

Sample Application for Small Business Funding

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(Privileged Communication)

PROGRAM CONTACT: Release Date: 12/14/2016 Charles Washabaugh **Revised Date:** Application Number: 2 R44 AR064111-02 Principal Investigators (Listed Alphabetically): **BESCHORNER. KURT E.** MOYER, BRIAN EVAN (Contact) Applicant Organization: CROSSROADS CONSULTING, LLC Review Group: ZRG1 MOSS-V (15) **Center for Scientific Review Special Emphasis Panel Muscloskeletal Rehabilitation Small Business** *RFA/PA:* PA16-302 Meeting Date: 11/21/2016 **JAN 2017** PCC: 3 B Council: Requested Start: 05/01/2017 Dual IC(s): AG, HD, NR Project Title: Portable Slip-Testing Device for Measuring Shoe-Floor Coefficient of Friction SRG Action: Impact Score:29 Visit http://grants.nih.gov/grants/next_steps.htm Next Steps: 30-Human subjects involved - Certified, no SRG concerns Human Subjects: Animal Subjects: 10-No live vertebrate animals involved for competing appl. Gender: 1A-Both genders, scientifically acceptable 1A-Minorities and non-minorities, scientifically acceptable Minority: 3A-No children included, scientifically acceptable Children: Clinical Research - not NIH-defined Phase III Trial Project **Direct Costs** Estimated Year Requested **Total Cost** 2 3 TOTAL

ADMINISTRATIVE BUDGET NOTE: The budget shown is the requested budget and has not been adjusted to reflect any recommendations made by reviewers. If an award is planned, the costs will be calculated by Institute grants management staff based on the recommendations outlined below in the COMMITTEE **BUDGET RECOMMENDATIONS section.**

2R44AR064111-02 Moyer, Brian

ADMINISTRATIVE NOTE

RESUME AND SUMMARY OF DISCUSSION: The purpose of this new Phase II SBIR application is to create a portable slip-testing device STEPS (Shoe Tribometer for Enhancing Predictive Safety) to measure the available coefficient of friction (ACOF) that is predictive of slipping probability. High significance of this application relates to developing a tool for providing reliable predictions of slipping to improve the current slip-testing technology. Some reviewers noted that the approach is innovative in respect to creating a low-cost and low-weight device for biofidelic slip-testing on a whole shoe. In contrast, others appeared to be less positive about the innovation of the proposed study. The discussed strengths of the application include the supportive preliminary data from the Phase I study assuring the feasibility of the proposed research, a mechanistic approach to reduce the number of actuators, the experienced research team, the focus on licensing of the software, and a potentially large market in industrial force to protect working environments. Reviewers also identified several weaknesses of the application including a limited statistical support, and an overambitious number of testing conditions and trials questioning the power of the studies. Reviewers also raised a concern about potential difficulties in commercialization due to the availability of competing products, the need for expertise in using OpenSource that may be lacking in small users, and the challenges in educating the market about a not yet adopted new standard system. After an extensive discussion, the difference of opinions about the innovation of the study could not be resolved among the reviewers, and many reviewers remained highly enthusiastic about the success of this application.

DESCRIPTION (provided by applicant): Slip and fall accidents are a major and growing source of occupational injuries. Increasing the available coefficient of friction (ACOF) between the shoe and floor surface is an effective method for reducing slipping risk. A significant need exists for portable, costeffective shoe-floor ACOF testing equipment that is valid for predicting slip risk. Filling this need is likely to increase the use of rigorous slip-testing in the field, customizing footwear programs to a specific workplace, and selecting the most effective footwear or flooring intervention. The overall objective of this SBIR Phase II (R44) research study is to develop a portable ACOF testing device that predicts whether a person is likely to slip with sensitivity and specificity. The feasibility of this approach is supported by preliminary development of a biofidelic slip-testing device. The potential for our approach to improve the validity of slip-testing is supported by preliminary data that found that current testing methods do not reflect the kinematics of slipping and that the under-shoe testing condition are critical to the tester's ability to predict slips. The proposed research will be accomplished with four aims: Aim 1: Identify a set of testing conditions (force, sliding speed and shoe-floor angle profiles) that best predict slip events; Aim 2: Develop a slip-tester that is portable, inexpensive and biofidelic; Aim 3: Quantify reproducibility and repeatability of the device using an interlaboratory study; and Aim 4: Validate the ability of the portable testing device to predict slipping events. Aim 1 will use previously-collected human slipping data and the biofidelic slip-tester to identify testing kinematics and kinetics that best predict slips. Aim 2 will create a portable device that uses kinematic linkage systems to achieve the testing conditions identified in Aim 1 using stepper motors and calculates ACOF based on forces measured with a load cell. Aim 2 will also include a hypothesis (H2.1) that the developed device will yield ACOF values that are well correlated with the biofidelic slip-testing device developed in Phase 1. Aim 3 will perform a multiple site interlaboratory study to quantify repeatability of the device and reproducibility across operators and devices. Aim 3 will include a hypothesis (H3.1) that differences in ACOF values will not be observed across operators and devices. Aim 4 will quantify the validity of the device for prospectively predicting human slip propensity based on ACOF data collected with the device. Aim 4 includes a hypothesis (H4.1) that the device will predict slipping risk. This proposed research is expected to lead to a state-of-the art device that will promote interventions that reduce accidental injuries due to slipping. Commercializing this innovation will position Crossroads Consulting,

LLC to reach new markets for both laboratory and field slip-testing, targeting safety and occupational health consultants, smaller shoe and flooring manufactures, as well as the research community. As a result, Crossroads Consulting, LLC is anticipated to grow in size and revenues through product sales and service agreements.

PUBLIC HEALTH RELEVANCE: Slip and fall accidents are a significant source injuries and fatalities for all age groups. Valid measurements of ACOF between shoes and flooring surfaces is essential to identify circumstances in need of intervention and identifying the optimal intervention. The purpose of this research is to develop a portable, valid and cost- effective design for measuring shoe-floor ACOF.

CRITIQUE 1:

Significance: 1 Investigator(s): 2 Innovation: 1 Approach: 2 Environment: 1

Overall Impact: In this Phase II SBIR application the investigators will create a portable slip-testing device – the Shoe Tribometer for Enhancing Predictive Safety (STEPS) – that will yield valid available coefficient of friction (ACOF) measurements that are predictive of slipping probability. The optimal testing conditions for predicting slips will be examined, the portability and cost to manufacture of the device will be explored, the reproducibility and repeatability of the device will be tested; and the ability of this slip-tester to reliably predict slipping accidents will be quantified. This is a well-planned Phase II application.

1. Significance:

Strengths

• There a strong scientific premise for this work: slips and falls continue to be among the leading generators of work-related injuries and workers' compensation claims, and represent the primary cause of lost days from work.

Weaknesses

• None noted.

2. Investigator(s):

Strengths

- The PI is a well-trained bioengineer with a background in mechanics. He is well qualified to lead this effort.
- The team appears to be qualified.
- Strong results from Phase I indicate a successful team.

Weaknesses

 Investigators have some, but not extensive experience in leading NIH projects of this size and scope.

3. Innovation:

Strengths

• Existing technology for measuring ACOF currently does not meet the need for environmental and biomechanical fidelity. This device should fill a need.

Weaknesses

• None noted.

4. Approach:

Strengths

- For aim 1, 128 different set of testing conditions will be examined. This represents a sound and rigorous approach.
- Aim 2 takes a hypothesis-driven approach to develop a portable, inexpensive and biofidelic sliptester.
- In Aim 3 the investigators will quantify reproducibility and repeatability using 3 different shoefloor-contaminant combinations. The data analysis is rigorous and appropriate.
- Aim 4 will examine the validity or the device predictions of slipping events by testing 90 subjects under a variety of conditions. Taken together, these are sound approaches.
- The research accounts for sex and other relevant biological variables.

Weaknesses

• The plans are very aggressive and might be over-ambitious to accomplish in the two-year time-span.

5. Environment:

Strengths

• The facilities are very good for this work.

Weaknesses

• No concerns.

Phase II (Type 2 R42 and Type 2 R44 applications):

Acceptable

Protections for Human Subjects:

Acceptable Risks and Adequate Protections Data and Safety Monitoring Plan (Applicable for Clinical Trials Only): Not Applicable (No Clinical Trials)

Inclusion of Women, Minorities and Children:

- Sex/Gender: Distribution justified scientifically
- Race/Ethnicity: Distribution justified scientifically
- For NIH-Defined Phase III trials, Plans for valid design and analysis:

• Inclusion/Exclusion of Children under 18: Excluding ages <18; justified scientifically

Authentication of Key Biological and/or Chemical Resources:

Not Applicable (No Relevant Resources)

• There are no key biological and/or chemical resources to authenticate, so this is not a concern

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Budget and Period of Support:

Recommend as Requested.

CRITIQUE 2:

Significance: 3 Investigator(s): 2 Innovation: 2 Approach: 3 Environment: 2

Overall Impact: This application builds on successful Phase-I results to develop a highly innovative portable device to measure the available coefficient of friction (ACOF) using an entire shoe, at lower cost than other commercially available devices (which are not both portable and capable of using an entire shoe). The team and environment are both excellent. The study and prevention of slips and resulting falls is significant, though tempered by a concern that the device would reach wide use since the company primarily intends for customers to buy a kit to build the device, essentially releasing the hardware as open-source and using a sales model based on software licensing. Overall the approach is very strong, but requires a very large number of experiments and human subjects, increasing the risk of failure to complete these tasks.

1. Significance:

Strengths

 This proposed work addresses the need for better tools in evaluating and preventing slips and falls due to foot/surface interactions - falls are an extremely large burden, both in terms of cost and on affected quality of life, and while the bulk of research addresses older adult falls, this proposed work would address the significant portion of falls due to slips/falls, many of which occur in an industrial setting.

Weaknesses

- The proposed sales approach of open-source with a software license seems likely to unnecessarily limit total sales – there may be interested buyers who do not wish to build their own device. The commercialization plan does mention that "Crossroads will package these components into complete build kits or assemble devices for clients as a service with little to no direct manufacturing required" but elsewhere makes it clear that the primary focus is on licensing the software.
- Having (the majority?) of users build their own device seems could affect the device performance.

2. Investigator(s):

Strengths

 The PI (Moyer) and subcontract PI (Beschorner) both have extensive expertise in the area of slips and falls, both in terms of the biomechanics and of the instrumentation required to understand the root causes.

Weaknesses

• The 10 hours of statistical support available to the subcontract PI (Beschorner) seems low given the complexity of the experiments, particularly since this support may not be available for the experiments done at the PI's (Moyer's) company.

3. Innovation:

Strengths

The proposed solution for determining ACOF addresses key customer needs of low cost and
portability while accommodating an entire shoe for testing, by using kinematic linkages to couple
vertical and horizontal motion, which reduces the required actuators (thus reducing size/weight
for portability, and reducing components for decreased cost).

Weaknesses

None noted.

4. Approach:

Strengths

• Overall, the aims are rationally designed to advance the prototype developed during Phase-I to a market-ready design with the necessary supporting experiments to evaluate and characterize the prototypes.

Weaknesses

A very large number of experiments are required as presented, both with the equipment (630 trials – which is perhaps a typo – shouldn't it be 640 = 4*4*4*2*5) and the human subjects (90 participants, randomly assigned to one of six floor/shoe combinations). Use of "design of experiments" methods may allow the number of trials (particularly for the >600 equipment experiments) to be reduced by systematically selecting a subset of the combinations.

5. Environment:

Strengths

• Both the company and the academic partner have the resources necessary.

Weaknesses

• None noted.

Phase II (Type 2 R42 and Type 2 R44 applications):

Acceptable

- This application builds on successful Phase-I results.
- Concerns about the sales model are discussed under significance.

Protections for Human Subjects:

Acceptable Risks and Adequate Protections

• Approach is reasonable

Data and Safety Monitoring Plan (Applicable for Clinical Trials Only): Not Applicable (No Clinical Trials)

Inclusion of Women, Minorities and Children:

- Sex/Gender: Distribution justified scientifically
- Race/Ethnicity: Distribution justified scientifically
- For NIH-Defined Phase III trials, Plans for valid design and analysis: Not applicable
- Inclusion/Exclusion of Children under 18: Including ages <18; justified scientifically
- Approach is reasonable

Budget and Period of Support:

Recommend as Requested.

CRITIQUE 3:

Significance: 2 Investigator(s): 2 Innovation: 3 Approach: 3 Environment: 2

Overall Impact: Initially enthusiasm for this application was quite high due to the importance of the addressed problem; slip and fall accidents. This team has accomplished an impressive amount of work in phase I by developing a proof of concept device, including the controller and software interface and collected repeatable data from two different shoes on a wet ceramic floor surface. These accomplishments give confidence in the team's ability to perform the engineering work and develop the proposed system. The background literature was thoroughly reviewed further demonstrating the team's expertise in this field. The team has years of experience in guantifying risk factors for slip and fall accidents, strong knowledge of important design parameters, and how the proposed system fits within the competitive landscape. The development and testing approach is detailed and rigorous, including a "round-robin" testing of the phase II system for determining repeatability and reproducibility across multiple sites and machines. Enthusiasm waned slightly as the commercialization plan has some weaknesses (see below). The Sequential nature of the aims is also a concern, as the entire project hangs on the ability to identify a set of testing conditions that best predict a slip, Aim 1 however, this is somewhat minimized by the successful work in phase I. The timeline is aggressive when considering the proposed amount of testing and human subject trials. In summary; the overall impact remains high despite these challenges because the proposed solution address a highly significant problem. However, the overall impact is not as high as it could be, due to the weak revenue projections. The concern here is that the business case should be attractive enough to incentivize the company to push through any unforeseen challenges.

1. Significance:

Strengths

- Slip and fall accidents are a major source of injuries and fatalities across all age groups and lead to substantial medical expenditures.
- The standards are being updated and the proposed development is useful for testing to the new standard.
- Simulates the entire contact region of the shoe, portable so specific shoes can be tested on specific surfaces which will lead to better recommendations for footwear in different environments.
- Great background literature review and strong preliminary data.
- Strong knowledge of important design parameters.

Weaknesses

- The new standard has not yet been adopted.
- It's unclear how quickly the new standard will be adopted and how much interest will be generated from industry when compared to other low cost solutions.

2. Investigator(s):

Strengths

- Brian Moyer Ph.D. (PI): Experienced engineer, researcher, educator and entrepreneur, including extensive experience in slip and fall research on the biomechanics side and shoe-floor friction testing.
- Kurt Beschorner Ph.D (MPI): 12 years of experience in applying tribology, biomechanics and ergonomics to quantifying risk factors for slip and fall accidents.

Weaknesses

• None noted.

3. Innovation:

Strengths

- The objectives of the STEP system are to improve current slip-testing technology by creating a low-cost device and low-weight device capable of performing biofidelic slip-testing.
- The proposed system is moderately innovate. It is using a kinematic linkage for coupling vertical and horizontal motion to reduce the number of actuated degrees of freedom and more importantly, human slipping data will be used to select the most predictive set of testing conditions.

Weaknesses

• None noted.

4. Approach:

Strengths

- Success criteria well defined for each objective.
- Aims are strong and backed up with thorough testing; 1) to identify a set of testing conditions that best predict a slip; 2) build an inexpensive and portable device to test these specific conditions; 3) validate the operation of the testing device with an interlaboratory study; 4) Conduct human subject testing (90 subjects) to validate the prediction abilities.

- Testing repeatability and reproducibility across multiple sites and machines is a disciplined approach.
- A lot of work was done in phase I providing confidence in the team's ability to successfully build the proposed system.
- Revenue model is to use an Open Hardware License or purchase a build kit from the company. Then the user's will license the STEPS software and receive calibration support. This is a smart plan as hardware can easily be copied but the software will be a copyright.
- Proposed system addresses the market needs: Current guidelines are not based on the latest science and commercially available portable testing devices do not meet the recommendations for preferred loading conditions.
- Author conducted a customer needs analysis to determine important system criteria: 1) relevant to the current understanding of the biomechanics and tribology of slipping, as reflected in the pending **standard**; 2) can provide feedback for reducing slipping accidents; 3) is easy to use, reliable and reproducible; 4) is portable to enables improved environmental fidelity; and 5) is affordable.
- Early sales strategy will be to focus primarily in the safety and ergonomic research and consulting sectors, with market penetration eventually expanding to the industrial sector as shoe and flooring manufacturers adopt the new test standard.
- Crossroads consulting is working to build the business structure and human resources to begin a transition to product sales by bringing on an additional business partner and beginning to research sales representatives.
- Identified strong market segments in industrial, footwear, flooring, and researchers (anticipated early adopters).
- PI has a good understanding of market competitors.
- They will be 1st to market with a device that meets the requirements of the new standard.

Weaknesses

- Success of sequential aims, otherwise the proposed system will become bigger and more expensive; impacting the business plan.
- Commercial plan is highly dependent on the new standard being approved.
- There is a risk that manufacturers of footwear and flooring will not adopt the new standard even if it is approved as long as they can still label their products as "slip resistant."
- Educating the market on the new standard and why the customers should care about it will be expensive. However, the author is aware of this challenge.
- There are currently lower cost competitors in the market. Crossroad's STEPS performs better but is still 2x their cost. The new standard will be important for the users of the low-cost systems to be motivated to upgrade.
- Unimpressive 5-year revenue projection with hardware sales projected to drop in year 4.
- Aggressive R&D timeline with all the planned testing. The Human Subject testing happening in parallel helps minimize this concern.

5. Environment:

Strengths

• Crossroads Consulting, LLC: small but capable shop for prototyping.

- University of Pittsburgh: Biomechanics labs, Tribology Lab, access to machine shops, 3D scanners, Statistical support through the clinical and translational science institute (CTSI)
- The application team has access to the necessary resources to be successful.

Weaknesses

• None noted.

Phase II (Type 2 R42 and Type 2 R44 applications):

Acceptable, however there are some concerns as the business case and adoption of the technology is predicated on the passage of the new **standard** and the costs and effort required to educate the market on the importance of the new standard may be slightly underestimated. Additionally, the 5-year revenue projection is so small that there is little room to absorb unforeseen costs and still have a healthy business.

Protections for Human Subjects:

Acceptable Risks and Adequate Protections

• Adequate protections are noted

Data and Safety Monitoring Plan (Applicable for Clinical Trials Only):

Not Applicable (No Clinical Trials)

Inclusion of Women, Minorities and Children

- Sex/Gender: Distribution justified scientifically
- Race/Ethnicity: Distribution justified scientifically
- For NIH-Defined Phase III trials, Plans for valid design and analysis:
- Inclusion/Exclusion of Children under 18: Excluding ages <18; justified scientifically

Budget and Period of Support:

Recommend as Requested.

THE FOLLOWING SECTIONS WERE PREPARED BY THE SCIENTIFIC REVIEW OFFICER TO SUMMARIZE THE OUTCOME OF DISCUSSIONS OF THE REVIEW COMMITTEE, OR REVIEWERS' WRITTEN CRITIQUES, ON THE FOLLOWING ISSUES:

PROTECTION OF HUMAN SUBJECTS (Resume): ACCEPTABLE

INCLUSION OF WOMEN PLAN (Resume): ACCEPTABLE

INCLUSION OF MINORITIES PLAN (Resume): ACCEPTABLE

INCLUSION OF CHILDREN PLAN (Resume): ACCEPTABLE

COMMITTEE BUDGET RECOMMENDATIONS: The budget was recommended as requested.

ADMINISTRATIVE NOTE: Applications submitted for due dates on or after January 25, 2016 are required to include a new PDF attachment describing plans for Authentication of Key Biological and/or Chemical Resources that will be used in that research study (see <u>NOT-OD-16-011</u>). Reviewers were asked to consider information provided in this attachment as part of their evaluation of your application. This attachment was missing from your application and could not be assessed.

Footnotes for 2 R44 AR064111-02; PI Name: Moyer, Brian Evan

NIH has modified its policy regarding the receipt of resubmissions (amended applications). See Guide Notice NOT-OD-14-074 at http://grants.nih.gov/grants/guide/notice-files/NOT-OD-14-074. The impact/priority score is calculated after discussion of an application by averaging the overall scores (1-9) given by all voting reviewers on the committee and multiplying by 10. The criterion scores are submitted prior to the meeting by the individual reviewers assigned to an application, and are not discussed specifically at the review meeting or calculated into the overall impact score. Some applications also receive a percentile ranking. For details on the review process, see http://grants.nih.gov/grants/peer review process.htm#scoring.

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MEETING ROSTER Center for Scientific Review Special Emphasis Panel

CENTER FOR SCIENTIFIC REVIEW Muscloskeletal Rehabilitation Small Business ZRG1 MOSS-V (15) 11/21/2016

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LAVENDER, STEVEN A, PHD ASSOCIATE PROFESSOR DEPARTMENT OF INDUSTRIAL, WELDING AND SYSTEMS ENGINEERING THE OHIO STATE UNIVERSITY

SIMPSON, RICHARD C, PHD ASSOCIATE DEAN FOR RESEARCH SCHOOL OF ENGINEERING AND COMPUTING SCIENCES NEW YORK INSTITUTE OF TECHNOLOGY

SPAULDING, SANDI J, PHD PROFESSOR SCHOOL OF OCCUPATIONAL THERAPY THE UNIVERSITY OF WESTERN ONTARIO FACULTY OF HEALTH SCIENCE ELBORN COLLEGE LONDON ONTARIO N6G 1H1 CANADA

TOWNSEND, WILLIAM T, PHD FOUNDER BARRETT TECHNOLOGY TRIOLO, RONALD J, PHD PROFESSOR DEPARTMENT OF VETERANS AFFAIRS APT CENTER OF EXCELLENCE DEPARTMENT OF ORTHOPAEDICAND BIOMEDICAL ENGINEERS CASE WESTERN RESERVE UNIVERSITY

USWATTE, GITENDRA, PHD PROFESSOR DEPARTMENT OF PSYCHOLOGY UNIVERSITY OF ALABAMA AT BIRMINGHAM

WARD, JEFFREY, PHD SENIOR MECHANICAL ENGINEER SPRINGACTIVE, INC.

WHITALL, JILL, PHD PROFESSOR DEPARTMENT OF PHYSICAL THERAPY AND REHABILITATION SCIENCE SCHOOL OF MEDICINE UNIVERSITY OF MARYLAND

MAIL REVIEWER(S) MARGOLIS, DAVID J, MD, PHD PROFESSOR OF DERMATOLOGY AND EPIDEMIOLOGY PERELMAN SCHOOL OF MEDICINE UNIVERSITY OF PENNSYLVANIA

PRILUTSKY, BORIS I, PHD ASSOCIATE PROFESSOR SCHOOL OF APPLIED PHYSIOLOGY GEORGIA INSTITUTE OF TECHNOLOGY

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EXTRAMURAL SUPPORT ASSISTANT CLEVELAND, BEVERLY A EXTRAMURAL SUPPORT ASSISTANT CENTER FOR SCIENTIFIC REVIEW NATIONAL INSTITUTES OF HEALTH

Consultants are required to absent themselves from the room during the review of any application if their presence would constitute or appear to constitute a conflict of interest.