed startups, it is not clear that they can meet this requirement.

For these reasons, the proposal does not meet the requirements of the RFP on Commercialization Strategy.

- **Performance Goals**

The Gene Reprogramming Therapeutics platform lead and client companies project to receive $22 million in revenues, federal grants, and equity funding by the end of Year 3, and $59 million by Year 5. The projected job creation numbers are that the platform will create at least 10 jobs by the end of Year 3 and 16 jobs by the end of Year 5. However, there are several concerns with these projections. It is not clear how these projections were estimated, because these details were not provided in the proposal, and the individuals representing the client companies at the interview were not able to provide sufficient clarification. The timeline for getting FDA approval for the lead drug is optimistic. Despite the preclinical and clinical work that has already been performed, there are several potential pitfalls that could delay FDA approval, including difficulty in recruitment for the clinical trials and difficulty in obtaining funding for the sickle cell clinical trial. There is insufficient work performed by the team on the companion biomarkers to instill confidence in the generation of marketable assays within the timeframe required to generate the revenues projected. The nano-linking technology is relatively immature, and the proposal did not provide enough details about the technical plan to judge whether the revenue projections for this client company are reasonable. For these reasons, this proposal does not meet the requirements of the RFP on Performance Goals.

- **Experience and Qualifications**

The principle investigator, Yogen Saunthararajah, MD, has been working on the lead drug and its application in cancer and sickle cell populations for many years and has significant experience in designing and leading clinical trials. The other key personnel listed in the proposal have complementary expertise that strengthens the platform. However, because the client companies are new and have not yet employed personnel, there is no way to judge the expertise at each of the client companies. Because the success of the platform depends on the clients, the expertise of both must be considered. For this reason, this proposal does not meet the requirements of the RFP on Experience and Qualifications.

- **Budget and Cost Share**

The cost share ratio for this project is 1.03, and the ratio of indirect operating funds to total operating funds is 8.4%, which is reasonable. The budget narrative lacks detail, however, making it difficult to fully evaluate. The proportion of funds residing with the lead applicant is of concern, as the RFP states that a supermajority of OTF funding should be provided to the lead applicant. According to the budget provided, only 50.28% of that funding will remain at the Cleveland Clinic/GRT (14-320 proposal pages 31-34). Furthermore, it is stated on page 4 of the proposal that "While the Clinic is the lead applicant for this proposal, all funds awarded by the State will be deployed directly to the . . . collaborators." The proposal does not meet the requirements of the RFP on Budget and Cost Share.

Summary and Recommendation:

Several focus areas are described in the beginning of the proposal, but the main foci of the development of therapeutics and diagnostics for several diseases is oncology and internal medicine. The proposed work and resulting products, if the work is successful, have the potential to improve lifespan and quality of life for patients with these diseases. However, there are several concerns with the proposal, which have been outlined above.

The most concerning areas of the proposed collaboration involve the client companies. The RFP clearly states that each team must include at least three for-profit client companies that are unrelated to each other and the lead applicant. The personnel listed as members of the client companies in the proposal and the representatives present at the interview are actually employees of either Cleveland Clinic or Innovations at Cleveland Clinic, and thus are *not* independent of the lead applicant. Furthermore, some of the personnel listed in the proposal as members of one client were present at the interview representing a different client. Thus, the clients do not appear to be independent of each other or the lead applicant.

Furthermore, the RFP states that each client must be an established Ohio for-profit company that has late-stage technical needs in bringing to market in Ohio a new product, next generation product, or new product innovations that can best be provided by the lead applicant. All of the clients are new start-ups, and it was mentioned in the interview that at least some of the clients do not have any employees at this stage. The clients must have the complete wherewithal to commercialize the resulting products, next-gen products, and product innovations in Ohio in 3 to 5 years, and these clients are not sufficiently established enough to demonstrate this capability. Because the client companies in this case do not meet the requirements of the RFP, the committee does not recommend that this proposal be considered for funds under the Ohio Third Frontier Innovation Platform Program.

Appendix C
Evaluation Worksheet

A. Technical Merit and Plan	**GRADE:**
1. **<u>Evaluate the degree to which technical challenges can be met</u>**	
2. Platform Description. Does the proposal align with the definition of a platform? A platform technology should have multiple applications in different fields, are these applications described in sufficient detail?	
3. Problem Statement: Does the Lead Applicant understand the eventual customer and market needs as well as performance requirements? If not, what does the Lead Applicant not understand? What performance requirements are missing?	
4. Project Goals and Objectives: Does the project have realistic goals and objectives? i. The goals should cover the Innovation Platform's near-term commercialization and innovation purposes that are driven by the Ohio for-profit company clients. If they do not, what is missing? ii. The objectives should be related to the commercialization, innovation, and new product development activities that will be performed for each opportunity and how they are expected to provide the evidence and proof needed to carry the technology forward into market entry. If they do not, what is missing?	
5. Technical Approach: a. How will goals and objectives be met? i. Proposal should include a comparison of research and development techniques, methods, facilities, and equipment with alternatives. If it does not, what is missing? ii. **<u>The description of the specific tasks should be detailed enough so that the technical approach can be clearly evaluated as to whether there is a credible plan for moving the technology from the current stage of development to the next. If they do not, what is missing?</u>** iii. How will progress be made and measured, how will risks or challenges be overcome, and how will the project generate the proof necessary to attract additional financial resources required to advance the technology toward successful commercialization? b. What are the project's deliverables and schedule? i. Do the deliverables include tangible evidence of commercialization, innovation and technical progress? ii. The schedule should graphically display the duration of tasks, interactions between the tasks, and the timing of deliverables and other key milestones in terms of weeks or months...Is the schedule realistic?	
6. Sustainability: Does the proposal include a plan beyond the 3 year time period for sustainable programs that will continue to utilize the Innovation Platform and its resources?	

B. Commercialization Strategy	**GRADE:**

1. Commercial Applications: Assess the platform's multiple commercial applications. Are they realistic?

2. Value Proposition. What are the specific value propositions of the different commercial applications? Is sufficient evidence provided to support the contention that the market values these benefits?

3. Potential for Products and Future Pipeline: Are the near-term (within 3 to 5 years) industry and economic impacts significant and realistic? **The Innovation Platform must have already achieved at least Proof of Principle**. What are the competitive advantages of the IPP's technologies or products over existing and alternative technologies? Assess the viability of post-Project period commercialization opportunities.

4. Management of Intellectual Property (IP). **Control and management of Intellectual Property (IP) are key success factors**. How will new Intellectual Property be managed to benefit Ohio-based companies?

5. Ability to Achieve Market Entry: Does the team understand the total resource requirements for achieving market entry and full commercialization, the type of knowledge that must be produced at the identified positioning stage, and who will likely be the funding providers for the market entry stage?

6. The Proposal describes several other elements of its commercialization strategy, are the descriptions credible? Assess the overall strength of these:

Financial Resources	Size of the Opportunity	Degree of Customer Readiness
Receptive Capital Markets	Ability to Leverage Ohio's Supply Chain	Potential for Leverage
Ability to Compete Globally	Degree of Sustainable Competitive Advantage	Investment and Time to Market

C. Performance Goals	**GRADE:**

1. Assess the platform's stated impact on Ohio in:
   a. job creation (for-profit, not-for-profit, retained);
   b. personal wealth (average salary of jobs created);
   c. new sales of products;
   d. follow-on investments and new industry funding for research and technical services that fit the Platform's mission

2. Appropriate to the technology being pursued, additional impact in Ohio should be assessed in the areas of: companies created or attracted to Ohio; talent recruitment; enhanced national and/or international recognition which leads to further interest and potential sources of funding and collaboration

3. **The Proposal must contain a realistic forecast of the economic impacts of the Innovation Platform**, including: direct employment, payroll, product revenue, and other leverage that will be achieved in three and five years. **Only direct impacts should be reported**. Note: The RFP clearly indicates that if the platform is an extension of, or related to, a prior Ohio Third Frontier Grant(s), then all economic impacts must be in addition to and separate from the impacts from every related project.

4. Performance on Prior OTF Awards: When appropriate, applicants must provide information related to their past performance. Based on these, identify any potential problems for the current project. Upon request, Ohio will provide the committee with data on past performance information including Semi-Annual Metrics Reports, Quarterly Reports, and the Final Report for every related prior grant.	
D. Experience and Qualifications	**GRADE:**
1. Do the Lead Applicant and Clients have the direct experience needed to perform both the technical and commercial work being proposed? If not, what is missing?	
2. Commercialization, scientific, collaborative, regulatory, and programmatic leadership experience must be demonstrated in the proposal. Leadership should be evident for IP protection, regulatory compliance, product development, leveraging of additional funding/investment capital, and commercialization.	
3. Who are the key personnel (technical director and commercialization director)? Do they have the required skills and experience to serve in their capacities? If not, what is missing?	
4. Management Plan: a. Proposal must discuss plans for internal means of communication, coordination of data and information management, evaluation and assessment of progress, allocation of funds and personnel, and other specific issues relevant to the proposed activities. If not, what is missing? b. Sub-awards: Assess the Lead Applicant's oversight plan for any sub-awards, particularly how the Lead will ensure both financial accountability as well as adherence to the Innovation Platform's scope of work.	
E. Budget and Cost Share	**GRADE:**
1. **Is the budget justified in a detailed narrative with the appropriate forms? Is it adequate to meet proposal goals? Is the cost share necessary and reasonable? If not, explain why not.**	
2. Cost Share: (at least 1:1 ratio with state funds) a. Refer to the RFP for more details b. **What form does the cost share take? Ohio gives preference to discretionary, unrestricted and unallocated cash cost share** c. **Cost Share must be in the form of cash** and must be for allowable costs that are verifiable d. Other OTF or other State funding may not be used as Cost Share for this Proposal e. **Proposed Cost Share must be firmly committed, with no contingencies or conditions, from known sources and available to the Innovation Platform at the time of Proposal submittal**	
3. Assess the detailed Budget Narrative: The narrative should cover an explanation of the costs for both the Ohio Third Frontier Funds requested and Cost Share committed. The value, purpose and sources of the Cost Share should be defined.	
4. Commitment letters must be provided from each Cost Share provider. The letters must address the nature and duration of the services to be received by the Client, how the platform will contribute to the strategy of the Client, and the specific amount and source of the Cost Share.	

Appendix D
Innovation Platform Program Definitions, Goals, and Critical Criteria

As outlined in the Ohio Third Frontier Innovation Platform Program Fiscal Year 2014 Request for Proposals (RFP),[1] the Ohio Development Services Agency anticipates awarding up to $21 million in Grants through the CY14 Innovation Platform Program. Development anticipates awarding 7 to 10 Grants through the Innovation Platform Program, with each Grant in the range of $1 million to $3 million. (p. 8).

Innovation Platform is defined as an already existing capacity that incorporates unique technology capabilities and strengths, talent, equipment, facilities, engaged industry partners, a track record of research commercialization and innovation, intellectual property and other resources in a particular technology area that collectively can serve as a vehicle for significant, industry-defined and directed opportunities through the development and commercialization of new products and innovations. To be considered a Platform Technology, there must be multiple applications to commercial products that are capable of being developed by independent Ohio for-profit companies (p. 5).

The purpose of the IPP is to link the development and innovation capabilities and capacities of an already established Innovation Platform and all its resources at an Ohio college or university or not-for-profit research institution to specific late stage development and innovation needs of Ohio companies. This linkage must in turn lead to job creation and business opportunities within Ohio through development and commercialization of product innovation, next generation products and new products that will have beneficial long-term economic impacts for Ohio (p. 5).

A **major goal** is to catalyze collaborations in technology commercialization, innovation and product development between the State's colleges and universities and Ohio industry. The Innovation Platform Program supports this goal by offering Grants to provide funding for operations, capital equipment and facility costs of existing Innovation Platforms that will benefit commercial purposes in the short-term and contribute to the sustainability and industrial relevance and use of the Innovation Platform in the long-term (p. 5).

The specific goal of the IPP is to support commercial partnerships involving an Innovation Platform at a single Ohio college, university or other not-for-profit research institutions, and Ohio for-profit companies. Partnerships are to be formed to further the near-term (within 3 to 5 years of the start of the Project Period) commercialization of product innovation, next generation products and new products (p. 5, revised).

The **objectives of IPP** are:

- To support existing Innovation Platforms at Ohio colleges, universities or not-for-profit research institutions that will serve specifically defined near-term commercialization objectives of 3 or more non-related Ohio for-profit companies;

[1] Ohio Third Frontier Innovation Platform Program Fiscal Year 2013 Request for Proposals (RFP), available at http://development.ohio.gov/files/otf/FY2013%20OTF%20IPP%20RFP%20-%20Final.pdf, p. 5.

- To support Innovation Platforms that will develop and launch new products, innovations or services into the commercial market within 3 to 5 years of the Project start date among all of those 3 or more non-related Ohio for-profit companies;
- To kick-start the long-term, sustained use of the Innovation Platform by multiple Ohio industry partners; and
- To support Innovation Platforms that will create wealth and employment opportunities within Ohio. (p. 6).

Each Proposal must address at least one or a combination of the following technology areas:

- Advanced Materials related to advanced polymers, ceramics, composites, carbon fibers and nanotubes, and specialty metals and alloys
- Aeropropulsion Power Management
- Fuel Cells and Energy Storage
- Medical Technology related to imaging, surgical instruments/equipment, implant devices and regenerative medicine
- Software Applications for business and healthcare
- Sensing and Automation Technologies
- Situational Awareness and Surveillance Systems
- Solar Photovoltaics
- Agribusiness and Food Processing
- Shale (pages 6-7)

A Lead Applicant is the entity that submits a Proposal and will be legally and financially responsible for the administration of any resulting award of Ohio Third Frontier Funds. The Lead Applicant will be responsible for the administration of the Proposal should it be awarded. The Lead Applicant must also serve as administrative director of the Innovation Platform. The technical direction of the Innovation Platform is to be determined and controlled by the Ohio for-profit Client companies (p. 7).

A Client is an Ohio for-profit company that is not an affiliate of the Lead Applicant is contributing cash Cost Share and will utilize the platform to develop and commercialize new product, new product innovations and next generation products.

Proposals must include Client service relationships with at least 3 unrelated Ohio for-profit companies. Three is an absolute minimum; strong proposals will have 4 or more Clients. All Clients must be represented by a lead individual and submit an itemized budget on Budget Form 2 (see Appendix C – Application Forms and Budget Forms). A Client must be designated on Budget Form 2 to contribute cash Cost Share.

The Clients must have the capability for commercializing any resulting product innovation, next generation products and new products and be committed to the long-term commercialization of the technology. A contribution of cash Cost Share resources by a Client is strong evidence of that commitment. Proposals must have a minimum of 50% of the cash Cost Share contributed by the Client Ohio for-profit companies. Strong Proposals will have a super majority of cash Cost Share contributed by the Client Ohio for-profit companies as evidence of their commitment to the value of the technology platform. Teams with strong commercialization structures are required. Any commercialization that results must benefit Ohio through investment, sales, job creation and/or business capitalization (p. 8, revised).

A committed end-user is a business or governmental entity that has a commercial interest in, and

commits to commercial application of, the results of the Innovation Platform. A committed end-user may submit a letter consistent with the directions of Section 3.3.12. Committed end-users do not require designation on Budget Form 2 (p. 8).

Term of the Project is the plan of activity or activities that make up the total scope of work for which an award of Ohio Third Frontier Funds is requested and for which a Proposal is approved. The Project Period during which the active work funded by the Grant will take place shall be no more than 3 years. For an additional 2 years, annual reports detailing the overall status of commercialization and innovation activities and the economic impacts of the Innovation Platform will be required (p. 9).

Evaluation Criteria: Only the most meritorious proposals are sought for funding. Proposals will be evaluated based on responsiveness to all the requirements of this RFP and on the Lead Applicant's response to any additional information that may be requested. Implicit in those requirements and evaluation criteria is the quality of the Proposal and budget (p. 22).

Specific criteria designated in the RFP with the highest relevance to and weighting for the IPP:

- Alignment of the Proposal with the Innovation Platform Program purpose, goals, objectives, eligibility, funding and Cost Share requirements as described in Section 2 of this RFP.
- Quality of the responses to the requirements of this RFP as outlined in the Statement of Work, including the Platform Information, the Commercialization Strategy, Performance Goals, Experience and Qualifications and Budget. The following specific elements of the Proposal will be examined:
  - Fit with the definition of a platform as defined in Section 2.1
  - Commitment of Ohio for-profit company Clients as evidenced by their contribution of cash Cost Share
  - Evidence of a sustainable pipeline of commercialization opportunities
  - Degree to which technical challenges can be met
  - Degree to which applicant has a protected position with respect to their proposed technology
  - Quality and likely achievability of the commercial path to market
  - Financial stability of the Ohio for-profit company Clients who will take the technologies to the market
  - Degree to which this Innovation Platform will help build the State's supply chain and overall technology cluster
  - Impact of the Innovation Platform in terms of additional revenue and employment in 3 and 5 years
  - Realism and achievability of the proposed business model
  - Sustainability and continued relevance and likely use of the innovation platform by Ohio industry
- Compliance with this RFP's administrative requirements.
- If applicable, the current economic impact of previous related Ohio Third Frontier Grant(s).
- The evaluation criteria are designed to support the mission and goals of Ohio Third Frontier and its various programs. (pp. 22-23).

Cost Share:

It is required that a super majority, or more, of Ohio Third Frontier Funds remain with the Lead Applicant to support the Innovation Platform's work for its Clients as well as on collaborative projects for the platform's Clients, the Ohio for-profit companies (p. 7).

Cost Share Requirements—Magnitude: The monetary value of the cash Cost Share commitment must be $1 for every $1 of Ohio Third Frontier Funds requested (i.e., a ratio of 1:1). All Cost Share must be identified in the Proposal by amount, proposed use and source. If the Cost Share ratio reflected in a Proposal exceeds 1:1, the higher Cost Share ratio will be used as a requirement for a Grant awarded to that Proposal. The amount of Cost Share committed by Ohio for-profit company Clients will be a requirement of the Grant awarded and cannot later be reduced. (p. 19).

Cost Share Requirements—Sources and Uses: Cost Share must be in the form of cash and must be for allowable costs that are verifiable and auditable. Cost Share must be used directly in support of the Innovation Platform rather than for coincidental or related/similar allocations. Cost Share must be necessary and reasonable to support the Innovation Platform objectives.
If an organization has a published Indirect Cost rate, un-recovered Indirect Costs (the difference between 20% and the published rate) may be used as Cost Share. Only Indirect Costs not fully recovered from the requested Ohio Third Frontier Funds are eligible to be used as Cost Share. Please note, a published Indirect Cost rate must be published as part of the general policies of the organization and applied uniformly to all grants or contracts. A federally negotiated and approved Indirect Cost rate is one form of a published Indirect Cost rate.

In those cases where the Lead Applicant does not have a published Indirect Cost rate agreement, the Lead Applicant is limited to using 20% of its Cost Shared direct costs as Cost Shared Indirect Costs and no other un-recovered Indirect Costs from the operating budget may be claimed.

The expense of the Cost Share must take place during the Project Period. Cost Share must be charged to resources of the Lead Applicant or Client and documented within the financial books of the Lead Applicant or Client, as the context requires (p. 20).

Cost Share Requirements–Constraints: Resources that have already been designated as Cost Share for some other award cannot be used as Cost Share for an Innovation Platform Program award. The Cost Share must be applied to the Innovation Platform during the Project Period. Expenses incurred outside of the Grant Period do not count toward the Cost Share requirement.

The Lead Applicant is solely responsible to have adequate funds to cover all expenses of the Innovation Platform not covered by the Ohio Third Frontier Funds awarded. **Please note, the cash Cost Share proposed by the Lead Applicant and all Clients must be firmly committed, with no contingencies or conditions, from known sources and available to the Innovation Platform at the time of Proposal submittal** (p. 20).

Appendix E
Biographical Sketches of Committee Members and Staff

COMMITTEE MEMBERS

T.S. SUDARSHAN, *Chair*, is president and CEO of Materials Modification, Inc. He is responsible for the management and technical development of innovative materials, processes, and techniques and the development of new technologies related to surface engineering and nanotechnology. He has raised more than $40 million in government agency and industrially sponsored programs centered on high-risk, high-payoff advanced technology proposals that were awarded through competition and in non-traditional areas. Dr. Sudarshan has been the recipient of numerous awards and honors, including the Outstanding Young Manufacturing Engineer award from SAE International, Design News Award and R&D 100 for the microwave plasma technique Nanogen and for the Plasma Pressure Compaction technique. He has served on numerous committees of the National Science Foundation, National Institutes of Health, Department of Energy, U.S. Army, Michigan Economic Development Council, and ASM International–The Materials Information Society. He currently serves as a trustee for ASM International. He has also served on the technical advisory boards of numerous companies over the past two decades. Dr. Sudarshan is the editor of the journals *Materials and Manufacturing Processes* and *Surface Engineering*. He is a fellow of ASM International, the International Federation for Heat Treatment and Surface Engineering and the Institute of Mining, Metallurgy and Materials, and distinguished alumnus of IIT Madras. Dr. Sudarshan received his B.Tech. in metallurgy from the Indian Institute of Technology in Madras, India, and his M.S. and Ph.D. degrees in materials engineering science from the Virginia Polytechnic Institute and State University. In the area of surface modification technologies, he has published 30 books and more than 175 papers and holds more than 20 patents. He has previously been involved with several National Research Council (NRC) activities, including committees that reviewed proposals for the State of Ohio (2008 and 2009 as a member and 2010-2013 as chair); the Committee on Small Business Innovative Research to Support Aging Aircraft; the Committee on Review of the National Nanotechnology Initiative; and the Committee on Lightweight Materials for Army Applications, and he has been a member of the National Materials Advisory Board.

CATHERINE G. AMBROSE is an associate professor and director of research of the Department of Orthopaedic Surgery at the University of Texas Health Science Center at Houston. She is also the director of the Orthopaedic Biomechanics Laboratory at the University of Texas Medical School at Houston. Dr. Ambrose also serves as an adjunct associate professor of bioengineering at Rice University, an adjoint associate professor of biomedical engineering at the University of Texas, Austin, and as a member of the scientific staff at Shriners Hospitals for Children in Houston. Her research interests are in material property assessment for orthopaedic materials, including bone, cartilage, ligaments, and tendons; biodegradable materials for orthopaedic applications; diagnosis and treatment of metabolic bone diseases, including osteoporosis and osteogenesis imperfecta; and in vitro and in vivo models for orthopaedic applications. She received her B.S. in mechanical engineering from Washington University and her M.S. in biomedical engineering and Ph.D. in mechanical engineering from the University of Texas, Austin.

DAVID E. ASPNES is a Distinguished University Professor in the Department of Physics at North Carolina State University. He is also a member of the Department of Physics of KyungHee University, Seoul, as part of a World Class University appointment by the Republic of Korea. He received his Ph.D. in physics from the University of Illinois, Urbana-Champaign. Following a year as a postdoctoral

research associate at the University of Illinois and another at Brown University, he joined Bell Laboratories in Murray Hill, New Jersey, as a member of the technical staff. Dr. Aspnes then became head of the Interface Physics Department in the newly created Bellcore, the part of Bell Laboratories associated with the operating companies in the AT&T divestiture. He joined North Carolina State University as a professor of physics and was named Distinguished University Professor of Physics in 1999. Dr. Aspnes is best known for his experimental and theoretical contributions to the development and application of optical techniques for the analysis of materials, thin films, interfaces, and structures. These include the theory and practice of spectroscopic ellipsometry, modulation spectroscopy, reflectance-difference spectroscopy, and materials and interface analysis using nonlinear optics. He is a member of the National Academy of Sciences and has served on various NRC committees, including the Committee on Airport Passenger Screening Backscatter X-Ray Machines, the Committee on NIST Technical Programs Panel on Manufacturing Engineering, and the Committee on NIST Technical Programs Panel on Chemical Science and Technology.

ENRIQUE C. BRITO is a partner at Tatum, LLC. He has served as strategy advisor, senior managing director, principal, and director of corporate finance at public and private companies in the healthcare, investment banking, aerospace and defense, telecommunications, and manufacturing industries. He specializes in advisory services focusing on preparing organizations for exit strategies and liquidity events; executing growth plans involving acquisitions, post-transaction integrations and capital raises; and implementing operational improvement and value maximization strategies.

CAROL CHERKIS is a life sciences industry consultant at NewCap Partners, Inc. With more than 30 years of experience in that industry, she supports the investment banking firm's efforts by helping its clients in that industry to identify partner companies for mergers and acquisitions, strategic alliances, and corporate equity investments. Dr. Cherkis is also the president of BioInfoStrategies, a consulting firm that she founded after a 20-year multi-functional career with Dow Chemical Company where her advisory services focus on assisting small and medium-sized, fast-growing companies in biotechnology/pharmaceuticals, diagnostics, medical devices, mobile, and IT-health, regenerative medicine, biochemical reagents, and the biology-related areas of cleantech (biodetection/instrumentation and production of chemicals and biomaterials from biomass) with assessing the commercial feasibility of their technologies, developing and implementing business strategies, and establishing licensing, co-development, marketing, and distribution alliances. Her client base includes government agencies, start-ups, and well-established companies. She has and continues to serve as a director on company boards. Recently, her efforts have focused on work with companies and or government groups in the United States, China, Japan, Canada, and Brazil. Dr. Cherkis started her career with Dow Chemical Company. After 10 years as a scientist and research manager, she moved into the company's business functions. In her last position at Dow, she was the Biotechnology Program director in the Corporate Ventures Group and had global responsibility for identifying small and medium-sized companies as sources of new technology as well as corporate partners to expedite market penetration of existing and future products. Later, she served as the director of healthcare at Frost & Sullivan. Dr. Cherkis has a Ph.D. in biological chemistry from the University of Michigan Medical School and an A.B. in biology from Bryn Mawr College. She previously served on the 2011, 2012, and 2013 NRC committees that reviewed proposals for the State of Ohio.

BRUCE D. GITTER is professor of pharmacology at Indiana University School of Dentistry. He also serves as adjunct professor of radiology and imaging sciences at Indiana University School of Medicine. In addition, Dr. Gitter serves as a scientific consultant for the pharmaceutical industry, focusing on neurodegenerative and psychiatric diseases drug discovery, neuroimaging, nuclear medicine technologies, and neuropharmacology. In his previous position as senior principal scientist/manager at Covance, Dr. Gitter led the Nuclear Medicine Department with responsibilities for in vivo and ex vivo nuclear medicine imaging, focusing principally on pre-clinical neuroscience, cardiovascular, diabetes, and cancer models.

His team used small-animal PET imaging, autoradiography, membrane receptor pharmacology, and immunohistochemistry to examine neurodegenerative changes in rodent disease models and pharmacodynamic effects of drugs in the central nervous system. His team was also responsible for discovering and validating novel tracer biomarkers for multiple therapeutic applications. Prior to joining Covance in 2008, Dr. Gitter worked on drug discovery and development at Eli Lilly & Co., for 25 years. During his career, he has issued 10 U.S. patents, authored or co-authored 41 peer-reviewed scientific publications, and served as a peer reviewer for multiple neuroscience and pharmacology journals. Dr. Gitter received his B.S. in biochemistry and chemistry, M.S. in microbiology, and Ph.D. in immunoparasitology from the University of Georgia.

SRINIVAS IYER is the group leader of Bioenergy and Biome Sciences at the Los Alamos National Laboratory (LANL). In this capacity, he is responsible for the day-to-day functioning of a 60-member research group, establishing research directions, providing business stewardship, and managing the funding portfolio. Dr. Iyer also maintains his scientific interests in biological mass spectrometry. He directs the LANL proteomics facility and is involved in multiple projects funded by Department of Energy and Department of Defense. Dr. Iyer is currently establishing a new ion mobility mass spectrometry capability to support the analytics for a Defense Threat Reduction Agency funded artificial organ platform. He also maintains an interest in lipid based biomaterial assemblies. Dr. Iyer performs reviews for National Institutes of Health and several journals. He is also one of the co-founders of the Biotechnology track at the TechConnect and Nanotech Conference series. He obtained his Ph.D. in biochemistry from the University of Houston.

JAHAN K. JEWAYNI is an independent consultant who works as a financial advisor with a national financial advisory firm. His practice focuses on advising middle-market companies in the $10 million to $150 million revenue range. Mr. Jewayni has over 20 years of experience in finance and operations of companies ranging from start-ups to Fortune-500 companies. His work covers areas such as renewable energy, satellite communications, consumer electronics, commercial real estate, consumer products, and non-profits. Specifically in the renewables area, he reviews dozens of executive summaries and business plans per year for companies seeking seed capital, growth capital, and advisory services. Some of the recent opportunities involved a concentrated solar power company, a small-scale utility solar installation company, and a fund that would build energy-efficient, low-income housing communities in developing countries. Prior to his work in the financial services industry, Mr. Jewayni spent more than a decade as a small business owner and financial consultant to small and medium enterprises. He is actively involved with a number of non-profits and is a board member of Devotion to Children, an organization focused on helping children from economically disadvantaged families. Mr. Jewayni earned a B.S. in accounting from the Robert H. Smith School of Business at University of Maryland and became a Certified Public Accountant in 1995. Additionally, he is a Certified Financial Planner™ certificant, a designation awarded by the Certified Financial Planner Board of Standards, Inc.

SHALINI PRASAD is the Cecil and Ida Green Professor in Systems Biology and associate professor of bioengineering at University of Texas, Dallas. Dr. Prasad is also the associate department head of Bioengineering at University of Texas, Dallas. She holds an adjunct appointment in the Department of Physics at Portland State University. Dr. Prasad is the director of the Biomedical Microdevices and Nanotechnology Laboratory, which has supported over 100 researchers. Dr. Prasad's research laboratory has been actively participating in developing translational technologies for affordable molecular diagnostics platforms. Her research work has been supported by a number of federal and state agencies as well as corporate entities. She has more than 100 peer-reviewed publications. Dr. Prasad received her B.E. from the University of Madras, India, in electronics and communication engineering. She obtained her Ph.D. degree in electrical engineering from the University of California, Riverside.

JAMES C. STEVENS is the Dow Distinguished Fellow in the Core Research and Development Department of The Dow Chemical Company, where he has worked for 35 years. His primary field of research is in the area of new catalysts, particularly in the area of polyethylene, polypropylene, ethylene/styrene copolymers, and the combinatorial discovery of organometallic single-site catalysts. Dr. Stevens has been involved with the discovery and commercial implementation of Dow's INSITE Technology and Constrained-Geometry Catalysts, which are used in the production of more than 2 billion pounds of polyolefins per year. He is a member of the National Academy of Engineering, an inventor on 102 issued U.S. patents and more than 1,100 foreign patents, has 18 publications, and is the editor of two books. He won the Dow "Inventor of the Year" award five times and was presented with the Dow Central Research "Excellence in Science" Award. In 1994, Dr. Stevens was a co-recipient of the U.S. "National Inventor of the Year" Award, presented in the U.S. Congress. In 2002, The Dow Chemical Company was awarded the National Medal of Technology by President George Bush, based in part on the work of Dr. Stevens in the area of olefin polymerization catalysis. He is the 2004 recipient of the American Chemical Society (ACS) Delaware Section Carothers Award, honoring scientific innovators who have made outstanding advances and contributions to industrial chemistry. He was awarded the ACS Award in Industrial Chemistry in 2006. Dr. Stevens also received the Herbert H. Dow Medal, the highest honor Dow awards to the company's scientists and researchers. He recently was awarded the 100th presentation of the Perkin Medal, widely considered to be the highest honor in American industrial chemistry. Dr. Stevens was the 2007 recipient of the University of Chicago Bloch Medal. He received a B.A. in chemistry from the College of Wooster and obtained a Ph.D. in inorganic chemistry from Ohio State University. He has previously served on the NRC Committee on the Review of Basic Energy Sciences Catalysis Program.

NORMAN M. WERELEY is the Minta Martin Professor and chair at University of Maryland, College Park. Previous to that, he served as techno-sciences professor and associate chair of aerospace engineering. His research interests are in dynamics and control of smart structures, with emphasis on active and passive vibration isolation and shock mitigation applied primarily to rotorcraft as well as other aerospace and automotive systems. A key focus of his research is the theory and application of magnetorheological (MR) fluids and semi-active MR dampers and their application to occupant protection, vibration isolation, and stability augmentation systems using advanced feedback control strategies. Dr. Wereley's research has been funded under a U.S. Army Research Office Young Investigator Award and a National Science Foundation CAREER Award, as well as grants from the Defense Advanced Research Projects Agency, the Army Research Laboratory, the Air Force Office of Scientific Research, NASA, the Office of Naval Research, and numerous corporations. Dr. Wereley has published more than 140 journal articles, 10 book chapter contributions, and more than 230 conference articles. Dr. Wereley is a co-inventor on 10 patents, with more than a dozen patents pending. Dr. Wereley serves as editor of the *Journal of Intelligent Material Systems and Structures* as an associate editor for the Institute of Physics' journal *Smart Materials and Structures* and *AIAA Journal*. He is currently serving as chair of the SPIE Symposium on Smart Structures. Dr. Wereley was awarded the American Society of Mechanical Engineers (ASME) Adaptive Structures and Adaptive Materials Best Paper Award and was named the American Institute of Aeronautics and Astronautics (AIAA) National Capital Section Engineer of the Year. He was also awarded the A. James Clark School of Engineering Faculty Service Award and the AIAA Sustained Service Award. Most recently, Dr. Wereley was awarded the Harry T. Jenson Award from the American Helicopter Society for contributions to active crash protection systems in helicopters (team award with Boeing, U.S. Army, Honeywell, and the University of Maryland). Dr. Wereley will be awarded the ASME Adaptive Structures and Materials Systems Prize. He is a fellow of AIAA, ASME, and the Institute of Physics and a lifetime member of the American Helicopter Society. Dr. Wereley holds a B.E.in mechanical engineering from McGill University in Montreal, Canada, and M.S. and Ph.D. degrees in aeronautics and astronautics from the Massachusetts Institute of Technology.

J.W. (JIM) WHEELER recently formed PQR Energy, LLC, a management consulting firm formed to address critical energy challenges facing state and local governments, educational institutions, and other groups in need of implementing long-term energy reduction solutions. PQR's goal is to help their customers become smart buyers of energy solutions. Mr. Wheeler's immediate prior position was senior vice president, economic competitiveness policy and research for Thomas P. Miller and Associates (TPMA). Prior to joining TPMA, he was the Midwest lead for Electricore, where he was charged with developing corporate-university partnerships in advanced technology development. Previously, as executive vice president for TechPoint—a merger between Indiana Technology Partnership (ITP) and Indiana Information Technology Association—and as president of ITP, Mr. Wheeler served as a leader for the Indiana technology community's public policy and economic development initiatives. He has a diverse background in economic development, research, strategy and planning, public policy, and technology programs. He has previously served on several NRC committees that reviewed proposals for the state of Ohio.

STAFF

DWAYNE DAY, *Study Director*, is a senior program officer with the ASEB. Dr. Day started with the Space Studies Board (SSB) in 2005 before joining the Aeronautics and Space Engineering Board (ASEB). He has served as the staff officer and study director for NRC studies on the assessment of space radiation hazards to astronauts, the future of NASA's workforce, Air Force space object tracking, and 3D printing in space. Prior to joining the SSB, he worked as an investigator for the Columbia Accident Investigation Board. He has a Ph.D. in political science from George Washington University, specializing in space and national security policy. Dr. Day is the author of *Lightning Rod*, a history of the Air Force chief scientist's office; has co-edited or edited several books and journal issues, and has written on American civil and military space policy and history. Prior to that, he worked for the Congressional Budget Office and at George Washington University's Space Policy Institute.

ANDREA M. REBHOLZ joined the ASEB as a program associate in 2009. She began her career at the National Academies in 2005 as a senior program assistant for the Institute of Medicine's Forum on Drug Discovery, Development, and Translation. Prior to the Academies, she worked in the communications department of a D.C.-based think tank. Ms. Rebholz graduated from George Mason University's New Century College in 2003 with a B.A. in integrative studies–event management and has more than 7 years of experience in event planning.

MICHAEL H. MOLONEY is the director of the SSB and the ASEB at the NRC of the National Academies. Since joining the NRC in 2001, Dr. Moloney has served as a study director at the National Materials Advisory Board, the Board on Physics and Astronomy (BPA), the Board on Manufacturing and Engineering Design, and the Center for Economic, Governance, and International Studies. In his time at the ASEB/SSB Dr. Moloney has overseen the production of more than 30 reports, including three decadal surveys—in planetary science, life and microgravity science, and solar and space physics, a prioritization of NASA space technology roadmaps, as well as reports on issues such as NASA's Strategic Direction, orbital debris, the future of NASA's astronaut corps, and NASA's flight research program. Before joining the SSB and ASEB in 2010, Dr. Moloney was associate director of the BPA and study director for the decadal survey for astronomy and astrophysics (Astro2010). With 12 years' experience at the NRC, Dr. Moloney has served as study director or senior staff for a series of reports on subject matters as varied as quantum physics, nanotechnology, cosmology, the operation of the nation's helium reserve, new anti-counterfeiting technologies for currency, corrosion science, and nuclear fusion. In addition to his professional experience at the Academies, Dr. Moloney has more than 7 years' experience as a foreign-service officer for the Irish government—including serving at the Irish Embassy in Washington and the Irish Mission to the United Nations in New York. A physicist, Dr. Moloney did his Ph.D. work at Trinity

College Dublin in Ireland. He received his undergraduate degree in experimental physics at University College Dublin, where he was awarded the Nevin Medal for Physics.