I-FAST full proposal

I-FAST Team:

I-FAST team is comprised of the following:

Majed El-Dweik (PI) is Associate Professor and Founder and Director of the Center of Nanotechnology at Lincoln University. Lincoln University is an HBCU and a minority serving institute. He has a B.S and M.S in Electrical and Computer Engineering and a PhD in Biological Engineering in 2007 from the University of Missouri-Columbia. He specializes in the development of biosensors and Nano-biosensors for rapid detection of foodborne pathogens. In the Center of Nanotechnology he has a team that consists of microbiologist, chemist, engineers, and graduate students. His current, developed technique for the rapid detection of foodborne pathogens will prevent fatalities and illness of consumers who consume contaminated food and will save food industries from recalled products which results in loss of capital and damaging of brand image which leads to loss of business.

Elijah Sharpe (EL) is Business Administration student at Lincoln University and is dean's list classified. Elijah currently serves as the president of Net Impact (a nonprofit membership organization for students and professionals interested in using business skills in support of various social and environmental causes), vice president of DECA (an international association of high school and college students and teachers of marketing management and entrepreneurship in business, finance, hospitality, and marketing sales and service). The involvement in various organizations has been instrumental in the development of Elijah's entrepreneurial experience. Entrepreneurship competitions, venture presentations, and real world sales have also contributed to Elijah's overall entrepreneurial expertise. Elijah has spent his last two years with Dr. Dweik learning about various bio-engineering technologies. Elijah has continuously been active in analyzing and identifying food safety problems, solutions, differentiation, market plans, and commercialization plans of proposed concept.

Sonny Garcia (Mentor) is the president and chief revenue officer at Oculus360. Sonny has spent the last 16 years growing various startup ventures. One of the most significant startups he helped grow was Research Now, the market research industry's largest online panel company. While at Research Now, he led two global business units. One was focused on bringing custom panel and community solutions to the market and the other was focused on bringing integrated big data solutions to the market. Prior to this role, Sonny incubated and led client development for a business unit at Research Now focused on serving strategic advisory clients such as management consulting and private equity firms. Sonny was also responsible for managing the largest sales region at e-Rewards (Research Now's former parent company). Sonny earned his BS in Industrial Engineering from Stanford University and his MBA from The Wharton School at the University of Pennsylvania. Through Sonny's ventures he has established various relationships with many large companies within the food industry. Sonny has served as Elijah's advisor and has guided him in the business development of the proposed innovation. Dr. Dweik and Elijah have collaborated on substantial amounts of research including novel nanomaterials and pathogen detection technology. The rationale for the team's formation was based on the involvement of all members, from the beginning, and through the evolution of the concept. Elijah and Sonny's entrepreneurial experience/expertise and Dr. Dweik's multiple awards from USDA grants also led the team to believe that its collaboration would lead to a successful I-FAST team.

Lineage of the Proposed Innovation:

Dr. Dweik has received several grants from USDA. In 2008, he received NIFA Capacity Building Grant to build capacity in food safety and nano-biotechnology. He was able to initiate the research in rapid foodborne pathogens by utilizing nanomaterials to build sensitive platform. In 2009, he received Evans Allen grant for basic research to investigate variety of sensing mechanisms including electrochemical, MEMS, and optical detection platforms for E. coli O157:H7 in Beef. In 2010, he was CoPI for MEMS system development. In 2012, a second Evans Allan was awarded for development of optical rapid detection for E. coli O157:H7. This system has led to fast detection technique by utilizing Florescence Resonance Energy Transfer principles. In 2014, NIFA Capacity Building Grant was awarded to further the fabrication process for the rapid detection platform by building capacity in clean room for microfabrication and target single cell detection. The novel developed platform will allow controlling a small volume of cells then arranging them in a single line then a single cell platform will identify that cell.

The extensive work on detection platforms and the results obtained supported the hypothesis that developing a rapid and sensitive detection system could benefit the food industry, and led the team to believe in the transfer of this biotechnology from the laboratory to commercialization. The team recognizes the urgent need from the market for a fast and rapid technology to sense and detect foodborne pathogens. E. coli O157:H7 has caused many fatalities and huge losses in the food industry. Our biotechnology will allow restaurants and food preparing industries to test food for E. coli O157:H7 prior to the products reaching consumers. This biotechnology will give results in 1 hour. Our biotechnology is much faster, when compared to its current competition that gives results in, at least, 36 hours. We have improved the enrichment process and also fabricated a sensitive platform to detect around 200 cells in 1 ml volume. Also, the peer reviewed publications in scientific journals with the high impact factor, was another motivator in the advancement of the commercialization of this biotechnology. Our team has also done extensive research companies who need to implement of this biotechnology.

Currently, we are working on finalizing the patenting for our biotechnology. I-FAST opportunity will be constructive in assisting us in moving toward commercialization. Our ultimate objective is to receive funding from USDA-SBIR phase I, II and III to help in transferring this novel biotechnology to the commercial world. I-FAST will facilitate to reach our ultimate objective by establishing business relationship with large restaurant chains and food service industries. This relationship can be utilized in getting letter of support and further collaboration. Our preliminary plans from the support of I-FAST are the following:

1. Our team will identify and locate companies of interest and set a timetable to approach and set meetings for physical meetings
2. Prepare and customize presentations for the companies visiting.
3. While visiting with companies and stakeholders we will discover about how they handle quality control for E. coli O157:H7 testing and cost of testing. This will give us feedback on how to implement our detection system.
4. Our technical team will work on the ultimate design and features needed by the industries.
5. Our team will establish market value for our biotechnology based on completion available and need for our product special features.
6. Our team will know the size of the available market and determine the five years sales target.

Commercial Impact:

The customers of our proposed concept range across all sectors of the food industry. Processing facilities, distributors, retailers, government agencies, and farmers of all geographical regions and demographics will be potential customers for the optical pathogen detection concept.

Farmers: in recent years, E .Coli O157:H7 has been identified in outbreaks of foodborne illnesses linked to fresh produce and meat. In Europe for example, BBC News had reported on June 6, 2015: *"a farm in northern Germany has been identified as the most likely source of many of the infections in the E. coli outbreak that has left 22 people dead."* Also on August 8, 2015 KATU News reported that there was an E. coli outbreak in a batch of strawberries that had left 10 people sick after consumption. This was traced to the Newberg Strawberry farm in Portland Oregon. After observing both these reports, one can see how a small or large farmer can be dramatically affected by such an outbreak affecting the food they produce and sell to their customers. This could result in damages to the business reputation and its trademark. Having our pathogen detection biotechnology would terminate the risk of farmers supplying contaminated food to their direct customers, processing facilities, distributors and retailers.

Processing Facilities: our biotechnology would be beneficial to processing facilities to protect their human customers as well as the pets of these customers (pet food has also been a major concern of E. coli contamination). If contaminated food has been supplied to these processing facilities, it is just another step in the food chain. Both human consumers and animal consumers are put at risk in regards to their health and safety. If a facility is equipped with our biotechnology, and contaminated food or meat is delivered to the processing facility- the damage and contamination can be controlled/detected prior to processing. In July 2002, Food Safety and Inspection Service released a recall statement that read: "ConAgra Beef Company, a Greeley Colorado establishment, is voluntarily recalling approximately 19 million pounds of beef trim and fresh and frozen ground beef products that may be contaminated with *E. coli* O157:H7, the U.S. Department of Agriculture's Food Safety and Inspection Service (FSIS) announced today." The breakthrough in our biotechnology is being pro-active. The biotechnology would save these processing facilities time and money, while protecting the health of its customers.

Distributors and Retailers: these would be the businesses and/or facilities that would benefit to a much greater extent from having our biotechnology. The retailer is the direct provider of food products to customers. If there is contaminated food that results in hospitalization of a customer(s), this could pose great losses for that business. Though the company will recover financially for the foods being recalled, it may never recover from the backlash its reputation receives from its customers. Word of mouth may retard sales and hence, cause financial losses to the business. Having our biotechnology is a 'must have' for these organizations. This is the final stage in the distribution chain and with the opportunity to protect the customers, the company can work to improve health standards as opposed to settling for the status quo.

Companies in the food industry need more effective, efficient, reliable, and accurate method of pathogen detection. We will be meeting the needs of food industry companies in these ways-

Time for detection: we have minimized the overall detection time in pathogen testing. This innovative step is the driving force behind the vast distinction between our concept and our competitors. Faster detection translates to isolating products earlier in the food supply chain and prevents contaminated food from entering the market and benefits in terms of cost, efficiency, and overall safe consumable products for the public.

Cost: our detection concept saves time, energy and money.

Disposable concept: our test kit will be disposable. This prevents risk of cross contamination and omits the process of sending specimens to a lab due to automatic detection.
Concept parameters: the size and weight of our concept makes our potential product portable and flexible for users. This will be beneficial for multiple units in a food plant (ex. members of quality control to identify harmful pathogens on or in products before distribution).
Sample enrichment: the efficient of selective enrichment steps shortens analysis time due to the fact that this product will allow members of quality control to test each batch prior to final stage in production. This will ultimately save the company money due to the fact that entire batches of products will not go to waste, due to real-time and rapid detection. This eliminates potential product recalls, lawsuits, and a tarnished reputation.
Variety in Applications: identification of certain microbial pathogens, such as etiologic agents responsible for chronic diseases, is leading to new treatments and prevention strategies for these diseases. Specificity; high levels of specificity minimize problems with false positive tests. Our focus is on *E. coli, and our concept has the potential to also detect Salmonella, Listeria,* and *Campylobacter jejuni.*

The competition for our biotechnology is slim to none at this time. Although there are other researchers working on pathogen detection, they have not yet been able to reach the level of accurateness or preciseness that our biotechnology has reached. PCR and Real-Time PCR is currently used in testing laboratories. They are large and very costly set up and not affordable by food industries to own. These systems are typically priced around $100,000. Furthermore, the current technologies of these systems require lab testing that is carried out generally at an off-site facility by experienced personnel. The specified testing conditions of these devices come about for three main reasons: 1) The equipment is cumbersome, 2) The equipment is expensive, and 3) The sensors degrade due to environmental conditions. Our pathogen detection concept addresses all three of these problems head on. The affordability and the low cost per sample testing and the easy use of our biotechnology will make our product extremely attractive for our customers. According to preliminary data obtained from testing laboratories, the cost per sample testing is around $45 and it will take an average of 36 hours from the time the sample received by the laboratory. Our biotechnology can be set in the user facility which will save on shipping and contamination of samples also will provide results in 6 hours for the cost of around $25 per sample.

Our innovative approach is to provide the following:

1. Fast and accurate biotechnology for specific foodborne pathogen detection.
2. Affordable and easy to setup system that will be custom designed and manufactured to fit the operation of the end user.
3. Disposable testing kit and maintenance free system.
4. User friendly which can be operated by any person who will go through short online training to learn about the order of preparing and placing the sample in the system to get the reading.

Project Plan:

Our team has been making great progress in the optical pathogen detection project. Prior to the initial stages of the development of this biotechnological detection system extensive literature review was performed about foodborne pathogen detection systems. We were able to evaluate them based on their performance factors. The performance factors consist of sensitivity, selectivity, detection limits, response time, results repeatability and system reliability. Our biotechnology has been tested and validated for its performance factors. In sampling and testing for E.coli O157:H7 we use Food safety Inspection Services (FSIS) standards. The sensitivity is very high. Our system is designed to detect less than 100 cells. Our system is highly selective due to the use of specific antibodies which has high affinity to the E. coli O157:H7. Since the system can detect low concentration of cells, our enrichment process is performed in 5 hours then the detection will take 1 hour. The obtained results have been consistent as experiments ran numerous times. The project has past the proof-of-principle and now we have a proof-of-concept to move forward that can be utilized by the food industries and we are in the process to build a prototype.

The optical detection system consists of the following:

1. Sampling preparation. This step will allow solid sample to be liquefied and then purified to enrich for 5 hours
2. Optical platform. This step consists of optical reagents which consist of labeled antibodies and labeled enzyme. With the assistant of our portable design of the optical instrument, detection of E. coli O157:H7 will be obtained at a specific wave length after 1 hour of incubation.

The process is easy and user friendly. The above steps are designed to be conducted by any person with simple training that we will offer. We will offer for sale the system which includes purification, enrichment and testing. The optical platform (reagents) will be also sold in ready to test vials as a kit. The low cost designed optical equipment will be part of the system. By the end of the project, we will have the setup of the proof-of-concept and all the support data provided by the industries. This will include the modified of design and functions that are needed by the industries. Also we will know the actual size of the market and adjust our business plan to fit the data obtained about the market. The price of the system and the cost of reagents will be made competitive to those currently used systems.

We believe that I-FAST will pave the road to our success and give us great support to the next step of applying to USDA-SBIR phase I. Our novel biotechnology offers great tool to solve food safety and food security challenge. Our team members have years of experience and extensive knowledge and background about the food safety challenge and how to bridge the research findings to cross over to the commercial market. The team is committed to this project and ready to meet and interact with the industries and end users. The biotechnology does not only impact our economy but it will impact human health which will lead to better social life. The ultimate mission of the team is to work very hard and succeed by executing the proposed above indicated plans and with the assistant of I-FAST organized support and experts.