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## Technology Validation and Start-Up Fund

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### Round 5 Submittal Evaluations

Submitted: FEB 2014

Submitted To:

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## EXECUTIVE SUMMARY

YourEncore was selected as the contractor to perform the review process based upon having over 7,000 subject matter experts with a collective average of over 25 years of experience. For each of the ten areas of “project focus” a technical expert was selected to review the proposals. Once the technical review was complete, a business reviewer and senior YourEncore managers reviewed each proposal. These experts have diverse backgrounds and a plethora of experience that make them ideally suited to review the proposals and recommend where the state of Ohio should invest to achieve maximum benefit to the state’s economic development goals.

For Round 5, a total of 46 requests for funding were submitted to OTF’s Technology Validation and Start-Up Fund, 28 for Phase 1 and 18 for Phase 2. This is the highest number of requests received to date, though likely driven by a relatively large gap between rounds as compared to prior rounds. Of these 46 requests, 12 requests in Phase 1 (43%) and 6 in Phase 2 (33%) were recommended for funding to OTF by the expert Review Team. Three additional Phase 2 proposals (17%) are conditionally recommended upon successful completion of identified essential actions by the applicants. As with the first four rounds, the Review Team was composed of subject matter experts in each field of technology, a business reviewer, and YourEncore senior managers. The Review Team evaluated each proposal based on the information submitted for review, and according to the criteria specified by OTF.

Proposal quality varied widely, from highly professional and complete to unfocused and incomplete. Some were not well constructed and confusing, while others made ambitious but unsubstantiated claims, giving the impression that involvement from university TTOs may have been less rigorous than expected.

A total of 11 applications not previously recommended for funding were resubmitted in this round. Four of seven Phase 1 reapplications are recommended, and two of four Phase 2 resubmissions are recommended with one additional Phase 2 resubmission recommended as conditional. More than one third of these resubmissions still do not meet the full criteria necessary for approval. Therefore, teams that plan on resubmission are encouraged to take advantage of the opportunity to debrief with the review team to discuss potential improvements, as this may help clarify and focus the comments offered in this report.

Generally, the technologies as proposed are sound, and most requests that were not recommended for funding were lacking in fundamental elements of business strategy. Phase 1 proposals not recommended for funding (with one exception) were either deficient in Generation of Proof (11 of 28 had this fatal flaw) and/or Path to Market (7 of 28). While Generation of Proof can be a technical issue, for most applications it was a business issue; that is, even if technical goals are met for the project, those goals are insufficient to validate the technology. Deficiencies in the latter category were most often linked to a poorly articulated sales channel and marketing plan, though in some instances it was apparent that a viable market simply does not exist. Phase 2 proposals not recommended for funding were nearly all deficient, at least to an extent, in their business model, which is a continuing theme from earlier rounds. The review team saw a lack of adequate preparation and understanding of market dynamics, pricing, or the basic business model itself, meaning, the product, license or royalty structure, partner model, etc. were poorly defined.

Grant dollars recommended for funding is approximately \$1,162,000 with an additional \$300,000 conditional for a potential total of \$1,462,000 for this round, versus \$950,000 for round 1, \$900,000 for round 2, \$610,000 for Round 3, and \$864,000 for round 4. High dollar amounts reflect the largest number of applications to date as a result of the long period since the previous cycle. There were two grants recommended that did not submit their request for the maximum allowable amount.

*THE PHASE 1 PROPOSALS THAT ARE RECOMMENDED FOR FUNDING*

Phase	PROPOSAL #	LEAD APPLICANT	PROJECT TITLE	PROJECT FOCUS	Total Project Budget	OTF Funds Requested
1	13-501	Cleveland Clinic	<i>Reinforced Extracellular Matrix Device for Ventral Hernia Repair</i>	Medical Technology	\$100,000	\$50,000
1	13-504	Ohio University	<i>A Matlab Toolkit for 3D Visualization of Real and Synthetic Flight Data</i>	Situational Awareness & Surveillance	\$100,000	\$50,000
1	13-506	University of Akron	<i>OXAID: Oxygenated Hydrogel Wound Dressings</i>	Medical Technology	\$100,000	\$50,000
1	13-507	University of Akron	<i>Mechanoluminescence Sensors</i>	Sensing & Automation Technology	\$100,000	\$50,000
1	13-509	University of Akron	<i>Smart Phone Based Universal Water Quality Sensor</i>	Sensing & Automation Technology	\$100,000	\$50,000
1	13-512	Ohio State	<i>Single-Chain Antibodies for Immunohistochemistry Cancer Diagnosis</i>	Medical Technology	\$100,000	\$50,000
1	13-515	Kent State	<i>End-Effector and Robot Workcell for Automated Assembly of Fuel Cell Stacks Using Robotic Technology</i>	Fuel Cells & Energy Storage	\$53,232	\$26,616
1	13-516	Cleveland Clinic	<i>Endovascular IOPS: Validation of Dual-Modality Registration Markers</i>	Medical Technology	\$100,000	\$50,000
1	13-523	University of Toledo	<i>Ankle Foot Orthosis Using Shape Memory Alloys for Addressing Foot Drop</i>	Advanced Materials	\$100,000	\$50,000
1	13-525	University of Akron	<i>Aqueous Biphasic Tumor Spheroids for Drug Discovery</i>	Medical Technology	\$100,000	\$50,000
1	13-526	Case Western	<i>Software for Quantification and Visualization of Intravascular Optical Coherence Tomography</i>	Medical Technology	\$100,000	\$50,000
1	13-528	Kent State	<i>Smart Energy Saving Liquid Crystal Window</i>	Advanced Materials	\$70,008	\$35,004

***THE PHASE 2 PROPOSALS THAT ARE RECOMMENDED FOR FUNDING***

Phase	PROPOSAL #	Licensing Institution	LEAD APPLICANT	PROJECT TITLE	PROJECT FOCUS	Total Project Budget	OTF Funds Requested
2	13-532	Ohio State	SimpleFill, Inc	<i>SimpleFill - High Pressure Natural Gas Compression</i>	Fuel Cells & Energy Storage	\$115,000	\$100,000
2	13-535	University of Cincinnati	MicrobeCapture, LLC	<i>Novel Rapid Diagnostic Assay for Influenza</i>	Medical Technology	\$282,068	\$100,000
2	13-537	University of Toledo	IRISense, LLC	<i>IRISense, LLC</i>	Medical Technology	\$100,000	\$100,000
2	13-538	Ohio State	ProteoSense, LLC	<i>Commercialization of ImmunoFET Sensors for Food Safety Pathogen Detection</i>	Sensing & Automation Technology	\$148,600	\$100,000
2	13-542	University of Akron	Akron Surface Technologies	<i>Surface Treatment Platforms</i>	Advanced Materials	\$100,000	\$100,000
2	13-546	Ohio State	3Bar Biologics, Inc	<i>Commercializing Biological Inoculants to Increase Yield in Production Agriculture</i>	Agribusiness	\$100,000	\$100,000

***THE PHASE 2 PROPOSALS THAT ARE RECOMMENDED FOR CONDITIONAL FUNDING***

Phase	PROPOSAL #	Licensing Institution	LEAD APPLICANT	PROJECT TITLE	PROJECT FOCUS	Total Project Budget	OTF Funds Requested
2	13-534	University of Cincinnati	Eccrine Systems, LLC	<i>Wearable Blue Tooth Sweat Sensor Prototype</i>	Sensing & Automation Technology	\$200,000	\$100,000
2	13-541	Ohio State	QuTel, Inc	<i>Quantum Tunneling Electronics for Ultra-Low Power Electronics</i>	Advanced Materials	\$100,000	\$100,000
2	13-545	University of Toledo	Spinal Balance, Inc	<i>Facet Screw System</i>	Medical Technology	\$100,000	\$100,000

## PROPOSAL RECOMMENDATIONS - PHASE 1 SUMMARY MATRIX

PROPOSAL #	Licensing Institution	PROJECT TITLE	Q1	Q2	Q3	Q4	Q5	Q6	Q7	Q8
			Generation of Proof to be Licensed	Project Plan / Team (1 Year)	Independent 3rd Party Review	Reasonable Path to Mkt	IP Protection	Start-up in Ohio	Market Opportunity / Size	Budget Narrative / Use of Funds
13-501	Cleveland Clinic	Reinforced Extracellular Matrix Device for Ventral Hernia Repair	Green	Green	Yellow	Yellow	Green	Green	Yellow	Green
13-502	Cincinnati Children's	Antibody for Prevention of Catheter Line Infection and Biofilm Growth	Red	Yellow	Yellow	Red	Green	Yellow	Red	Red
13-503	Ohio University	Development of a New Versatile LC/MS Interface via Non-Destructive Mass Spectrometric Sensing	Red	Yellow	Red	Yellow	Green	Yellow	Green	Green
13-504	Ohio University	A Matlab Toolkit for 3D Visualization of Real and Synthetic Flight Data	Green	Green	Green	Green	Green	Green	Green	Green
13-505	Austen BioInnovation Institute in Akron	Digital Dx	Green	Green	Yellow	Yellow	Green	Green	Red	Green
13-506	University of Akron	OXAID: Oxygenated Hydrogel Wound Dressings	Green	Green	Yellow	Yellow	Green	Green	Green	Green
13-507	University of Akron	Mechanoluminescence (ML) Sensors	Green	Green	Green	Green	Green	Green	Yellow	Green
13-508	Case Western	Replacing Endoscopic Imaging With Non-Invasive Office Based Screening Test for Barrett's Esophagus	Red	Green	Yellow	Yellow	Yellow	Green	Yellow	Green
13-509	University of Akron	Smart Phone Based Universal Water Quality Sensor	Green	Green	Green	Green	Green	Green	Yellow	Green
13-510	University of Akron	Osteoporosis Home Screening Kit	Red	Green	Green	Red	Green	Green	Yellow	Green
13-511	University of Akron	Additively Manufactured Prosthetic Socket Cooling System	Red	Green	Green	Yellow	Green	Green	Green	Yellow
13-512	Ohio State	Single-Chain Antibodies for Immunohistochemistry Cancer Diagnosis	Green	Green	Yellow	Green	Green	Green	Yellow	Green
13-513	Ohio State	FleetCalc	Green	Green	Red	Red	Yellow	Green	Red	Green
13-514	Case Western	Stonelyzer for Instant Identification of Kidney Stones at the Point of Care	Red	Green	Yellow	Yellow	Green	Green	Yellow	Green
13-515	Kent State	End-Effector and Robot Workcell for Automated Assembly of Fuel Cell Stacks Using Robotic Technology	Green	Green	Green	Yellow	Green	Green	Yellow	Green
13-516	Cleveland Clinic	Endovascular IOPS: Validation of Dual-Modality Registration Markers	Green	Green	Green	Yellow	Green	Green	Green	Green

13-517	Cleveland Clinic	Coronary Chronic Total Occlusion Guidewire Family to Treat Coronary Artery Disease	Green	Green	Green	Green	Yellow	Red	Green	Red
13-518	Cleveland Clinic	Multidisciplinary Patient Management Conferences	Red	Red	Red	Red	Yellow	Green	Yellow	Green
13-519	Case Western	Software Suite for Diagnostic Imaging of the Retina by Two-Photon Fluorescence Microscopy	Green	Green	Red	Green	Yellow	Green	Yellow	Red
13-520	Case Western	Development of Novel Tools for Health IT - COBALT	Red	Green	Red	Green	Yellow	Green	Red	Yellow
13-521	Case Western	Trial Prospector: Clinical Trials Matching Application for Oncology	Red	Green	Green	Red	Red	Green	Green	Green
13-522	Kent State	Novel Non-Photobleaching Fluorescent Magnetic Nanoparticles (FL-MNPs) as Advanced Bioimaging Agents	Red	Green	Green	Red	Green	Green	Green	Yellow
13-523	University of Toledo	Ankle Foot Orthosis Using Shape Memory Alloys for Addressing Drop Foot	Green	Green	Green	Green	Green	Yellow	Green	Green
13-524	University of Toledo	Development of an Electromagnetic Antifouling Composite Coating	Green	Yellow	Yellow	Red	Green	Yellow	Green	Green
13-525	University of Akron	Aqueous Biphasic Tumor Spheroids for Drug Discovery	Green	Green	Green	Yellow	Green	Green	Yellow	Green
13-526	Case Western	Software for Quantification and Visualization of Intravascular Optical Coherence Tomography	Green	Green	Yellow	Yellow	Yellow	Yellow	Yellow	Green
13-527	Kent State	A Platform Technology Based on Biocompatible Liquid Crystal Elastomers	Red	Red	Green	Yellow	Green	Green	Green	Yellow
13-528	Kent State	Smart Energy-Saving Liquid Crystal Window	Green	Green	Yellow	Yellow	Green	Yellow	Green	Green
	Key					Key				
	Recommended for Funding					Meets Expectations				
	Conditional					Marginal				
	Not recommended					Does not meet				

*DEFINITION OF COLUMNS:*

Proposal # – A unique OTF number for each proposal

Licensing Institution – The Ohio Institution of higher learning that is requesting funds

Project Title – The Project Title for the Request for Proposals Application Page

Generation of Proof to be Licensed – The proposed proof needed to move the technology to a point where it is ready to be licensed to a start-up or young company is deemed meaningful and likely impactful to that end

Project Plan/Team – Proposed proof that the technology can be generated during a one year project period with the proposed resources to move the technology to a point where it is ready to be licensed by a start-up or young company

Independent 3<sup>rd</sup> Party Review – Will the validation/proof process be conducted or overseen by an independent party

Reasonable Path to Market – The technology has a commercially reasonable path to market entry of first product

IP Protection – Degree to which the intellectual property is protected

Start-up in Ohio – Degree to which the proposed project will likely lead to a start-up company if the technology validation is successful and needed proof is generated

Market Opportunity/Size – Is this technology a viable commercial opportunity in regards to the potential market size and competition

Budget Narrative/Use of Funds-newly added for Round 2, description of how the entity proposes to use the funding if received

## DETAILS OF PHASE 1 RECOMMENDATIONS

**Proposal 13-501**, Cleveland Clinic, Reinforced Extracellular Matrix Device for Ventral Hernia Repair, \$50,000 requested.

**Amount recommended: \$50,000**

**Rationale:** This proposal from the Cleveland Clinic is a resubmission of a proposal submitted in the prior round. The current proposal concerns further development of a reinforced matrix to repair abdominal hernias, typically though not always, caused by prior surgical incisions. A hernia is a protrusion of an organ or part of an organ through a wall that normally contains the organ. Repair often involves not only closing the rupture surgically but also adding a mesh to strengthen the wall at the site of the hernia. The mesh may consist entirely of artificial materials or it may consist of natural biological membrane. Natural membranes are often formed into a mesh to facilitate growth of the patient's natural tissues into the mesh. This proposal deals with a biological mesh reinforced with plastic fibers sewn into the mesh, thus providing greater strength. The applicants believe this technology to be a platform for other repairs such as rotator cuff repair, breast reconstruction, pelvic floor repair, and repair of torn Achilles tendons. All these possible applications derive from the laboratory work of Kathleen Derwin, PhD, whose lab at the Cleveland Clinic has all the necessary equipment and expertise necessary for development of the products enumerated.

There are around 350,000 cases of abdominal hernia repair in the US each year. Of these, approximately 250,000 use a mesh, and of those, an estimated 10%-20% use biologic mesh. The cost of biologic mesh is quoted at \$10,000, implying that the total value of the market for such products is \$250-500 million. Typical mesh failure modes are by ballooning, stretching, or tearing prematurely and require another repair. Reduction of those repairs needed result in increased patient care outcomes and significant cost savings. The business plan calls for an aggressive 5% market capture in the first year.

The present proposal envisions a 20 week validation study implanting meshes in 12 miniature pigs and measuring any tendency to bulge, stretch or tear and, at autopsy, assessing the extent to which the meshes excite immune response or damage to adjacent viscera. The budget is highly detailed and appropriate for the plan.

The current proposal addresses the previous concerns, and meets the criteria for funding.

**Proposal 13-502 Antibody for Prevention of Catheter Line Infection and Biofilm Growth** \$50,000 requested.

**Amount recommended: \$0**

**Rationale:** This proposal is to develop an antibody that can be applied to catheter lumens which will inhibit or prevent biofilm formation, thereby significantly reducing the incidence of central line-associated blood stream infections (CLABSI). The applicant intends to define a regulatory pathway, devise a business plan, and form a

commercial enterprise within 12 months after grant award. The applicant is seeking a grant of \$50,000 from the State of Ohio to supplement like funding from the Cincinnati Children's Hospital Medical Center (CCHMC).

Market share potential is not identified in the proposal. The applicants note 'there is no way to predict who will be infected' which may put significant pressure on a future pricing model. Without a means to identify at-risk patients it may be difficult to command a price premium. The applicants also note a decline in CLABSI due to improved hospital protocols, bringing further question to the potential market opportunity. The proposal does not adequately distinguish between other, competing technologies and the technology under development, e.g., antimicrobial lock solutions which reduce risk of central line infection.

The proposal requests funding for three purposes: hire a regulatory consultant to plan the IND path; hire a business consultant to develop a business plan; and formation of the commercial enterprise. The funds being requested, namely the building of business and regulatory plans and the formation of a startup company, do not seem appropriate for the goal of a Phase 1 grant, which should be more focused on technology validation. A study in a rat model is already in progress and may bring critical insights to address the concern around true differentiation of the product.

Since the proposed plan is not consistent with the goals of the TVSF Phase 1 program, it is not recommended for funding.

**Recommendations for Improvement:** Should the applicant desire to reapply, a clear differentiation between this product and others on the market should be provided. While assertions of superiority are made throughout the current request, there is virtually no evidence provided to validate the claims or to make meaningful comparisons. It may be that the current rat model study will provide useful data in that regard. Some effort should be made to provide price points for comparison, as a superior product may not be used if the price premium is significant and at-risk patients cannot be targeted.

**Proposal 15-503**, Ohio University, Development of a New Versatile LC/MS Interface via Non-Destructive Mass Spectrometric Sensing, \$50,000 requested.

**Amount recommended: \$0**

**Rationale:** The coupling of Liquid Chromatography (LC) with Mass Spectroscopy (MS) is a common analytical tool, found in universities as well as industrial labs. The LC portion of the instrument separates the analyte mixture into its various components which are then identified utilizing the MS. In practicality after the sample has been separated by the LC, it is split into 2 portions; one of which is sent to waste and the other to the MS. This function is performed by a splitter which costs approximately \$2,000. The LC/MS systems cost approximately \$500,000 and there are approximately 5,000 instruments sold annually. Ohio University has developed a new LC/MS interface which has a new splitting protocol. This new interface has several advantages, including the prevention of sample destruction by the MS. The device has been developed as a prototype to show feasibility and has a patent pending. The proposed proof tasks in this effort include development a simplified automated software user interface, a miniaturization of the prototype device and then validation testing.

The grant application proof does not provide commercial targets such as how much improvement in LS/MS efficiency needs to be achieved, to differentiate the final developed concept. It is also unclear if the automation task, which is being performed prior to the miniaturization, will be impacted by the reduced orifice. Specific and measurable goals are missing for both automation and miniaturization, though the concepts are articulated. Specific goals are needed to validate the outcome of the work.

The research team has a cooperative agreement with ABSciex (a Massachusetts corporation) for technical advice and also plans to utilize this relationship for market distribution. Since the interface is integral to the LC/MS instrument, it must be tested with the other components to prove commercial viability, and partnering with a recognized LC/MS manufacturer is necessary. However, partnering with only one of nearly a dozen manufacturers for market entry presumably precludes sales to the others. The stated market size is \$350MM, but capturable share is not identified in the proposal. Also, there are numerous LC/MS applications where destruction of the sample during analysis is not a detriment, so the customer could opt for the less expensive traditional splitter. Would it be more cost effective for ABSciex to manufacture the proposed splitter interface, and if so, the economic value for the State of Ohio is greatly diminished. The grant application does not state there will be third party validation, but one could assume that ABSciex would perform this function.

This grant application is not recommended for funding as it is incomplete without verifiable proof at the end of the project, and validation of same by an objective third party.

**Recommendations for Improvement:** An improved application would provide specific and verifiable targets for the work, and these should be clearly tied to performance of the device and ultimate differentiation in the market.

**Proposal 13-504**, Ohio University, A Matlab Toolkit for 3D Visualization of Real and Synthetic Flight Data  
\$50,000 requested.

**Amount recommended: \$50,000**

**Rationale:** The proposal is for the development of a Matlab kit that will be used to create an analytical tool to diagnose and troubleshoot interface to sensors and synthetic data software in a unified format, and to render a coherent 3D Visualization and simulation for situational awareness. The proof necessary for licensing and commercialization is divided into two main tasks: Validation of Matlab's ability to interoperate with this system and 3rd party feedback with regard to application and requirements. Development of this capability will make it possible to effectively develop 3D visualization Situational Awareness for UAV Controllers.

This is resubmittal of the 13-401 grant proposal where the primary concerns were around the business opportunity – potential market size and projected revenues. The applicants thoroughly and articulately addressed these concerns and this proposal is therefore recommended for funding. While further refinements of the addressable market will be needed, the close partnership the applicants have formed with potential customers place them in a favorable position to do so.

**Proposal 13-505**, Austen BioInnovation Institute in Akron, Digital Dx, \$49,500 requested.

**Amount recommended: \$0**

**Rationale:** The offering by Austen BioInnovation Institute/Digital Dx is a wound assessment tool whose value proposition is to reduce the labor cost by reducing time spent in the wound assessment process by a nurse, PA or doctor. The software is used to create a standard score which would need to be adopted by the wound community at large. In addition to the software, a disposable disk that will test for the presence of volatile organic compounds that are linked to certain bacteria is required as input to the algorithm. The disk data and the image obtained from an “off the shelf” high resolution camera (sold separately) will serve as the input to determine the wound score.

This is a resubmittal of grant proposal 13-419 where the applicants did not articulate how their technology would compare to or compete with at least one other established competitor, WoundRounds, and therefore were not recommended for funding. In this proposal, they do indicate that WoundRounds involves manual entry, so time savings may be presumed but the specific differences in the technologies and time required were not provided. Further, the proposal fails to explain why there is the need for standardized scores and if they would alter treatment protocols, which was a concern for the prior application. In addition, there appears to be added features, such as VOC color-changing discs without providing the insight as to clinical or commercial relevance. It seems likely that this addition to the system will increase cost, but to what extent or how that would impact their competitive position is unknown.

The proposal identifies the primary product as consisting of three key components: “1) Data processing algorithms; 2) image quantification disk and 3) knowledge management system.” In describing the Stage of Development the applicant states: “Image IQ is confident that it will be able to develop and custom-tailor a set of software algorithms”. Proof activities listed include “Develop Initial Proof-of-Concept Software Algorithms”. The purpose of the Phase 1 grant is to validate existing technology to ‘move technology to the point that it is ready to be licensed by an Ohio start-up company or deemed unfeasible...’ Based upon the proposed proof and current state description, the technology described in the proposal does not appear to be far enough along the path of development to qualify.

Lack of market adoption of this as a standard scoring process could be a significant risk to success. What evidence does the company have that a standard system will be adopted? The revenue and cost models have not been documented. How will the value proposition be validated?

**Recommendations for Improvement:** The application needs to provide an understanding as to commercial viability of the product, including competitive landscape, the value proposition, barriers to market adoption, etc. and justification of the proof plan as leading to validation of the technology towards commercialization.

**Proposal 13-506**, University of Akron, OXAID: Oxygenated Hydrogel Wound Dressings, \$50,000 requested.

**Amount recommended: \$50,000**

**Rationale:** The proposal from the University of Akron concerns a modification of hydrogel wound dressings so that they can carry oxygen. It is well-known that oxygen promotes wound healing, and most

wounds with adequate blood supply get sufficient oxygen from the blood. However, wounds on patients with compromised blood flow, such as patients with diabetes or patients with bed sores often do not heal properly and become chronic wounds. Bandages made with hydrogels, which keep the wound moist and protected, are of some help and are widely used. In some cases the treatment can be improved by bringing oxygen to the site, either by placing the patient in a hyperbaric chamber or by covering the wound site with some kind of tent, but these treatments are expensive and awkward to carry out.

The applicants propose creating a new hydrogel that also has the ability to release oxygen to the wound directly. The bandage is constructed from chitosan modified with perfluorocarbon chains. Both products are already approved and the expectation is that a 510K pathway is viable. The UA applicants call their compound MACF (methacrylamide chitosan with fluorocarbons). The bandages have been named OXAID. OXAID has been studied in vitro, and the applicants are now ready to move on to animal studies.

The plan addressed in the current proposal is to test the efficacy of the new bandage on pigs, which furnish a model closer to humans than do mice or rats. While the research is still at an early stage, the principles described are sound and the applicants describe a well-thought-out plan. It is expected that this program will provide data sufficient to seek FDA approval to move to first experiments in humans and is recommended for funding. Should the applicants return to seek funding under TVSF Phase 2 the review team will expect clear and compelling proof supported by data from this program.

**Proposal 13-507**, University of Akron, Mechanoluminescence (ML) Sensors, \$50,000 requested.

**Amount recommended: \$50,000**

**Rationale:** This proposal describes the development of a mechanoluminescence (ML) technology concept into a paint or coating for measurement of full field stress and strain analysis. The concept is based on two patents: a ML paint sensor for stress and crack visualization and an apparatus for measurements and stress distributions from ML materials. These can be used for non-destructive testing or load cell force measures in aerospace, civil engineering and naval markets. The benefits of this would offer full-field measures, applicable to various materials, which are less skill intensive and with less hazard exposure. The University of Akron has worked an extensive effort in investigating market opportunities, identifying strategic partners, assessing competitive products and the concept's competitive advantages. The team decided on the aerospace market as an initial entry point because of their unique needs in non-destructive testing and full field evaluation. They have a detailed description of the engineering development efforts needed to bring the concept to a startup. The validation effort is to have the developed prototypes sent to end users in the aerospace industry for usage and feedback.

The proposal identified a business plan consisting of a 3 phase business development effort with the startup company being phase 2 after the phase 1 engineering development proposal completion. Funding for the various phases has been identified as well as numerous partner organizations. Phase 3 focuses on manufacturing and will secure funding through venture capital. The phase 3 has goal date of end of 2016 for initial sales in market.

This proposal was well written and thought out. All of the criteria were addressed in detail. The team has already been coordinating with customers and users to develop a good engineering development plan. The number of organizations interested in and supporting this concept shows the utility, feasibility and marketability of it. The project plan is thorough with meaningful deliverables. More detail should be provided for specific use cases and operational concepts that should be part of the validation. This is so that considerations as to other augmenting equipment such as imaging sensors, measurement characteristics and timelines can be addressed. These are valuable in determining utility and thus marketability of the concept.

The proposal is recommended for funding.

**13-508**, Case Western Reserve University, Replacing Endoscopic Imaging with Non-Invasive Office-Based Screening Test for Barrett's Esophagus, \$50,000 requested.

**Amount recommended: \$0**

**Rationale:** This proposal from Case Western Reserve University proposes development and initial clinical trials of a new device and new test that will enable early detection of Barrett's esophagus (BE) with a simple office-based semi-invasive test. The project director, Dr. Sanford Markowitz, and his collaborators published in 2012 their findings that DNA samples from the lower esophagus in more than 90% of patients with BE displayed a feature called aberrant vimentin gene methylation (VIM). Methylation is a principal means by which the expression of genes can be turned on or turned off, furnishing a more subtle aspect of genetic transfer called epigenetics. Methylation of certain elements in genes is normal, but sometimes this effect is abnormal and indicative of malignancy or a precursor of malignancy, as here. Thus, a DNA test, which is routine in DNA labs, purportedly can be used with high sensitivity and specificity to detect BE.

This development is important because BE is known to be a precursor of cancer of the esophagus, a deadly disease that causes 15,000 deaths in the US annually. Furthermore, BE is often associated with (and thought to be a consequence of) gastroesophageal reflux disease (GERD), said to affect 10 million Americans. The standard method for detecting BE is endoscopy, inserting an endoscope into the stomach and beyond to inspect the tissues of the small intestine, stomach and esophagus with the patient under sedation. This method is expensive, time-consuming, and not suited to office practice. Furthermore, it is generally performed only on patients with severe GERD symptoms so that many cases of BE go undetected. Patients with BE can be more closely monitored, allowing earlier intervention if they show signs of progressing to esophageal cancer.

The proposal describes an inflatable balloon, which would be swallowed by the patient, after which the balloon would be inflated and withdrawn from the stomach and the lower esophagus. This can be done without sedation. The balloon has fine fibers attached to its surface so that it will gently remove surface material from the interior wall of the esophagus. After withdrawal of the balloon, this material can be subjected to DNA analysis. Another virtue of the balloon, as opposed to a sponge, is that it can be deflated while still in the lower region of the esophagus so that it does not pick up contamination from

the upper esophagus on withdrawal. Such contamination in the form of VIM in the upper esophagus due to smoking is less clinically significant.

The plan is to manufacture 60 balloons for a clinical experiment involving 60 patients, 20 of whom are known to have BE and are undergoing endoscopy for surveillance purposes, and 40 of whom are not known to have BE but are undergoing endoscopy for other indications. Taking endoscopy as the gold standard, the experiment will provide evidence of the sensitivity (proportion of true positives) and specificity (proportion of true negatives) for the new procedure. It will also provide evidence of the degree to which patients find the semi-invasive procedure tolerable.

The foundational test for this technology is uncertain. The original test (Exact Sciences PreGen-Plus) was removed from the market after a warning letter<sup>1</sup> from the FDA as an unapproved test. Subsequently it was remarketed as a lab developed test through LabCorp as ColoSure. Without FDA approval it is classified as investigational. Therefore, it is not routinely reimbursed by insurance or Medicare making the path to market more difficult. Further, a 2011 CDC sponsored study stated: *"the clinical validity of methylated vimentin as a biomarker for CRC screening remains to be determined"*<sup>2</sup> The basis commercial test referenced in the application has been taken off the market and the market is waiting for an improved multi marker replacement (Exact Sciences' ColoGuard) to be FDA approved. Proof of balloon concept is theoretical based upon analogous work of others from 20 years ago; a prototype has not yet been constructed.

This proposal is not recommended for funding.

**Recommendation for Improvement:** Should the applicant wish to reapply, the validity of the underlying test should be determined, or abandoned in favor of an improved test if and when FDA approved.

**Proposal 13-509**, University of Akron, Smart Phone Based Universal Water Quality Sensor, \$50,000 requested.

**Amount recommended: \$50,000**

**Rationale:** This proposal develops a University of Akron sensor technology into a product for use in the hydroponic, aquarium, and pool and spa applications. The product is a single unit that measures key factors like pH, particle concentration, temperature and water level in an easy to use device. These outputs can be connected to social media via a smart phone app for ease of remote monitoring. The key to the marketability is developing this as an easy to use but comprehensive product at a lower price point than the many other monitoring systems on the market. The unique technology development is the use of a single electrode to measure the key parameters and this is protected with a provisional patent. The feasibility of the other functions has been demonstrated but, on a "breadboard" model. The goal of the project plan is to provide these functions via integrated circuits critical for the low cost, then have them validated and updated for beta testing to provide sufficient confidence for the startup company.

<sup>1</sup> <http://www.fda.gov/iceci/enforcementactions/warningletters/2007/ucm076536.htm>

<sup>2</sup> Ned RM, Melillo S, Marrone M. Fecal DNA testing for Colorectal Cancer Screening: the ColoSure™ test. PLOS Currents Evidence on Genomic Tests. 2011 Mar 22. Edition 1. doi: 10.1371/currents.RRN1220.

This proposal is a resubmittal of the 13-415 application, which was not recommended for funding due to the ambiguous value proposition. In this proposal, the market and the value were better defined and though the market is relatively limited (\$70M in total) it seems reasonable that a profitable start-up could form based upon this technology, especially in light of the applicants' industry connections and partners.

The market for this technology is the water monitoring of complex hydroponic systems and contained water systems. The estimated market size for hydroponic systems monitoring is about \$50 million, while for the salt water aquarium, monitoring is about \$20 million. The key for market penetration is a target price of \$50 which is lower than any similar device currently on the market. It should be noted that there are already about 1180 hydroponic equipment retailers in the U.S.

Since water monitoring is an established market with many providers and retailers, the market needs to be monitored carefully to assess competitive products. Establishing an entry point, keeping price low and continuing product improvements will be essential in this environment.

Proposal is recommended for funding with the caution that the market is crowded.

**Proposal 13-510**, University of Akron, Osteoporosis Home Screening Kit, \$50,000 requested.

**Amount recommended: \$0**

**Rationale:** This proposal from the University of Akron addresses development of a home screening kit for osteoporosis, which is a normal part of aging. Screening is worthwhile because simple preventive treatments such as dietary supplements and lifestyle changes are available. The condition affects both sexes, but it is more common in women than men. Guidelines for testing suggest that women should be tested biennially beginning at age 55 and men beginning at age 65. While additional screening options may be needed or desirable, the statements made in the proposal around limited insurance coverage are not entirely accurate and overstate the actual gap in availability of screening tools and reimbursement of same. For example, Medicare covers bone density measurement every two years, or more often when medically necessary.<sup>3</sup>

Among the tests in current use are DEXA (dual energy X-ray), which uses a dedicated X-ray source to measure bone density in the spine or hip (the most crucial areas where bone loss is significant); CT scanning; ultrasound to measure density of the calcaneus (heel bone); and a variety of blood tests and urine tests.

The proposal is based upon a urine test that measures the amount of a certain compound called cTx (C-terminal telopeptide) found in blood and urine and indicative of bone turnover. The applicants have devised a prototype disposable test device that appears to be easy to manufacture and to use in the home or in a doctor's office. It works like a syringe to take up a urine sample from a collection jar, passing the sample over a small sheet treated with an antibody to bind cTx, and providing quantitative read-out

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<sup>3</sup> <http://www.medicare.gov/coverage/bone-density.html>

based on color change. The applicants believe that the new device can be sold for approximately \$20, making it much less expensive than the tests based on X-rays or ultrasound. Other currently available urine and blood tests are typically priced at levels over \$100.

Proposed benefits include:

- It can be used at home or in a physician's office with no need to send samples elsewhere for testing
- Results are quantitative, which will guide therapy better than unquantified results
- Results are immediately available, meaning that, if the test is done in a physician's office, treatment can be prescribed without an extra visit.
- Device is self-powered
- Device is self-contained
- At an anticipated cost of \$20, the device is inexpensive compared with alternatives.

On these bases the applicants believe that their device has a commercially reasonable path to market entry. One issue not addressed in the proposal, however, is the accuracy of a urine test for cTx as a marker for osteoporosis. If the test is inaccurate (too many false positives or too many false negatives), all its other putative advantages will not matter. In addition, there are already tests on the market that use urine or blood as the test material, and the proposal does not address how the proposed test will be differentiated. It may be that the existing tests are more expensive, but, if they are based on a similar technology, they too can be made as inexpensively as the proposed device.

Measuring bone mineral density is the gold standard for diagnosing osteoporosis. To be commercially viable, the proof plan needs to address how accurately measuring cTx compares with this standard. The premise of the proposal is that the measurement of cTx is reliably associated with osteoporosis, however, literature references do not support this view, nor do the applicants provide supporting evidence for the assertion. Also, the proposal does not address the competition that a new test will face from others already established in the marketplace and how the new product will compete in an established space.

Finally, the proposal states the team is 2 years away from license, but TVSF requirement is a one year proof plan.

**Recommendation for Improvement:** An improved application would provide evidence that cTx can be reliably associated with osteoporosis and not just measurement of bone turnover. Careful consideration should be given to the crowded market and how this test will be differentiated, and whether the proposed price point can be achieved with the robust marketing plans described. A definitive proof point must be described and a plan assembled to deliver that proof point with the resources requested and within the one-year time period for the project.

**Proposal 13-511**, University of Akron, Additively Manufactured Prosthetic Socket Cooling System, \$50,000 requested.

**Amount recommended: \$0**

**Rationale:** A problem with current prostheses, particularly leg prostheses fitted to a femoral or a tibial residual limb, is that for active wearers the limb within the prosthesis and the prosthesis itself become hot, leading not only to pain but also to skin breakdown, a condition called maceration, which takes long times to cure and in any case limits the wearer's activity. The problem is aggravated by the fact that, when hot, the residual limb may swell, increasing pressure on it. The proposal states that there are 1.5 million US patients with leg amputations above or below the knee, and of these some 40%, or 600,000 lead active lives and it can be presumed that this demographic might benefit from a device that could be cooled.

The applicants propose to develop such a prosthesis utilizing the technique of additive manufacture, a.k.a. 3D printing, where an object is created via computer guided deposition of polymeric material which hardens soon after deposition and adheres strongly to the underlying layers. This technique makes it possible to create intricate shapes without complicated machining steps. It also lends itself to fabrication of unique items such as a prosthesis fitted to an individual patient. The proposal focuses on the development of the additive manufacture process for the prosthetic application and the testing of the products for strength, durability and other necessary mechanical properties.

However, as presented, the technology lacks any description of the cooling system, which is an essential component of a marketable replacement for existing prostheses. For the wearer to carry a pump and batteries could be possible but rather cumbersome. Convective cooling alone is not likely to be adequate. Page 2 of the application states that monitoring of temperature and running coolant through the channel are listed as goals for the technical development, but they are not addressed in the project plan. Since additive manufacturing is a core competency of the applicants the review team is confident the plan as articulated could be successfully executed, but it is fundamentally incomplete. Because of these concerns with the proof plan, it is hard to conclude that the technology has a commercially reasonable path to market entry at the conclusion of the proposed program. Incidentally, the cover sheet on the proposal shows a budget of \$100,000, while the internal table shows a budget of \$78,253.

**Recommendation for Improvement:** TVSF Phase 1 funding is designed to generate the proof necessary for the start-up to be in position to license the technology from the research institution. For this technology to be successful, the entire system must work together. Therefore, the development efforts should be complete with the generation of the proof in round 1. For this grant application, there is no mention of the cooling system in the project plan, and the grant does not state that it has already been developed. Thus the proof is incomplete, resulting in a limited or non-existent pathway to market.

**Proposal 13-512,** The Ohio State University, Single-Chain Antibodies for Immunohistochemistry Cancer Diagnosis, \$50,000 requested.

**Amount recommended: \$50,000**

**Rationale:** The applicant proposes to evaluate and optimize a new antibody fragment (3E8.scFv) for use as a substitute for the standard antibodies (B72.3 and CC49) currently applied commercially in immunohistochemistry (IHC) kits for the histological detection of certain cancers in humans. Potential enhanced performance and lower production costs in comparison to the current standard antibodies in use are a potential benefit. The stated milestones, if accomplished would provide the technology foundation for an Ohio start-up to commercialize one or more new cancer diagnostic modalities.

While IHC is of critical importance in definitive cancer diagnostics and that market is of substantial size, the size of the market for the particular antibody fragment being proposed for evaluation is not addressed. Commercial viability will ultimately depend upon the proposed product's performance and manufacturing cost. Though the research is at a comparatively early stage, the experiments are robust and are based on sound principles and evidence. If diagnostic performance of the proposed antibody fragment can be shown to be significantly better than the standard IHC methods in use today, a significant clinical and commercial opportunity is likely.

The independence of the third party review is somewhat questionable since the application states the analysis will be performed by independent technicians and validated again within OSU pathology lab, but this concern alone is not a significant barrier.

Grant proposal is recommended for funding.

**Proposal 13-513**, The Ohio State University, FleetCalc, \$50,000 requested.

**Amount recommended: \$0**

**Rationale:** The submitters propose the use of the TVSF funds to develop further a software package that would enable owners of vehicle fleets to compare the performance of various vehicles that they might purchase. The tasks for the project include perfecting the underlying algorithms, testing the software in house and beta testing with the vehicles of fleet owners that have already indicated that they wish to participate in testing. An alpha version of the software is available at [www.FleetCalc.com](http://www.FleetCalc.com), and its existence makes one reasonably confident that estimates of the time and resources necessary to complete the software and test it are accurate.

Additional testing, beyond the three months allotted in the proposal's Gantt chart, is expected to be necessary to gather data on the ability of the software to predict vehicle performance under a variety of local conditions; such as traffic density, temperatures, topography and inclement weather. Similarly, numerous variables related to vehicle maintenance and performance may have to be addressed, such as vehicle lifecycle, tire pressure, air filters, standard vehicle loads, etc.

The submitters state that the Ohio State Center for Automotive Research's TESS group will conduct the initial testing. Though this group's test results will no doubt be objective, the overlap between this group and the project staff leads one to conclude that it is not a completely independent overseer.

Potential customers will want to see test results that demonstrate that FleetCalc will provide accurate analyses of the performance of various vehicles that they might purchase for their fleets. Market interest will depend upon proof that the analyses are accurate and meaningfully superior to simple methodologies, such as: manual calculations or the manufacturers' MPG stated on the window sticker. The proposal does not address, however, how the algorithms will be updated, nor how much effort it takes to add additional vehicles or variables.

For this application, the review team recommends market research be conducted that determines a level of membership renewal necessary for a successful product. The number of small to medium fleet owners in the U.S. is approximately 1,000,000, according to the proposal. Thus, it appears that there is a large pool of potential customers for FleetCalc. The question is how often they would use the software. If most

fleet owners replace vehicles only once every few years, they may not be able to justify paying membership fees every year. Would FleetCalc be a commercial success if that were the case? Also, there are several software tools currently on the market, and a differentiating value proposition is needed for commercial viability.

The submitters state that OSU is preparing an application for a patent that would protect the data acquisition methods and algorithms that underlie FleetCalc. The TVSF requires, "the technology must already have, at the time of application to this program, intellectual property protection defined as patent-pending, patent-issued, or copyright as appropriate."

**Recommendation for improvement:** The applicants should consider a market assessment to determine if there is a viable pathway to sales, and if the subscription model is viable for fleets. The presumption is that FleetCalc will offer a more precise means of assessing fleet efficiency through a sophisticated simulation. However, there would appear to be many variables unaccounted for in the proposal, and the applicants should take care to either 1) clearly describe the variables they will account for and the associated effort to incorporate them into their simulation, or 2) acknowledge that those variables will not be included and provide an assessment of the true value of the tool absent those variables as compared to simple methods of calculating fleet efficiency.

**Proposal 13-514, Case Western, Stonelyzer for Instant Identification of Kidney Stones at the Point of Care, \$32,374 requested.**

**Amount recommended: \$0**

**Rationale:** This application from Case Western Reserve University proposes development of a device for use in a physician's office that would chemically analyze kidney stones. The composition of kidney stones is variable, calcium oxalate, uric acid, cystine, or struvite, and the appropriate treatment depends on which type of stone is present. Thus, there is medical value in knowing what type of stone is troubling a patient.

Kidney stones, if they are not too large, may pass spontaneously and be found by a patient in his or her urine. In a similar manner, stone fragments following lithotripsy (breaking up the stones within the kidney by applying energy from outside the body) may be collected from the urine, or stones may be extracted surgically. The urine of high-risk patients undergoing prophylactic testing may contain tiny stones. These *ex vivo* stones can be sent to a laboratory for chemical analysis. Methods for characterizing kidney stones *in vivo*, such as X-rays, CT, ultrasound, and urinalysis can be used, but they have drawbacks and do not always yield useful results. To address this dilemma, the applicants envision a machine, which they call a Stonelyzer, that would characterize *ex vivo stones* in the doctor's (probably a urologist or a nephrologist) office.

The proposed method of analysis is Raman spectroscopy (RS), a standard method of chemical analysis, which involves illuminating the specimen with a monochromatic (laser) light and analyzing the scattered light whose frequencies shift according to the chemical properties of the specimen. How well Raman spectroscopy will work in this application is not yet clear, and elucidating the technical feasibility of using RS to characterize kidney stones is one of the tasks envisioned in this proposal. However, the validation study is too small to achieve statistical significance.

The machine would contain a laser source, suitable light filters to reject noise in the measurements, and a desktop or other computer to analyze and present results. At this stage, the applicants are seeking funds to provide a proof of concept by building and experimenting with a bench-top apparatus. These are necessary steps to establish technical feasibility, which is not certain. A major limitation of RS is the signal-to-noise ratio since the laser excitation also excites scattered light that may mask the signal. This is known to be an especially severe problem with organic substances like kidney stones. Assuming that the concept proves feasible, they will design a commercial version.

The program outlined above is expected to establish technical feasibility of using RS to characterize kidney stones. However, there is also the question of “clinical feasibility,” that is, whether practicing urologists and nephrologists would be attracted to an office-based RS analyzer for kidney stones. The applicants state that the current practice of sending *ex vivo* stones to a lab for analysis would be supplanted by an analysis that could be done immediately in the office because the office physician could make money by doing so and because the result would be available immediately, perhaps avoiding the patient’s return to the office.

The applicants state they can sell the machine for \$10,000 and that the user can be reimbursed \$200 for each determination, meaning that payback requires only 50 patients, not a large number. However, if a machine such as the one they envision were available and used frequently, the insurance payments for its use would be sharply reduced, just as they were for mammography, which generally is no longer profitable for radiology practices.

**Recommendation for improvement:** The plan in this proposal addresses only technical feasibility coupled with a supposition that a machine of the kind they propose can be sold profitably for \$10,000. However, the plan does not address adequately “clinical feasibility” and “business feasibility.” Therefore, the technology at the end of the year and with the resources requested will not have reached the stage where a company could reasonably be founded to pursue commercialization. The applicants have already established an Ohio company, Raman Photonics, LLC, whose “mission ... is to facilitate innovation and discovery in the life sciences by enabling Raman scattering as an affordable real-time imaging tool.” They say the company is “highly interested in partnering” with them on this development, but it should be noted the founders of the company and the applicants are the same people.

**Proposal 13-515, Kent State University, End-Effector and Robot Workcell for Automated Assembly of Fuel Cell Stacks Using Robotic Technology, \$26,615.76 requested**

**Amount recommended: \$26,615.76**

**Rationale:** This proposal aims to reduce the cost of manufacturing for PEM Fuel Cells. Proton exchange membrane (PEM) fuel cells require precision assembly to promote uniform performance and avoid gas leaks. This is typically a labor-intensive manual process. The KSU end-effector prototype project aims to automate this process using robotics. Building on experiences of previous teams, the proposed automated process enabled by the end-effector is expected to significantly decrease per-unit manufacturing costs and increase quality by reducing opportunity for human error.

The applicants describe a plan and success criteria for the project: design and build a robotic end-effector prototype, fabricate the fuel cell components that work with the process and design, and demonstrate

the technology by building a fuel cell, and validating the resulting stack and lack of gas leaks within the 1-year time period. The system will be independently tested and the team intends to license the technology to a local start-up company upon the successful test. Some additional work to understand the cost advantages should be undertaken, as the precise amount of productivity gains is yet to be determined. However, the review team believes that the gains are likely to be significant, and while the market is not large at the moment the applicants are addressing the main barrier to market growth, which is the time-consuming process of assembling the stacks. Funding of this project is recommended.

**Proposal 13-516**, Cleveland Clinic, Endovascular IOPS: Validation of Dual-Modality Registration Markers, \$50,000 requested.

**Amount recommended: \$50,000**

**Rationale:** This proposal originates from the Medical Device Solutions Department of the Cleveland Clinic Lerner Research Institute, which has had under development for several years an Intra-Operative Positioning System (IOPS). The motivation to produce such a system lies in the ever-expanding world of minimally invasive surgery using catheters and guide wires threaded through the arteriovenous system for diagnosis and therapy, such as reducing blockages and narrowing in arteries, placing stents, and effecting heart and vessel repair. Currently, such procedures are done using fluoroscopy to visualize the anatomical structures of interest (blood vessels, heart chambers, and other organs) and to guide the catheter or guide wire along a tortuous path. However, extended use of fluoroscopy exposes the patient and the operating room personnel to high doses of ionizing radiation, which is known to be deleterious to the body. This fact provides a motivation to find other ways of guiding catheters and wires during such procedures.

Using a C-arm fluoroscope (an X-ray machine with the X-ray source at one end of a C-shaped support and the digital image receptor at the other end) and an injection of a contrast agent into the blood stream, several images of the patient's vasculature in a region of interest from different angles are recorded. A computer reconstructs these 2D images into a 3D rendering of the vasculature, including shading so that the vessels appear to be rounded shapes. A second system uses electromagnetic signals (radio waves) to locate a number of sensors (tiny coils of wire that reflect an exciting signal), one of which is located at the tip of a catheter and a number of others that are in markers located on the outside of the patient's body. A computer locates all the sensors in three dimensions, much as a GPS locates a device in three dimensions.

The external markers are called dual-modality markers because they contain not only an electromagnetic sensor but also radiopaque components so that they can be located in the 3D image derived from fluoroscopic data. The markers provide fiducial information making it possible to bring the data from the fluoroscopic images into registration with the electromagnetic images, in particular the location of the catheter tip within the blood vessels. Once the fluoroscopic images have been captured, the electromagnetic system can be used to guide the catheter to its desired destination, thus avoiding extended exposure to X-rays for both the patient and the operating room personnel.

A prototype system that operates in the manner outlined has been built and tested by the applicants for this TVSF grant. This proposal addresses further testing using the machine in clinical trials, as approved by

the local Institutional Review Board (IRB), first on a group of five patients chosen in part for their different physical characteristics, chiefly weight or body mass index (BMI), followed by another clinical trial involving different surgeons and a group of 5-10 patients.

At the conclusion of this program the applicants believe that they will have sufficient information to submit an application to the FDA for approval as a Class II device. In light of the need for reduced radiation in performing increasingly common endovascular procedures and the successful clinical test of the prototype device, this milestone (application to the FDA) should be enough to enable formation of a new company to commercialize IOPS. Use of local suppliers bodes well for maintaining an Ohio presence. Note: the short window to market seems aggressive. Grant is recommended for funding.

**Proposal 13-517, ,** Cleveland Clinic, Coronary Chronic Total Occlusion Guidewire Family to Treat Coronary Artery Disease, \$50,000 requested.

**Amount recommended: \$0**

**Rationale:** The applicant requests cost-sharing funding for a program aimed at completing development and commercializing a family of devices for use during percutaneous coronary intervention (PCI) procedures specifically applied to crossing chronic total occlusions (CTOs, blocked vessels). CTO procedures present an alternative to coronary artery bypass graft (CABG) surgery, a much more invasive and expensive procedure. The applicant intends to develop a starting (workhorse) guidewire to complement the six stiffer wires already developed and to engage an Ohio service provider to perform animal testing and establish biocompatibility of the entire family of wires. Achievement of this milestone is necessary to achieve regulatory clearance of the product family, a remaining requirement for market entry. This appears to be a viable opportunity as long as the performance of these wires is clearly superior to those already marketed in the US. An important inhibiting factor to commercialization is the US custom of performing CABG as first-line therapy for CTO, which is opposite of the Japanese preference.

The grant application states, “a new Ohio entity will be formed to own the IP, leveraging Cleveland Clinic cardiology expertise and that of a Japanese multinational partner with an established track record in guide wire manufacturing”. The intent of the TVSF is to fund promising technology to be commercialized in Ohio for economic development. It appears the planned start-up would have no employees, and the profits would be generated by the manufacture and sale of the technology by an entity outside the state of Ohio.

Although this project seems feasible technically, given the path to market and the partners involved; the purpose of an Ohio start-up is less clear, whereas direct licensing to the multinational partner appears a more natural path. As such, it would seem more appropriate for Yokowo, as the obvious commercial manufacturing partner, to provide the commercialization co-funding.

**Recommendation for Improvement:** To be considered for funding in the TVSF program, the return on the state’s investment needs to be better articulated, or, if the applicants believe that rationale is there based on the need for this technology to complete the guidewire suite, a better articulation of Yokowo’s inability to fund this development work.

**Proposal 13-518**, Cleveland Clinic, Multidisciplinary Patient Management Conferences, \$50,000 requested.

**Amount recommended: \$0**

**Rationale:** : The applicant proposes to augment the capabilities of a 12 year old in-house developed software system for conducting multidisciplinary patient management conferences and to ultimately commercialize the augmented software product (MDMC) for use beyond the Cleveland Clinic. The value proposition of this informational amalgamation for the disparate disciplines was clearly described.

The value of extending this software into other areas of care would directly benefit the Lead Applicant and should therefore be self-funded. In addition, the technical hurdles of porting home grown software solutions from one institution to another are extraordinary and typically result in costs that far exceed those needed to build from the ground up where commercial offerings are not already available. Furthermore, since this tool has been in use for more than a dozen years; it is reasonable to conclude that other institutions have generated their own solutions to the problems described. While those solutions may be sub-optimal, they may present barriers to adoption of an outside system given the concerns described here.

Notwithstanding the challenges above, many of the requirements of the TVSF program are not identified in the application. Namely pre-existing IP protection; proof needed to commercialize; path to market; start up necessity; commercial opportunity or market potential all remain undefined in the proposal.

**Recommendation for improvement:** In order to reapply, applicant would need to show a clear financial return to the State of Ohio significantly exceeding internal benefits, and close the gaps with respect to TVSF requirements.

**Proposal 13-519, Case Western**, Software Suite for Diagnostic Imaging of the Retina by Two-Photon Fluorescence Microscopy, \$50,000 requested.

**Amount recommended: \$0**

**Rationale:** This proposal intends to develop two-photon fluorescence microscopy (TPM) for the potential of non-invasive diagnostic imaging of the retina. TPM coupled with adaptive optics can detect the chemical signatures of retinal diseases at subcellular resolutions before damage occurs. The team has developed proprietary software which allows recent technical advances in hardware to be leveraged for the entire imaging system. The proof of concept has successfully enabled mouse retinal diagnostics.

This software offering is used in conjunction with ophthalmology instrumentation that currently exists to diagnose retinal disease. The software enhances the image processing and the quality of the image. The commercial application would be to detect or image fluorescence which is caused by retinal deterioration, in a non-invasive manner, for example in macular degeneration. The plan is three phased approach to improve the software for fast image acquisition, optimal focus imaging, and post process image averages for quality enhancement. The plan appears to be achievable within schedule and budget.

Of concern to the review team is the relationship of the applicant and the commercial partner Polgenix who is providing the matching funds. The \$50k match comes from Polgenix, a company founded by one of the principals. However, the application states in several places that funds "will be used for service

purchased from ...Polgenix". This makes the matching funds circular and thus "in-kind" as opposed to the required cash cost share. The grant application states that Polgenix is the third party reviewer, but it appears to be the same team as the grant applicants. This negates the objectivity of the review, and thus is not deemed an independent 3<sup>rd</sup> party. Note: the funding requested on the cover sheet is \$100,000, which does not match the application narrative or Phase 1 TVSF funding maximum of \$50,000. Further, the application briefly mentions a stand-alone start up, but it is clear from the narrative that Polgenix intends to license the technology. The applicants state 'the software has the utility and market potential to fully support an independent start-up company'. Because the applicants and Polgenix are largely one and the same, there would appear to be little reason to start an independent company. If the technology will be directly licensed to Polgenix as the start-up, the description of Polgenix as 'cash positive since its incorporation in 2006' calls into question the definition of a start-up being applicable in that circumstance.

**Recommendation for Improvement:** Cost share must be in cash. True 3<sup>rd</sup> party validation and new start up verification would be helpful. Capturable market understanding is also needed to define business viability.

**Proposal 13-520**, Case Western Reserve University, Development of Novel Tools for Health IT – COBALT, \$50,000 requested.

**Amount recommended: \$ 0**

**Rationale:** The grant proposal is a resubmission of a prior Phase 2 application by NeoProteomics (NEO) for the development of an algorithm, named COBALT **C**over-Based **A**lgorithm subne**T**works, which will be utilized by pharmaceutical companies to improve the odds in drug development. The submitters propose to further develop this algorithm for identifying biomarkers that distinguish subsets of patients with a particular disease, identification that would aid clinicians in deciding on courses of treatment. The TVSF funding would support porting of the algorithm to Java, user interface development, further testing of the algorithm and market research.

The submitters note that they have filed an invention disclosure and that the CWRU Technology Transfer Office will decide whether to pursue a patent or to rely on a copyright alone. It is likely that a patent application would cover the algorithm rather than the general concept of using software to identify biomarkers, which is probably obvious to "a person having ordinary skill in the art."

COBALT currently exists in Matlab software and needs code development and an interface in a JAVA based prototype to understand if it is a commercially viable product.

It appears that there is a relatively small number of potential customers – companies doing pharmaceutical research and academic or nonprofit medical centers. Also, it would probably not be necessary to apply the COBALT analysis to a given disease more than once, a circumstance that would limit the potential market.

The application proposes that NeoProteomics, the potential licensee, will be doing the prototype and validation work, and thus would be the recipient of the funding. This model does not fit the intent of the Phase 1 grants. The requirements of the TVSF state that "Allowable expenses must be...2) charged to

resources of the Grantee. Thus, Phase 1 funding is typically support for proof generation within the university in order for the technology to be ready for licensing. Further, NEO was founded more than 7 years ago and is already generating revenue from previously licensed CWRU algorithms. This technology was the subject of an earlier Phase 2 grant request for the TVSF, and was not recommended for funding for several reasons, not least of which was the business model for NeoProteomics and the fit of that model under the TVSF. By submitting as a Phase 1 request the applicants may not need to address the business model concerns expressed by the review team, but the questions around fit for the TVSF program remain.

The validation plan is not concentrated on generating proof needed to further the technology. Rather it focuses on marketing research regarding commercial interest.

The proposal is not recommended for funding due to the limited potential market, inappropriate use of funds, the lack of independent evaluation and concerns regarding the proof.

**Recommendation for Improvement:** In order to reapply the above concerns would need to be remedied. Namely creating a proof for commercialization and performing that work within the applicant's institution. In addition 3<sup>rd</sup> party evaluation and definition of additional addressable market potential would be helpful.

**Proposal 13-521**, Case Western Reserve University, Trial Prospector: Clinical Trials Matching Application for Oncology, \$50,000 requested.

**Amount recommended: \$ 0**

**Rationale:** This proposal from Case Western Reserve University concerns a software development called Trial Prospector. The software is intended for use principally by oncologists who may wish to enroll some of their patients in clinical trials of new cancer therapies. At any given time there are dozens of clinical trials in progress or in prospect in the US and elsewhere aimed at measuring the therapeutic value of a particular treatment versus some other alternative. To comply with good scientific practices, these trials almost always have strict rules governing selection of patients to participate. For a practicing oncologist even to be aware of all these trials, let alone being knowledgeable about selection criteria, is a daunting task. Trial Prospector is designed to alleviate that task.

In its ultimate form Trial Prospector would have listed all clinical trials concerning cancer therapies including the associated selection criteria, location, start date, contact information, and other relevant data. It would also have access to each participating oncologist's daily patient schedule and access to relevant clinical data on each patient (demographic information, diagnosis, etc.) The program would then compare each patient's information with the selection criteria for all relevant trials and present to the oncologist a description of the trials for which each patient being seen that day might be eligible. Depending on his or her clinical judgment, the oncologist might recommend to eligible patients participation in suitable clinical trials.

A prototype version of Trial Prospector has been developed at CWRU and tested in a pilot study with generally favorable results, demonstrating that the approach was feasible and the system found usable and effective by nearly all the oncologists who used it. The system was 100% accurate – that is, it did not

indicate enrollment of any patient who was not eligible or fail to indicate enrollment of any patient who was eligible.

The proposal plans to develop various enhancements to the prototype version and to test the enhanced version in a larger trial involving community oncology sites served by University Hospitals and a wider range of cancer types. Although practicing oncologists are the primary users of the system, others are beneficiaries: pharmaceutical companies and others who initiate and fund clinical trials; clinical research organizations that carry out clinical trials; patients who may benefit from participation in a trial; and possibly payers who may ultimately save money through more effective treatment. The developers believe that pharmaceutical companies are the most likely to recognize the benefits of Trial Prospector and therefore be the most likely to pay for such a service. The complexity of such a path to market (the buyer is not the user) reduces likelihood of success.

The review team notes that it will potentially take \$1,000,000 of investment to bring the product to market, with IP protection undefined to date. How the plan proof secures the next round of funding towards the \$1MM need is not defined, and thus path to market is obscure. While modification and refinement of the tool within University Hospitals seems achievable, the task of linking disparate electronic health records from other medical systems is significant. Preparation of the application for this integration is part of the project scope, but it is unclear whether that task can be accomplished in any meaningful way with the resources available. And, while user feedback on the tool was quite positive, critical elements such as how much time was saved or changes in decision making were not cited from the study. Finally, the applicants mention interviews with executives from three CROs who expressed interest in the tool, but no mention is made of specific performance criteria for the tool which the review team could use to better evaluate the proposed project plan.

**Recommendation for Improvement:** The next source of funding and the proof needed to secure it need to be defined, and a clear path to commercialization should be developed to ensure business viability. If the applicants have additional market insights, from CROs or physicians, which address the above concerns on utility and value of the tool, those should be provided.

**Proposal 13-522** Kent State University, Novel Non-Photobleaching Fluorescent Magnetic Nanoparticles (FL-MNPs) as Advanced Bioimaging Agents, \$49,934.75 requested.

**Amount recommended: \$ 0**

**Rationale:** This proposal is a resubmission from round 4 (13-421). The applicants for this grant request propose further development of nanoparticles composed of a paramagnetic core coated with a fluorescent polymer. When a targeting functional group (TFG) is attached, the over expression of receptors for the TFG in cancer cells would cause an accumulation of these nanoparticles at the site of the cancer, thereby permitting detection, or, with the addition of a therapeutic agent to the particle, treatment. There would certainly appear to be potential in this application, and the lead applicant is clearly a highly capable scientist.

Improvements in the initial application and path to market along with third party budgeting have been made. The applicants have also made improvements in describing the advantages of the proposed technology and how it may be differentiated from other imaging agents. However, the primary concern of the review team remains that the proposed work appears to be early stage basic research rather than validation of an existing

technology. The applicants estimate it will take 3 to 5 years and up to \$2 million in capital to reach the market after completion of this project phase. The addressable market is \$50 to \$100 million, which, while certainly not insignificant does not necessarily justify the significant investment in time, resources and risk mitigation that would be required to reach the market. The applicants appear to recognize the significance of the task – while most of the requested budget is for personnel and supplies to conduct the technical work, \$5,000 is set aside for 1) third-party validation, 2) travel to customer sites, 3) identification of industrial partners, 4) marketing the technology at a major conference, and 5) identifying personnel for the start-up company. The review team remains concerned that a meaningful outcome can be achieved under the time frame and budget allocated.

**Recommendations for Improvement:** The main area to be addressed is the basic nature of the research. While promising, there isn't enough evidence at this point to give confidence in the approach. Additional work is required before resubmission – to ensure confidence that a commercially promising product has been developed. This would include assurance that suggested end points of TVSF project work are achievable, and will bring the technology to a point where it is ready for license.

**Proposal 13-523** University of Toledo, Ankle Foot Orthosis Using Shape Memory Alloys for Addressing Drop Foot, \$50,000 requested.

**Amount recommended: \$ 50,000**

**Rationale:** This proposal from the University of Toledo is for an orthotic device that compensates for foot drop, an abnormality of gait, usually from neurological causes, that allows the foot to drop while walking. Persons suffering from this affliction have difficulty walking and are subject to falling. According to the applicants, the market for ankle-foot orthotics (AFO) is projected to be more than \$700 million in 2015.

This proposal deals with a concept that is an improvement on all existing AFO devices. It is a brace made from nitinol (a nickel/titanium alloy), which has the unusual property of retaining “memory” of its original shape after it has been deformed. Conventional nitinol undergoes deformation at one temperature and then regains its shape when it is heated, but the applicants have a modified material, the University's “core” technology, that does not require heating to achieve this effect. This shape memory alloy (SMA) stores energy when it is deformed as the foot hits the ground in walking, and it releases the energy when the foot is raised to swing forward. SMAs are similar to a spring-loaded device that stores energy and then releases it when triggered, but they are much more elegant with no moving parts except at the molecular level, which suits them well to applications with patients who already suffer some impairment.

Reaching the cited plan milestones will provide solid evidence (or not) of the effectiveness and usefulness of AFO devices using the new hinges made from this advanced SMA. If successful, this program should enable formation of a new company to manufacture and market the devices. The FDA already classifies AFOs in Class I, which require only registration, not permission to market.

In addition, the applicants believe that the AFO is only one of many devices that might exploit the unique properties of SMAs. They cite knee-ankle-foot orthoses and perhaps rehabilitative splints. Thus, there is platform technology for the startup company if the proof is successful. The researchers have identified a

commercial entity to who will build the prototype and evaluate the success of their proof as well as a potential market entry source. As such, they are not completely independent.

The program is recommended for funding because no barriers are anticipated in prevention of reaching the goal of having a workable AFO incorporating an SMA. In addition, the path to market is easier than for many medical devices because the AFO is in Class I (no FDA approval required).

**Proposal 13-524** University of Toledo, Development of an Electromagnetic Antifouling Composite Coating, \$45,000 requested.

**Amount recommended: \$ 0**

**Rationale:** The University of Toledo proposes to validate improved anti-fouling activity on surfaces coated with composite coatings. The initial target surfaces being urinary catheters, in which the technology is intended to reduce the incidence of catheter-associated urinary tract infections (UTIs). A one-year project is proposed to quantify the effects of the composite coating, select a coating process, conduct an animal study, and conduct a validation study to prepare for FDA submission. The proposed project activities are rational as measured against the stated objectives. However, the one-year timeline is aggressive, especially since the proposal states 21 months in question #6, but 12 months in question #3.

The Office of Naval Research will “test and evaluate the product for FDA approval”. This oversight may be technically sufficient as to anti-fouling capability but likely not as a prelude to FDA filing. The FDA clearance is essential, yet the required predicate device likely does not exist (due to the anticipated long usage period and presumably novel coating) which calls into question the 510(k) clearance path, especially given the need to ensure biocompatibility and safety of the coating materials. A more arduous premarket approval pathway would add years to the commercialization timeline and could discourage corporate partner participation.

While an Ohio startup company is a possible outcome, that company may serve only as a vehicle for technology sublicensing and business partnering. A new long-term manufacturing and marketing entity in Ohio is unlikely.

Also, the overall market for urinary catheters is indeed large, however, clinical practice – notably catheter change-out – has become commonplace recently, which has caused the UTI incidence rate to decline, thus lowering the market potential for this product.

This proposal is not recommended for funding principally due to the concern of the validation for FDA approval, and the apparent lack of the necessary predicate for the 510(k) filing.

**Recommendations for Improvement:** The applicants should provide a clear rationale for their proposed FDA pathway and should consider third party validation from the medical community. The project plan should also be re-worked, as many of the described tasks have to be run in parallel, though the interdependence of the tasks would make this seem impractical and proof unlikely to be generated within one year.

**Proposal 13-525** University of Akron, Aqueous Biphasic Tumor Spheroids for Drug Discovery, \$50,000 requested.

**Amount recommended: \$ 50,000**

**Rationale:** This proposal from the University of Akron envisions further development and validation of a robotic system to evaluate candidate anti-cancer drugs for multiple kinds of cancer. Now commonplace in biology laboratories are robotic devices that under computer control fill multiple tiny wells in a plate with various fluids under study. The device at hand uses a plate with 96 wells partially filled with aqueous polyethylene glycol (PEG). To each well is added a mixture of cancer cells, dextran and water. The result is that the cell-dextran mixture forms a submerged liquid sphere in each well. Subsequently, another fluid that mixes with the cell-dextran mixture, such as an anti-cancer drug, can be added and its effects measured by colorimetry or some other method. This method has many advantages over current techniques for screening anti-cancer drugs, most notably much greater throughput, accuracy, and convenience using standard robotic gear.

This proposal is aimed at demonstrating that the technology will work for a variety of human cancer cell lines treated with a variety of known (and widely used) anti-cancer drugs, thus providing proof that the technology can serve in experiments to screen candidate anti-cancer drugs

The applicants note that major pharmaceutical companies spend billions of dollars each year on research including drug discovery. (Note: the application states that Pfizer spent \$108,173 billion on R&D over a 15-year period. The correct figure is \$108 billion).

The technology described in this proposal is an ingenious idea that offers real and significant advantages over existing techniques for testing drug effects on cancer cells. It holds promise as the basis for a new and successful Ohio business, and the applicants are well qualified to carry out the development. This grant is recommend for funding with the notation that the technology is 3-4 years away from commercialization.

**Proposal 13-526** Case Western Reserve University, Software for Quantification and Visualization of Intravascular Optical Coherence Tomography, \$50,000 requested.

**Amount recommended: \$ 50,000**

**Rationale:** This proposal from Case Western Reserve University contemplates further development of software to process data collected by intravascular Optical Coherence Tomography (iOCT). OCT functions in much the same manner as ultrasound imaging except that it uses light (or near infrared) as the interrogating signal. In the vascular application, an OCT device emits a pulse of light and measures the time to return of reflections from underlying structures that compose the blood vessel. Such signals can be picked up from a depth of a few millimeters and resolve structures with an accuracy measured in micrometers. A single pulse provides data along a single radius from the device, but multiple pulses provide data around the entire circumference of a blood vessel, and the simple act of slowly withdrawing the device provides data along a length of the vessel.

Thus, iOCT provides slice data over a series of contiguous slices in a manner comparable to CT, filling an entire volume. Such data can then be used to construct 3D volume renderings, arbitrary cross-sections,

and other presentations of interest. In particular, iOCT can be used to create pictures of intra-arterial plaque or of stents placed in a vessel. Not all plaques are the same, and so-called thin wall plaques have been found to be especially dangerous because they can rupture creating a thrombus that may cause problems elsewhere in the body. Similarly, stents can be misplaced so that they create more problems than they solve.

The signal processing necessary to create such images is complex and subtle because the software must reliably distinguish among the pixels that represent different structures, a process called segmentation. Similarly, a 3D presentation must show overlying structures as if they were partially transparent so that one can see the underlying structures. Creating such displays often requires interaction of software with an observer. CWRU has developed a number of software programs to support reconstructions from iOCT data.

Most of the current proposal is devoted to further development of image analysis of stents in clinical trials. When new designs of stents are proposed, they must undergo clinical trials to obtain FDA approval to market them, and iOCT has proved to be the best way to evaluate their safety and efficacy. Such evaluations can be done offline, that is, sometime after the iOCT data have been collected. The software for evaluations does not itself need FDA approval (as it will when sold for use in patient care). They envision that a start-up formed to market iOCT software products can generate income from the beginning by offering evaluative services for new stents.

There are several concerns with the grant proposal, none of which preclude the recommendation for funding. The applicants are performing most of the oversight themselves, but are engaging a small user group. The proposal outlines 3 pathways to market, there are many software companies in this space, and the iOCT is the combination of published algorithms.

**Proposal 13-527** Kent State, A Platform Technology Based on Biocompatible Liquid Crystal Elastomers, \$41,072 requested.

**Amount recommended: \$ 0**

**Rationale:** This proposal is a resubmission of an earlier application, 13-423. Kent State has developed a smart responsive scaffold (SRS) biocompatible liquid crystal elastomeric platform technology, based on FDA approved materials. This technology has significant potential for usage in large commercial biological/medical markets. In these types of markets such physical/chemical properties as transparency, tunable porosity/pore size, biodegradability and responsiveness to stimuli are critical. Specific fields of application could include cardiovascular and bone tissue engineering, cell/tissue regeneration, temperature sensing, as well tamper evident security devices.

This Phase 1 project plan makes use of some very reputable validation partner companies and clinical research centers based in Ohio. These partners could also serve a role of independent monitors for this project.

The proposal indicates that the preferred path to commercialization would be through licensing the SRS technology to a start-up in Ohio. This would allow for pursuing funding for further development of the scaffolds to meet specific market needs of Ohio-based end users. It is estimated that the SRS products

would reach the market place within 4-5 years after the validation studies are completed. Other studies and certifications will be required for the type of medical applications that would be pursued.

The key project objective is to provide proof-of-concept scaffold materials ready for testing by the outside validating partners that takes full advantage of the custom-tailored internal morphology and porosity. It will be most critical to meet the customer specifications and needs in the target market based on the critical feedback provided by the validating partners.

However, the proposal cannot be recommended for funding due to the long time line to market which makes it incompatible with the TVSF objectives to commercialize products. This product is 5-6 years prior to commercialization. In addition, the proof presented did not provide end points, which are needed to verify the technology is ready to be licensed and commercialized.

**Recommendations for Improvement:** The previous application was not recommended for funding as it was not well-organized or focused, and the proposed proof lacked specific outcomes. This proposal suffers from similar shortcomings. End points must be clear and verifiable, and while the technology may be applicable to numerous markets (at least four are mentioned) the work should be focused on the needs of a particular market which is best suited to an initial product launch. The potential promise of the technology remains, but the applicants must provide confidence the proposed work can be completed in one year and will yield relevant and verifiable results.

**Proposal 13-528** Kent State University, Smart Energy-Saving Liquid Crystal Window, \$35,004 requested.

**Amount recommended: \$ 35,004**

**Rationale:** This proposed project is a resubmission of an earlier proposal (13-403), which was not recommended for funding. Request No. 13-403 was declined due to the lack of: 1) a definitive project plan, 2) defined new product performance objectives/goals 3) sufficient details regarding the characterization/validation process, and 4) the lack of a more definitive budget narrative. However, being that this current proposal carefully and adequately addresses these previous issues and concerns, the funding recommendation now has been changed to "Recommend for Funding".

This proposal describes a Phase 1 path forward for development and validation of a novel Smart Energy-saving reversible and tunable photochromic liquid crystal (LC) glass/window technology. If successful, it would provide for a switchable (clear to opaque & vice versa) and tunable/controllable energy-saving windows system that would have several advantages over state-of-the-art (SOTA) LC switchable glass products. It could be used for privacy control windows for such applications as bedrooms, hospital rooms, offices, and bathrooms, plus other applications where quick sunlight blockage is critical, such as for automotive and aircraft windshields. It could also be used as energy-flow (sunlight) control architectural windows for large buildings, greenhouses, etc. Such a tunable Smart Window system would also provide energy/heat flow control, which in turn could result in significant energy savings compared to current LC glass switchable methodologies. The downstream commercial markets for such reversible, tunable glass/window products would be sizeable.

During Phase 1, the noted reversible photochromic liquid crystal technology would be synthesized, optimized and characterized via 2"x 2" prototype panels to demonstrate feasibility of the technology and to better position the new technology for acquisition by window companies, possible spinoff to high-tech Ohio startup companies or be licensed.

Although the proposal does not specifically identify an independent party that would monitor this validation/proof process, the proposal does note that there is a great deal of project interest from a large glass manufacturer, Anderson Windows, who could evaluate the proof. Should the applicants present this technology for consideration as a Phase 2 grant this evaluation will be a critical part of the presentation.

However, it is a potential that Anderson Windows, located in Bayport, MN would partner, license or acquire this technology. Since there are options for these criteria which are Ohio based, the grant is recommended for funding with the above noted risk.

## PROPOSAL RECOMMENDATIONS - PHASE 2 SUMMARY MATRIX

PROPOSAL #	Licensing Institution	Lead Applicant	PROJECT TITLE	Q1	Q2	Q3	Q4	Q5	Q6	Q7	Q8	Q9	Q10	Q11
				Proof	Project Plan (one year)	Likelihood of Additional Funds at project end	Team	Business Model	Company Backing	IP Protection	Opportunity / Mkt. Size	Budget / Use of Funds	Start-up in Ohio	License with Ohio Institution
13-529	Ohio State	AwareAbility, LLC	AwareAbility Ultra Low Power Sensors and Software Application	Green	Green	Green	Green	Red	Green	Yellow	Green	Green	Green	Yellow
13-530	Cleveland Clinic	Ion-Vac, Inc	Wound Healing System	Green	Yellow	Green	Yellow	Red	Yellow	Green	Yellow	Green	Green	Green
13-531	CCHMC	Sepsis Newco, LLC	Commercial Translation of Biomarker-Based Algorithm for Severe Sepsis and Septic Shock	Green	Green	Green	Yellow	Red	Yellow	Green	Yellow	Green	Yellow	Green
13-532	Ohio State	SimpleFill, Inc	SimpleFill - High Pressure Natural Gas Compression	Yellow	Green	Green	Green	Green	Green	Green	Yellow	Green	Green	Green
13-533	Kent State	iRxReminder, LLC	iLidRx: Interoperating Medication Container for mHealth Management of Chronic Illnesses	Green	Green	Green	Green	Green	Green	Green	Green	Red	Red	Green
13-534	University of Cincinnati	Eccrine Systems, LLC	Wearable Blue Tooth Sweat Sensor Prototype	Green	Yellow	Green	Yellow	Red	Green	Green	Yellow	Green	Green	Green
13-535	University of Cincinnati	MicrobeCapture, LLC	Novel Rapid Diagnostic Assay for Influenza	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green
13-536	University of Akron	Telkesis, Inc	Minimal Shock Set Screws (MS3) for Spinal Surgeries	Yellow	Green	Yellow	Red	Red	Green	Green	Red	Yellow	Yellow	Yellow
13-537	University of Toledo	IRISense, LLC	IRISense, LLC	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green
15-538	Ohio State	ProteoSense, LLC	Commercialization of ImmunoFET Sensors for Food Safety Pathogen Detection	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green
13-539	Case Western	Miach Medical Innovation, Inc	A Cost Effective, Smart Endotracheal Tube that Improves Intubations	Yellow	Yellow	Green	Yellow	Red	Green	Green	Yellow	Green	Green	Green
13-540	Case Western	BEAR Software	A Wireless Intra-Oral Palatometer	Green	Yellow	Green	Yellow	Red	Green	Red	Yellow	Yellow	Green	Yellow
13-541	Ohio State	QuTel, Inc	Quantum Tunneling Electronics for Ultra-Low Power Electronics	Red	Green	Yellow	Yellow	Green	Red	Green	Green	Green	Green	Green
13-542	University of Akron	Akron Surface Technologies	Surface Treatment Platforms	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green
13-543	Case Western	ProImage Diagnostics, LLC	PTPmu Molecular Imaging Probes Identify Cancer Cells During Surgical Resection of Tumors	Red	Green	Red	Red	Red	Yellow	Green	Green	Yellow	Green	Green
13-544	University of Toledo	OsteoNovus, Inc	Improving Bone Graft Technology	Red	Green	Yellow	Yellow	Red	Yellow	Green	Red	Green	Green	Green
13-545	University of Toledo	Spinal Balance, Inc	Facet Screw System	Red	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green
13-546	Ohio State	3Bar Biologics, Inc	Commercializing Biological Inoculants to Increase Yield in Production Agriculture	Green	Green	Yellow	Green	Yellow	Green	Yellow	Green	Green	Green	Green
Key								Key						
Recommended for Funding								Meets Expectations						
Conditional								Marginal						
Not recommended								Does not meet						

*DEFINITION OF COLUMNS:*

Proposal # – A unique OTF number for each proposal

Lead Applicant – The Ohio start-up company that is requesting funds

Project Title – The Project Title for the Request for Proposals Application Page

Proof to Raise Additional Funds – The proposed proof needed to raise additional funds for commercialization

Project Plan – Proposed proof needed to move the technology can be generated during the one year project period with the proposed resources

Likelihood of Additional Funds at Project End – Likelihood of being able to raise additional funds for commercialization at the end of the project

Team – Experience and commitment of the team members in the commercializing new technology

Business Model – Realism and achievability of the proposed business model

Company Backing – Stability and backing of company, must have demonstrated backing and support independent of the university

IP Protection – Degree to which the intellectual property is protected relative to both the technology and the proposed business model

Opportunity/Market Size – Potential opportunity for the start-up in regards to the potential market size and competition

Budget /Use of Funds-newly added for Round 2, description of how the entity proposes to use the funding if received

Start-up in Ohio – Company plans to stay in Ohio

License with Ohio Institution – Company will execute a license with the Ohio institute of higher education within nine months of the date of the application

## DETAILS OF PHASE 2 RECOMMENDATIONS

**Proposal 13-529**, AwareAbility, LLC, Ultra Low Power Sensors and Software Application \$100,000 requested.

**Amount recommended: \$ 0**

**Rationale** AwareAbility LLC is utilizing an invention by The Ohio State University ElectroScience lab for developing battery-less, ultralow power sensor devices that can be used for monitoring. The product consists of proprietary software, proprietary firmware and hardware that enable customers to monitor physical events and activities, initiate automated actions, in inconvenient or inaccessible locations. The ultralow power will enable monitoring of a myriad of situations where electricity is not readily available and battery change out is not practical. The team has identified and coordinated with the city of Delaware Ohio Fire Department as a pilot client for an application of helping protecting aging building structures.

The invention has significant utility and application in several verticals. The team has appropriate background and experience. The business model is to sell the sensors essentially at cost, and to charge a software subscription type of license with a monthly fee based upon number of sensors deployed; the Software as a Service (SaaS) model. In the model, it will be the responsibility of the purchaser or a third party to integrate and monitor the sensors. The review team does not recommend funding because of the concern that the applicant will, with time, lose its value proposition thereby reducing the long term sustainability of the company. With time, the ultimate customer will have lost contact with AwareAbility, whose cash flow is based upon service, but there is no longer any easily identifiable service being provided. There will be a passive sensor waiting for an event, monitored by another entity. This entity will become the “face” of the system to the customer.

**Recommendations for Improvement:** The applicant should consider revision to their business model such as either selling the hardware device unit at the appropriate price point to the integrator/monitoring company, or by offering the full service integration model where they offer the service of monitoring the system including the integrated sensor, software and firmware. Energy harvesting and ultralow power technologies are becoming more common, making it unlikely the applicants can sustain the assumed price premium for their software without adding a more significant service component. The “unit” being sold consists of the sensor connected to a transceiver which contains the patented ultra-low power antenna, plus the associated software and firmware. The latter two are proprietary and not patented which is common, however this still reduces the strength of the IP.

**Proposal 13-530**, Ion-Vac, Inc., Wound Healing System \$100,000 requested.

**Amount recommended: \$0**

**Rationale:** The applicant proposes to market an iontophoretic drug delivery in combination with negative pressure wound therapy system (NPWT). NPWT systems seal wounds with a specialized dressing which introduces negative pressure (partial vacuum), thereby drawing out the edema and increasing blood flow which increases healing rates. The system is unique in that it simultaneously allows for drug delivery utilizing an electric field to drive medications into the wound with opposing force to the vacuum draw, thus improving the wound recovery outcome. The applicant proposes to test this unique wound-healing

product in a pig model and pursue FDA clearance via the 510K route in order to market the product in the US.

The technology appears to be fundamentally sound, the team well qualified, and has attracted significant levels of funding to date, though sources of those funds were not specified. The grant application articulated some aspects of a business model such as regulatory pathway, value proposition, and target clients. However, it lacked any financials, including projected revenue, price and cost points, or anticipated market penetration, and was defined vaguely as 'to be determined based on prototype efficacy'. This lack of detail resulted in the recommendation to not fund this proposal. Additionally, the pathway to market is suggested to be through a strategic partnership with a NPWT supplier. On the surface, this could appear to be a competitor. The applicants note the significant savings per wound treated by the competitors' technology, noting these have recently come off-patent. While the review team understands this could create partnership opportunities, and that the competing products do not offer all the benefits of this technology; it may also cause significant pricing pressure. This was not addressed in the grant request. There is no mention if any contact has been made with these potential partners/competitors. Also, please note that the budget narrative did not match the summary chart of financials, nor was the source of matching funds identified.

**Recommendations for Improvement:** Should Ion-Vac choose to reapply for TVSF funding, the grant application should contain sufficient business model information to demonstrate the financial viability of the company. This should include an objective assessment of market dynamics with efficacious competing products coming off patent. The review team would like to better understand sources and uses of funds.

**Proposal 13-531,** Sepsis Newco, LLC, Commercial Translation of Biomarker-Based Algorithm for Severe Sepsis and Septic Shock \$100,000 requested.

**Amount recommended: \$0**

**Rationale:** The product of Sepsis Newco is a mortality risk score for sepsis which is cloud based clinical informatics and focused on the improvement of clinical decisions and finances. Revenues would result from Software as a Service (SaaS) when the algorithm is run. Three market paths were identified. Initial market entry will involve measurement of the quality of care by providing quality officers with predicted mortality vs. actual mortality. The TVSF funding is designated for the lab to do this testing. This entry point will aid in the necessary data collection for convincing physicians to utilize the tool for clinical decision making, which is the second identified market. The tool, which appears to outperform current scoring standards like APACHE, would then serve as a guide to physicians to apply the appropriate level of resource aggressiveness for the patient based upon calculated risk profile of mortality. Path to market with this mode would be to partner with existing test equipment manufacturers to run the algorithm on existing platforms. With clinical acceptance, Sepsis Newco will migrate to the third market vertical, companion diagnostics for drug trial stratification, where the applicants believe is the significant financial reward. Per the grant application, projected revenue in 2018 is \$17 million.

The company is currently in the quiet launch phase and as such the financials such as the pro forma are being built, making it difficult for the review team to perform the fiduciary responsibility, especially with the need for \$5 million in order to reach the stated goal of \$14.5 million for year 5 revenue. (The review team noted after the interview that this statement does not reconcile with the grant application which states that projected revenue is \$17 million in 2018). In addition, the large revenue and profit generator

was stated to be the companion diagnostics for pharmaceutical development, but current focus of big pharmaceutical companies does not appear to be sepsis treatment, so this may result in adjustment of the modeling. Other areas of concern are identified money to date is not from the investment community, the identified CEO comes from a large medical device company and does not have start up experience (although the Executive Chairman does), and several principals are on loan from CincyTech rather than dedicated to the start up.

With sepsis being the leading cause of death in hospitals, the need for tools to improve the outcome is certainly an unmet need. The algorithms under development still need refinement but have demonstrated significant early promise and should have a place in the market.

**Recommendations for Improvement:** Once the financial models have been constructed, the majority of the essential data necessary for an affirmative recommendation should be available, and Sepsis Newco could reapply if they chose to do so. An improved application would include clear and justifiable timelines to launch for each of the three markets, and sources and uses of funds, including early revenue, until the company is self-sustaining. The revenue estimates should have a basis for the assumptions from each of the three targeted markets.

**Proposal 13-532**, SimpleFill, Inc., High Pressure Natural Gas Compression, \$100,000 requested.

**Amount recommended: \$100,000**

**Rationale:** This funding request is a resubmission of previous requests which were not recommended for funding. The underlying technology is a solution for compressed natural gas (CNG) fuel-at-location systems for personal and commercial vehicles. The system is simple to install, relatively affordable, and would appear to be easy to maintain as well, and on balance it's a compelling concept. Previous submissions had substantive issues in the business model, and the review team saw unrealistic projections in terms of investment, market opportunity, pricing and distribution. This current submission adequately addresses past concerns. For example, market research has been performed and the plan consequently refined from targeting consumers (although several bi-fuel vehicles are now emerging) to targeting small to mid-sized fleets. This range was selected since there are competitors for the large fleet market. Similarly, the applicants recognize the need of potential investors to see a well-designed and executed alpha prototype and have focused their efforts on development.

With this shift in focus, the system has been redesigned to increase the volume from 1 GGE to 4GGE. In the redesign, detailed engineering design was performed, which revealed unrecognized challenges which have been overcome and patents filed on the solution. The engineering redesign also revealed additional cost items which have been incorporated into the modified business plan. Fundraising has occurred with multiple entities now backing the startup. For additional funding, Simple Fill needs to develop the alpha prototype for the high pressure. The beta system will be independently tested by the Canadian Standards Association.

The grant proposal is recommended for funding, with notation that all previous concerns have been rectified with the modification to the plan. There are still challenges ahead, not least of which is helping to create this

market, but the review team is confident the development team has progressed to the point where they are ready to anticipate and overcome the hurdles they face.

**Proposal 13-533**, iRxReminder, LLC, iLidRx: Interoperating Medication Container for Health Management of Chronic Illnesses, \$100,000 requested.

**Amount recommended: \$0**

**Rationale:** This team received phase 1 funding in March of 2012 for “a monitored, interoperating medication cabinet”...”using low-cost smart phone system to deliver real time monitoring by reporting to the health care team via EMR (electronic medical records).” At the time the target market was to monitor compliance with a drug regimen for patients with chronic conditions and participants in drug safety and efficacy studies.

This Phase 2 proposal is for a self-management system which consists of three components: the pill dispensing box, the smart phone application and the control center. The latter will be cloud based and have license and monitoring fees. The team has shifted the target market from chronic illness to monitoring bone marrow transplant patients, with plans to then migrate to solid organ transplant patients, and thereafter return to the chronic illness patient market. The desired funding would cover completion of the iLidRx prototyping testing and validation of the information transfer and conducting field testing with 3 patients.

In review of the funding, 55% of the requested funds are for personnel salaries, and 12.5% is for prototype completion. In the interview the team stated that part of the funding was to be used to upgrade the appearance of the smart phone app. The review team did confirm the app is currently available iTunes. The company was founded in 2009, and while not yet profitable it is generating revenue and has a positive outlook for 2014.

Personnel salaries are clearly prohibited under the terms of the Phase 2 TVSF grant application, and while the applicants appeared unaware of this in the in-person interview, this cannot be overlooked. In addition, the core technology developed in Phase 1 was the prototype pill dispensing box, while much of the current development work is for add-ons to the system. While this additional work is necessary to improve the commercial offering, the intent of the TVSF Phase 2 is to “generate the proof needed to move the technology to the point where additional funds needed for commercialization can be raised or to commercialize the technology.” The company has raised nearly \$1 million in grant funding to date, and has a product on the market, making the requested grant funding less critical. Further, the application is not a good fit for the intended purposes of the TVSF.

**Recommendations for Improvement:** Since the company is established, future product improvements and salaries should be funded from the company revenues, investors, partners, or other sources of funding intended for early-stage revenue generating companies.

**Proposal 13-534**, Eccrine Systems, LLC, Wearable Blue Tooth Sweat Sensor Prototype, \$100,000 requested.

**Amount recommended (conditional): \$100,000**

**Rationale:** This phase 2 proposal is to complete the development of a 'Wearable Blue-Tooth Sweat Sensor Prototype' to commercialization. This platform technology sensor can capture, quantify and report the real time status of the specific sweat molecules relevant to a user application. The sensor has been developed by the University of Cincinnati as a first generation prototype with RFID connectivity. The proposed project plan is to take this RFID device to the next step as a low cost, wearable sensor for hydration monitoring, with blue tooth connectivity to a smart device, and provide this to additional potential customers to determine commercial proof of interest. An example of utilization of this product would be the medical staff real time monitoring of elite athletes (e.g. football players) in practice to ensure they perform to their maximum, without causing damage to the body.

The go to market plan for the company is to utilize Exclusive Channel Collaborations (ECCs), whereby Eccrine LLC focuses on enhancing the core sweat sensor for differing verticals and collaborators are responsible for scale up and market entry within a given vertical. The initial vertical at this point has not been selected. The interim CEO is on salary with the local business incubator.

Although the interim team understands the potential market; potential go to market strategy; and with the recognition that the pathway to market can be relatively short: the initial vertical has not been selected and the business plan has not been well articulated, largely due to the nature of the ECC model and the fact that the ECCs have the deep market knowledge and insight to fill in critical business plan details. The applicant stated that the formal plan could be provided in approximately three weeks. Therefore, the grant is recommended for funding, conditional upon the submission of an appropriate business plan for the initial vertical and subsequent approval.

**Recommendations for Improvement:** The recommendation for funding is contingent upon submission of a properly focused written business plan with financial projections. This would include the targeted market, projected price points for that market with appropriate rationale for the proposed pricing, identified partners, timelines and key milestones, and any other information needed to confirm the target market can be addressed profitably. Although ECC partnerships will provide significant support for this business model, there will need to be sufficient leadership applied by the team to drive the ongoing business to success. As such, the future leadership structure should be identified.

**Proposal 13-535**, MicrobeCapture, LLC, Novel Rapid Diagnostic Assay for Influenza, \$100,000 requested.

**Amount recommended: \$100,000**

**Rationale:** The applicant proposes to complete the development of, and then commercialize, an *in vitro* diagnostic test to assess patient infection by an influenza virus in order to guide appropriate selection of an effective flu therapy by indicating which anti-viral drug a patient's specific influenza virus is susceptible. The product would be a laboratory test kit which could be on the market for the 2015/16 flu season via the 510K regulatory pathway. Initial testing indicates a tenfold increase in sensitivity and unlike current

testing protocols; it is completely insensitive to antigenic variation, rendering the proposal kit capable of 100% detection. Therefore, the performance of the test is expected to exceed the performance of similar tests currently marketed. Also, since it tests for the actual flu virus, its life cycle would be indefinite versus the current need to reformulate every couple of years to follow strain mutations. The project proof is to generate the evidence of FDA approvability and to demonstrate compliant manufacturing and distribution capabilities will qualify the company (MicrobeCapture, LLC) for additional fundraising. Future POC lateral flow products are expected.

Areas of concern which were not sufficient to preclude funding include the team currently consisting of only the inventors and an advisor. Although technical ability was clearly evident, the presenters in the interview gave the impression of a lack of business acumen. Future fundraising will be more successful if improvements can be made in that area. Those future funding sources should be promptly identified as well.

**Proposal 13-536**, Telkesis, Inc., Minimal Shock Set Screws (MS3) for Spinal Surgeries. \$100,000 requested.

**Amount recommended: \$0**

**Rationale:** Currently in spinal fusion surgery, screws are implanted which need to be torqued to a proper setting, resulting in approximately 800Gs of elastic shock, which has the potential to cause injury to the patient. The applicant proposes to commercialize a new set-screw design for use in spinal implants, a design which is intended to reduce this mechanical shock that is transmitted to patients and surgeons as these implants are installed during spinal surgery. There are two types of set-screws, specified torque and break off. The invention being commercialized by Telkesis would reduce the elastic shock of the break off type of screw to approximately 100Gs by utilizing a more gradual deformation of the shear interface.

The review team cannot recommend this application for funding due to numerous concerns with the business model. While the number of screws was a known entity, the ratio of torque versus break off types was not known. This information is critical to defining potential market. In addition, a pro forma has not yet been developed. The company was formed approximately one year ago. The grant request plan has an equity owner being the recipient of purchased services and has an unidentified consultant being compensated \$50,000 for an undefined scope of work. The principal representing the company at the interview was uncertain who would be granting the license to be negotiated, the university or the university's foundation. If it is the later, they are the current majority owner in the company. The likely scenario for this invention would be an alliance with a major medical device company who currently distributes set screws. The current manufacturing partner is not medical device manufacturing certified. Further, the targeted alliance companies frequently have their own preferred suppliers, thus driving the business model to a licensing situation where an executive with business acumen would be critical to the license negotiations. Further, the manufacturing partner, as an equity holder, should contribute to the manufacturing scale up costs. The potential returns to the State of Ohio would appear to be minimal, especially if a device company partner takes manufacturing out of Ohio.

**Recommendations for Improvement:** Should the team desire to resubmit, they should consider a dedicated business executive to lead in the development of the business plan as well as to address the majority of the business issues cited above.

**Proposal 13-537**, IRISense, LLC, \$100,000 requested.

**Amount recommended: \$100,000**

**Rationale:** This is the third time that IRISense has submitted a Phase 2 proposal. The previous submission was rejected, mostly due to lack of a well-designed and vetted business model.

The basic technology involves inferring blood glucose levels from a simple optical measurement of the iris of the eye, using an “app” designed to run on almost any smart phone. Many patients with diabetes are told to measure their blood glucose level multiple times per day. The standard way of doing this is a “finger prick” to obtain a small blood sample, which is then applied to a test strip for quantitative read-out. The procedure is mildly painful but a considerable nuisance. And it can be surprisingly expensive, since the lancet and the strip are discarded after each use. IRISense is non-invasive and expected to be at least as accurate as the conventional method. The number of diabetic patients in the US numbers around 28 million and 233 million globally.

Since submitting their prior proposals, the applicants have engaged the services of a consulting firm to guide them with regard to FDA approval. The applicants believe, and the consultants have confirmed, that the completed system will be a Class III device, requiring pre-market approval from the FDA if it is sold as a diagnostic device on which therapy will be based. This will be a lengthy process, so the applicants business plan is to first sell the device as a method to view blood glucose trends (not diagnosis or treatment), which will place it in Class II. For Class II approval, the company must show that the product’s performance is as good as or better than existing blood glucose monitors; for Class III approval, the company must meet a higher standard. The leadership team has been strengthened and additional funding secured.

The project plan in the grant application proposes the initial experiments which will involve 20 diabetic patients instead of 20 non-diabetic patients. The goal is to demonstrate that sensing from the iris works for the relevant population, with much greater variability in blood glucose levels. In addition, an integrated glucometer will be constructed and a mobile platform developed.

With the assistance of the aforementioned regulatory consultant, the business plan is well designed and vetted, resulting in a favorable recommendation for funding. That said, the team should consider increased transparency to stakeholders with respect to data sharing. (For example, patients’ concerns with physician data accessibility; or endocrinologist/PCP resistance of adoption knowing insurance companies can monitor Quality of Care). In addition, with the end goal of a smart phone application, a software engineer should be in the short term planning process. The team will be faced with the challenge

of marketing a Class II device, but with the large number of diabetics, a small market penetration will provide the necessary revenues to move the technology to Class III.

**Proposal 13:538**, ProteoSense, LLC, Commercialization of ImmunoFET Sensors for Food Safety Pathogen Detection, \$100,000 requested.

**Amount recommended: \$100,000**

**Rationale:** ProteoSense LLC is a startup company formed to license and commercialize a breakthrough solid state biosensor, invented and provisionally patented by the Ohio State University. The device consists of an immunoHFET as a handheld meter with various sensor cartridge types that can be inserted to measure specific analytes, depending on the type of protein, or other macromolecular biomarker being measured. These measurements can provide critical characteristics for the food, biomedical and environmental industries.

The initial focus for the sensor market has been on the food safety testing market, estimated at \$3.4 billion in 2010 for the US. With the implementation of the Food Safety Modernization Act, this market will continue to expand. Rules are being promulgated for farmers to test irrigation water for bacterial contamination. Specifically, the company is targeting the fresh produce supply chain. Currently, samples are taken every shift throughout the chain of control and sent to regional laboratories for testing. Meanwhile, the produce flows toward the consumer. Test results are obtained several days later and if they are positive, then a costly recall is initiated.

The value proposition of this invention is speed. The proposed device offers a solution for the prevention of recalls and improvement in food quality. The invention being commercialized by ProteoSense can test for pathogens in the field, distribution center, warehouse etc., and provide lab quality results in 5 minutes.

The business model is to sell the meter at low cost to the different parts of the food chain and to then continue to provide the various sensor elements on an ongoing basis on a more profitable foundation. The team has an understanding of the regulatory/certification pathway to market. They have performed market analysis for their initial market, identified a critical unmet need, and developed a sound plan to exploit this unmet need. There is currently no known competitor who is able to test for pathogens with sufficient timeliness to be able to stop shipment of contaminated produce. AOAC endorsement is crucial to market acceptance. The development team recognizes the funding necessary to reach commercialization and is led by an experienced, proven "fund raiser". This proposal is a reapplication. The previous submission was rejected primarily for a lack of business plan. This proposal addresses all prior concerns and is recommended for funding.

**Proposal 13-539**, Miach Medical Innovation, Inc., A Cost Effective, Smart Endotracheal Tube that Improves Intubations, \$99,800 requested.

**Amount recommended: \$0**

**Rationale:** The proposed grant is for the development and commercialization of an endotracheal tube capable of sensing its anatomical location and movement to guide its placement and signal retention in a patient and thereby mitigate intubation errors. The device, once fully developed, would be accompanied by a clinician-monitored display for use in surgical and critical care settings. The team believes the technology has the potential to form a platform of bio medical carbon nanotube device products such as feeding tubes and catheters with sensors. The requested grant funding would support the nanotube prototype, biocompatibility analysis and delineation of the regulatory pathway. The review team had several concerns, but they are interrelated around the lack of a well-defined business model. For the endotracheal tubes, the grant applicants knew the cost of current endotracheal tubes is approximately \$2, and the additional cost of the sensors is \$1. Cost savings in the areas of remediation of the typical 20% failure rate and avoidance of daily \$200-\$400 X-ray testing were identified. However hospitals have been shown as unwilling to pay \$25 for products with similar value proposition to their proposed product. Critical to the success of the project is the market research to determine items such as whether hospitals will pay any surcharge for tubes with sensors.

In addition, the user interface is not yet defined. Hardware and/or software connections between the tube and the interface have not been accounted for in the pricing strategy, and the potential costs associated have not been calculated. While it's clear there is an unmet need, it is unclear what level of price premium can be obtained and whether these units can be produced and marketed profitably once full development is complete.

**Recommendations for Improvement:** In order to receive recommendation for funding, the financial aspects of the business model require refinement. Without the market research, the team may have selected the incorrect proof for additional funding and an improved application will detail all elements of systems development and associated costs. The business plan also needs to identify how the additional approximately \$1.8 million needed for commercialization will be raised.

**Proposal 13-540, BEAR Software, A Wireless Intra-Oral Palatometer, \$100,000 requested.**

**Amount recommended: \$0**

**Rationale:** For Dysphagia, or difficulty in swallowing, tongue motion is critical to therapeutic efforts, but devices which unobtrusively provide data to the therapist do not exist. The applicant proposes to develop the second-generation prototype (one more reflective of a marketable device) of an intra-oral palatometer for use in the evaluation and training of patients suffering from dysphagia (oral weakness), including victims of stroke, traumatic brain injury, cerebral palsy, Parkinson's and multiple sclerosis. In the opinion of the review team, the one year plan to miniaturize the prototype, make it wireless and reduce the cost appears to be aggressive. The proof of the proposal is to produce a robust, wireless palatometer that can be constructed using standard manufacturing processes for less than \$50 per unit and which exhibits clinically acceptable performance with an acceptable patient interface. This newly designed palatometer is expected to be marketed to speech and language pathologists through existing rehabilitation equipment manufacturers. The potential market appears to be attractive based upon

known patient populations. However, the number of current palatometer “encounters” is not estimated. That estimate would provide a better indication of quantitative market potential.

The applicant proposes to sell the recording system (and presumably each palatometer) and license the software to speech and language pathologists (SLPs). The assumed palatometer price is about \$100, which seems reasonable. However, the means by which SLPs and patients can be reimbursed for clinical procedures are not addressed. A reimbursement pathway is critical to commercial success in the US.

For long term sustainability of a startup company there needs to be something which provides a market edge and is well protected from competitors. Therefore, the TVSF has a requirement IP protection. For this proposal, the current stage of protection is filing of an Invention Disclosure with the University. The grant application makes no reference of a patent application, or any other protection of the technology. Further concern lies around the fact that no mention of product safety was made for an intra-oral wireless device for persons with compromised oral and tracheal abilities (choke hazard potential).

**Recommendations for Improvement:** In order to provide long term economic return for the State of Ohio TVSF funded startup companies must have IP protection in some form. In addition, should the applicant choose to reapply for funding, the business model should include items such as how SLPs would be reimbursed, projections on market penetration and market size, etc.

**Proposal 13-541**, QuTel, Inc., Quantum Tunneling Electronics for Ultra-Low Power Electronics, \$100,000 requested.

**Amount recommended (conditional): \$100,000**

**Rationale:** This proposal, which is a second submission, describes a validation/commercialization plan whereby Dr. Paul R. Berger, Professor of Electrical and Computer Engineering at Ohio State University and CEO of QuTel Inc., will draw upon five already existing, related OSU patents pertaining to Si-based tunnel diode technologies. The project described will be an effort to validate the new RITD technology and demonstrate to major electronics/semiconductor chip manufacturers, such as Intel, AMD, IBM, Samsung, QUALCOMM, etc., the benefits of the new technology for improving chip performance with significantly lower power consumption compared to existing commonly used CMOS technologies. The technical challenge is that to meet the chip size requirements of these major chip manufacturers, QuTel will need to significantly scale down the physical size of the demonstration pieces to the sub-100nm range typically utilized by the industry. The plan is to utilize MIT Lincoln Labs, along with QuTel’s internal facilities for the creation and testing of the necessary submicron sized devices.

The licensing business model planned for QuTel, Inc., is based on that of another very successful British digital components company, ARM Holdings, which does not involve the manufacturing and selling of any physical products such as semiconductor chips. The proposed business model only involves the designing and licensing of IP for which fee collection and royalties would be involved, i.e., manufacturing facilities or actual physical products, such as electronic chips/diodes would not be involved due to the multiple billion dollar investment needed for foundry construction.

The grant application indicates that down-the-road, if QuTel Inc. is successful, significant opportunities would be available for high paying technical / engineering jobs in Central Ohio. The basis for this positive employment outlook is that by comparison ARM employed 2,392 people, mostly engineers, in 2012.

The review team recognizes the considerable potential of this technology, including the fact that a Nobel Prize has been recently awarded in this area. The project plan is to utilize the CMOS facilities for the prototyping of the reduced geometry. While this work is both important and necessary, it is, in and of itself, insufficient. The applicant states on page 3, “step 2 is required to give prospective licensees confidence the technology will deliver significant advantage...” and thusly generate commercial interest in furthering the products. This fact was corroborated by the team’s Venture Capital expert as necessary for garnering the required next funding stage of \$1MM. Step 2 is the beta prototype memory array with the smaller cell and power reduction. To achieve this necessary milestone for commercialization an additional \$750,000 in funding is required, as detailed in the grant request. The recommendation is therefore that the grant be approved, conditional upon submission to the State of Ohio proof of funding commitments to cover the additional \$750,000 necessary for memory array prototyping. In addition, the potential CEO, who has been identified since the previous application should become a full member of the team along with this funding for best chances of business viability.

**Recommendations for Improvement:** The recommendation for funding is contingent upon provision of proof of additional funding commitments sufficient to satisfy the State of Ohio.

**Proposal 13-542, Akron Surface Technologies, Surface Treatment Platforms, \$100,000,**

**Amount recommended: \$100,000**

**Rationale:** The IP associated with this company formation is technology which simultaneously provides wear resistance comparable to Tantalum carbide (TaC), and coefficient of friction nearly equal to frictionless carbon. The result of application of a thin coating layer to metal is an extremely wear resistant surface and virtually non-abrasive to mating steel surfaces.

Akron Surface Technologies states that the increased reduction in friction will provide the users a longer life for any “system” that has been designed to use lubricants. The longer life will reduce maintenance costs. Longer life for, as an example, an automotive engine, is a high priority objective for OEM companies that want to differentiate themselves in the marketplace and is a very high priority for users who need to increase profit by reducing maintenance costs and increase the useful life of their assets. This would be attractive for an investor or even an OEM investment to complete the commercialization lifecycle.

The TVSF funds would be used to validate the technology in a variety of environments in order to commercialize the coating. The company has a market segment selected, a go to market plan, interested potential customers, a pro forma financial plan, protected IP and a team in place. If successful in the proof, the review team sees all critical components in place to commercialize this potentially disruptive technology.

**Proposal 13-543**, Protimage Diagnostics, LLC, PTPmu Molecular Imaging Probes Identify Cancer Cells During Surgical Resection of Tumors \$100,000 requested.

**Amount recommended: \$0**

**Rationale:** The technology under consideration for this grant proposal is the ability to detect within minutes, cancer at the cellular level and the ability to detect migrating and invasive cells at the tumor edge.

This proposal from Protimage Diagnostics, LLC, Cleveland, OH, addresses further testing which is expected to lead to a limited clinical trial. The first product of the company is based on the properties of a molecule called PTPmu (protein tyrosine phosphatase mu – the mu distinguishes a particular member in the family of PTPs). It is known that PTPmu binds to cell walls and also to itself and further that some cancer cells are able to cleave the bonds between adjacent PTPmu molecules. Therefore a probe that binds to cleaved PTPmu amounts to a probe for cancer, theoretically right down to the level of a single cancer cell.

These probes, are made detectable by tagging with either fluorescing material or paramagnetic material the first enabling detection under suitable illumination; the second using magnetic resonance imaging. The initial product is a probe suited for detection of a brain tumor called a glioblastoma. The idea is to inject the probe prior to surgery and to use suitable illumination during the course of surgery to identify regions where cancer is present, thus guiding the surgeon to remove whatever cancer is present while preserving tissue that has not been invaded by cancer. There is reason to think that additional probes suited for other kinds of cancer and other means of detection can be developed. In addition, a probe might also be used to carry a therapeutically active material selectively to the cancer sites.

The importance of being able to discern the margins of cancer invasion at surgery needs no emphasis. The initial application – surgical removal of brain tumors – is said to amount to about 150,000 cases per year in the US as a cost of some \$5 billion (\$33,000 per surgery). With a tentative pricing of the probe for each patient at \$2,500, the company anticipates a business that could amount to \$375 million per year for this single application.

The tasks addressed in this proposal are aimed at gaining FDA approval for a limited clinical trial. The probes will be manufactured by an Ohio-based company, Ricerca, adhering to Good Manufacturing Practices (GMPs). The probes will then be tested for toxicity in rats. Armed with these (presumably favorable) results, the company will approach the FDA to gain permission to conduct a limited clinical trial involving five to ten patients undergoing surgery to treat glioblastoma. Assuming that the surgical outcomes are improved, the company believes that it will then be in a good position to interest larger pharmaceutical firms in its products. Most of the money sought in this proposal will be used to pay two consultants: a regulatory specialist and a biotech business consultant.

While the review team recognizes the importance of this technology, concern with the proposed proof is there is no milestone stated as such in the proposal except that the goal is to obtain FDA approval for a limited clinical trial using the company's probe to better delineate cancerous tumors during surgery. Getting FDA approval is a necessary first step and having it could presumably be used to seek additional funds to carry out the trial, but it is insufficient to attract outside investment.

The current proposal makes no mention of the goals of the trial or the measurements that may be used to ascertain that use of the probe provides better surgical outcomes but simply presumes that surgeons will find the probes valuable, which may or may not be true. (For instance, if the probe produces false positives, it could be deleterious.)

The business plan only indicates the overall market size and the intended sale unit pricing. No understanding of the capturable market share and market adoption rates are identified. Nor are the costs presented.

As far as the proposal indicates, the company has but one member – Professor Brady-Kalnay – the review team reasonably expects additional team members, both to bring balanced skill sets to the development work and to be dedicated to the success of the company.

If it comes, the phase 2 proof will come from the clinical trials, which are not the subject of this proposal. Without an indication that use of the probe improves surgical outcomes (or at least improves surgeons' confidence that they have successfully removed tumor and preserved healthy tissue), there is not a "strong likelihood" that additional funds for the company will be forthcoming.

**Recommendations for Improvement:** As stated above, the proof necessary to generate additional funding would be successful clinical trials. Without this proof, additional funding will be difficult to obtain. The applicant should consider a Phase 2 application having an appropriate business model developed which includes pricing, costing margin, go to market strategy, etc., with dedicated team members to execute the plan.

**Proposal 13-544, OsteoNovus, Inc., Improving Bone Graft Technology, \$100,000 requested.**

**Amount recommended: \$0**

**Rationale:** This Phase 2 proposal follows on two prior Phase 1 proposals to the TVSF program (12-419 and 12-466). The first proposal was deficient in that, while the steps to be undertaken were necessary to demonstrate the alleged superiority of the new cement, they were not sufficient because they did not include measuring corresponding properties of existing cements. The second proposal was funded as a Phase 1 in August of 2012.

According to the current proposal, the applicants have formed an Ohio start-up called OsteoNovus, Inc., and turned their attention to a different but related compound, called Novogro, which is not only a cement but also a Bone Growth Substitute (BGS). Its composition is not clearly described in the proposal, but it is evidently a silicated compound of di-calcium phosphate anhydrous (DCPA). It can be formed into different shapes and used as an implant to replace natural bone with a matrix into which natural bone will grow.

The applicants claim superiority to other BGS materials, but provide no evidence, despite reporting successful completion of 'cadaver, chemical and initial small animal pilot testing'. The market for orthopedic implants is large and growing, and, if Novogro and related products actually possess all the virtues claimed for them vis-à-vis other products now on the market, they should provide a real opportunity for a start-up. However, there was no indication in the proposal of the capturable market size or expected adoption rate.

The application cites work that will be done with the requested funding, but fails to state what proof is needed to either commercialize the product or to entice outside funding. This, combined with lack of information or results from earlier work is a significant concern. Without the explanation of the necessary proof, the review team cannot evaluate the whether the tasks outlined, and thus the State of Ohio's funds, will be useful towards commercialization.

Finally, the report contains contradictory statements regarding funding; namely stating "OsteoNovus received \$50,000 from an angel investor and has received commitments of an additional \$150,000" for the 'stage of funding' section and then later states: "OsteoNovus has received great interest...from angel investors...None have committed funds as of yet"

**Recommendations for Improvement:** Should OsteoNovus re-apply for TVSF funding, a detailed explanation of the proof needed to bring the product to market should be articulated and supported by the evidence collected to date. Then the tasks and associated funding to accomplish the proof should be outlined. In addition, the business model section of the grant should detail potential revenues, costs etc.

**Proposal 13-545**, Spinal Balance, Inc., Facet Screw System, \$100,000 requested.

**Amount recommended, (conditional): \$100,000**

**Rationale:** This proposal from The University of Toledo concerns development of a facet fixation screw, which would be used in surgery of the spine to stabilize vertebrae made unstable by disk degeneration, injury, or other causes. This is the fourth overall submission for this technology, which did not receive a recommendation for Phase 1 funding on first two prior instances due to lack of detail on the facet screw itself – how it is different from other facet screws and how it is employed. This latest submission overcame previous deficiencies, and as a result, a positive recommendation was given for phase 1 in December of 2012.

An unstable vertebra moves out of alignment with the vertebra above or below, and the misalignment can cause local narrowing of the spinal canal and pinching of nerves, which cause pain. There are many treatments, and one of them is spinal fusion – causing two vertebrae to grow together in a properly aligned configuration. While such fusion is occurring, the two vertebrae must be fixed so that they do not move with respect to one another. One way of doing this is to place screws through the bony processes that protrude upward from each vertebra and articulate with processes that protrude downward from the vertebra above. Where these processes meet is a joint called the facet joint. This method of fixation has some advantages over alternatives in that the surgery is minimally invasive and the resultant fixation is not so rigid that it causes undue stresses on the vertebrae above and below those at the surgical site. Fixation with facet screws is just one of several methods currently in use. Facet screws are currently available from many established manufacturers as are so-called pedicle screws, which serve the same function – fixation so that one vertebra cannot move with respect to another.

The facet screw under consideration is different from other screws in two respects: it is secured only at the distal end where the screw has threads; the length of the screw between the head and the threaded portion carries a sleeve of human bone, derived from cadavers, that facilitates growth of the patient's bone around the screw and across the fixated joint between the upper and lower facets. Inserting facet screws is easier and less disruptive to the tissues that surround the spine than pedicle screws that are

installed in pairs in adjacent vertebrae and connected by rods. In addition, there is not the second surgery entry point for bone harvesting, so time in the operating theater is significantly reduced and recovery is faster.

The proof necessary for commercialization is the animal study, regulatory approval and clinical trials for surgeon acceptance. The team has an acceptable project plan, which is predicated on confirmation of the proposed screw having the strength of currently used screws. This study is presently in process and estimated for completion in April 2014. The team has performed a market survey and defined the pathway to market, their costs, etc. They know the selling price of currently marketed facet screws and can generate acceptable margin my matching current pricing.

Prior to attempting to raise additional funding, the applicant should refine their response as to why they have a very conservative estimate of market penetration if their product is superior to competitive materials and at the same price point.

The review team recommends approval with the condition that the grant requester must submit for review the finalized strength testing report from the above in-progress study. The concern is if the study results are not positive, then the proof being generated would not lead to commercialization.

**Recommendations for Improvement:** The recommendation for funding is contingent upon submission of affirmative strength test results.

**Proposal 13-546**, 3Bar Biologics, Inc., Commercializing Biological Inoculants to Increase Yield in Production Agriculture, \$100,000 requested.

**Amount recommended: \$100,000**

**Rationale:** This project proposes the initial sale and validation of a device for agricultural crop yield improvement by selecting beneficial microbiological inoculants from the targeted geographic region which will be grown and delivered via a bioreactor that will grow the microorganisms in sufficient volume with high enough titer to deliver viable inoculants to the soil. Initially, the pilot will be run in Ohio, utilizing proprietary microorganisms obtained from the Ohio State University (OSU). The microorganisms will be activated by the farmer by performing 5 easy steps, and then added to either the starter fertilizer or the seed. Initial testing indicates that the yield will be increased 5-10%, with higher values (up to 30%) obtained in stress conditions.

The business model projects the cost to the farmer per acre of approximately \$5, would result in improved yields generating an additional \$50 in revenue. In addition, the applicants have recognized the need for market penetration. Ease of use by the farmer is critical and they have therefore designed a simple system which will need TVSF funding for the container mold to be developed. By utilization of microbiological inoculants from the targeted geographic region, the microorganisms are deemed to be soil additives, thus easing the regulatory pathway to market. The review team, however, notes that the business plan could be improved with contingency planning for potential cash flow issues, reduction of the projected steep revenue

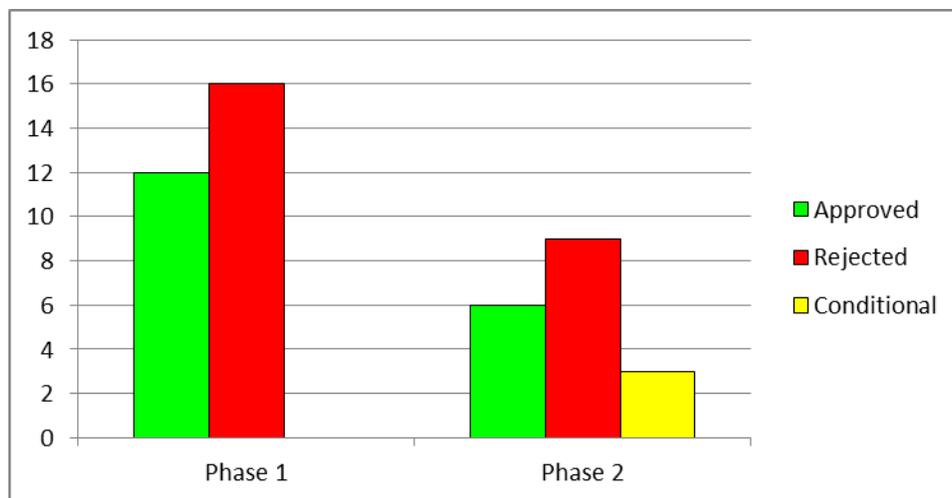
growth curve as well as accounting for the needed SG&A costs. The applicant should consider redirection of funds from planned testing in satellite states to more immediate needs of company formation and sustainability. The applicant should also obtain an opinion, in writing, from the EPA to confirm the assumption that regulatory approvals are not needed to sell the locally-sourced microbes so as to prevent unnecessary delays in commercialization. These concerns, while noted do not preclude the recommendation for funding.

## FINAL SUMMARY

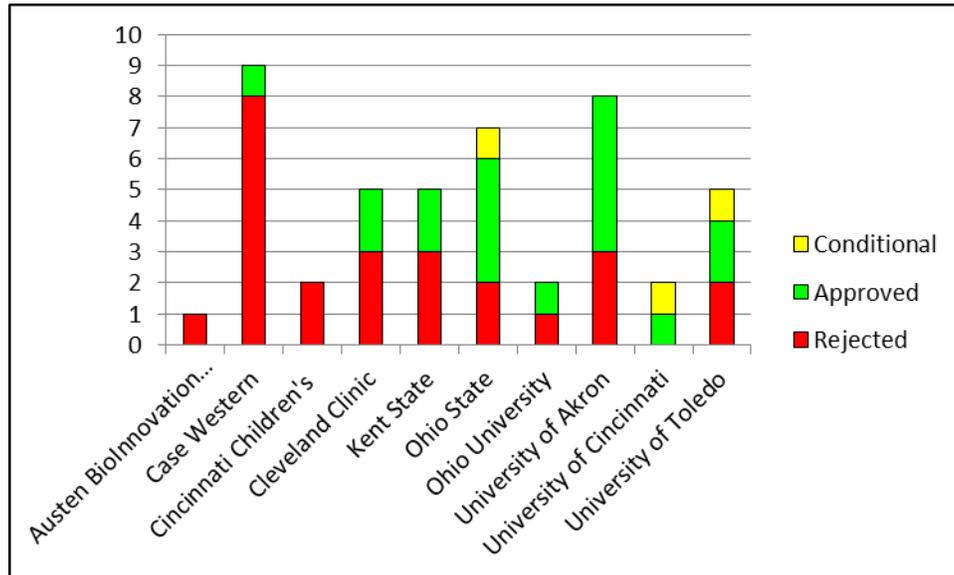
The Review Team is recommending 18 of the 46 submitted grants for review (39%). The previous low was 30% in Round 4, and the high was 52% for Round 2. For this current round, 12 of the 28 Phase 1 proposals are recommended for funding (43%). For Phase 2, six of the 18 submitted grants are recommended for funding (33%). Three of the 18 submitted Phase 2 proposals (17%) have conditional recommendations and require subsequent action by the applicant before final acceptance and funding. If conditions are met, then total Phase 2 funding would be 50%, with overall recommendations yielding 21 of 46 (46%). With the Ohio Third Frontier accepting grants on an approximate quarterly basis, the Review Team expects that many of the grants will be revised to address the concerns of the review team.

For both Phase 1 and Phase 2, grants which were recommended for funding without conditions did not have a “fatal flaw” in the proposal. The “fatal flaw” is described in the reviewers’ comments in the previous sections and readily identified as red in the charts at the beginning of the each of the phase reviews. Conditional recommendations were made for applications that were fundamentally sound, but contained significant concerns for success if they do not address the stipulations referenced.

*PHASE 1 AND 2 RECOMMENDATIONS CHART*



*COMBINED APPROVED/REJECTED CHART BY INSTITUTION*



If any applicant desires feedback or further clarification on the above recommendations a review session can be arranged through the Ohio Development Services Agency.

## APPENDIX A-TEAM MEMBERS

### *TECHNICAL REVIEWERS' CREDENTIALS*

#### **John Banisaukas (Advanced Materials)**

##### Summary:

An independent consultant specializing in Government Contracts Program Management and Administration, as well as a technical consultant to the carbon fibers advanced composites industry. Has a broad background and over forty years' experience in advanced composite materials.

##### Core Competencies/Field of Expertise:

Carbon Fiber

Advanced Composites

UCC's Parma, OH Research Center

Carbon Fiber Research and Development Engineer

UCC / BPA Carbon Fiber & Advanced Composites facility, Greenville, SC 21 years

Chairman of the Suppliers of Advanced Composite Materials Association (SACMA) Technical Affairs Steering Committee

### **Marshall Heard (Aero Propulsion and Power Management)**

#### Summary:

Expert joined the Florida Aerospace Alliance in 1999 after a 34-year career with the Boeing Company. He served as both Vice Chairman of the Alliance and Executive Director prior to becoming Chairman. While with Boeing, he divided his efforts between engineering, marketing/business development, and project management. As a Vice President he directed the Tandem Rotors Programs (CH-46 and CH-47), the Comanche Program (RAH-66), and served as the Deputy Program manager of the V-22 Joint Program Office. He was also Vice President of marketing/business development for Boeing's passenger, cargo, and tanker military aircraft programs and was Boeing Aerospace's senior executive in their Washington, D.C. office.

Expert has served on numerous Cabinet-level panels and commissions (including the Defense Science Board and the Commercial Space Transportation Advisory Committee). He has been a frequent witness before both the U.S. Congress and foreign legislative bodies on the subjects of strategic deterrence, battlefield mobility, and the role of technology in national defense policy. In addition to his role with the Florida Aviation Aerospace Alliance he also serves on the boards of Enterprise Florida, Inc., the National Aerospace Technical Advisory Committee and several other organizations. He has a keen interest in promoting science, technology, engineering and math (STEM) and serves on the Florida Coalition for the Improvement of Math and Science (CIMS), the Florida Center for Advanced Aero-Propulsion and is an Executive Committee member of the Aerospace Resources Center (ARC), the state's first BANNER center. Expert has an active aerospace related consulting practice specializing in business development and the integration of large scale systems.

#### Education:

A graduate of the U.S. Naval Academy, he also holds advanced degrees in engineering and business management from the University of Illinois and the Massachusetts Institute of Technology

### **James Mellentine (Fuel Cell and Energy Storage)**

#### Summary:

A Project Management Professional (PMP) and LEED Green Associate, combining years of fast-paced business consulting experience with renewable energy & energy storage technology, economics, and policy research. Directed the analysis, design, quality assurance, deployment, and training activities for complex system implementations and business transformations. Recommended logistics process transformations and performance management solutions based on industry best practices customized for client needs. Conducted broad energy systems and policy research.

#### Core Competencies:

- Project Management
- Business Consulting
- Renewable Energy
- Energy Storage
- Flow Batteries
- Energy Systems Analysis
- Project Financial Analysis
- Energy Project Feasibility
- Life Cycle Assessment

## Sustainable Building

### Education & Certifications:

University of Iceland/University of Akureyri, Master of Science, Renewable Energy Systems & Policy  
University of Michigan, Bachelor of Engineering, Mechanical Engineering  
University of Michigan, Bachelor of Engineering, Aerospace Engineering  
Project Management Professional (PMP), Project Management Institute  
LEED Green Associate, Green Building Certification Council

### **Phil Drew (Medical Technology)**

#### Summary:

Expert provides data and analysis to users and manufacturers of medical imaging equipment. For hospitals and radiologists, the Expert provides strategic planning services, program and space planning studies, studies of financial and organizational feasibility, and related assistance. For manufacturers and others interested in the commercial aspects of medical imaging he provides technological and market forecasts based on analysis of technical, clinical, operational and competition-related factors, as well as assistance in strategic planning, product planning and acquisition studies.

#### Experience:

Mallinckrodt Institute of Radiology  
Department of Radiology for the State University of New York at Stony Brook  
Cardiovascular Division of the Washington University School of Medicine  
Arthur D. Little, Inc.

#### Core Competencies/Field of Expertise:

Electrical engineering  
Mechanical engineering  
Health care  
Medical imaging  
Hospital operations

#### Education:

Harvard University, Degree: Ph.D. Electrical engineering  
Harvard University, Degree: M.S. Applied Mathematics  
Carnegie-Mellon University, Degree: B.S. Mechanical Engineering

### **John McClure (Business Reviewer)**

#### Summary:

Over 20 years of management experience. Expert builds shareholder and customer value through the development and implementation of creative business strategies and new product/service offerings for existing and new markets. Demonstrates the ability to successfully start up technology business ventures, including hardware, software, Internet, e-Commerce, and telecommunications solutions.

#### Experience

Sicuro-China LLC. - President & Chief Executive Officer  
Comm South Companies, Inc. - President & Chief Executive Officer  
ADVAIL Communications, Inc. – 2001 - Chief Operating Officer & General Manager  
Wintegrity, Inc. – President & Chief Executive Officer

Electronic Data Systems Corporation (EDS) – Business Unit Vice President, Strategic Global Opportunities

Core Competencies/Field of Expertise:

Bankruptcy  
Mergers and acquisitions including due diligence  
Operations management  
Financial support including public and private fund raising  
Support of the development and presentation of client business plans

Education:

University of Iowa & Roosevelt University, Accounting

**Joel Studebaker (Software Applications)**

Summary:

Over 30 years of experience in project management and in all phases of the software development life cycle for pharmaceuticals, biotechnology, blood banking, and other industries. Experience in drug discovery, high-throughput genotyping, and analysis of medical and pharmacy claims.

Experience

Integrated eCare Solutions – Director of Data Analysis  
CareAdvantage – Senior Data Manager  
Orchid BioSciences – AD of Informatics  
IBM – Advisory Engineer, Senior Industry Specialist

Core Competencies/Field of Expertise:

Project Management  
Oracle 10g  
Informatica 8.1  
Erwin Data Modeling  
SQL  
Clinical Risk Grouper  
SAS  
Toad

Education:

Harvard University, Degree: Ph.D. Chemical Physics  
Stanford University, Degree: B.S. Chemistry

**Thomas Jones (Sensing and Automation Technologies)**

Summary:

Over 25 years technical management and engineering analysis experience with the system engineering and integration of Electro Optical and Spectral remote sensing collection systems. Excellent communicator who provides briefings to all levels of corporate and government organizations, as well as technical and program management. Functional oversight and administrative management of group of lead senior remote sensing technologists.

Experience:

System Engineering Consultant

Lockheed Martin:

Management lead and technical oversight for multiple year remote sensing modeling corporate research & development effort. Resulting models used in proposals, studies and contracts and instrumental in acquiring new business.

Technical management coordinator of system integration support to government sensor technology research and technology customers. Provided technical oversight consultation of government contactors including technical roadmap development. Technology manager of senior remote sensor system analysts and technologist group.

Core Competencies:

System engineering for electro optical remote sensing collection systems including spectral analysis and requirements development/ system operations support/ sensor system modeling and simulations/ mission analysis / operations concepts/ technology roadmaps/ functional management/ project management/ research & development technical oversight and management / proposal and new business development

Education & Certifications:

BEE Villanova university 1964

MSEE Drexel University 1969

Multi-year System Engineering Course General Electric Co. 1970-72

Numerous Sensor engineering courses Lockheed Martin Co.

Numerous Proposal/Marketing courses Lockheed martin Co.

**Margaret Ryan (Sensing and Automation Technologies)**

Summary:

Chemistry Expert with broad range of Research, Consulting and Academic experience

Core Competencies/Field of Expertise:

Chemical sensors

Jet Propulsion Laboratory

Principal Member of the Engineering Staff, Power and SENSOR Systems Section,

Chemical sensors

Alternative SENSORS include an all silicon carbide sensor for identification of hydrocarbons and hydrocarbon mixtures for automotive applications, colorimetric oxidation sensors, and electronically conducting molecularly imprinted polymer sensors for identification of organic compounds in water.

Education:

PhD in Physical Chemistry from the University of Massachusetts

**Walter Gist (Situational Awareness and Surveillance Systems)**

Summary:

Successfully created and operates a consulting firm specializing in military aircraft avionics, advanced situational awareness, and weaponization. Several years of experience assisting foreign companies successfully market airborne equipment to the US military market. Organized and participated in proposal development, review and vetting. Has 41 years experience in marketing to the large US military OEMs like Boeing, Lockheed-Martin, Northrop Grumman, and BAE Systems. Understands the process by which foreign companies obtain access to International Trade in Arms Regulations (ITAR) controlled information and the rules and guidelines for doing so. He has also assisted in the merger and acquisition process.

Experience:

BAE SYSTEMS - Director, Business Development  
GEC-Marconi/Plessey, Plc - Marketing and Sales Manager  
Simmonds Precision - Aerospace Regional Manager

Core Competencies/Field of Expertise:

Mechanical Engineer by trade  
New Business Development  
Customer Relations  
Marketing and Sales  
Business Development Process

Education:

Business Administration, Pepperdine University Graziadio School of Business, Los Angeles CA

**Timothy Newbound (Solar Photovoltaics)**

Summary:

Organometallic synthesis of highly air- and moisture-sensitive compounds. Analytical evaluations using multi-nuclear NMR, FTIR, UV-vis, ESR, GC, x-ray structures and other methods to describe novel compounds described in peer-reviewed publications. Oil and Gas industry root-cause materials failure analysis for gas-oil separation plants (GOSPs), Water Injection Pump Stations (WIPS), pipeline systems (sour gas collection and Sales gas), Gas Plants (Amine sweetening and sulfur removal), natural gas and NGL fuel conditioning, dew-point control and light hydrocarbon separations. Research project management, project proposals, economic and technical feasibility studies and corporate strategic research assessments from industry-wide due diligence. Semiconductor materials development (Group IVA) and process scale-up for manufacturing of hydrocarbon functionalized nanocrystalline silicon free of surface oxides. Developed novel architectures using these materials in solar PV and Li-ion secondary batteries. Patent processing and intellectual property evaluation. Multiple international publications including ASME/IGTI O&G Division Best Paper Award, 2004.

Core Competencies:

Natural gas conditioning, dew-point control, dehydration, heavy-ends composition, (CGTs)  
Natural gas corrosion inhibitors (US patent # 6,920,802, July 26, 2005)  
Cross-functional team industrial applied research project management  
Analytical materials identification and root-cause failure determination  
Technical reporting and presentations preparation and delivery  
Organic, inorganic and organometallic synthesis and characterization  
Semiconductor (Group IVA) nanomaterials manufacturing process development

Education & Certifications:

Ph.D., Inorganic Chemistry, University of Utah  
Thesis: "Substitution Effects and Reaction Chemistry of Metal-Pentadienyl Complexes"  
B.S., Chemistry, Eastern Michigan University

**YourEncore Senior Manager**-Robert Worden

Robert has held a variety of sales, marketing and business development roles over a 20-year career, both as an individual contributor and as a manager. He has extensive work experience across the globe, with a concentration in Latin America. His core competencies include sales, marketing, business development, general management, and Six Sigma (certified Black Belt). He earned his MBA from the University of Virginia.

**YourEncore Senior Manager**-Camille Rechel, Director, Consumer Practice.

In addition to being a degreed chemist, Camille has over 25 years of Business Management experience. She holds several pioneering patents for polymeric coatings for optical fibers. She brings experience from the chemical industry and industrial electronics industry. Her core competencies include customer service and business development.

**YourEncore Project Manager**-David Young

David Young is a Project Manager with YourEncore and has led projects in numerous industries. He also assists with business development, rule harvesting and analysis, and Engagement Management. His core competencies include Project Management, Program Management, business rule definition and analysis, and process definition. If a proposal fell outside the technical experts' core capabilities, the Project Manager engaged an Expert from YourEncore's network with deep expertise in the proposal's specific technical area.

**YourEncore Expert – Gregory L Workman II**

Greg has a Master of Business Administration (MBA), BS Chemistry (ACS), is a Six Sigma Master Black Belt, and Certified Quality Manager, he has 25 years of industrial experience in Food/Pharma, Chemical Manufacturing, Electronics, Logistics, and Construction Services. Included in this experience are extensive Project Management and Business Process Design. He currently leverages this experience as a Your Encore expert to Create Business Processes and Implement Process Improvements to existing methodologies for firms of all sizes (Startups to Fortune 500) in diverse industries (Food, Medical Devices, Packaging, Cosmetics, etc.)

He utilizes his Project Management skills to lead the TVSF review process; and Business Evaluation skills to review the individual proposals for merit.

***Number of YourEncore Experts per Technology Area***

- *Advanced Materials: 63*
- *Aero Propulsion and Power Management: 19*
- *Fuel Cells and Energy Storage: 80*
- *Medical Technology: 86*
- *Software Applications: 109*

- *Sensing and Automation Technologies: 28*
- *Situational Awareness and Surveillance Systems: 31*
- *Solar Photovoltaic and Photovoltaic: 31*

## APPENDIX B-OVERVIEW TECHNOLOGY VALIDATION AND START-UP FUND

### *DEVELOPMENT’S PURPOSE FOR FUND*

Ohio’s Third Frontier (OTF) created the Technology Validation and Startup Fund (TVSF) to accelerate economic growth in Ohio through helping Ohio-based entrepreneurial companies commercialize technologies developed by Ohio institutions of higher education. The TVSF will accomplish this through:

1. **Validating Technologies:** Enhancing the commercial viability of protected technologies developed by Ohio institutions of higher education by supporting validation activities such as developing prototypes, demonstrations, and/or assessments. These validation activities will help generate the proof needed to either license the technology to an Ohio entrepreneurial firm or deem the technology unfeasible. The purpose of Phase 1 is to verify a milestone for licensing, not funding for basic research.
2. **Funding Startups:** Providing Ohio-based entrepreneurial firms the funding needed to accelerate the commercialization of licensed technologies from Ohio institutions of higher education. The goal is to enable these companies to 1) generate the proof needed to acquire additional outside funding to support commercialization or 2) support the commercialization of these licensed technologies. The purpose of Phase 2 is to establish start-up companies, independent of the university.

OFT has divided the Fund into 2 distinct Phases:

	<b>Phase 1: Technology Validation</b>	<b>Phase 2: Startup Fund</b>
<b>Objective</b>	<i>Evaluate the commercial viability of protected technology developed by Ohio institutions of higher education</i>	<i>Determine whether a company has the resources, acumen, and market opportunity to successfully commercialize licensed IP</i>
<b>Activities</b>	<ol style="list-style-type: none"> <li>1. Assess protected technologies from higher education institutions</li> <li>2. Suggest technology development alterations to improve feasibility</li> <li>3. Provide funding recommendations</li> </ol>	<ol style="list-style-type: none"> <li>1. Assess companies’ plan for commercializing licensed technologies</li> <li>2. Discuss improvement programs to unfunded Applicants</li> <li>3. Interview strong candidates</li> <li>4. Recommend funding candidates</li> </ol>

Assumptions	<ul style="list-style-type: none"> <li>▪ Submissions Per Year:               <ul style="list-style-type: none"> <li>- 2012: 50-80</li> <li>- 2013: 100-160</li> </ul> </li> <li>▪ 6 Page Grant Form</li> <li>▪ Grant Size: \$50K</li> <li>▪ Available Funds: \$3M</li> </ul>	<ul style="list-style-type: none"> <li>▪ Submissions Per Year:               <ul style="list-style-type: none"> <li>- 2012: 20-40</li> <li>- 2013: 40-80</li> </ul> </li> <li>▪ 6 Page Grant Form</li> <li>▪ Grant Size: \$100K</li> <li>▪ Available Funds: \$3M</li> </ul>
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Due to the technical nature of the Phase I / Phase II Proposals, OTF required the selected reviewing contractor to have subject matter expertise in the following technical areas:

- *Advanced Materials*
- *Aero Propulsion and Power Management*
- *Fuel Cells and Energy Storage*
- *Medical Technology*
- *Software Applications*
- *Sensing and Automation Technologies*
- *Situational Awareness and Surveillance Systems*
- *Solar Photovoltaic and Photovoltaic*

## APPENDIX C-EVALUATION CONTRACTOR-YOURENCORE, INC.

### CORPORATE BACKGROUND

YourEncore is a company of veteran scientific, engineering and technical Experts that provides clients with solutions based on a lifetime of proven expertise. YourEncore deploys its expertise against capability, capacity, and technical challenges in a confidential environment to help clients develop products essential to healthier, safer and richer lives. Given its diversity of expertise and flexible resourcing deployment model, YourEncore offers unique flexibility to swap in and out the right expertise or team size to meet the needs of client demands.

#### YourEncore Expert Network Profile:

- 7,000+ Experts
- Avg. 25+ years Experience
- 67% have advanced degrees
- Representing 1000+ different companies

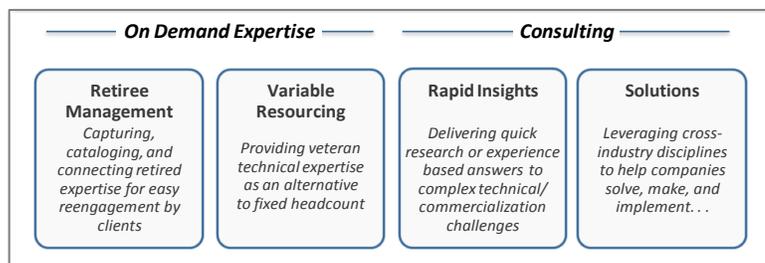
YourEncore understands the unique needs and challenges startups face since, 8 years ago, it was one. YourEncore was founded in 2003 by John Barnard of Barnard Associates. Barnard Associates is composed of a cross-functional team of highly experienced executive leaders, who advise start-ups on launching and growing businesses. Tim Tichenor, formerly the Director of the Business Development Center for Indiana University and Director of Business Advisory Services for Barnard Associates, is YourEncore’s CFO.

Today, YourEncore has over 75 employees and is a recognized leader in Expert advisory services. YourEncore has over 7,000 Experts in its network, and serves over 70 companies, including 9 of the top 12 pharmaceutical companies and 5 of the top 9 global consumer companies. YourEncore was awarded a top 100 “Most Brilliant Company” by Entrepreneur Magazine in 2011 and P&G’s “External Enabler of the Year” Award in 2009.

### SERVICES & EXPERIENCE

YourEncore deploys its Expertise in two ways: On-Demand Expertise, contracting of specialized Expertise to address short-term resource gaps, and Consulting. Within Consulting, technology assessment and due diligence are core offerings. YourEncore performs assessments for over 50% of its 70+ clients, the majority of which are global leaders in their industries.

Figure 1: YourEncore’s Services



### SUMMARY OF QUALIFICATIONS

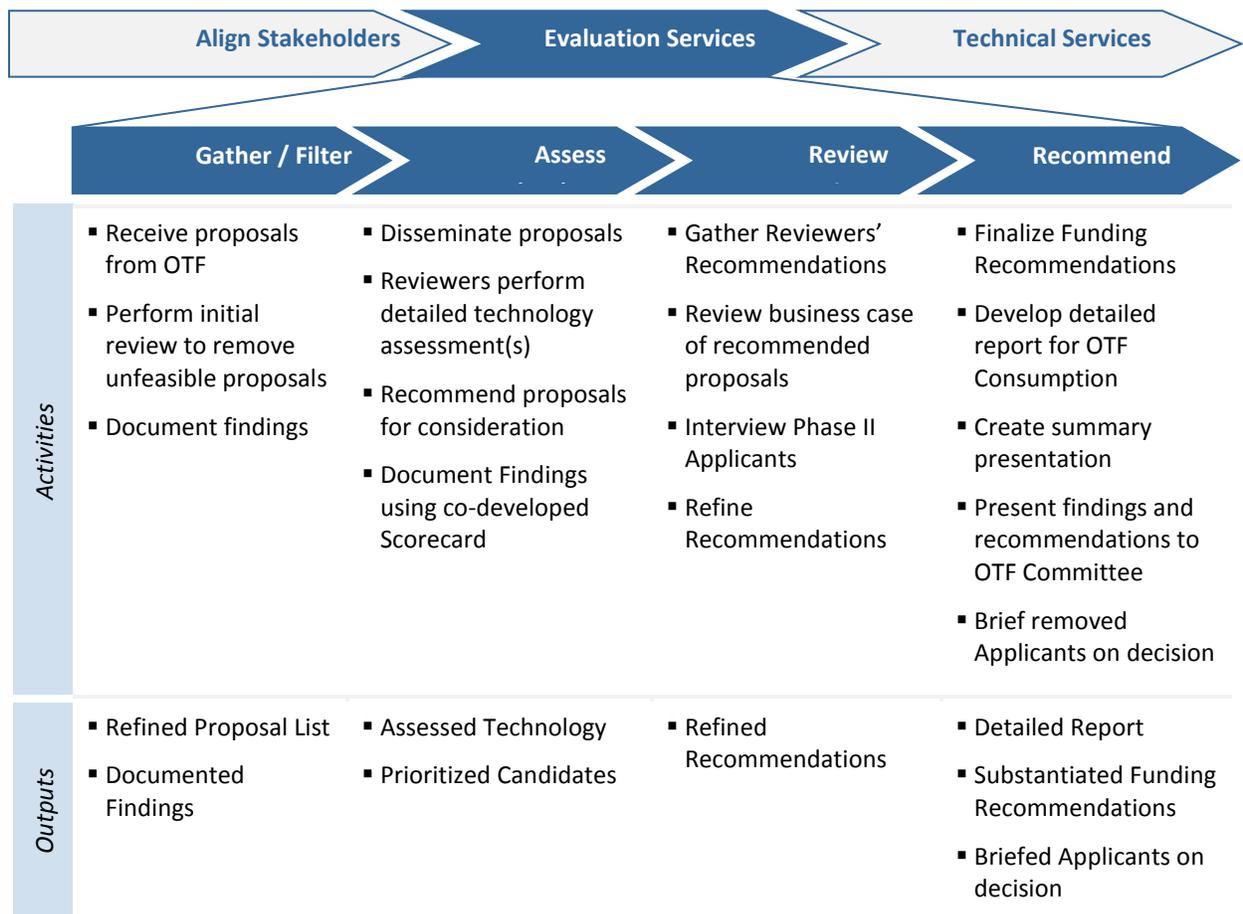
<b>1. Unparalleled Expertise</b>	<b>2. Recognized Leader</b>	<b>3. Flexible Resource Model</b>
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## APPENDIX D-EVALUATION PROCESS

### APPROACH AND MANAGEMENT PLAN

YourEncore engaged an Expert team comprised of a Project Manager, Business Reviewer, and eight Technical (i.e., Subject Matter) Reviewers along with 2 of its senior managers to most efficiently and accurately assess all Phase I / Phase II proposals. Prior to implementing a robust Phase I and Phase II RFP evaluation process, YourEncore conducted a grounding session to align stakeholders around common objectives and finalize the expertise requirements.

After the stakeholders were aligned, YourEncore deployed a comprehensive Proposal Evaluation process that initially gathered and filtered all submissions, engaged subject matter experts to assess technologies/firms, and provided substantiated funding recommendations. Finally, to ensure a robust review, YourEncore senior managers reviewed for consistency and quality.



## Align Stakeholders

Shortly after selection, YourEncore held a half-day grounding session with YourEncore's stakeholders (i.e., Account Director, Project Manager, Senior Managers) and OTF's desired stakeholders. This session assured alignment around common success criteria (i.e., funding goals, success metrics, and timelines), scoped the program's expertise requirements to ensure the right subject matter experts were engaged, and reviewed the evaluation scorecard. This scorecard included the following information:

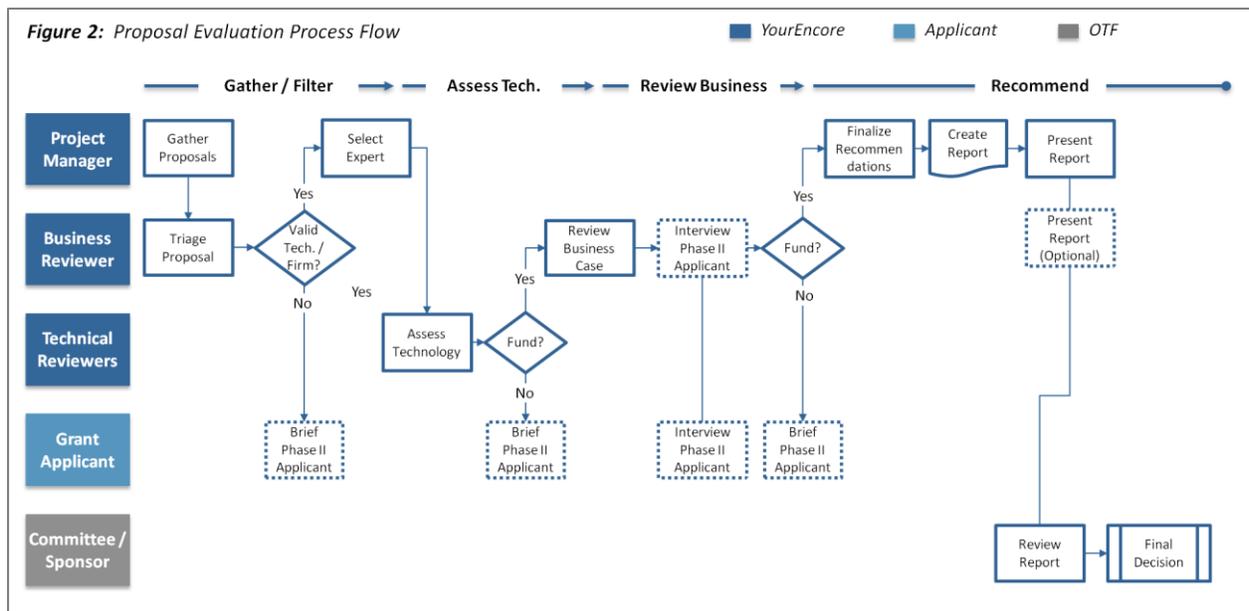
### **Key Evaluation Scorecard Components**

- *Alignment and quality of response to the TSVF's RFP requirements*
- *Demonstrated proof to move technology / business to a next major milestone*
- *Evidence that milestone can be obtained during the one-year period and with the proposed resources*
- *Validation / proof process will be overseen by independent 3rd party*
- *Achievability of the proposed technical application and/or business model*
- *Demonstrated support/ stable backing that is independent from the university. (Phase II only)*
- *Strength of Intellectual Property (IP) protection*
- *Likelihood project will lead to the creation and/or success of a Ohio-based entrepreneurial company*

In addition, YourEncore conducted a grounding session with all technical reviewers to assure they were aligned on the criteria and they judged each grant submission in a uniform manner.

## Evaluation Services

To assure a robust decision for each Phase I and Phase II Proposal YourEncore instituted a four part approach that encompassed gathering / filtering submissions, assessing the technical feasibility, reviewing the business case, and recommending funding prospects.



**Gather and Filter Submissions:** After gathering the Proposals from OTF the Project Manager collaborated with the Senior YourEncore Managers to remove all submissions deemed unfeasible, document findings, and brief Phase II applicants as required. For those submissions deemed feasible, the Project Manager then identified an Expert with the necessary technical background to perform an in-depth assessment.

**Assess Technology:** Upon receiving the proposal, the YourEncore Technical Reviewers’ leveraged the co-developed evaluation scorecard to perform assessments for the Phase I / Phase II submissions they were provided. Upon completion of the assessment the Technical Reviewers documented their recommendations.

**Review Business Case:** The Project Manager compiled the technical assessments and disseminated recommended Proposals to the Business Plan Reviewer. The Business Reviewer then reviewed the business case and analyzed the market potential of each recommended proposal. For all recommended Phase II applicants, the Business Reviewer, the Project Manager and YourEncore Senior Managers conducted a short on-site interview to further determine the company’s feasibility.

**Recommend Funding Decision:** After determining the final recommendations, the Project Manager and Senior YourEncore Managers developed this detailed report and summary presentation to share the assessments’ findings and the final funding recommendations, including dollar amount, with the OTF Committee. The OTF Committee will then use the final recommendations to distribute the funding as they deem appropriate.

## TEAM STRUCTURE AND QUALIFICATIONS

To successfully execute YourEncore's proposal a clear team structure (See Figure 3) with defined roles and responsibilities was required.

### DEVELOPMENT COMMITTEE

OTF has an established Committee to provide overall program sponsorship, guidance, and support to ensure the program's success.

### DEVELOPMENT SPONSOR

YourEncore worked with Dr. Andrew Hansen from Development to help set the direction for the team, review progress on a monthly basis, and work with YourEncore's Project Manager to resolve any issues. Furthermore, Dr. Hansen previewed the final outputs prior to Development Committee presentation and support implementation of improvement initiatives.

### PROJECT MANAGER

The YourEncore Project Manager managed the day-to-day operations of the program including ensuring all assessments are completed on-time. This individual established and managed the program's processes, assured process / scorecard compliance, and engaged / managed Technical Reviewers to ensure on-time completion of assessments. Furthermore, this individual leveraged YourEncore's internal Project Management system to track each proposal's submission, expert assignment, timelines, budget, and documented outputs.

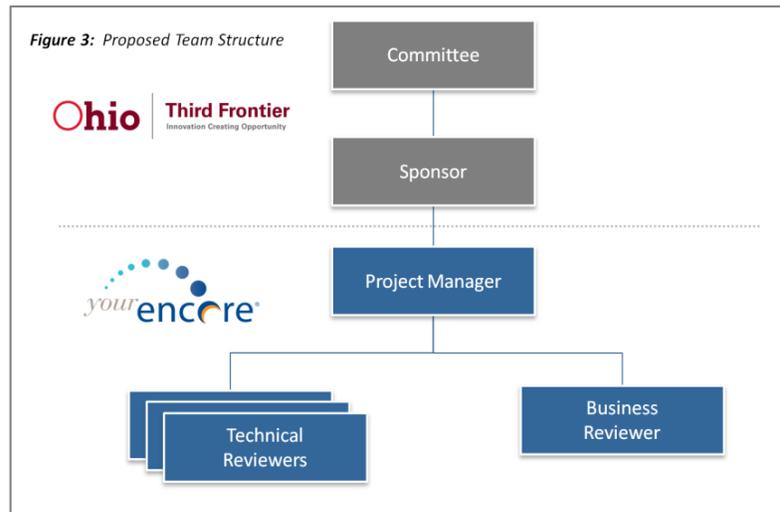
### BUSINESS REVIEWER

To validate the Experts' recommendations YourEncore engaged a strategic business development, entrepreneurial expert to perform review of all Proposals. Furthermore, this individual participated in all Phase II onsite interviews.

### TECHNICAL REVIEWERS

YourEncore identified and selected a team of nine subject matter experts to perform detailed technical assessments on Phase I and Phase II proposals, complete co-developed scorecard and document recommendations. Reviewers had expertise in each of the following areas.

- *Advanced Materials*
- *Aero Propulsion and Power Management*
- *Fuel Cells and Energy Storage*
- *Medical Technology*



- *Software Applications*
- *Sensing and Automation Technologies*
- *Situational Awareness and Surveillance Systems*
- *Solar Photovoltaic and Photovoltaic*

### *SYSTEM INFRASTRUCTURE AND UTILIZATION*

YourEncore leveraged its internal Project Management System, DelTek Vision, as the central system of record for the program. This system houses all information for thousands of YourEncore projects and has the capacity to handle all of OTF's Phase I / Phase II proposal information.

YourEncore believes this is the best solution due to the program's robust document repository, project management tools (i.e., timelines, budgets, experts engaged), reporting, and activity audit trail capabilities. By leveraging this system all Reviewers will utilize one system to house and track all the activities, scheduling, and documents associated with this program. Furthermore, this system will enable YourEncore to create reports on a regular basis to report on progress, budget utilization, and identify / reconcile issues.