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## Technology Validation and Start-Up Fund

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### Round 6 Submittal Evaluations

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Submitted To:

David Goodman

Director, Ohio Development Services Agency

Chair, Ohio Third Frontier Commission

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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 6, a total of 36 requests for funding were submitted to OTF’s Technology Validation and Start-Up Fund, 15 for Phase 1 and 21 for Phase 2. This represents a quantity of requests for this round that was a little greater than expected given the large number of submissions in the last round.

Of these 36 requests, seven requests in Phase 1 (47%) and seven in Phase 2 (33%) were recommended for funding to OTF by the expert Review Team. Two of the 21 Phase 2 applications were prior Phase 1 awardees; one of which has been recommended for funding this round. As with the previous five 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 again varied generally, 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. Five of Six Phase 1 reapplications (83%) are recommended, and one of five Phase 2 resubmissions (20%) is recommended. 45% 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 were not recommended for funding due to concerns in Generation of Proof (4 of 15 had this fatal flaw); Path to Market (5 of 15); and 3<sup>rd</sup> Party Review (4 of 15). 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 Path to Market 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 may not exist. Phase 2 proposals not recommended for funding were nearly all deficient, at least to an extent, in their business model (10 of 15), 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. Another area of deficiency is related to project financials. Budget or Use of Funds was of concern in seven of 21 applications (33%). Another major concern in six of 21 (29%) was for the Proof with similar themes as in Phase 1 proposals. Finally, with Proof issues in six of 21 (29%) proposals comes follow on funding deficits.

Grant dollars recommended for funding is approximately \$998,000, versus \$950,000 for round 1, \$900,000 for round 2, \$610,000 for Round 3, \$864,000 for round 4 and \$1,462,000 for Round 5. Dollar amounts and percentage approvals are approximately average compared to past rounds. There were two grants recommended that did not submit their request for the maximum allowable amount.

<b>Round</b>	<b>Approval Rate</b>	<b>\$\$ Recommended</b>
<b>1</b>	<b>35%</b>	<b>\$950,000</b>
<b>2</b>	<b>52%</b>	<b>\$900,000</b>
<b>3</b>	<b>44%</b>	<b>\$610,000</b>
<b>4</b>	<b>30%</b>	<b>\$864,000</b>
<b>5</b>	<b>46%</b>	<b>\$1,462,000</b>
<b>6</b>	<b>39%</b>	<b>\$998,000</b>

### THE PHASE 1 PROPOSALS THAT ARE RECOMMENDED FOR FUNDING

Proposal #	Lead Applicant	Proposal Title	Project Focus	State Funds Requested	Total Budget	Recommended
14-401	The University of Toledo	<i>Flow-induced electromagnetic anti-fouling technology (FI-EMAF Technology)</i>	<i>Advanced Materials</i>	\$43,653	\$87,306	\$43,653
14-402	Case Western Reserve University	<i>Software Suite for Diagnostic Imaging of the Retina by Two-Photon Florescence Microscopy</i>	<i>Software</i>	\$50,000	\$100,000	\$25,000
14-405	Ohio University	<i>Development of a New Versatile LC/MS Interface via Non-Destructive Mass Spectrometric Sensing</i>	<i>Sensing and Automation</i>	\$50,000	\$100,000	\$50,000
14-407	Case Western Reserve University	<i>Replacing Endoscopic Imaging with Non-Invasive Office Based Screening Test for Barrett's Esophagus</i>	<i>Medical Technology</i>	\$50,000	\$100,000	\$50,000
14-412	The Cleveland Clinic Foundation	<i>Coronary Chronic Total Occlusion Guidewire Family to Treat Coronary Artery Disease</i>	<i>Medical Technology</i>	\$50,000	\$100,000	\$50,000
14-414	Northeast Ohio Medical University (NEOMED)	<i>The Role of Osteoactivin in Bone Regeneration</i>	<i>Medical Technology</i>	\$30,000	\$60,000	\$30,000
14-415	The Cleveland Clinic Foundation	<i>Complex Arrhythmia EP Mapping Catheter</i>	<i>Medical Technology</i>	\$50,000	\$100,000	\$49,000

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

Proposal #	Lead Applicant	Licensing Institution	Proposal Title	Project Focus	State Funds Requested	Total Project Budget	Recommended
14-416	Sense Diagnostics, LLC	<i>University of Cincinnati</i>	<i>Sense Diagnostics, LLC: An Early Stage, Ohio Based, Scalable Neurotechnology Company</i>	<i>Sensing and Automation, Medical Technology</i>	\$100,000	\$100,000	\$100,000
14-423	TeraProbes Inc.	<i>The Ohio State University</i>	<i>Non-contact Probes for High-Frequency Electronic Chip Testing</i>	<i>Sensing and Automation, Medical Technology</i>	\$100,000	\$100,000	\$100,000
14-424	Lattice Biotech LLC	<i>Research Institute at Nationwide Children's Hospital</i>	<i>Broad Spectrum Anti-Infective Monoclonal Antibody for Chronic Infection Markets</i>	<i>Medical Technology</i>	\$100,000	\$147,000	\$100,000
14-425	Standard Bariatrics, Inc.	<i>University of Cincinnati Research Institute</i>	<i>Vertical Sleeve Gastrectomy Stapling Guide</i>	<i>Medical Technology</i>	\$100,000	\$125,000	\$100,000
14-431	Flexible ITO Solutions	<i>Kent State University</i>	<i>Commercialization of Cracked ITO Substrates for Smart Windows</i>	<i>Advanced Materials</i>	\$100,000	\$205,000	\$100,000
14-434	Ion-Vac, Inc.	<i>The Cleveland Clinic Foundation</i>	<i>Wound Healing System</i>	<i>Medical Technology</i>	\$100,000	\$173,000	\$100,000
14-436	Columbus Technology LLC	<i>The Ohio State University</i>	<i>DICE</i>	<i>Software</i>	\$100,000	\$200,000	\$100,000

## PROPOSAL RECOMMENDATIONS - PHASE 1 SUMMARY MATRIX

PROPOSAL #	Lead Applicant	PROJECT TITLE	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
14-401	The University of Toledo	Flow-induced electromagnetic anti-fouling technology (FI-EMAF Technology)								
14-402	Case Western Reserve University	Software Suite for Diagnostic Imaging of the Retina by Two-Photon Florescence Microscopy								
14-403	Cincinnati Children's Hospital Medical Center	Development of a Novel Electronic Adherence Monitoring Device								
14-404	The Ohio State University	KAir Battery								
14-405	Ohio University	Development of a New Versatile LC/MS Interface via Non-Destructive Mass Spectrometric Sensing								
14-406	University of Cincinnati Research Institute	Vertical Sleeve Gastrectomy Stapler								
14-407	Case Western Reserve University	Replacing Endoscopic Imaging with Non-Invasive Office Based Screening Test for Barrett's Esophagus								
14-408	Ohio University	Intelligence for Diabetes Support System (14DSS)								
14-409	The University of Toledo	Nanoelectronic Memristor Device								
14-410	The Cleveland Clinic Foundation	Autism Spectrum Disorder								
14-411	The Cleveland Clinic Foundation	Cardioscope Direct Intracardiac Imaging in Beating Heart								
14-412	The Cleveland Clinic Foundation	Coronary Chronic Total Occlusion Guidewire Family to Treat Coronary Artery Disease								
14-413	The Cleveland Clinic Foundation	Sleep Apnea								
14-414	Northeast Ohio Medical University (NEOMED)	The Role of Osteoactivin in Bone Reperation								
14-415	The Cleveland Clinic Foundation	Complex Arrhythmia EP Mapping Catheter								

*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 -- description of how the entity proposes to use the funding if received

## DETAILS OF PHASE 1 RECOMMENDATIONS

<b>Proposal 14-401</b>	<b>The University of Toledo</b>	<b>Flow-induced electromagnetic anti-fouling technology (FI-EMAF Technology)</b>
<b>Amount Requested:</b> <b>\$43,653</b>	<b>Recommended:</b> <b>\$43,653</b>	

**Rationale:** This application is a resubmission from 13-524 which was not recommended for funding due to unclear path to market, overly aggressive schedule, and a lack of third party validation.

This revised submission addresses our previous concerns. It proposes to develop Flow Induced Electromagnetic Force (FI-EMF) technology which utilizes a small electromagnetic force to prevent microbial and protein attachment to the surfaces of medical catheters with possible use for other major non-medical antifouling markets such as for marine products and food packaging applications. This antifouling technology combines a naturally-conducting polymer (cardanol-based compound) with magnetic particles to generate a small electromagnetic force on the surface of catheters (or other) devices/materials. This technology has demonstrated superior ability to prevent protein and cell attachment when tested at the University of Toledo using in vitro techniques by the primary investigator Dr. Dong-Shik Kim. Currently, available antifouling technologies include coatings that utilize silver or nitrofurazone, however numerous independent reports have been published demonstrating that these devices offer limited antifouling effects as compared to non-coated (control) devices tested. Funding from this TVSF grant is expected to further validate this technology and clearly show that the FI-EMF technology offers distinct advantages/benefits over currently available coated and non-coated devices. Such advantages/benefits include: 1/3 the cost, 4x life cycle, and will not contribute to creation of antibiotic resistant pathogens.

The proposal addresses all of the criteria for the phase 1 TVSF and is recommended for funding.

Additional concerns which were not sufficient to preclude funding relate to Path to Market and Use of Funds. Although NAMSA has suggested the regulatory pathway should be straightforward, further research may be needed to confirm a food contact predicate will be sufficient to clear 510(k) for a medical device. Also, the budget could be more granular in use of funds.

<b>Proposal 14-402</b>	<b>Case Western Reserve University</b>	<b>Software Suite for Diagnostic Imaging of the Retina by Two-Photon Fluorescence Microscopy</b>
<b>Amount Requested:</b> <b>\$50,000</b>	<b>Recommended:</b> <b>\$25,000</b>	

**Rationale:** This proposal is a resubmission of 13-519 that was not recommended for funding due to lack of Third Party Review and Use of Funds. This submission addresses the previous concerns of significance.

The proposal is 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 a 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.

The review team found significant concern related to the Budget/Use of Funds. The project plan narrative describes the use of \$50,000 not \$100,000. Thus this proposal is recommend for funding at the cost share level for the described use of funds at \$25,000.

Additional concerns which were not sufficient to preclude funding relate to Business Model and IP. These remain from before. There is a lack of capturable market understanding. In addition, some sales are dependent upon companion hardware which limits potential growth. Finally IP protection is only Trade Secret. Should CWRU choose to reapply for full TVSF funding, the grant application should detail the additional work to be covered by the increased budget.

<b>Proposal 14-403</b>	<b>Cincinnati Children's Hospital Medical Center</b>	<b>Development of a Novel Electronic Adherence Monitoring Device</b>
<b>Amount Requested:</b> <b>\$50,000</b>	<b>Recommended:</b> <b>\$0</b>	

**Rationale:** Applicant proposes development of an electronic device that would regularize and facilitate patients' adherence to a prescribed medication regimen, that patients with chronic conditions that require sustained medication, especially youths, often fail to adhere to the prescribed schedule and amounts, which is a significant problem, not only because it may increase need for care but also because physicians cannot distinguish between non-adherence and lack of response.

As described in the proposal, the device will allow the user to connect multiple pill bottles to a programmable dispensing component. Prior to use, the device will be programmed with the individual's medical regimen (number and type of pills to be taken, and at what time) via a mobile device, which will engage end users to promote use. When doses are due, visual and/or auditory reminders will signal that a medication needs to be taken. The user will then order the device to dispense a dose into a locking tray. The user will then access medications by opening the lid on the tray. The tray will be portable. Beyond this initial design concept, not much work has been done – no prototype, no patent applications.

Initial target market is juvenile patients with inflammatory bowel disease (IBD). It is expected that the design will be usable by most patients with chronic diseases regardless of their ages or particular ailments.

Although the concept is appealing, the review team found significant concerns related to Proof, Project Plan, 3<sup>rd</sup> Party Review, and IP Protection. First, the product is too nascent and is in the ideation stage, and it would appear very little work has been done to reduce this concept to practice. Producing a licensable product in 12 months is therefore unlikely. There is no 3<sup>rd</sup> party review. Finally, no IP protection exists. In fact this appears to be in the same space as the iLidRx (14-421) which is Patent Pending, so a patent landscape review may be required to ensure freedom to operate.

Additional concern which was not sufficient to preclude funding relates to the Ohio Startup criteria in that one of the partners appears to be operating in a similar commercial space with their "Pillbox" software.

The proposal is not recommended for funding.

**Recommendations for Improvement:** Should CCHMC choose to reapply for TVSF funding, the technology should be ready for validation. The plan should include a 3<sup>rd</sup> party independent review and a robust IP evaluation will need to be conducted.

<b>Proposal 14-404</b>	<b>The Ohio State University</b>	<b>KAir Battery</b>
<b>Amount Requested: \$50,000</b>	<b>Recommended: \$0</b>	

**Rationale:** Applicant proposes to develop coin cells for use in the stationary energy storage market with 2-4 watt hours (Wh) capacity that will be thoroughly tested and optimized and additionally tested and verified by a third party. The validation of the coin cell prototypes will demonstrate immediate applicability to the uninterruptable power supply (UPS) market and help attract further investment to research and develop higher-capacity and longer-life batteries for additional applications. Preliminary prototypes of the potassium-air battery have shown promising results, with 98% energy efficiency, 50 charge/discharge cycles, and low cost.

The KAir Battery team will use the funds for hiring a graduate student researcher, materials characterization services and lab fees, supplies, components, and equipment to produce the coin cell prototypes.

At the end of the 1-year project stage, the team has arranged for Honda to validate the performance of the prototype batteries. The team and technology has already attracted a number of other awards and grants and has a series of inventions to back up the intellectual property.

Although the technology appears sound with a reasonable chance of success, the review team found significant concern related to Path to Market. The need to bridge a funding gap of \$6MM, with no committed sources, makes commercialization unlikely. While the applicants list a number of prospective partners as potential investors, such as IBM and Tesla, no contact has been made with these companies to date. In addition, the applicants indicate in Year 2 they plan to seek additional government funding, suggesting that the research may not be ready for licensing with the TVSF funds. As such future sources of funds are speculative. Given the amount of funding needed, this is too large a gap to leave unaddressed, even at this relatively early stage of development.

Additional concerns which were not sufficient to preclude funding relate to Use of Funds, as the Budget and Plan narrative differ by \$5K for equipment.

**Recommendations for Improvement:** Should OSU choose to reapply for TVSF funding, the grant application should provide a funding plan to bridge the gap and clarify the current nature of their relationship with all outside parties on whom future development work is contingent.

<b>Proposal 14-405</b>	<b>Ohio University</b>	<b>Development of a New Versatile LC/MS Interface via Non-Destructive Mass Spectrometric Sensing</b>
<b>Amount Requested: \$50,000</b>	<b>Recommended: \$50,000</b>	

**Rationale:** This proposal is a resubmission of 13-503 which was not recommended for funding due to lack of Proof milestones and Third Party Review. This submission has addressed those previous concerns.

Applicant proposes to develop a new analytical interface technology for the chemical / biological market and is applicable to pharmaceutical development, petroleum producers, food industry, hospitals, and research laboratories. Although the device and technology is applicable to various sensors, the application being utilized in this effort is the Liquid Chromatography/Mass Spectrometry (LC/MS) sensing market. These devices have traditionally consisted of a column containing a solution, through which the substance being measured passes and separates at different rates. The resulting products go to a mass spectrometer which measures molecular masses to characterize the individual products. This inherently is an inefficient technique which

often results in waste products. The device is based on technology, Desorption Electrospray Ionization (DESI), developed by the university, which utilizes a fraction of the compound in the system. The proposal identifies four competitive advantages over traditional MS detection: 1) no backpressure which reduces maintenance, 2) nearly zero dead volume which prevents analyte diffusion 3) improved online collection of analytes as interface offers “real-time” MS sensing and; 4) interface offers an essentially “non-destructive” sensing as majority of sample is conserved. The inherent characteristics of this technology have potential for overall device lower cost and higher measurement throughput and accuracy. This device has been developed as a university lab prototype to show feasibility, and has a patent pending. The proposed tasks in this effort would develop an automated software user interface to expedite ease of operation and then provide for validation testing by independent parties. Successful completion of this testing would enable movement to an Ohio startup company, co-founded by the research team, which would continue product development and marketing strategy. The university has a relation with AB Sciex, an industry leader in mass spectrometry devices and technology and has identified them as a potential partner in the startup company.

One area of concern which is not sufficient to preclude funding relates to Market Opportunity. Since the device has a lower cost to produce, attempting to enter the market at price parity may be difficult, even though this product remedies some of the short comings of the competitive products. Although two of the five top MS manufacturers are to be interfaced initially, the relationship with AB Sciex creates concern that other manufacturers of LC/MS equipment may be precluded, thus reducing the market potential.

This proposal is recommended for funding.

<b>Proposal 14-406</b>	<b>University of Cincinnati Research Institute</b>	<b>Vertical Sleeve Gastrectomy Stapler</b>
<b>Amount Requested: \$50,000</b>	<b>Recommended: \$0</b>	

**Rationale:** This application proposes development of a vertical sleeve stapler used to reduce the volume of the stomach as a means to enable morbidly obese patients to lose weight. Current staplers must be fired multiple times to complete the procedure. According to the applicants, properly guiding the stapler for the multiple firings is difficult and subject to error, and only after all the staples have been placed is the surgeon able to discern the shape of the newly-created sleeve. The applicants are developing two products that they believe will revolutionize the practice of vertical sleeve gastrectomy – a special guide and a very long stapler. The guide is the subject of a TVSF Phase 2 application (14-425). The long, single-fire stapler is the subject of this proposal. Although the two devices are for the same surgical procedure, there is no business or technical dependency so each grant was reviewed on its own merits.

The challenges in designing a long stapler for this application come from the variable thickness of the stomach wall and the difficulty of creating a long anvil (the bottom part of a stapler that folds the staple into the desired B-shape) that is sufficiently stiff to do its task. The variable thickness of the wall means that the compressive device that holds the wall during placement of the staples and cutting away unwanted material must be unusually adaptive.

While the team appears to be well qualified, and the market has been well defined, the Review Team does not recommend this grant for approval. First, the technology appears to be pre-Phase 1. Phase 1 grants are to validate the technology is viable by having the completed proof generate the data to form the startup and license the technology from the institution. Per the grant submission, "We are currently in the idea stage for the sleeve gastrectomy stapler....The R&D early feasibility phase will be approximately 30 weeks". Secondly, there is no third party review, which is expected for Phase 1 projects. Thirdly, the applicants identify 18 months and \$1.25M for the first step of project, defined as 'Design Labor', with 27 weeks listed for the initial \$100k from TVSF and matching funds, leaving about a year for all the remaining work. Funding source for future work is unclear, other than \$350k in convertible debt, resulting in an \$800k gap over that next year. The applicants suggest that this proof of concept phase will enable them to raise the \$5M needed for the completion of the work, but this cycles back to the first concern that project is only in the concept phase. In addition, there is the potential conflict of interest in the vendors, who will be doing both the work and validation, will upon favorable reviews generate additional work for themselves.

**Recommendations for Improvement:** Should UCRI choose to reapply for TVSF funding, the applicants need to have developed the technology beyond the concept stage to the point of either a prototype or demo. In addition, the applicants need to further quantify how they will achieve their short time line and funding sources.

<b>Proposal 14-407</b>	<b>Case Western Reserve University</b>	<b>Replacing Endoscopic Imaging with Non-Invasive Office Based Screening Test for Barrett's Esophagus</b>
<b>Amount Requested: \$50,000</b>	<b>Recommended: \$50,000</b>	

**Rationale:** This proposal is a resubmission of 13-508 which was not recommended for funding due to concerns regarding Proof. The applicants have addressed those concerns.

This application proposes development and initial clinical trials of a new device for a 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 methylation of the protein vimentin gene (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, 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 reasons. 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.

A prototype has been constructed and successfully tested in a porcine model.

One concern which is not sufficient to preclude funding is that 3<sup>rd</sup> Party Review is minimal, with some amount of study oversight provided by the Institutional Review Board, and the data the applicants will produce during this study can be reviewed and interpreted objectively given the controlled nature of the work.

The proposal is recommended for funding.

<b>Proposal 14-408</b>	<b>Ohio University</b>	<b>Intelligence for Diabetes Support System (i4DSS)</b>
<b>Amount Requested:</b> <b>\$50,000</b>	<b>Recommended:</b> <b>\$0</b>	

**Rationale:** Applicant proposes to use case-based reasoning, a form of artificial intelligence, to analyze data from patients with type I diabetes and make recommendations regarding improvements in treatment. The data would include glucose levels, insulin infusion amounts and timing and the occurrence of life events likely to affect glucose levels (such as exercise and meals).

The review team found significant concern related to Proof, 3<sup>rd</sup> Party Review, Path to Market, and IP protection. The Proof plan is to review the system to determine what parameters need work to be validated as opposed to actually performing validation activities. While the product itself appears to have the ability to analyze vast amounts of data and can interpret same, it is unclear at this point how the applicants will acquire the robust data pool that will form the basis of the analysis. The applicants can either acquire a large data set or can possibly determine how to capture data from smart diabetes tools such as insulin pumps, but neither pathway is well described and the product has a limited future without such a data set. Though the applicants have access to detailed data on 80 subjects for research purposes, it's simply unclear how that pool will be expanded and incorporated into the end product. As such, the product will not be marketable in its current iteration. Third Party review is listed as desired but not scheduled. Finally, the review team has apprehension about the duration (7 yrs.) of Patent Pending status, and increasing probability that it will be deemed 'obvious to a person skilled in the art', and/or will be subject to infringement challenges.

Additional concern which was not sufficient to preclude funding relates to Use of Funds and would indicate that the grant would be better spent on activities with higher ROI.

**Recommendations for Improvement:** Should Ohio University choose to reapply for TVSF funding, the grant application should delineate a robust Proof plan with tangible outcomes, placing emphasis and focus on data set acquisition and/or data capture, describing data sources and costs, HIPAA compliance, and the vision for how to integrate disparate data sources from smart devices into this product.

<b>Proposal 14-409</b>	<b>The University of Toledo</b>	<b>Nanoelectronic Memristor Device</b>
<b>Amount Requested:</b> <b>\$50,000</b>	<b>Recommended:</b> <b>\$0</b>	

**Rationale:** This proposal is a resubmission of 13-409 which was not recommended for funding due to concerns around Path to Market. This proposal has not addressed those prior concerns.

Applicant proposes to further develop ReRAM memory devices. According to the proposal, non-volatile memory (NVM) devices are widely used for storing digital data (such as videos, files, and images) in almost all electronic products ranging from Smartphone's, tablets, USB drives, and cameras. Current NVM technologies use three terminal devices based on flash memory to form the non-volatile storing units. However, limited reliability and endurance has been an issue for flash memory devices. To address ever-increasing market demands for high-density non-volatile memory, 3D-NAND flash memories are already into production. However, 3D-NAND flash utilizes a very complex fabrication process and fundamental limitation of flash memory devices (such as high programming voltage, limited reliability and endurance, slow programming and erase speeds) are inherent in 3D-Flash memory devices as well. Therefore, there is an urgent need for novel memory devices that can not only overcome the scalability limits of existing memory devices, but also enable new features in electronic products. The University of Toledo's team competitive assessment is that this new Resistive Random Access Memory (ReRAM) technology is novel, as evidenced by an issued United States patent, uses unique materials, and solves the predominate issues inherent in currently available devices.

The proposed use of funds is for prototype fabrication, testing, and validation to create a specification sheet for this memory device and benchmark it against legacy memory technologies. This data sheet will be used to attract investors and companies for partnering, licensing and commercialization.

The review team found significant concern related to Path to Market still exists. Several competitors have announced competing patented ReRAM products that are already on the market or imminent. Application states "there is no commercially available ReRAM device". However, Panasonic has been producing them (MN101L) since August 2013 at the rate of one million per month. Other corporations, e.g., Hewlett Packard, have been delaying their own launches for unspecified reasons. Given the market need for this type of memory device and robust research activity it's clear there are issues with the technology, generally, perhaps related to the manufacturability of the devices. In addition, there are hundreds of patents already filed on the technology, so the IP space is crowded further hindering the path to market. The applicants have not helped the review team understand what the potential issues are nor how they will overcome them.

Additional concerns which were not sufficient to preclude funding relate to Market Opportunity and Proof. Given the advanced stage of development by others (Panasonic, Crossbar, Rambus, et al), market capture may be difficult. In addition the Proof plan would be better suited to compare applicant's ReRAM to competitive ReRAM devices instead of legacy technology.

**Recommendations for Improvement:** Should University of Toledo choose to reapply for TVSF funding, the grant application should address current market competition and its effect on long term opportunities, as well as greater insight as to how this particular technology will overcome the unspecified hurdles faced by major corporations that have delayed their launches.

<b>Proposal 14-410</b>	<b>The Cleveland Clinic Foundation</b>	<b>Autism Spectrum Disorder</b>
<b>Amount Requested:</b> <b>\$50,000</b>	<b>Recommended:</b> <b>\$0</b>	

**Rationale:** The applicant proposes to develop and validate the performance of a software system (Autism EYES), a rapid eye-tracking method for detecting social attention deficits that is diagnostic of autism spectrum disorder (ASD), prognostic of ASD trajectories, and that can be used to evaluate treatment progress. The plan proposes to use funds for Algorithm creation, validation data collection, data analysis, and software development within 12 months. Commercial launch would occur after three additional months.

The review team found significant concern related to Path to Market, Proof, 3<sup>rd</sup> Party Review, and IP protection. The primary concern is that diagnostic tools require FDA approval and there is no mention of a regulatory strategy in the proposal. If the applicants intend to make this a non-diagnostic tool they need to provide a better rationale as to what value health care practitioners will derive from the tool, as they will still need to provide a definitive diagnosis with or without this product. Without that strategy, any proposed Proof point may be insufficient to move the technology towards commercialization. In addition, the product is dependent upon the use of hardware from others. Finally, the target demographic is 2-6 year olds that may have already been diagnosed by then. There is no 3<sup>rd</sup> party validation or IP protection beyond trade secret.

Additional concerns which were not sufficient to preclude funding relate to Plan, Team, and Market opportunity. Any regulatory needs later identified will significantly extend the already aggressive project timeline, and likely do so beyond one year. Without an insurance reimbursement methodology, market uptake will see substantial resistance. The Team consists of only the inventor.

**Recommendations for Improvement:** Should Cleveland Clinic Foundation choose to reapply for TVSF funding, the grant application should evaluate the necessary regulatory requirements and apply those needs to the full plan. Identification of the hardware partners and the interface should be developed. Evaluation of the target demographic efficacy should be performed along with validation from an independent party.

<b>Proposal 14-411</b>	<b>The Cleveland Clinic Foundation</b>	<b>Cardioscope Direct Intracardiac Imaging in Beating Heart</b>
<b>Amount Requested:</b> <b>\$50,000</b>	<b>Recommended:</b> <b>\$0</b>	

**Rationale:** Applicant proposes further development of devices that enable percutaneous surgical procedures on the beating heart. The key development is a dual extracorporeal bypass system that introduces a clear liquid into a chamber of the heart to enable visualization with a catheter-mounted camera. An adjunct device is a collapsible hood that fits over the camera with a lens to

widen the visual field. Although not mentioned, the device must also include a fiber-optic illumination channel and catheter-mounted instruments to carry out surgery.

The hope of the inventors is that these devices, when perfected, can allow intra-cardiac visualization to aid diagnosis and to conduct surgery without opening the chest as is necessary now. They mention as examples of such surgery relatively simple, but still very important, procedures such as left atrial appendage occlusion (the appendage is a nonessential protuberance in the atrium that is thought to be a source of blood clots in patients with atrial fibrillation) and mitral valve repair (by methods such as placing an Alfieri clip, which ties together the two leaflets of the valve, diminishing regurgitation).

The proposal says that the system consists of a flexible hood to support the imaging unit, a steerable catheter, a balloon catheter to occlude certain vessels to allow introduction of the clear fluid, a sheath, and ancillary accessories. The proposal states that the system would be used in conjunction with the cardiopulmonary bypass equipment now in routine use for open heart surgery, such as coronary artery bypass grafts and valve repair and replacement. Prototypes of the system have been tested in a bovine animal model and have provided clear images inside a beating heart, where the system allowed placement of an Alfieri clip.

Part of the grant will be used to improve and lengthen the sheath and steerable catheter, but not enough information is provided for evaluation. Also the inventors state that a “low-cost version” of the system has been conceived and a patent applied for, but again little information is given.

Although the Team is well qualified and the technology compelling, the review team found significant concern related to Proof and 3<sup>rd</sup> Party review. The Proof plan lacks definitive milestone targets – the applicants generally describe the need to optimize the various elements of the device under development, but do not provide specific improvement targets which are necessary to ensure meaningful endpoints have been achieved. Further, should this technology successfully progress to the point that the applicants later apply for funding under a phase 2 grant; the review team will need to ensure any phase 1 work was completed under the terms of that grant. There is no third party validation.

Additional concerns which were not sufficient to preclude funding relate to Plan and Path to Market. Without targets, a timeline is difficult to verify. Path to Market is not identified.

This proposal is not recommended for funding.

**Recommendations for Improvement:** Should Cleveland Clinic Foundation choose to reapply for TVSF funding, the grant application should include substantial additional details including measurable improvement targets for Proof generation and sufficient specifics to evaluate the product.

<b>Proposal 14-412</b>	<b>The Cleveland Clinic Foundation</b>	<b>Coronary Chronic Total Occlusion Guidewire Family to Treat Coronary Artery Disease</b>
<b>Amount Requested:</b> <b>\$50,000</b>	<b>Recommended:</b> <b>\$50,000</b>	

**Rationale:** This proposal is a resubmission of 13-517 which was not recommend for funding due to concern regarding the return on the State of Ohio's investment. This submission provided additional clarity on this criterion.

Applicant proposes development and commercialization of a family of devices for use during percutaneous coronary intervention (PCI) procedures specifically applied to crossing chronic total occlusions (CTOs, or 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 conduct product validation testing of four versions of an advanced coronary guide wire. Achievement of this milestone is claimed to be sufficient to achieve regulatory clearance of the product family, as required for market entry. Given the considerable work done to date, the review team sees this as a low-risk proposition with all the necessary elements in place to achieve the proof point.

A remaining concern which was not sufficient to preclude funding relates to the need for an Ohio Startup. Applicant suggests that the new company will provide product and customer support as a value-add to the distributors. This is deemed feasible due to the niche market opportunity for the distributors; large enough to sell but too small to build in house support expertise, but should the applicants return for additional funding under a phase 2 TVSF grant this rationale will be re-examined

Thus the proposal addresses all of the criteria for the phase 1 TVSF and is recommended for funding.

<b>Proposal 14-413</b>	<b>The Cleveland Clinic Foundation</b>	<b>Sleep Apnea</b>
<b>Amount Requested:</b> <b>\$50,000</b>	<b>Recommended:</b> <b>\$0</b>	

**Rationale:** Applicant proposes development of an implantable neurostimulating device to alleviate sleep apnea caused by relaxation of the upper airway. The device would be permanently implanted and powered externally. It would stimulate specific tongue muscles, having the effect of pulling the rearward tongue base forward, thus opening the airway above the larynx and epiglottis.

Moderate to severe obstructive sleep apnea (OSA) is said to affect as many as 15 million Americans. There are many treatments, including head scarves, surgical removal of the uvula, and continuous positive airway pressure (CPAP). The last is effective, but it entails sleeping with

a face mask connected to a hose that delivers mildly compressed air, and many who use it find that it disturbs normal sleep.

This device has been designed, and studies on cadavers have explored electrode design and minimally invasive placement technique. The proposal seeks funding for prototype development and pre-clinical proof of concept in animals.

The review team found significant concern related to Path to Market. Known competitors already have approval in the EU, and it appears one potential competitor recently received FDA approval (Inspire Medical Systems, approved indication in US for OSA granted by FDA May 1, 2014). Given the financial resources (\$10MM) and duration (3-5 yrs.) needed to bring this to market, a better narrative on the competitive advantage of this technology is necessary to justify sustainability and commercial success. While the applicants claim advantages over more advanced technologies, specifically relating to battery life and less invasive surgeries, it is unclear whether the already approved competitive technologies will be able to address these deficiencies in the relative near-term by including an external power source and/or modifying the surgical placement of the devices, potentially eliminating the proposed advantages of this technology.

Additional concern which was not sufficient to preclude funding relate to Use of Funds, in that the budget seems overly large for testing on two canines.

Proposal is not recommended for funding

**Recommendations for Improvement:** Should Cleveland Clinic Foundation choose to reapply for TVSF funding, the grant application should better address the competitive landscape. Without a clear understanding of how this product will differentiate itself, not only currently but by the anticipated launch timing, a positive recommendation cannot be made.

<b>Proposal 14-414</b>	<b>Northeast Ohio Medical University (NEOMED)</b>	<b>The Role of Osteoactivin in Bone Regeneration</b>
<b>Amount Requested: \$30,000</b>	<b>Recommended: \$30,000</b>	

**Rationale:** Applicant proposes animal studies of a substance called osteoactivin, which promotes formation of bone, as a means of establishing its potential as a stimulant to promote growth of new bone following grafting procedures to repair damage from osteoporosis, injuries, spinal degeneration and other causes. The applicants say that they “have discovered and developed the role of the osteoactivin molecule to regenerate bone.” They have tested the idea of injecting osteoactivin in rat femurs and trepanned mouse skulls with results showing that osteoactivin promotes bone growth.

The proposal envisions an experiment involving larger animals, namely, sheep. The plan is to remove a short portion of the animals' tibia (a bone in the hind leg), fix the bone in place with external fixation, and to test four groups of four animals: no bone-growth stimulator, osteoactivin at two concentrations, and a commercially available substance called BMP-2. The stimulating materials will be mixed with autologous graft material consisting of ground bone taken from each animal's iliac crest (the usual site for harvesting bone). The applicants assert that in vitro studies show that osteoactivin has no toxic effects. They note that other substances in use for stimulating bone growth carry considerable risk of inducing bone cancer. The proposal will utilize funds for performance of the required surgical procedure on the subject sheep; periodic radiography to evaluate bone growth; micro computed tomography and histology to measure bone formation after the animals have been euthanized; technology assessment of the bone by measuring its mechanical properties in an independent lab and; finalization of results and data analysis.

Concerns which were not sufficient to preclude funding relate to Proof and Path to Market. Even with this pre-clinical Proof point, there is a long 5 year path to market. In addition, one study from McGill University whose conclusion was that "osteoactivin promotes breast cancer metastasis to bone," could be an issue when seeking FDA approval, though the review team recognizes this is only an issue when breast cancer is already present and should therefore be a manageable issue.

The proposal addresses all of the criteria for the phase 1 TVSF and is recommended for funding.

<b>Proposal 14-415</b>	<b>The Cleveland Clinic Foundation</b>	<b>Complex Arrhythmia EP Mapping Catheter</b>
<b>Amount Requested:</b> <b>\$50,000</b>	<b>Recommended:</b> <b>\$49,000</b>	

**Rationale:** The applicant proposes to complete development and validate for commercialization a new approach and device for detailed 'single beat' electrophysiology (EP) mapping of the human heart to ultimately improve the treatment of atrial fibrillation (AF) via guided catheter ablation treatment. The funds will be used to fabricate functional prototypes and perform validation animal testing. Upon validation, a venture capital firm has already been identified to invest in the new Ohio startup to commercialize the technology.

The review team found no major concerns with this proposal. A considerable amount of work has already been completed, and it should be a straightforward process to assemble the existing subassembly prototypes and components into a fully functional prototype. The animal study protocol has already been completed.

The proposal addresses all of the criteria for the phase 1 TVSF and is recommended for funding.  
 (Note: Actual budget is for \$98,000 generating funding of \$49,000 in contrast to cover request of \$50,000)

### PROPOSAL RECOMMENDATIONS - PHASE 2 SUMMARY MATRIX

PROPOSAL #	Licensing Institution	Lead Applicant	PROJECT TITLE	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
14-416	University of Cincinnati	Sense Diagnostics, LLC	Sense Diagnostics, LLC. An Early Stage, Ohio Based, Scalable Neurotechnology Company											
14-417	Case Western Reserve University	PolymerPlus LLC	Multilayered Coextrusion of Composite Filter Media for Liquid Filtration and Hydraulic Fracturing Applications											
14-418	The Ohio State University	Sight4All, Inc.	Mobile Vision Diagnostics											
14-419	The Ohio State University	Four Star Animal Health, Inc.	Advanced Adjuvant plus Nanoparticle Technology to Enable Autogenous PRRSV Swine Vaccine											
14-420	Cleveland Clinic	SportSafe LLC	Intelligent Mouthguards for Concussion Monitoring and Injury Prevention in Youth and Adult Contact Sports											
14-421	Kent State University	IRX Reminder	Interoperating Medication Container...											
14-422	University of Akron	TeleHealth Care Solutions	Virtual Physical Examination (VPE) Software											
14-423	The Ohio State University	TeraProbes Inc.	Non-contact Probes for High-Frequency Electronic Chip Testing											
14-424	Research Institute at Nationwide Children's Hospital	Lattice Biotech LLC	Broad Spectrum Anti-Infective Monoclonal Antibody for Chronic Infection Markets											
14-425	University of Cincinnati Research Institute	Standard Bariatrics, Inc.	Vertical Sleeve Gastrectomy Stapling Guide											
14-426	Case Western Reserve University	Red5 Pharmaceuticals LLC	Diagnostic Kits to Predict Patient Response to Chemotherapy											
14-427	University of Cincinnati	Xanthostat Diagnostics, Inc.	Develop Balistat II & 5 Unit Clinical Trial											
14-428	Ohio State University	QuTel, Inc.	Quantum Tunneling Electronics for Ultra-Low Power Electronics											
14-429	University of Toledo	Integrated Solar, LTD	Maximum Power Point Tracker to Interface BPV to DC Lighting											
14-430	The Ohio State University	Rekovo, LLC	Synaptic Arts											
14-431	Kent State University	Flexible ITO Solutions	Commercialization of Cracked ITO Substrates for Smart Windows											
14-432	The University of Toledo	OsteoNova, Inc.	Improving Bone Graft Technology											
14-433	Case Western Reserve University	ProImage Diagnostics, LLC	PTFmu Molecular Imaging Probes Identify Cancer Cells During Surgical Resection of Tumors											
14-434	The Cleveland Clinic Foundation	Ion-Vac, Inc.	Wound Healing System											
14-435	Nationwide Children's Hospital Research Institute	GenomeNext	GenomeNext: Cloud Genomic Analysis solution											
14-436	The Ohio State University	Columbus Technology LLC	DICE											

*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 Narrative/Use of Funds -- 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

<b>Proposal 14-416</b>	<b>Sense Diagnostics, LLC</b>	<b>An Early Stage, Ohio Based, Scalable Neurotechnology Company</b>
<b>Amount Requested: \$100,000</b>	<b>Recommended: \$100,000</b>	

**Rationale:** *Note: This application was twice previously submitted and not recommended as a Phase 1 grant for technical concerns. This is the first time this application has been submitted as a Phase 2 grant.*

Applicant proposes a development program to prepare for commercialization of a device named SENSE, a noninvasive RF sensor that detects changes in the brain including seizures, hemorrhage, and increased swelling/edema. Applicant claims that proof of concept has already been established for detecting acute hemorrhage in both in vitro and in vivo lab studies. The device will be wired to point of care standard telemetry displays and alert the clinicians of the above undesirable changes.

The value proposition of this platform technology is continuous monitoring at the bedside, which will allow faster treatment, thus generating improved outcomes, and reduce the cost of utilization of more expensive testing, such as CAT scanning. It allows for full depth scanning as a competitive advantage, as the RF frequency is able to fully penetrate the brain unlike shorter wavelengths that cannot penetrate to that depth.

The project funding will be used to manufacture four next generation prototypes and to study long term user wearability and comfort. These prototypes are critical to generate further investor support, as the team has learned through discussion with potential equity investors that a fully-functioning prototype is a requirement for them to consider investment.

The one area of concern which was not sufficient to preclude funding is in the Use of Funds. Applicant stated that user comfort was a critical data point, however the review team suggested that additional functional testing of the new prototypes might be of higher value at this stage of development.

The grant proposal is recommended for funding, with notation that all previous concerns from the Phase 1 applications have been rectified with the current submission.

<b>Proposal 14-417</b>	<b>PolymerPlus LLC</b>	<b>Multilayered Coextrusion of Composite Filter Media for Liquid Filtration and Hydraulic Fracturing Applications.</b>
<b>Amount Requested: \$100,000</b>	<b>Recommended: \$0</b>	

**Rationale:** The applicant proposes enhancement of polymer multilayer coextrusion processing technique currently used in various industries with a process invented at Case Western Reserve University which represents a new and disruptive technology for the liquid membrane filtration industry. Feedback from existing filter manufacturers indicated that coextrusion technology is outside their competency. To address this need, this proposal describes a one year Phase 2 project for microfilter membrane prototype fabrication, testing and validation of continuous polymer coextrusion technology, which is targeted to support waste water filtration/recovery applications necessary for reuse of large amounts of water utilized in the fracturing methods employed in current and future shale oil and natural gas drilling operations. The value proposition is manufacturing filter media using an environmentally friendly solvent-free process that simplifies manufacturing from layered approach into a single continuous step. This creates a novel fiber structure and expands the number of materials that can be utilized. The project will also independently compare the prototype material properties against current commercial polymer fiber materials utilized in water filtration membranes.

The application is not recommended for funding. The review team found two areas of significant concern. The business model does not define a market strategy, and is too focused on grant funding rather than revenue generation to propel this technology forward. The applicants stated during the in-person interview that the market strategy will be determined once work is complete and they can assess their options based on results of the work. While the applicants are free to pursue whatever path they wish, the review team expects to see a better-defined business case if State funds are requested. The second area that precludes recommendation is the Use of Funds. First, TVSF Phase 2 parameters do not permit funds to be used for the budgeted \$65,000 in personnel. In addition, this process has already been validated for the fuel industry; thusly the review team does not believe that it is appropriate to use State funds to enable the applicant to pivot product focus from one market to another for an already transferred and validated technology. Further, the applicant has achieved profits in the range of \$600,000 from other revenue sources and should reinvest those funds for further market activities.

Additional concerns which were not sufficient to preclude funding relate to the Likelihood of Additional Funding as heavy reliance on grant funding is speculative in nature, and the addressable Market Size was not well defined in the business plan.

**Recommendations for Improvement:** Should PolymerPlus LLC choose to reapply for TVSF funding, the grant application should provide a compelling narrative for the need for State support rather than company self-funding, a properly aligned budget, and a well-defined business model.

<b>Proposal 14-418</b>	<b>Sight4All, Inc.</b>	<b>Mobile Vision Diagnostics</b>
<b>Amount Requested: \$100,000</b>	<b>Recommended: \$0</b>	

**Rationale:** The applicant proposes further development of an autorefractor created at the Ohio State University School of Optometry. Autorefractors are computer-controlled machines that measure the distortion of an image projected onto the retina and infer the optical correction needed to compensate for defects in the eye, that is, a prescription for eyeglasses, contact lenses, or LASIK treatment. Dr. Bailey’s device is built into an Apple iPad, which contains a screen to present an image and a camera to capture the image from the retina, as well as software to generate the prescription.

Autorefractors for use in ophthalmologists’ and optometrists’ offices are in widespread use. The machines cost from around \$3000 to \$20,000, depending on features. Autorefractors furnish a good starting place for an exam by a technician, although they are not considered as accurate as the manual examination.

The device described in this proposal would be much less expensive to manufacture than conventional autorefractors. In addition to producing the data describing refractive error, the device also provides an estimate of visual acuity (e.g., 20/20 vision), a measurement of the interpupillary distance, which is necessary for designing lenses for eyeglasses, and additional data on eye alignment (called phoria or tropia). It would be easy to operate by the patient and would not require the presence of a doctor or technician.

The business concept being pursued by Sight4All is to design a kiosk incorporating the iPad autorefractor with proprietary software via an Internet-connected “app.” Then they will present the idea to executives of five of the leading companies in the vision correction industry. Applicant intends for these “strategic partners” to adopt these “screening and referral” kiosks as a way to advertise their businesses and would undertake to design, manufacture, operate and maintain the kiosks. They would pay a fee to Sight4All each time a referral from a kiosk produces a paying customer. Alternative partnerships could be developed with mail order companies like Warby-Parker and Essilor.

The review team found several areas of significant concern. The business model requires committed strategic partners to succeed. There is no path without a specific partnership with at least one of a handful of firms, and it does not appear that the applicant team has engaged any of these potential partners in even high-level discussion to gauge their interest in this approach. The applicants note that ‘it is unadvisable to make any disclosures until a marketable prototype becomes available’, but the review team cannot support a purely projected business model without some validation from critical partners/customers. Further, the pricing model and capturable market do not appear to have robust customer feedback. The second area; Company Backing, is integral with the first. There is no outside investment of any kind to support this

work, reinforcing the review team concern that this approach may not be embraced by the market. . IP protection has not been finalized. These major concerns preclude recommendation for funding.

Additional concerns which were not sufficient to preclude funding relate to the Likelihood of Additional funding given the unconsummated business model; One year plan is aggressive given that the algorithms are incomplete. . Note: Budget line items include costs that are not allowed by the RFP parameters (Legal, Licensing, Patent, Personnel) and must not be supported by TVSF funds. Additional granularity on the budget is needed for clarity on use of funds.

**Recommendations for Improvement:** Should Sight4All choose to reapply for TVSF funding, the grant application should provide a compelling and well-defined business model supported by market input and commitment, and IP protection in place.

<b>Proposal 14-419</b>	<b>Four Star Animal Health, Inc.</b>	<b>Advanced Adjuvant plus Nanoparticle Technology to Enable Autogenous PRRSv Swine Vaccine</b>
<b>Amount Requested: \$100,000</b>	<b>Recommended: \$0</b>	

**Rationale:** Applicant Four Star Animal Health, Inc. (4-Star) hopes to produce and eventually commercialize an innovative autogenous swine (pig) vaccine to treat the viral disease Porcine Reproductive and Respiratory Syndrome (PRRSv). PRRSv is a significant swine disease throughout the world with current commercial vaccines not demonstrating sufficient efficacy. Results from a small swine study by Four Star have demonstrated clearance of detectable replicating PRRSv in lungs and blood. It is proposed that for this proposal: (1) an Adjuvant Regulatory Assessment be done establishing the feasibility of USDA approval of Mycobacterium tuberculosis (WCL) as an adjuvant, (2) a Manufacturing Cost Assessment is done confirming that manufacturing costs fit a pricing model, (3) an Adjuvant and Vaccine Combination study is done demonstrating safety and effectiveness, (4) a Market Demand Validation is done to confirming and refining market size and demand projections, and (5) an Investor Readiness study is done to confirming investor requirements to release funds.

The review team found several areas of significant concern. The Use of Funds is inappropriate as applicants note their parent company is making significant investments in vaccine products, but are focused on candidates that are lower-risk and have immediate market potential. The review team does not believe State funds should be used simply to de-risk a potential opportunity and the company should re-prioritize its pipeline if they believe this is a worthwhile opportunity. Although significant self-funding has occurred, external Company Backing is lacking. In addition, the stated exit strategy of selling to a strategic buyer reduces the economic development benefits to Ohio. These major concerns preclude recommendation for funding.

Additional concerns which were not sufficient to preclude funding relate to the Business Model in that several additional costs will result from this product but have not been quantified in the application. Proof and One year plan are jeopardized by the expectation of USDA concerns of this adjuvant and injection site reactions.

**Recommendations for Improvement:** Should Four Star Animal Health choose to reapply for TVSF funding, the grant application should provide a compelling narrative for the need for State support. A fully developed business model would also be beneficial.

<b>Proposal 14-420</b>	<b>SportSafe LLC</b>	<b>Intelligent Mouthguards for concussion monitoring and injury prevention in youth and adult contact sports.</b>
<b>Amount Requested: \$100,000</b>	<b>Recommended: \$0</b>	

**Rationale:** Applicant proposes development of an intelligent mouthguard (IMG) biomedical device intended to provide indication of concussion in contact sports. It achieves this by measuring linear and rotational forces of head impact in all athletic activities in real time. The small size is accomplished thru the use of newer microelectromechanical (MEMS) gyroscopes and linear accelerometers; or just accelerometers, coupled with a data compression scheme and a transmitting device for sideline monitoring. The transmitted data is then processed using patented algorithms to assess injury risk. The proposal is sponsored by SportSafe LLC who developed this device based on Cleveland Clinic enabling intellectual property (IP). There are 3 versions of the device planned: V1, a high end version marketed to professional teams and costing about \$1000 per unit; V2, a customized simpler version marketed to organized sports and costing about \$250; V3, an injection molded mouthguard for retail sales and cost about \$37. Sportsafe has already done considerable marketing and fundraising and is requesting \$100k of OTF funds to augment other capital so to accelerate manufacturing of V1 units and deliver these beta units to National Football League (NFL) and to National Collegiate Athletic Association (NCAA) football programs. The proposal shows 5 tasks, each of which OTF funds will support but will be augmented by other sources. The tasks focus on the V1 development effort: determine custom mouthpiece manufacturing approach; prototype App development; data structure to integrate with electronic medical record; FDA consultation; and trade show support. Successful completion of this effort and distribution of beta products will enable additional funding to initiate sales to V1 market and continue development of V2 and V3 products. All organizations involved are Ohio based and manufacturing will be located in state.

The review team found significant concern related to the Business Model: It lacks focus in that there is a divergence of opinion with respect to addressing long term broad concussion science or simplified commercial application mouth guards. During the in-person interview the applicants could not clarify whether the more direct 'hit counter' approach to market was preferable or if the robust concussion science needs to be incorporated into the product. This leads to a lack of clarity on product strategy and return on investment. A smaller concern is that

an expected \$75K in revenue was not considered in the model. These concerns preclude recommendation for funding.

Additional concerns which were not sufficient to preclude funding relate to the Proof, One year plan, and Team. The market needs are not fully understood; therefore the proof needed is not refined. This stems from the fact that the correlation between physics and injury has not been established. Since the customer needs will be developed during the prototype testing, a one year timeline cannot be confirmed. Finally, without full time commitments of the Team, success will be more difficult. Please note: a clear expectation is that intercompany purchased services would be charged at cost so as not to represent profits to the principals involved in two companies, Sportsafe and Sportsguard.

**Recommendations for Improvement:** Should SportSafe choose to reapply for TVSF funding, the grant application should provide a compelling commercial market strategy. Market data from expected customers should support that direction. A plan for the future management team structure would be beneficial.

<b>Proposal 14-421</b>	<b>iRxReminder LLC</b>	iLidRx: Interoperating Medication Container for mHealth Management of Chronic Illnesses
<b>Amount Requested: \$100,000</b>	<b>Recommended: \$0</b>	

**Rationale:** Applicant 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. In addition this Phase 2 application is a resubmission of 13-533 that was not recommended for funding due to personnel inclusion in the budget as well as review team expectations for use of existing product revenue in lieu of TVSF. The applicant has rectified the budget structure, and promulgated that lower than expected revenue in the interim necessitates the need for TVSF funding. Significant additional funding has been committed since the last application as well.

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 early target market from chronic illness to monitoring bone marrow transplant patients and a newly identified potential to utilize a partial system to service the CRO drug trial market. The value-adds are a reduced dropout rate of participants and increased adherence. The desired funding would cover completion of the iLidRx prototyping, testing and validation of the information transfer, and conducting field testing with 3 patients.

The review team found significant concern related to the Business Model: It primarily lacks focus for commercial success. Several target markets have been identified over time without solidification. Market capture expectations and revenue projections are not defined as a result. Specifically, there are two parallel market opportunities: 1) the clinical research market using a simplified version of the product (pods) and 2) the consumer market with a more complex integrated system. During the in-person interview the applicants stated they could quickly obtain contracts for clinical research clients, which they claim have indicated a willingness to purchase. The consumer market approach is much more complex and resource intensive, and the three-person trial for young adults who have received bone marrow transplants seems an unnecessary distraction which will yield a statistically irrelevant result with regards to improved compliance and which will likely be insufficient for FDA clearance. Though the consumer market clearly has more potential over the long-run, the review team disagrees with this parallel pathway. The applicants claim that the result from a three person study will be sufficient to attract investment, but such a small sample size may yield an unfavorable outcome that would in fact discourage investment. The applicants have sufficient resources in hand, given a recent grant of \$100k, to finalize development of the pod and to begin marketing a finished product. This major concern precludes recommendation for funding.

Additional concerns which were not sufficient to preclude funding relate to Opportunity and Team. The Bone Marrow Transplant market seems rather small to create sustainability. The team has struggled to commercially focus this technology into a marketable strategy.

**Recommendations for Improvement:** Should IRxReminder choose to reapply for TVSF funding, the grant application should provide a compelling commercial market strategy. Market data from expected customers should support that direction. Supplementary advisors or team members with the business acumen to define a focused strategy and translate this technology into the market would be beneficial.

<b>Proposal 14-422</b>	<b>TeleHealth Care Solutions</b>	<b>Virtual Physical Examination (VPE) Software</b>
<b>Amount Requested:</b> <b>\$100,000</b>	<b>Recommended:</b> <b>\$0</b>	

**Rationale:** Applicant proposes to develop and commercialize telemedicine software to support a remotely located patient and technician in taking patient histories and physical examinations using “smartphone” devices and appropriate medical applications (apps) in order to free up physicians from this task and expand their reach out to underserved markets and remote locations.

The review team found significant concerns. The product does not appear to yet exist and thus is too early in the development cycle for TVSF, and while a complex process to capture detailed patient history in an automated way is envisioned, it does not appear to exist other than in

concept. There is no letter from the University TTO supporting transfer of technology and the applicant has stated that they filed a patent themselves. The proof plan is not well defined and the timeline is overly optimistic. For example, while the applicants correctly note that Bluetooth enabled blood pressure cuffs, glucometers, scales, etc. will be needed, they do not attempt to address how those materials will be procured or incorporated into their product, nor how the entire system will be transported to make it accessible to the underserved populations they target. Business model ramp up lacks credibility, by envisioning 33,000 licenses sold by end of year two, but with no plan to achieve this impressive number, whether through contracted sales force or other means. Regardless it is a critical omission for a phase 2 grant application and a significant unaccounted cost. Budgeted use of funds does not exist. Target markets lack infrastructure to take advantage of internet connected technology, as the underserved market target would presumably include remote and economically disadvantaged patients who may not have or cannot afford internet connections.

These major concerns preclude recommendation for funding.

**Recommendations for Improvement:** There is a significant amount of information missing which may be challenging for the applicants to address. Should TeleHealth Care Solutions choose to reapply for TVSF funding, the grant application should fully address all RFP requirements.

<b>Proposal 14-423</b>	<b>Terarobes Inc.</b>	<b>Non-contact Probes for High-frequency Electronic Chip Testing</b>
<b>Amount Requested: \$100,000</b>	<b>Recommended: \$100,000</b>	

**Rationale:** Applicant proposes a more efficient method of testing next generation electronic chips that feature billions of nanometer sized transistors on highly refined silicon wafers. The technology was conceptualized and developed at Ohio State University with provisional patents pending, and has been licensed to a startup company, TeraProbes, Inc, who is sponsoring this proposal. The key technical concept is a wireless link between test equipment and test chip using proprietary antenna designs that are integrated with the test chip, enabling contact-free characterization of electronic devices. The technology development has been funded by DoD for 3 years to a total of \$800,000. There is considerable interest in this potentially disruptive testing device. The chip market for electronics in the 50GHz – 3 THz market is over \$1.5 billion in the next 10 years. TeraProbes estimate they can penetrate this market by offering specialized testing, with potential for \$6 million in revenue over the next 3 years. TeraProbes has recognized the market potential for this, and has established relationships with Ohio based manufacturing companies to assist in lab prototype COTS based demo production. They are also coordinating with representative user organizations to distribute these demo products. TeraProbes is requesting TVFS funds of \$100k for 3 tasks: finalize product designs, develop demonstration products, and continue with market research.

The value add of this technology is that it increases the ability to test at higher frequencies and densities while reducing the test time and eliminating damage. The only risk to the business model is slow adoption of antenna incorporation in the chips.

The proposal addresses all of the criteria for the phase 2 TVSF funding. The project proof and plan are credible and achievable, and the budget is appropriate. Principals have invested their own money, and DoD investment of ~\$800K demonstrates interest in the technology. Proof of concept exists in a manually operated version. The market for the nano scale electronic chips is increasing as better techniques for their processing enables them to meet the constant demand for smaller chips with more transistors. The TeraProbe concept should enable faster quality testing as lower cost and should be available at a time when the market demand is increasing.

Their team has a combination of business and investment skills along with the technology concept developers from OSU and is a good mix to initiate the startup. The business plan of building initial beta production devices and distributing them to potential users is sound.

This proposal is recommended for funding.

<b>Proposal 14-424</b>	<b>Lattice Biotech LLC</b>	<b>Broad Spectrum Anti-Infective Monoclonal Antibody for Chronic Infection Markets</b>
<b>Amount Requested: \$100,000</b>	<b>Recommended: \$100,000</b>	

**Rationale:** Applicant proposes further development and eventual commercialization of a monoclonal antibody (mAb) that will disrupt biofilms that form in the lungs of patients with cystic fibrosis (CF). The technology is based on fundamental work done at the Research Institute of the Nationwide Children’s Hospital (RINCH) in Columbus, OH. Researchers at RINCH have discovered that bacterial extracellular DNA and a protein called DNABII provide structural integrity to biofilms. RINCH has also developed antibodies to DNABII, which break down biofilms and create a new way of treating lung infections in CF patients. By itself, anti-DNABII would enhance the natural immune response to infections, and in combination with antibiotics, anti-DNABII would allow the antibiotics to penetrate biofilm and reach infected tissues. Nationwide Children’s Hospital and its Research Institute are partners with Lattice in this enterprise.

CF is a rare chronic disease caused by a genetic disorder affecting some 30,000 people in the US and 70,000 worldwide. Among its effects are creation of mucus which clogs the lungs and leads to life-threatening lung infections, which are difficult to treat, requiring aggressive antibiotic therapy and lengthy hospitalizations, costing nearly \$60,000 each, adding up to \$866 million spent annually for such treatments. Anti-DNABII in combination with antibiotics and other therapeutic compounds would drastically reduce these expenditures.

The antibodies discovered by RINCH are polyclonal (that is, derived from many cells), and Lattice will have the task of selecting from them the particular antibodies that are effective and cloning them as monoclonal antibodies. Specifically, Lattice Biotech intends to demonstrate effectiveness of a monoclonal antibody in disrupting biofilms from four bacterial species (*S. aureus*, *H. influenza*, *P. aeruginosa*, and *B. cepacia*), which are common sources of infection in CF patients.

One concern which is not sufficient to preclude funding is that there is an expected exit strategy business model for this drugable antibody. However, the applicant plans to utilize the technology as a platform, generating additional products and economic development. As such, the review team recommends the applicants utilize as much Ohio infrastructure as possible to maximize Ohio's economic development.

The proposal addresses all of the criteria for the phase 2 TVSF funding. The project proof and plan are credible and achievable, the budget is appropriate. Principals have credible track records, and the technology is proven.

Proposal recommended for funding.

<b>Proposal 14-425</b>	<b>Standard Bariatrics, Inc.</b>	<b>Vertical Sleeve Gastrectomy Stapling Guide</b>
<b>Amount Requested: \$100,000</b>	<b>Recommended: \$100,000</b>	

**Rationale:** Applicant proposes further development of a guide for a stapler used to reduce the volume of the stomach as a means to enable morbidly obese patients to lose weight. The term "vertical sleeve" refers to the fact that the surgical operation changes the shape of the stomach to a sleeve or tube-like structure with a volume about 25% of the stomach's original volume. The operation is typically performed laparoscopically (through small incisions, guided by images from an endoscope) inserting a row of staples that seal off a portion of the stomach, simultaneously cutting away the sealed-off portion, which is then removed. The operation is irreversible.

In vertical sleeve gastrectomy, the full line of staples extends 20-30 cm. Existing stapler-cutters typically place a row of staples that extends 6 cm with each firing. For this reason, in this application, the stapler must be fired multiple times to complete the procedure. According to the applicants, properly guiding the stapler for the multiple firings is difficult and subject to error, and only after all the staples have been placed is the surgeon able to discern the shape of the newly-created sleeve.

The company, Standard Bariatrics, Inc., was formed to develop and market two products that they believe will revolutionize the practice of vertical sleeve gastrectomy – a special guide and a very long stapler, which together will make the procedure more reliable and effective. The guide

is the subject of this proposal. The long, single-fire stapler is the subject of a Phase 1 proposal (14-406).

The guide system consists of a calibration tube and a clamp to allow both anterior and posterior location assistance. Competitive products are sometimes just tubes designed for other purposes that have the right size and shape, such as gastroscopes and tubes used to open obstructions and sometimes specially designed devices like the ViSiGi 3D calibration device.

One concern of the review team, which is not sufficient to preclude funding, is that Dr. Thompson is only dedicating 20% of his time as interim CEO which could prove challenging to the venture's success.

The proposal addresses all of the criteria for the phase 2 TVSF funding. The project proof and plan are credible and achievable, the budget is appropriate. Principals have credible track records, and the technology is proven.

The Proposal is recommended for funding.

<b>Proposal 14-426</b>	<b>Red5 Pharmaceuticals LLC</b>	<b>Diagnostic Kits to Predict Patient Response to Chemotherapy</b>
<b>Amount Requested: \$99,985</b>	<b>Recommended: \$0</b>	

**Rationale:** The applicant proposes to develop its KRun kit, a companion diagnostic assay that can predict whether or not a patient's leukemia or brain cancer will respond to a specific chemotherapy regimen prior to the initiation of treatment.

The review team found significant concern related to the Business Model. Specifically, a five-year plan was presented which shows year five as the critical year to achieve robust profitability. However, the applicants could not explain how their gross margin in that year was significantly greater than expected gross margin when cost of goods are taken into account. As a result, any changes in valuation will challenge sustainability, and the review team cannot recommend funding for a company that cannot confirm future profitability or explain the assumptions that were included in their income statement. Given the lengthy time to market and estimated funds required, a lack of additional fund commitments reinforces the review team's concerns, and an incomplete business model lacks a compelling narrative to attract investment. These major concerns preclude recommendation for funding.

Additional concerns which were not sufficient to preclude funding relate to Team, Backing, and Ohio Start up. A lack of team business acumen, coupled with a less than full time focus on the venture present challenging paths to success. The small \$25K external support may be

insufficient to sustain the model, and finally an Exit Strategy model limits the return on Ohio's investment.

**Recommendations for Improvement:** Should Red5 Pharmaceuticals choose to reapply for TVSF funding, the grant application should provide a compelling commercial strategy that includes committed fund sources. Market data from expected customers should support that direction. Supplementary advisors or team members with the business acumen to define a focused strategy and translate this technology into the market would be beneficial.

<b>Proposal 14-427</b>	<b>Xanhostat Diagnostics, Inc.</b>	<b>Develop Bilistat II &amp; 5 Unit Clinical Trial</b>
<b>Amount Requested: \$100,000</b>	<b>Recommended: \$0</b>	

**Rationale:** The applicant proposes further development of a spectrophotometric device to measure the level of bilirubin in cerebrospinal fluid (CSF). The presence of bilirubin in the CSF of a patient who presents with a severe headache is diagnostic for subarachnoid hemorrhage (SAH). Use of the device is a potential replacement for sending the CSF sample from an emergency room or urgent care center to a laboratory for bilirubin analysis.

This company has been around since approximately 2005, working in iterations to bring this technology to market. Although the initial NIH funded prototype algorithm worked, early software compliance issues caused a restart of development a few years ago

The product will be a simple clinician accessible analysis device with a lower market entry price than competing technologies and provide point of care test results in approximately five minutes. An independent market study has demonstrated customer interest and informed the price structure. Project funding will further develop the prototype to a next iteration, as well as build five current units for hospital testing and feedback, with the expectation of positive testimonials to drive further funding.

The review team found significant concern related to the Use of Funds due to the fact that budgeted cost share is not committed. Because the budgeted cost share is significantly more than the TVSF contribution, work cannot be completed without this money in hand. This concern alone is sufficient to support a recommendation not to fund this work. The review team is also concerned that many of the customer insights may no longer be valid and thus may need to be re-explored since the team has only recently re-engaged to push this project forward commercially (technology development has been ongoing). For example, clinical practice may have changed in recent years, along with technology options to address this unmet need. While this concern may not be valid, the applicants should take care, should they decide to reapply, to be clear as to what steps they have taken to confirm dated market insights. These major concerns preclude recommendation for funding.

Additional concerns which were not sufficient to preclude funding relate to Team and Ohio Start up. A lack of team focus has failed to drive this technology through the starts and stops into the market. Further, the age of the company, notwithstanding lack of progress, brings into question their status as a Start Up.

**Recommendations for Improvement:** Should Xanthostat Diagnostics choose to reapply for TVSF funding, the grant application should provide a compelling commercial strategy that pushes the technology over the finish line. Supplementary advisors or team members with the drive to translate this technology into the market would be beneficial. Finally, a compelling narrative that supports the company's classification as a Start Up would be needed.

<b>Proposal 14-428</b>	<b>QuTel, Inc.</b>	<b>Quantum Tunneling Electronics for Ultra-Low Power Electronics</b>
<b>Amount Requested: \$100,000</b>	<b>Recommended: \$0</b>	

**Rationale:** This proposal is essentially a re-write and re-submittal of previous TVSF Proposals No.13-541 (Dec. 2013) and No. 13-024 (Oct. 2012), the former was not recommended for funding and the later was conditionally recommended pending significant funding commitments to attain the additional required proof point. The issues and concerns raised in the earlier reviews have not been adequately addressed in this revised proposal.

In this proposal, QuTel, (QUantum Tunneling Electronics) has developed a technology which allows for ultra-low power operation for semiconductor devices, enabling a dramatic drop in power consumption over current CMOS (Complementary Metal Oxide Semiconductor) technologies, as well as a substantial reduction in die size. Lower power has become the driving force of the majority of semiconductor products. Markets that are fundamentally sensitive to semiconductor power include all mobile devices, all devices used in data centers, and many embedded devices such as those in appliances, automobiles, etc. and all semiconductor markets are subject to cost pressures. Given that CMOS is the worldwide standard semiconductor electronics technology, and that QuTel technology is easily integrated into CMOS, the opportunity is to enhance the substantial share of the ~\$300B worldwide annual semiconductor market that is CMOS and is sensitive to power and die size.

Through breakthroughs by Paul R. Berger, Professor of Electrical and Computer Engineering at Ohio State University, new quantum tunneling devices have been developed that can now be directly inserted seamlessly into current CMOS production lines using their existing infrastructure. This is in contrast to previous work on tunneling, which was not compatible with CMOS. The initial device is the Resonant Interband Tunneling Diode (RITD) and the follow-on device is the Tunneling Field Effect Transistor (TFET).

The proposed QuTel business plan is based on that of a British Company, Advanced Research Machines or ARM. ARM is the developer of the enhanced processor designs used in a majority of mobile products today. ARM offers these designs to semiconductor OEM customers at a modest 1% FRAND royalty on the revenue the OEM realizes from the chip in which the ARM design is used. QuTel will do exactly the same. Dr. Berger's proposed business model only involves the designing and licensing of IP for which fee collection and royalties would be involved, i.e., no startups, brick-and-mortar manufacturing facilities or actual physical products, such as electronic chips/diodes would be involved. Thus, there is no guarantee that a significant number of jobs would result from this project for the State of Ohio.

QuTel, Inc. currently has no outside funding and is solely self-funded by QuTel's founder, Prof. Berger. Meetings with commercial venture capitalists (VCs) have indicated that VC funding becomes possible when the first licensee is signed and a detailed plan of resources and funding is co-developed. QuTel is also in discussions with the Ohio Technical Angel Funds network about presenting the company for funding. However, to date, no additional outside funding has been committed.

The IP Position appears quite robust. The QuTel founder has acquired six germane patents pertaining to this new Tunneling Technology, all of which are owned by Ohio State University (OSU). Although the proposal states that "These patents are all owned by Ohio State University and will be exclusively licensed to QuTel with an expected start date of Jan 2014." However, a license has not yet been issued by OSU to QuTel. In its attached support letter, dated April 14, 2014, the OSU Technology Commercialization Office (TCO) states that it is working diligently to complete a license agreement with QuTel. Thus there seems to be some discrepancy related to timing on this licensing matter and there is no indication of license exclusivity in the TCO letter.

The review team's significant concerns related to Proof, Likelihood of Additional Funds, and Company backing are detailed above. The earlier Venture Capital Required Proof point of TS Ram Prototyping has simply been removed from this revision without explanation for the newfound lack of exigence. This new application provides a proof endpoint that is considerably different than past applications and at a minimum this shift in expectations should be substantiated with customer or technical insights that would make the applicant's earlier assertions for a more advanced prototype moot. The review team continues to believe, based on the applicant's past assertions, that significant resources will still be needed beyond the end of this project stage to instill sustainability through commercialization.

The additional concerns which were not sufficient to preclude funding relate to Team and License. The team consists solely of the founder. Further, the license discrepancy is worrisome.

The current proposal is not recommended for funding. However, the earlier conditional recommendation remains in place.

**Recommendations for Improvement:** Should QuTel choose to reapply for TVSF funding, the grant application should provide a compelling and complete narrative with respect to proof point deliverables and how they will drive further external investment. A fully developed plan for company management and the team needed to drive the product into the market should be provided. Finally, a thorough presentation of the license agreement resolution should be included. Otherwise, the applicants may still opt to accept the earlier conditional recommendation and secure resources to complete necessary prototyping work.

<b>Proposal 14-429</b>	<b>Integrated Solar, LTD</b>	<b>Maximum Power Point Tracker to Interface BIPV to DC Fluorescent Lighting</b>
<b>Amount Requested: \$100,000</b>	<b>Recommended: \$0</b>	

**Rationale:** The applicant proposes to design, build and evaluate a Maximum Power Point Tracking energy management demonstration system for Building Integrated Photovoltaic (BIPV) DC lighting circuits.

Maximum power point tracking (MPPT) is a technique that is used to get the maximum possible power from one or more photovoltaic devices, typically solar panels. Solar cells have a complex relationship between solar irradiation, temperature and total resistance that produces non-linear output efficiency. It is the purpose of the MPPT system to sample the output and apply the proper load to maximize power for any given set of conditions.

Although interest in solar power continues to grow as the component prices fall, the review team found significant concerns with the application related to the Team, Business Model, Company Backing, IP Protection, and Ohio Startup. The team consists of solely the principal, Mr. Witte. The business model gives no details on cost, selling price, margins, or the cohesive plan to bring this successfully to market. The company is only backed by the other solar company that the principal owns. Finally, there is no IP protection. Applicant plans to keep their intellectual property trade secret, due to the ease of copy. These major concerns preclude recommendation for funding.

Additional concerns which were not sufficient to preclude funding relate to Opportunity and Use of Funds. Given that the sales goal is 5 systems the first year and 50 systems per year after five years and existing MPPT devices are selling for \$500, this translates to a small opportunity. Further, since the principal already has a 20 year old solar company with \$30MM in historical revenue, it brings into question the need for a Start Up.

**Recommendations for Improvement:** Should Integrated Solar choose to reapply for TVSF funding, the grant application should provide a compelling commercial strategy with full delineation of financial structure and ROI. External backing should be secured. Supplementary advisors or team members with the business acumen to define a focused strategy and translate

this technology into the market would be beneficial. Finally, a compelling narrative that supports the justification for a Start Up would be needed.

<b>Proposal 14-430</b>	<b>Rekovo, LLC</b>	<b>Synaptic Arts</b>
<b>Amount Requested: \$100,000</b>	<b>Recommended: \$0</b>	

**Rationale:** The applicant proposes to provide therapy to patients with balance and movement difficulties. Their product includes software and a feedback monitor that reinforce proper movement on the patient's part by creating an abstract art pattern. A preliminary study showed a decrease in the time required to improve patients' balance and positive responses to the system from both patients and therapists. The product will be a cloud based Software as a Service with a \$14.95/month/ therapist subscription. The first market is skilled therapists in care facilities. The second target will be home healthcare. A final future target will be consumer oriented. Sales are expected to start after six months.

The review team found significant concerns with the application related to the Proof, Business Model, and Additional Funds. The ability to provide a proof is suspect due to the fact that applicant does not know the state of the existing code, and therefore the funds needed to migrate to the cloud are based upon assumptions versus factual confirmation. This, in and of itself, may not be a significant issue, but there is no room for error in the rollout plan given the lean funding plan presented in the grant request – a significant miss in the estimate to migrate the code could derail the entire project. In addition, a multitude of business assumptions do not match industry expected norms. For example Cost of Acquisition appears understated, and is based on very optimistic capture rates for marketing channels like direct mail. Here again, if the assumptions are wrong and cost of acquisition is higher than expected the company will quickly deplete its funds and work will stall. Similarly, Cost of Ownership – maintaining existing clients, updating software code, maintaining performance, etc., is not accounted for. The Business Model is too lean to absorb variations in the assumptions and remain sustainable. Finally, applicant has not identified nor approached any sources of additional funding. These major concerns preclude recommendation for funding.

The additional concern which was not sufficient to preclude funding relate to Use of Funds, in that a small budget line item for legal fees is not permitted by the TVSF RFP requirements.

**Recommendations for Improvement:** Should Rekovo choose to reapply for TVSF funding, the grant application should provide a compelling commercial strategy with full delineation of financial structure and contingencies. The Proof plan must take into account the current state and subsequent migration of the code. Future funding opportunities should be identified and vetted.

<b>Proposal 14-431</b>	<b>Flexible ITO Solutions (FITOS)</b>	<b>Commercialization of Cracked ITO Substrates for Smart Windows</b>
<b>Amount Requested: \$100,000</b>	<b>Recommended: \$100,000</b>	

**Rationale:** The applicant proposes to further develop Flexible ITO (indium tin oxide) films and will focus on the Smart Window Market for its first products. The active smart window market will reach \$4.2 Billion in 2016 including both architectural and transportation sectors. FITOS will produce a segmented flexible substrate that will add unique function and value to these smart windows. The FITOS substrates will later be developed for the much larger, but more demanding touch screen market, predicted by Display Search 2012 to reach \$30B in 2016. Specifically the FITOS substrates will be used for capacitive touch screens, which are replacing the inferior resistive screens in most applications. Addressing these two markets the projected annual sales revenue is \$625,000.00 in three years and \$4.50 Million after 5 years. While these projections are relatively modest, the applicant start-up is a very lean organization which will leverage an existing partnership to market their smart window product and will have a guaranteed order in place upon launch, making this a low-risk investment for the State which could provide significant returns in later years.

FITOS produces transparent, conductive electrodes on flexible plastic substrates by mechanical cracking of the brittle ITO conducting film. This is achieved through a simple proprietary (3 patent applications) mechanical process that turns the brittleness of the conducting layer to an advantage. The resulting electrodes are of higher resolution and density than is possible using conventional photolithographic or laser etching techniques. A prototype has been fabricated which demonstrates how the FITOS substrates can be used in smart windows to create an electronic venetian blind. This effect is unattainable using conventional techniques to form the electrode patterns. This adds great functionality to the window at relatively low cost. Once developed, the same manufacturing process can be used to make substrates for the capacitive touch screens found in smart phones and electronic tablets. These will replace the much more costly alternatives.

The product implementation strategy begins with a focus on a unique application that can only be achieved using FITOS substrates and highlighting their performance. It will start with a low volume high value added market and once established move into increasingly larger markets with more demanding supply chain and performance specifications. The FITOS team will work with a partner device manufacturer to develop products incorporating the FITOS substrates. The team engaged a US smart-window manufacturer, Polytronix, located in Richardson Texas; to identify the optimum, low volume, high value added first application: windows for new hospital construction and specifically for rooms in intensive care. This is an ideal application because the sterile environment of the intensive care precludes traditional window treatments as a means of securing privacy and light glow. The team has entered into a preliminary agreement with Polytronix and will execute a formal MOU to jointly develop this product. FITOS will provide 2' x

4' sheets of the patterned flexible substrates that Polytronix will use to produce the switchable, smart windows. The requested funding for this project is to design and demonstrate the ability to produce these substrates with the required performance.

The proposal addresses all of the criteria for the phase 2 TVSF funding. The review team found technology compelling; the short and medium business model is well thought out with a window manufacturer partnership; external backing and IP have been secured; the initial market is sufficient; the project plan is meaningful and achievable, and the team leadership is prepared for success.

The only concern which was not sufficient to preclude funding relates to the Business Model's long term plans being incomplete.

This application is recommended for funding.

<b>Proposal 14-432</b>	<b>OsteoNovus, Inc.</b>	<b>Improving Bone Graft Technology</b>
<b>Amount Requested: \$100,000</b>	<b>Recommended: \$0</b>	

**Rationale:** This Phase 2 proposal is a resubmission of 13-544 which was not recommended for funding due to an undefined Proof and inadequately enumerated Business Model. Prior to this there were two Phase 1 proposals, the first of which (12-419) was not recommended for funding and the second of which was.

OsteoNovus's first product is a novel compound christened 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), also known as Monelite. The silicated compound can be formed into different shapes and used as an implant to supplement or replace natural bone with a matrix into which natural bone will grow. According to the applicants, Novogro is superior to other bone cements on the market in that it is biocompatible and radiopaque, does not generate high temperatures during setting, and offers ideal resorption and bone formation rates, that is, it gets resorbed at about the same rate that new bone can infiltrate the material.

Novogro is said to be applicable for a range of orthopedic procedures. This platform technology is excellent for future prospects, but appears to have caused confusion for this application. The Proof plan is for the Trauma related paste product and the Business Model is built around the lumbar spinal fusion product.

Thus the review team found significant concerns with the application related to those two requirements: Proof and Business Model. The Proof milestones are not focused on the grant

funded studies. The plan lists several activities all of which the proposal identifies as “*needed to gather additional proof to persuade investors for further funding.*” These activities include: Regulatory Support; Regulatory Testing for: Sterilization, Packaging, Shipping, and Shelf life: and two animal studies. The TVSF funding is only to address one of the two animal studies and none of the other work. The Business Model detailed the financials for another product (Lumbar) that was not the focus of this project. Further, the financials given were not internally consistent. These major concerns preclude recommendation for funding.

The additional concern which was not sufficient to preclude funding relate to Team: the principals where not aligned on the business model basics and could not explain the above inconsistencies.

**Recommendations for Improvement:** Should OsteoNovus choose to reapply for TVSF funding, the grant application should provide a compelling Business Model that is directly related to the product being commercialized and agrees with the narrative presented. The Proof plan must be focused on the grant funded activities.

<b>Proposal 14-433</b>	<b>Protimage Diagnostics, LLC</b>	<b>PTPmu Molecular Imaging Probes Identify Cancer Cells During Surgical Resection of Tumors</b>
<b>Amount Requested: \$100,000</b>	<b>Recommended: \$0</b>	

**Rationale:** This proposal is the second submission to advance a product called PROT001 through proof of concept in humans via a so-called Phase 0 clinical trial as an FDA Exploratory Investigational New Drug (eIND). The review team did not recommend funding on the first application (13-543) due to the lack of meaningful Proof objectives, insufficient Business Plan, and a Team of one. This resubmission has not fully addressed the earlier concerns.

PROT001 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). The substance has been widely studied, not only by Susann Brady-Kalnay, who is President and Chief Scientific Officer of Protimage and a professor at Case Western Reserve University, but also by many others. It is now 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.

Professor Brady-Kalnay has developed such probes, one of which is PROT001. The initial target is glioblastoma multiform (GBM), a type of brain tumor. 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, such as probes tagged with paramagnetic material whose location could be found using diagnostic MRI. Indeed, the company asserts that the principal investigator has already done so.

A new product, Gliolan, manufactured by a German company and approved for use in the EU, functions in the same manner as PROT001, that is, to guide surgery of GBM using a fluorescence microscope. This is said to be relevant because it paves the way for a similar product like PROT001. The proposal asserts that PROT001 is superior to Gliolan

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. The probes will then be tested for toxicity in rats. Armed with these (presumably favorable) results, consultants representing 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. The PROT001 used in these trials will be manufactured by a different company, Bachem. The proposal states that this clinical trial will be primarily addressed to demonstrating absence of serious toxicity, but that the company hopes it will also demonstrate improved confidence among surgeons and perhaps improved clinical outcomes (though no details about how outcomes will be measured are mentioned).

The proposal seeks \$100,000 from the TVSF program and asserts that an “angel investor,” already identified though not named, is prepared to contribute \$250,000 to complete the Phase 0 clinical trial.

Assuming that the results of this work are favorable, the company believes that it will then be in a good position to interest larger pharmaceutical and imaging equipment firms to invest.

The review team found that the previously identified and significant concerns with the application have not been resolved. The Proof milestones are not likely sufficient to attract additional funding because they are too early in the research cycle. There are simply too many unknowns at this point for this work to be considered for Phase 2 commercialization work. These would include the efficacy of PROT001 as a visualizing medium for intra-operative use during surgery – specificity, sensitivity, how detection of even a single cancerous cell can be put into practice during surgery, duration of effect considering the length of the operation, how addition of a tracer may impact effectiveness, etc. While a great deal of work has been done in the lab, the proof point described is safety, and the critical questions on product performance, cost of goods, funds needed to commercialize, etc., will remain unknown. These major concerns preclude recommendation for funding.

Additional concerns which were not sufficient to preclude funding also persist from the previous submission. The Business Model remains vague, and the team still only consists of the inventor on a part time basis, though additional outside consultants have been identified who will join the

company's 'board of managers'. While inclusion of part-time consultants is understandable given the current stage of development, the fact that full-time employees are not part of this application reinforces the review team's perception that this is more of a research project and not a commercialization project.

**Recommendations for Improvement:** Should Protimage Diagnostics choose to reapply for TVSF funding, the grant application should provide compelling Proof points that are farther along the development cycle to attract investment. Supplementary team members with the business acumen to define a focused strategy and translate this technology into the market would be beneficial.

<b>Proposal 14-434</b>	<b>Ion-Vac, Inc.</b>	<b>Wound Healing System</b>
<b>Amount Requested: \$100,000</b>	<b>Recommended: \$100,000</b>	

**Rationale:** This proposal is a resubmission of 13-530 to further develop their novel wound healing system. It was not recommended for funding due to an insufficient Business Model and absence of detail on source and use of funds. This application has remediated those previous concerns.

The system employs negative pressure wound therapy (NPWT) combined with iontophoretic delivery of an antiseptic material (silver). NPWT is a standard method for dealing with chronic wounds such as pressure ulcers (bed sores), venous stasis, and diabetic foot ulcers. It uses a special dressing combined with a pump that creates a negative pressure on the wound, drawing out edematous fluids and promoting blood flow to the site, leading to faster healing and better outcomes. However, NPWT by itself can induce pain and inflammation as well as overgrowth of biofilm, which is a bacterially induced layer that protects the bacteria below the layer but, of course, harms the patient.

Iontophoresis alleviates these problems. It is a well-established method for delivering ionizable pharmaceuticals and penetrating a biofilm layer. The delivery system consists of two pads on the skin, one on the wound and one on a site opposite the wound. An electric field (voltage) applied across the two pads causes migration of electrically charged ions into the wound.

Advanced wound care – that is, care of chronic wounds – is, according to the applicants, a \$1.9 billion market in the US in 2010, growing at more than 9% per year. The applicants believe that the combined therapy described above has sufficient advantages for them to capture significant market share. Specifically, the combined therapy will reduce frequency of dressing changes, accelerate wound healing, diminish staff needed for wound care, and most significantly penetrate the biofilm layer, thus improving healing.

The proposal addresses all of the criteria for the phase 2 TVSF funding. The review team found technology compelling; the business model is adequate; external backing and IP have been secured; the market is sufficient; the project plan is meaningful and achievable, and the team leadership is prepared for success.

The only concern which was not sufficient to preclude funding relates to the Business Model as it does not anticipate competitor reaction to their market entry.

This proposal is recommended for funding.

<b>Proposal 14-435</b>	<b>GenomeNext</b>	<b>Cloud Genomic Analysis solution</b>
<b>Amount Requested: \$100,000</b>	<b>Recommended: \$0</b>	

**Rationale:** The applicants propose to take the Churchill genetic analysis software, developed at the Nationwide Children’s Hospital Research Institute in Columbus, and use it as the basis for a cloud software offering. The business would offer storage of genetic data as well as analysis. The applicants claim Churchill provides results that are identical in quality to the much slower (2 weeks vs. 2 hours) gold standard bioinformatics approach, achieving the clinical gold standard of 100% reproducibility.

The review team found significant concerns with the application with respect to most Phase 2 requirements. The Proof milestones are not defined for the TVSF project - the grant application has a total budget of \$1.6 million to be spent on 12 major tasks identified in the proposal. Since those major tasks are quite general in nature, ‘Research and Development’, for example, we do not see a specific proof point. Significant amounts of company financial needs are identified, but not tied into the Ohio project for use of funds. The needed commercialization funds gap exceeds \$1.5MM with no committed source of funds – the applicants target a \$600k capital raise, but provide no detail on the source of the remaining \$900k. The review team assumes they will self-fund, which calls into question the necessity of state funding to subsidize such small part of the overall project. Regardless of source, the gaps are significant and expose state funds to too much risk. Even if funds are in place and sources confirmed, it’s entirely unclear from the sparse budget narrative how TVSF funds would be spent. Team and Ohio startup concerns stem from the fact that the principals of the company are also principals of the proposed partner which is based in Maryland. Since the partner company of the proposed start-up ‘will provide professional services to GenomeNext’ there is a concern about use of state funds and potential conflicts of interest. Market opportunity for whole genome sequencing may be constrained to institutional genetic research versus the broader consumer market. This is due to pricing sensitivity and information overload. The current consumer market is focused on single nucleotide polymorphisms which inform Personalized Medicine. These major concerns preclude recommendation for funding.

**Recommendations for Improvement:** Should GenomeNext choose to reapply for TVSF funding, the grant application should provide compelling Proof points that are succinct and achievable within the scope of this project. Utilize that Proof point plan to tie the financial budget to those specific tasks. Identify how that proof plan will get the project to next funding. Provide market insight into customer uptake expectations. Finally explain the relationship between the principals and JHC and why this new company will be tied to Ohio versus attracted to Maryland.

<b>Proposal 14-436</b>	<b>Columbus Technology LLC</b>	<b>DICE (Distributed Interactive Cube Exploration)</b>
<b>Amount Requested: \$100,000</b>	<b>Recommended: \$100,000</b>	

**Rationale:** The applicant proposes to further develop the DICE system for analyzing very large sets of data, focusing particularly on cases where a data set may reside in multiple databases with different formats. Because large insurance companies have very large sets of data in disparate formats and because several such companies have their headquarters in Ohio, the team is aiming its first offerings at the insurance industry. The value-add is the ability to quilt disparate live and legacy data with double the speed while maintaining accuracy. The business model is to charge a flat fee with unlimited queries, differentiating from variable cost competitors.

Project funds will be used to (1) develop an industry-specific graphical user interface to replace the current command line-driven system, a development that would make the tool suitable for a wider range of users. (2) Create a base set of queries specific to the insurance industry. (3) Develop the data interconnect tool to reach data in a heterogeneous collection of data sources.

Once these milestones are reached, DICE should be ready for installation and initial use by the staff at Grange and State Auto, which have been identified as early customer targets.

The proposal addresses all of the criteria for the phase 2 TVSF funding. The review team found technology compelling; the business model is adequate; external backing and IP have been secured; the market is sufficient; the project plan is meaningful and achievable, and the team leadership is prepared for success.

The areas of concern which were not sufficient to preclude funding relate to the Business Model, timeline, and IP. Revenue projections and Product features cannot be fully defined until after the beta work with pilot customers, therefore costs have not been fully vetted. The unknowns have the potential to stretch the timeline beyond one year. Trade Secret IP is not the most secure protection.

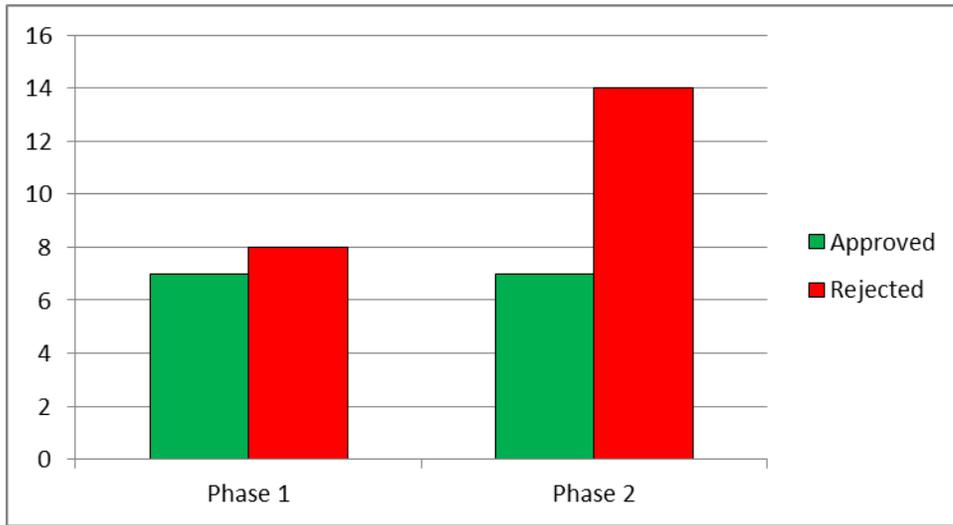
The Proposal is recommend for Funding.

## FINAL SUMMARY

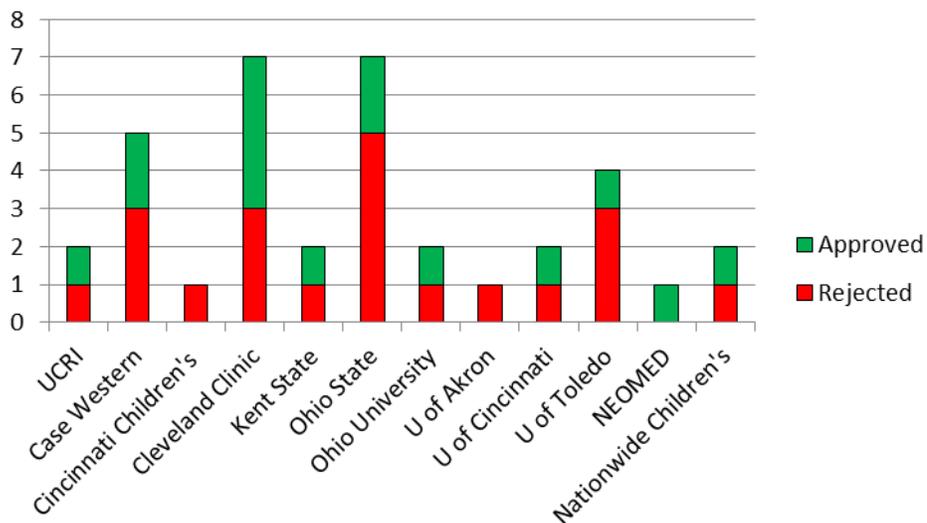
The Review Team is recommending 14 of the 36 grants submitted for review (39%). The previous low was 30% in Round 4, and the high was 52% for Round 2. For this current round, seven of the 15 Phase 1 proposals are recommended for funding (47%). For Phase 2, seven of the 21 submitted grants are recommended for funding (33%). 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 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.

*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

ADVAL 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 contractors 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 YourEncore 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

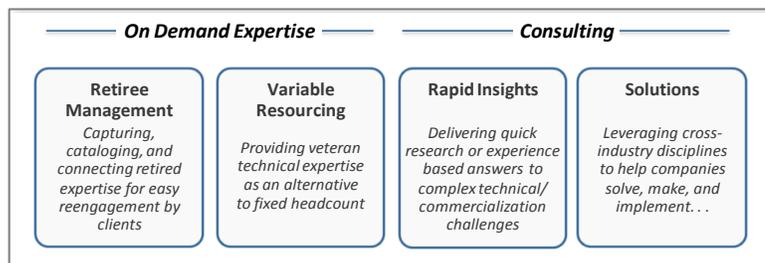
YourEncore understands the unique needs and challenges startups face since, 8 years ago, it was one. YourEncore was founded in 2003 by John Barnard of Barnard Associates. Barnard Associates is composed of a cross-functional team of highly experienced executive leaders, who advise start-ups on launching 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

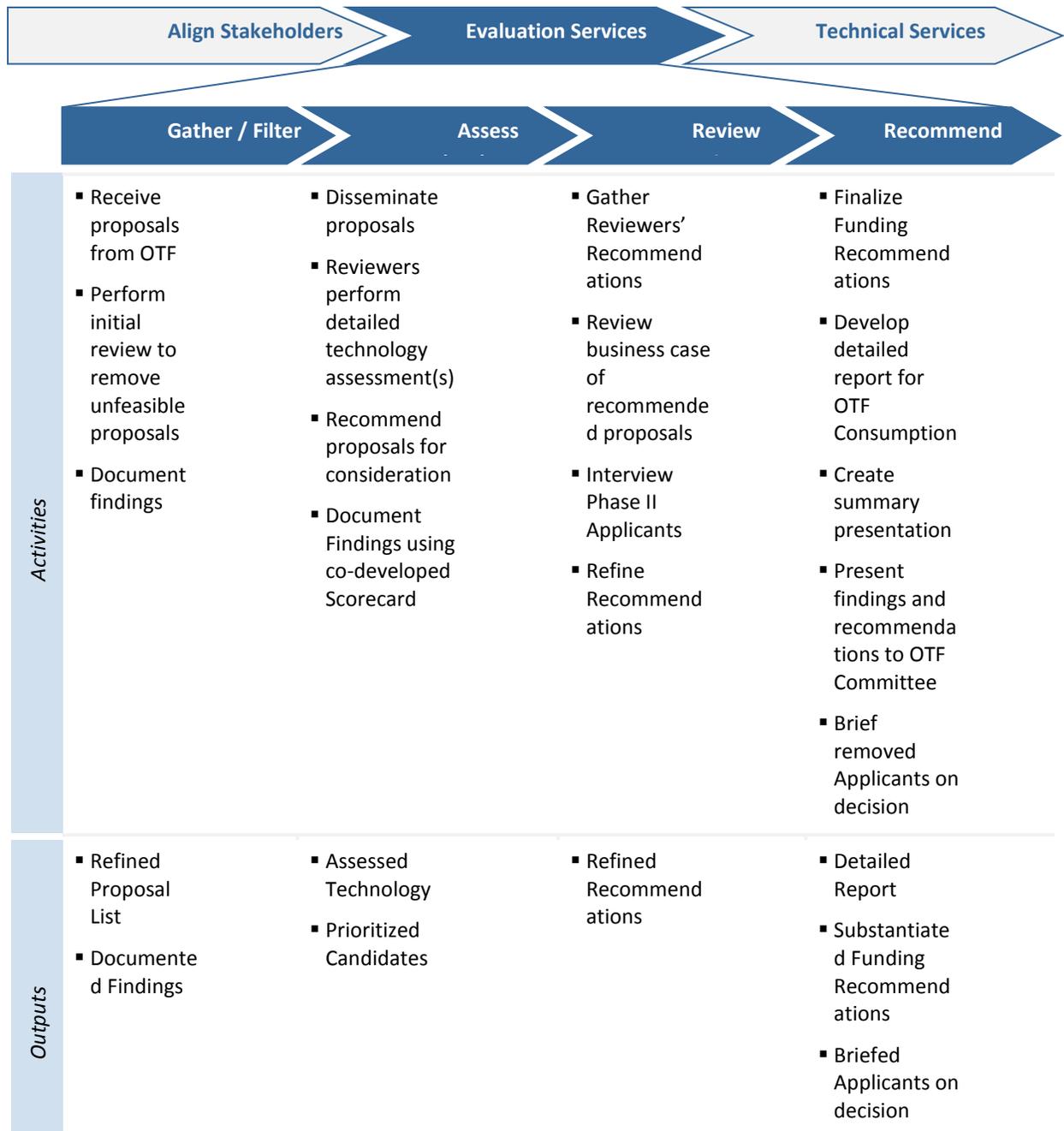
<b>1. Unparalleled Expertise</b>	<b>2. Recognized Leader</b>	<b>3. Flexible Resource Model</b>
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## APPENDIX D-EVALUATION PROCESS

### *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:

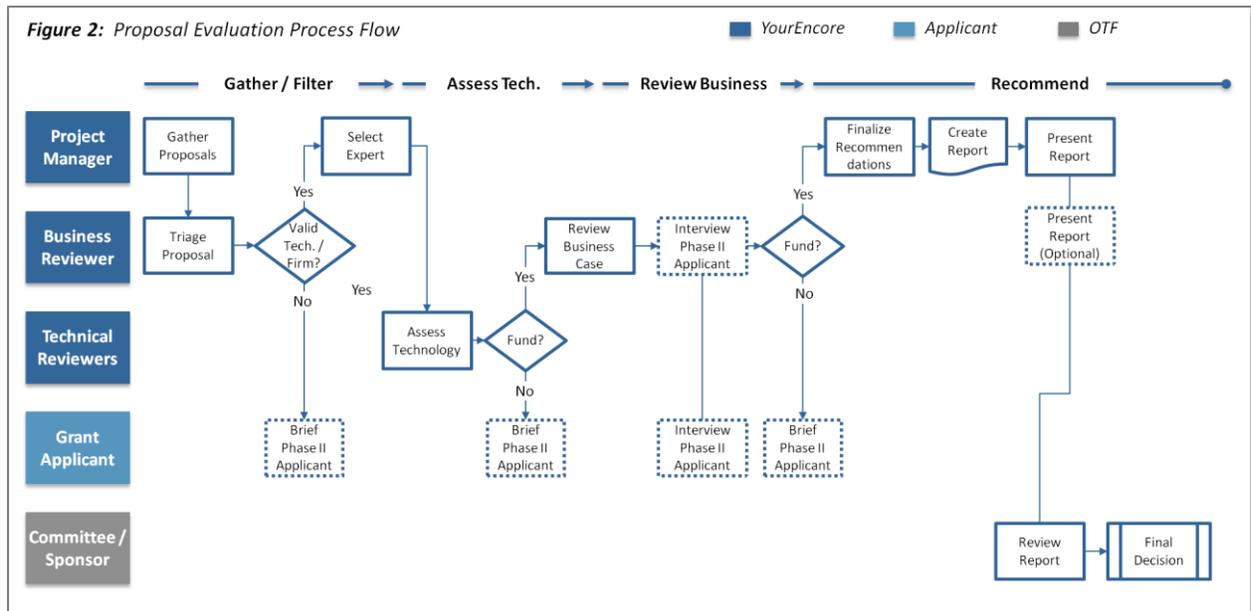
### **Key Evaluation Scorecard Components**

- *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.

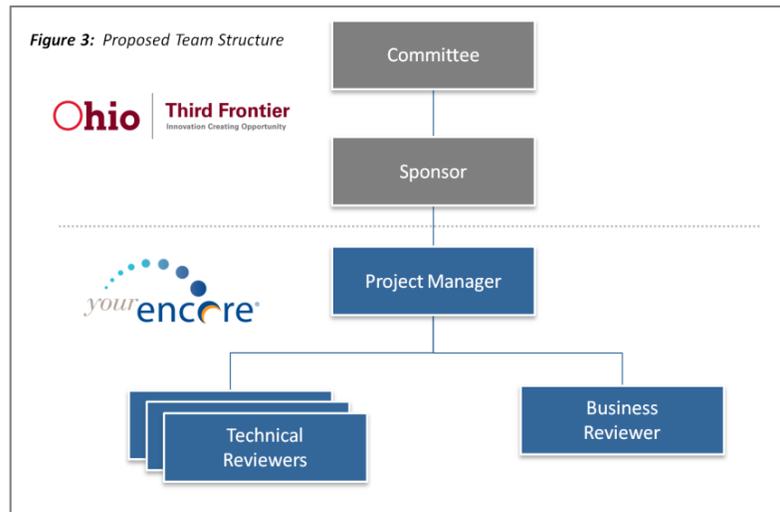
### BUSINESS REVIEWER

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.