Florida State University
Division of Sponsored Research

PROPOSAL TRANSMITTAL FORM

Shaded areas are reserved. See form instructions at http://www.research.fsu.edu/contractsgrants/forms.html

PROPOSAL IDENTIFIERS:	SRA Log #	OMNI ID's:

1. Select administering business unit: ☐ **FSU01** (FSU Sponsored Research) ☒ **FSRF1** (FSU Research Foundation)

DEADLINE INFORMATION

2. Is there a sponsor deadline? ☒ Yes ☐ No
If yes, Sponsor Deadline: Date: **11/13/17** Time: Time Zone: ☒ Electronic or ☐ Paper ; ☐ Postmark or ☒ Receipt

3. Response to Solicitation #: | Solicitation URL: https://www.research.fsu.edu/research-offices/oc/gap/

4. If there is no sponsor deadline, PI's requested submission/completion date:

5. **Proposal Contact** (if different from PI) Fill in contact information below:

Contact Name:	PHONE #:	EMAIL:

6. **PRINCIPAL INVESTIGATOR INFORMATION** See page 3 for additional investigators and approvals.

PI NAME:	PHONE #:	EMAIL:

7. SPONSOR: **FSU Research Foundation**

	Sponsor ID	
8. FEDERAL FLOW-THRU: ☐ Yes ☒ No. If Yes, Federal agency where funds originated:	Sponsor ID	CFDA

9. PROPOSAL TITLE (as submitted to sponsor):

10. PROPOSAL TYPE: ☒ New ☐ Continuation ☐ Renewal ☐ Supplement ☐ Revision

11. PROJECT DATES: Start: End:

12. PROJECT LOCATION: ☒ On-Campus (non-NHMFL) ☐ Off-Campus (non-NHMFL) ☐ NHMFL (On-Campus) ☐ NHMFL (Off-Campus)
Off-Campus Performance Site:

13. F&A INFORMATION:	If F&A Rate proposed is less than the Federally-negotiated rate, is the reduction mandated by sponsor's written policy or voluntarily waived by FSU?
Rate: **0.00** % Base: ☐ MD ☐ TD ☒ N/A ☐ SLFR	☒ Mandated ☐ Voluntary

14. PROJECT PURPOSE: ☒ Research ☐ Other Sponsored Activity ☐ Instruction

SRA Use Only					
	☐ FONRE	☐ FONIN	☐ FONOS	☐ FMAG	
	☐ ONRES	☐ ONINS	☐ ONOSA	☐ ONMAG	
	☐ OFRES	☐ OFINS	☐ OFOSA	☐ OFMAG	☐ MAG (Core)

PROPOSED COSTS

15. Total Requested from Sponsor	$ **37,127**	Attach detailed budgets for all proposed costs.	
16. Total FSU Cost Sharing	$	☐ Voluntary ☐ Required by Sponsor	Attach FSU C/S Commitment Form & detailed budget.
17. Total Third-Party Match	$	Attach Third-Party C/S Commitment Form & detailed budget.	

18. **PROJECT DEPARTMENT:** Identify the dept. responsible for financial management of the project if awarded. This DeptID will be used in the budget chartfield combination.	Dept Name:	DeptID:

19. **REPORTING CREDIT AND INDIRECT COST DISTRIBUTION BY DEPARTMENT:** This data is used for institutional reporting purposes and distribution of F&A. Allocate credit using whole numbers only. Sum of credit distribution must equal 100%. This is a required field even if it duplicates the department named in block 18.

Dept Name:	Credit DeptID:	Distribution:	
Dept Name: Dept Name:	Credit DeptID:	Distribution:	
	Credit DeptID:	Distribution:	%
Dept Name:	Credit DeptID:	Distribution:	%
Dept Name:	Credit DeptID:	Distribution:	%

MISCELLANEOUS INFORMATION

20. Non-Faculty Support: This data is collected for department use. Identify the total number of the following personnel supported by this grant (numbers should be based on headcount, not FTE):

	YEAR 1	YEAR 2	YEAR 3	YEAR 4	YEAR 5
Total # Undergraduate Students:	4				
Total # Graduate Students:					
Total # Postdoctoral Associates:					
Total # Non-Students/Non-Ranked Faculty :	1				

CERTIFICATIONS

Do any of the following apply to this project? Please provide attachments when applicable:

21. Vertebrate Animals	Protocol #	Attach ASU Form ☐	☐ Yes ☒ No
22. Human Subjects			☒ Yes ☐ No
23. [reserved; leave blank]			
24. DNA/RNA Use			☐ Yes ☒ No
25. Radioactive Materials			☐ Yes ☒ No
26. Hazardous Chemicals			☐ Yes ☒ No
27. Select Agents			☐ Yes ☒ No
28. Nanomaterials			☐ Yes ☒ No
29. Marine Lab (SRA will send a copy of proposal to the Director of the FSUCML.)			☐ Yes ☒ No
30. Compressed Air Diving (ADP) (SRA will send a copy of proposal to the Chair of the Dive Control Board & the ADP Coordinator.)			☐ Yes ☒ No
31. Dual Compensation			☐ Yes ☒ No
32. Workshops/Conferences			☐ Yes ☒ No
33. If 32 is Yes, will fees be collected?			☐ Yes ☐ No
34. If 33 is Yes, is the dept collecting the fees a Certified Cash Handling Site?			☐ Yes ☐ No
35. If 32 is Yes, will Continuing Education Units (CEU's) be issued?			☐ Yes ☐ No

36. Are Subcontract(s) and/or consultant(s) proposed? ☐ Yes ☒ No.
If yes, is more than 50% of the award being subcontracted out? ☐ Yes ☐ No.
If yes and they are named, please provide budget, scope of work and letter of commitment from each, as applicable.

37. Will income, other than payments from the sponsor, be generated as a result of this project? (aka, Program Income such as registration fees, sales of products, etc.)	☐ Yes ☒ No
38. Is this project is continuation of a previous project? If yes, enter Project ID: Awd %	☐ Yes ☒ No
39. Will additional resources such as animal or non-animal space, equipment, utility service, etc., be needed to conduct this project in addition to what is currently available to you or is budgeted for this in the proposal? If yes, complete the following: Resource Requested: ____ Estimated Cost: ____. Requested From: ____ Request Approved: ____	☐ Yes ☒ No
40. Will NHMFL facilities be used to conduct any part of this project?	☐ Yes ☒ No

41. MATRICULATION and/or TUITION FEE WAIVERS: (CHECK ONLY ONE) Waiver 1 is the default if no grad salary charged.

☒ **WAIVER 1** **(1)** Charge the project all matriculation fees for qualifying graduate assistants and out-of-state tuition for Eng majors paid from project funds; **(2)** No qualifying grad students proposed; or **(3)** Grad student salaries not allowed.	☐ **WAIVER 2** The College/ School Waiver Allocation will cover all tuition of students paid or supported by this proposed project.	☐ **WAIVER 3** An alternate source will cover all tuition of students paid or supported by this project. The dept is responsible for processing departmental billings to pay tuition for all students paid from this project. If the dept does not process a departmental billing, the tuition will be charged automatically to the waiver allocation of the College/School associated with the student's major.	☐ **WAIVER 4** This Contract/Grant will pay **only** the matriculation fee for graduate assistants, even if engineering majors are paid from this project.

42. KEYWORDS

Enter as many as desired, but at least one is required:
View Proposal Keywords at:

Muscle stretching, peripheral artery disease, ankle dorsiflexion splint, endothelium, lower limb blood flow

. If desired keyword is not on list, you may enter suggested additions.

43. CONFLICT OF INTEREST

The PI is aware that a participating faculty, staff, student, or partnering entity has an actual, potential, or perceived conflict of interest as described in FSU's Conflict of Interest Policy. If "Yes" is checked, review and follow the applicable conflict of interest disclosure procedure to disclose the conflict.	☐ Yes ☒ No

"Investigator" means the principal investigator, co-principal investigators, and any other person who is responsible for the design, conduct or reporting of the research or educational activities funded or proposed for funding by the applicable funding agencies. Investigators may include subrecipient investigators, contractors, consultants, collaborators, undergraduate and graduate students, and post-docs. A list of non-PHS agencies who have adopted PHS regulations can be found at http://nrc59.nas.edu/pub/fcoi_agencies_phs_regs.html.

Each signer below certifies that:

- He/she has reviewed this proposal and approves of this activity;
- Cost sharing funds, if required, will be made available when the project is funded;
- Office, laboratory, or any other space including non-animal space or space for animals, if appropriate, particularly associated with this project is available; and
- He/she has read and understood FSU's Investigator Financial Disclosure policy and FSU's Conflict of Interest policy and all required disclosures have been made.
- If this proposal is requesting funding directly or indirectly from the National Institutes of Health (NIH), he/she has read and understood the NIH Public Access Policy and agrees to comply with its requirements.

44. INVESTIGATOR APPROVALS

This data is collected for department use. Allocate credit using **whole** numbers. Each investigator must receive a minimum of 1% credit. Sum of all allocations must equal 100%. This information is not intended for allocation of credit for institutional reporting purposes or indirect cost distribution (see Block 19). Use the Proposal Transmittal Form Continuation Page if needed.

	ROLE	INVESTIGATOR NAME	EMPLID	Appointed as Post Doc or Grad Student?	CREDIT Min 1%	INVESTIGATOR Signature	DATE
Line 1	PI (from pg 1)		000104986	☐ PD or ☐ GS	50 %		
Line 2	Co-PI		000109180	☐ PD or ☐ GS	50 %		
Line 3	Co-PI			☐ PD or ☐ GS	%		
Line 4	Co-PI			☐ PD or ☐ GS	%		
Line 5	Co-PI			☐ PD or ☐ GS	%		

45. EFFORT COMMITMENTS

This proposal ☐ **Does** or ☒ **Does Not** contain effort commitments by Key Personnel. See the *Effort Commitment Policy* at http://www.research.fsu.edu/media/1463/policy-7a-9.docx.

46. CHAIR and DEAN APPROVALS for above investigators:

Approvals for Lines in Block 45	CHAIR SIGNATURE	DATE	DEAN SIGNATURE	DATE
Line 1				
Line 2				
Line 3				
Line 4				
Line 5				

47. ADDITIONAL NAMED FACULTY APPROVALS

If this proposal names individual FSU faculty who will contribute to this project but are not identified as the PI or a Co-PI, list those individuals here and obtain their signature along with the signatures of their chair and dean. These faculty members will not receive any reporting credit for this project. Use the Proposal Transmittal Form Continuation Page if needed.

		INVESTIGATOR		CHAIR		DEAN	
NAMED FACULTY	DEPT NAME	SIGNATURE	Date	SIGNATURE	Date	SIGNATURE	Date

FOR SRA INTERNAL USE ONLY	APPROVED FOR VPR (Initials/Date):	NSF Code: NSF_____	Type of Research: ☐ Basic ☐ Applied ☐ Development

48. SBIR/STTR ATTRIBUTE:

☐ SBIR I (Small Business Innovation Research I) ☐ SBIR II (Small Business Innovation Research II)
☐ STTR I (Small Business Technology Transfer I) ☐ STTR II (Small Business Technology Transfer II)

49. OMNI PROPOSAL RESOURCES & POST-AWARD PROJECT TEAM

The PI and Co-PI's listed on page 3, and other users listed below will be added to Proposal Resources for read-only access to the OMNI Proposal record.

If the proposal is awarded, the Project Team will be set up as follows:

Project Spending Authority for non-travel transactions:

- ***PI*** will automatically have expenditure authority for all non-travel financial transactions.
- ***Co-PIs*** will not have expenditure authority on the Project unless specifically authorized below.
- ***SP Managers with ePRO*** means the user will have expenditure authority for all non-travel financial transactions, including the ability to approve requisitions in OMNI.
- ***SP Managers w/o ePRO*** means the user will have expenditure authority for all non-travel financial transactions, except the ability to approve requisitions in OMNI.
- ***Dept Rep*** means the user will have no post-award expenditure authority. Users with this role on the Proposal will only have access to view proposal information.

Project Spending Authority for travel transactions:

- Only one user is allowed to approve travel for a project. The PI will be made the default travel approver unless an alternate is listed below. Note that the Project Travel Approver cannot approve his/her own travel transactions. The travel approver role is "Project Manger" which is different from a "Sponsored Project Manger (SP Manager)."

Co-PIs with Spending Authority:		EMPLID	EMPLID

***SP Managers with ePRO* authority**:

NAME	EMPLID	NAME	EMPLID
Travis Lampinen			

***SP Managers w/o ePRO* authority**:

NAME	EMPLID	NAME	EMPLID

Project Manager (Travel Approver):

NAME	EMPLID

***Dept Rep*:**

NAME	EMPLID	NAME	EMPLID

50. POST AWARD NOTIFICATIONS

Project Setup Notifications (Optional): Identify people to be notified (by SRAS) when project is set up or modified, in addition to the PI and Contact shown at top of page 1:

Name	Email Address

Milestone Notifications (Optional): Identify people to be included on report due-date reminder emails (milestone notifications), in addition to the PI shown at top of first page:

Name	Email Address

GAP Proposal:
Splinting for Treatment of Peripheral Artery Disease

Dr.XXXXX, Biomedical Sciences, FSU College of Medicine
Dr. XXXXXXX, Chemical and Biomedical Engineering, FAMU-FSU College of Engineering

The Problem

Peripheral arterial disease (PAD) affects 8.5 million Americans and over 200 million worldwide. PAD prevalence increases with age, affecting 12-30% of patients age 65 or older. Patients with peripheral arterial disease (PAD) often have walking impairment due to insufficient oxygen supply to skeletal muscle, most often in the lower leg. Although walking programs are safe and may improve symptoms, they are often difficult to adhere to over the long-term, especially in elderly patients in whom frailty, arthritis, and other symptoms limit patient compliance. There is an unmet need to provide relief from symptoms and improve mobility and quality of life in PAD patients, even if walking has become problematic or not possible.

A program of supervised exercise training is recommended as an initial treatment. However, participation rates are low in elderly PAD patients, and as many as 1/3 of these older patients drop out of exercise programs because they are difficult or painful to maintain. This lack of exercise allows progression of PAD, leading to surgery, amputation, or death. In the US and Europe, PAD is responsible for 240,000 amputations each year. As the American population ages, PAD rates are climbing.

The Potential Solution

Our initial clinical study demonstrates improved patient symptoms when a therapeutic splint is used at home by the patient. The splint holds the foot at a 15 degree angle relative to the leg, and is worn for 30 minutes a day each day for a 4 week period. This short period of stress induces microchanges and growth within the muscle tissue. Our study links this passive stretching to measured improvements in blood vessel formation and improvement of pain levels during walking. Improved walking leads to better outcomes in many other aspects of health.

Our Novel Technology

Our proposed splinting device holds the foot in the desired position at 15 degrees relative to the calf. This angle may be pre-set and the flexion accomplished after the brace is put on. The splint is low cost, safe and is designed for at-home self-application which renders is suitable for a broad range of patients with PAD. Currently, no brace exists for automated control of ankle flexion. There are also no static stretching devices indicated for the treatment of PAD. Our splint is strapped to the leg and a programmed angle setting to move the foot to the 15 degrees of flexion of the foot relative to the calf. The patient can use the splint at home from their bed or couch, or within a hospital or specialized care facility.

The convenience, effectiveness, safety and low cost of this simple intervention render it attractive for commercialization.

The Market

Our results and the existing body of research suggest that the splint therapy would be inexpensive to implement and broadly applicable to this large, growing market. Patients' greater capacity for exercise leads to an overall improvement in health and life for elderly or frail patients in many cases. Given these far-reaching benefits and minimal incremental cost/expertise required to implement our procedure, we believe that following further clinical trials/research, this intervention and device will ultimately be widely adopted by physicians, benefit patients, and be lucrative for FSU – below, we provide a high-level summary of the facts upon which we predicate that assertion.

The US Center for Medicare and Medicaid Services reports that approximately 8.5 million Americans above the age of 40 are affected by PAD – this is after revascularization or false-negative results with ABI, which is in-line with estimates of prevalence of PAD based on nationwide claims data from large employers' health plans and from Medicare and Medicaid programs between 2003 and 2008. Of this 8.5 million, 60% experience leg pain as a symptom, leaving a population of patients 'at risk' of non-compliance with a walking program at approximately 5.1 million. Private practitioners estimate that 30% of elderly PAD patients fail to adhere to their prescribed walking regimens specifically because of this leg pain. This has also been borne out in multiple academic studies[1], where the rate of program drop-out due to leg pain has been as high as 20%, irregardless of age. We conservatively estimate that 2 million patients fail to complete their prescribed walking programs due to the physical discomfort accompanying walking, etc. These rates are similar for both at-home and supervised populations, indicating that the level of pain remains a robust predictor of walking program success.

A $100 marginal expenditure per patient[2] associated with incorporating our splint and other modifications could significantly reduce the rate of program drop-out for a population as great as 1 million. It would also extend the potential duration of patient walking during their exercise therapy[3] and generally improve efficacy of PAD treatment programs for the broader population of 8.5 million. Given that this a fraction of the cost necessary for these programs, it seems likely that private insurers and government providers of care would be likely to both cover and recommend (if not require) patients utilize such a splint as a part of their treatment program – as such, we believe the potential addressable market could generate as much as $50 million per year in the US alone.

[1] https://www.cardiosmart.org/News-and-Events/2011/02/Exercise-for-PAD-Trying-it-at-Home
[2] The retail cost of the splint can be seen here.
[3] A meta-analysis conducted by Lane et al concluded that "The optimal exercise program for improving claudication pain distances in patients with peripheral arterial disease uses intermittent walking to near-maximal pain during a program of at least 6 months"

Potential Commercialization Partners

We have contacted a number of physicians who enthusiastically support this endeavor, as evidenced by the letters included in the Supporting Letters of Interest section of this proposal. As key opinion leaders, their endorsement is a critical component to establishing commercialization partners within either the vascular intervention market or the orthopedic brace market.

We believe companies currently offering device-oriented PAD treatments would be interested, such as Medtronic, Johnson and Johnson, and ProMedica. Additionally, we expect to attract attention from traditional orthopedic brace companies because our splint design would allow access to a huge, entirely new cardiovascular market. These companies include DonJoy Aircast, Breg, Hanger, and FLA Orthopedics, among others.

Proposed Use of GAP Funding

The GAP funding would be used to pay for the hardware, software and research labor needed to develop a working prototype of the therapeutic splint.

The Phase I design incorporates best practices in patient interactions based on our previous study. It is simple and accommodates a large range of patient body types. Materials are inexpensive. ABS plastic in an additive manufacturing model will allow rapid prototyping of the device geometry while other materials are considered for strength and functionality. Hinges present in the heel area of the splint allow various dorsiflexion angles to be measured and held. Phase II allows feedback to the design process by allowing patients to try and give feedback on the device. The Phase III model involves automation of the dorsiflexion angle. With the push of a button on the brace or a remote, the angle is adjusted via a motor. Other features may include bracing behind the knee to ensure the limb is straightened during the treatment period.

Splinting for Treatment of Peripheral Artery Disease

Professional Biography

XXXXXX, Ph.D.
Biomedical Sciences FSU
College of Medicine

November 9, 2017

Splinting for Treatment of Peripheral Artery Disease

Professional Biography

XXXXXXXXX, Ph.D.
Chemical and Biomedical Engineering
FAMU-FSU College of Engineering

November 9, 2017

Splinting for Treatment of Peripheral Artery Disease

Diagrams and Device Drawings

XXXXXX, Ph.D.
Biomedical Sciences
FSU College of Medicine

XXXXXXXXX, Ph.D.
Chemical and Biomedical
Engineering FAMU-FSU College of
Engineering

November 9, 2017

Possible extender to maintain straight leg during splint use

Angle display and control buttons

Comfort straps to hold foot in place against padded splint

15° dorsiflexion

(exaggerated angle shown for emphasis)

Splinting for Treatment of Peripheral Artery Disease

Cost and Activities Plan

XXXXXXX, Ph.D.
Biomedical Sciences
FSU College of Medicine

XXXXXXX, Ph.D.
Chemical and Biomedical Engineering
FAMU-FSU College of Engineering

November 9, 2017

Phased Implementation Plan

The GAP funding would be used to pay for the hardware, software and research labor needed to develop a working prototype of the therapeutic splint.

Phase I. Development of manual clinical therapeutic splint prototype

Objective: The Phase I design incorporates best practices in patient interactions based on our previous study. It is simple and accommodates a large range of patient body types. Materials are inexpensive. ABS plastic in an additive manufacturing model will allow rapid prototyping of the device. Hinges present in the heel area of the splint allow various dorsiflexion angles to be measured and held.

Timetable: January 5, 2018 – March 17, 2018

Required funding: $8,160

Failure point: Ability of the splint to withstand stresses of 15 degrees dorsiflexion of the foot.

If successful, proceed to Phases II and III.

Phase II. Therapeutic splint use-case tests.

Objective: "Customer" survey and use-case tests to refine splint design.

Timetable: March 17, 2018 – May 15, 2018

Required funding: $2,280

Failure point: N/A

The design feedback from Phase II should be incorporated as design changes to Phase III.

Phase III. Development of automated therapeutic splint.

Objective: This model involves automation of the dorsiflexion angle to allow the physician to prescribe a value or series of values over the treatment period. With the push of a button on the brace or a remote, the angle is adjusted via a motor. Other features may include bracing behind the knee to ensure the limb is straightened during the treatment period.

Timetable: March 17, 2018 – December 31, 2018

Required funding: $26,240

Failure point: Splint should vary the angle of the splint to a set value and withstand stresses due to up to 15 degrees dorsiflexion of the foot.

If successful, move to find manufacturing partner.

Splinting for Treatment of Peripheral Artery Disease

Supporting Letters of Interest

XXXXXX, Ph.D.
Biomedical Sciences
FSU College of Medicine

XXXXXXXX, Ph.D.
Chemical and Biomedical Engineering
FAMU-FSU College of Engineering

November 9, 2017