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**Protocol Title:** Sensitivity and specificity of digital ankle brachial index (ABI) as a screening tool in detecting peripheral arterial disease: A single center, prospective clinical trial

**Protocol Status:** APPROVED

**Date Submitted:** 04/04/2018

**Approval Period:** 04/20/2018-04/19/2019

**Important Note:** This Print View may not reflect all comments and contingencies for approval. Please check the comments section of the online protocol. Questions that appear to not have been answered may not have been required for this submission. Please see the system application for more details.

\* \* \* Continuing Review \* \* \*

### Continuing Review Request

#### WHAT TO UPLOAD WITH YOUR CONTINUING REVIEW APPLICATION

For studies where research activities are limited to data analysis, upload subject safety information and publications (e.g., manuscripts, abstracts) since the last IRB approval, if applicable.

NOTE: if activities are limited to data analysis of de-identified/anonymous data (data that can no longer be linked to subject identifiers directly or through use of a code with master list kept), the study can likely be closed via the Final Report Form. See the SLU IRB Guidance for Closure of Human Subjects Research Studies.

For all other studies, upload:

- Subject safety information including the most current Serious Adverse Event (SAE) cumulative table and data safety monitoring reports since the last IRB approval, if applicable.
- Any publications (e.g., manuscripts, abstracts) since the last IRB approval.

Any changes, updated and/or new study materials should be uploaded and questions 19 - 24 of this form should be completed.

1. Please indicate the status of the study:

- a)           The study has not started but will become active.  
              Please explain why the study has not started.
- b)   X       The study is ACTIVE (please check the appropriate box below):  
              Study is open to accrual.  
              X       Study is on hold or halted.

Please explain what needs to occur before accrual can resume.

We targeted recruitment for several months in the summer of 2017, and plan to begin again after reconvening the study team and creating and executing the workflow again. Nothing else is needed to start accrual again.

Study is permanently closed to accrual.

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- i. Have all subjects completed all research related activities/interventions?
- ii. Will the research only remain active for long-term follow-up of subjects?
- iii. Are remaining research activities limited to data analysis only? (See instructions above).
- iv. For studies that are closed to subject accrual, do any subjects need to be re-consented (to inform them about changes to study procedures, study risks, study personnel, etc.)?

For IRB office use: \* may qualify for expedited review

- c) The study has expired and needs to be re-initiated.  
Explain any research activities occurring during lapse in IRB approval.

- |  |            |
|--|------------|
| 2. Date the study was initially approved by the IRB:   | 04/26/2017 |
| 3. Approval date of previous continuing review:  |            |
| 4. Total number of participants/records/specimens you are approved to enroll.                                    | 400        |
| 5. Total number of subjects that have given consent (verbal or written) to date.                                 | 264        |
| 6. Total number of subjects that failed screening (if not applicable, state N/A).                                | 26         |
| 7. Total number of participants accrued since the beginning of the project.                                      | 238        |
| 8. For multi-center studies, number of subjects approved for accrual study-wide (SLU site plus all other sites). | NA         |
| 9. For multi-center studies, number of subjects enrolled study-wide (SLU site plus other sites).                 | NA         |
| 10. Number of withdrawals from the research and explanation/reasons for withdrawals.                             | none       |

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11. Description and number of:

a) Reportable Protocol Deviations/Violations since the last approval date:

4/2/18 Protocol Violation: 26 subjects are unusable since 23 consents we signed by subjects after being altered by hand. An additional 3 subjects are unusable since the HIPAA and consent signature pages were hand-written. Consents were signed by people who were not approved members of the research team.

b) Unanticipated Problems (UPs) since the last approval date:

none.

c) Serious Adverse Events (SAEs) since the last approval date: Note: Information here should be consistent with the cumulative table, which should also be attached in section #16.

none.

12. Have there been any complaints about the research during the last year? N  
If yes, please describe.

13. Briefly describe the progress of the study to date. Provide a status of participants in study, for example, where is the most recently accrued participant in terms of timeline in the study? If participants are in long-term follow-up, explain what this consists of in terms of data collection and/or intervention. Provide any new information in regard to risks. Summarize or attach publications or presentations.

All accrued subjects have completed all required study activities. No long-term follow up is needed.

14. Is there a Data Safety Monitoring (DSM) plan for this study?

Y No

Yes, a copy of the DSM report(s) for the last approval period is attached.

Yes, but a copy of the DSM reports(s) for the last approval period is not attached. Please explain below.

15. FDA Regulated Studies

Is this a Food and Drug Administration (FDA) Regulated Study, (i.e., involves drugs, devices, biologics)? If yes, please answer the following questions: N

a) Have there been any changes in the FDA status of any drug or device used in the study?

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If yes, please explain:

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- b) Have any of the investigational drugs or devices used in this study received FDA approval?

If yes, please explain:

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- c) Have any new alternative drugs or devices been approved for treatment of the study condition that may affect subjects willingness to participate?

If yes, please explain:

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Have current subjects been notified? Please explain:

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- d) Has there been a change in the standard care that may be considered as an alternative to the investigational drug or device or that would affect the original study design?

If yes, please explain:

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Have current subjects been notified? Please explain:

---

- e) Is there any new information that might affect the risk/benefit ratio and the willingness of current study subjects to participate or to continue to participate in the research?

If yes, please explain:

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Have current subjects been notified? Please explain:

---

- f) Does the study include an investigator's brochure (IB)?

If yes, what is the current version date?

(If study has multiple IBs, attach current versions in Attachments section (#16))

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16. Provide a summary of any recent findings, literature, or other relevant information (especially pertaining to risks), if applicable.

Of the 238 subjects with usable data, QuantaFlo detected positive results for Peripheral Artery Disease in 44 subjects: 10 with severe, 15 with moderate, and 19 with mild disease. Of the 10 designated severe by QuantaFlo, 8 were confirmed upon follow-up exams and imaging (positive predictive value of 67%). Of those 34 designated mild or moderate by QuantaFlo, 2 were confirmed upon follow-up exams and imaging (positive predictive value of 14%).

17. Have there been any significant amendments or revisions to the protocol during the past approval period? (Significant amendments include changes in study design or risk level including those that resulted in a change in consent). N
- If yes, please briefly summarize the changes:

18. Y The consent materials attached to this eIRB application (including consent documents, assent documents, recruitment statements or other materials used to obtain consent) are the versions being used in the conduct of this study and all enrolled subjects have signed consent forms on file, if required. (If the requirement to obtain consent was waived or if no participants have enrolled since last continuing review, check N/A).

NOTE: The IRB routinely monitors consent document usage and may request copies of redacted participant consent forms.

19. Are any changes (amendments) requested with this Continuing Review?

Y Yes, please complete the remainder of this form.  
No, form is complete. Please submit.

20. Summarize the proposed changes to the protocol in lay terms, including the type of change AND what the change involves.

If this is a change in PI a new Department Chair review is required. Please upload the signed document in the Attachments section.

We would like to increase the sample size from 400 to 750. This change involves using the same protocol on additional subjects by re-instituting the workflow at screening locations. We are also adding a study team member, Scott Wilson-Flewelling.

21. Provide justification/explanation for the proposed changes.

Given the low PPV of QuantaFlo, and considering the manufacturing company has different results, we would like to continue the study and increase enrollment to increase the power of our analysis.

22. Will currently accrued subjects need to be notified of changes? N

If no, please justify why not.

All subjects who have been accrued have completed all study activities and will not be affected by additional subjects being accrued.

additional subjects being accrued.

If yes, please explain how AND when notification or re-consenting will occur.

- |     |  |   |
|-----|--|---|
| 23. | Does the SLU IRB Protocol need to be modified? | Y |
| 24. | Are consent documents modified?                | Y |

Proceed to the appropriate section(s) of the protocol and make your changes. Also make necessary changes in the Consent Form(s), Assent Form(s), Recruitment Statement, Questionnaire, or other attachments, as applicable. Upload any revised IRB materials. Please provide the entire revised document (not just revised pages). Use track changes or highlight (in yellow) changes to documents being revised. Please upload a tracked/highlighted copy of each revised document to be stamped upon IRB approval. NOTE: Upload a clean copy (changes or highlights removed) of documents in file formats other than Microsoft Word (i.e., the IRB will remove the tracked changes/highlights on uploaded Word documents).

NOTE: Protocol amendments must receive IRB review and approval before they are implemented, unless an immediate change is necessary to eliminate an apparent hazard to the subjects.

Sponsored Studies: Remember to update the Sponsor's Protocol version number and date in the Funding section of the protocol (this information will appear on the approval letter).

List of changed sections:  
 Personnel Information  
 Subject Population 8(a-g)  
 Informed Consent (13)

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 \* \* \* Personnel Information \* \* \*

**Study Personnel Roles:**

- Principal Investigator: accepts responsibility for study, must sign obligations, can edit protocol and submit to IRB
- Administrative Contact: additional study contact, may or may not also be member of research team, can edit/prepare protocol and submit to IRB
- Key Personnel (Research Team): SLU member of research team, can view protocol (not edit)
- Non-SLU Collaborator: member of research team from another institution or organization outside of SLU, has no access to system, must be provided with PDF of protocol. NOTE: SLUH/SSM employees who collaborate regularly may obtain a guest SLU account if access to system is needed.
- Department Chair: Official Department Chair, may or may not also be a member of research team, can view the protocol (not edit). NOTE: a proxy may be listed if the Chair is the PI.

**IMPORTANT NOTE:** Human Subjects Protection Training is mandatory for all research team personnel.

Principal Investigator (PI) Mandatory



PI must be SLU affiliate.

Name of Principal Investigator (Faculty, Staff or Student)	Degree (MD/PhD)	Title
Pereira, Keith	MD	Assistant Professor
Email	Phone	Fax
pereirak@slu.edu	577-8025	
Department Name		
Radiology		

Human Subjects Training Completed? Y

WARNING: Proof of training must show below or the application will be returned. If your training information isn't showing, upload a copy in the Attachments section.

Research Experience \*?HELP?\*

Dr. Pereira is a board certified Interventional Radiologist As an Interventional Radiologist on tenure track, I have expertise in minimally invasive procedures (MIIPs) for PAD as a clinician focused in prevention and developing new PAD treatment options,

Research Team Member Duties Picklist

- |   |  |
|---|--|
| 1. <input checked="" type="checkbox"/> Recruitment                                      | 2. <input checked="" type="checkbox"/> Obtains consent                                 |
| 3. <input checked="" type="checkbox"/> Determine Subject Eligibility for Accrual        | 4a. <input checked="" type="checkbox"/> Subject Physical Examinations                  |
| 4b. <input checked="" type="checkbox"/> Follow-up Visits including physical assessments | 5. <input checked="" type="checkbox"/> Perform study procedures or Specimen Collection |
| 6a. Administer and/or Dispense Study Drugs, Biologics or Devices (must be licensed)     | 6b. Receive, Store, Manipulate or Account for Study Drugs, Biologics or Devices        |
| 7. <input checked="" type="checkbox"/> Subject Randomization or Registry                | 8. <input checked="" type="checkbox"/> Collection of Subject Data                      |
| 9. <input checked="" type="checkbox"/> Report Data (CRFs, e-CRFs, Spreadsheets)         | 10. <input checked="" type="checkbox"/> Data Analysis                                  |
| 11a. <input checked="" type="checkbox"/> Review Adverse Events                          | 11b. <input checked="" type="checkbox"/> Treat and Classify Adverse Events             |
| 12. Other (Please insert explanation below.)  |  |

UserID	CourseCompletionDate	Course
pereirak	04-12-2016	CITI Biomedical Research Basic Training

Administrative Contact

Name of Administrative Contact	Degree	Title
Hardy, Anna	RN, MPH	Research Nurse

Key Personnel (Research Team)

Name of Key Personnel (Research Team)	Degree	Title	Department Name
Manard, William	MD	Associate Professor	Family and Community Medicine
Gupta, Deepashree	MD	Assistant Professor	IM-Endocrinology
Hellebusch, Dana	FNP	Nurse Practitioner	IM-Endocrinology
Morley, John	MD	Professor	IM-Geriatrics
Gammack, Julie	MD	Associate Dean	IM-Geriatrics
Gorukanti, Srecharan	MD Candidate	Student	Radiology
Salamo, Russell	MD candidate	Student	Radiology
McLaughlin, Lauren	NP	Faculty/Staff	Radiology
Wilson-Flewelling, Scott	MD candidate	Student	Radiology

**Department Chair Mandatory**

The official Department Chair should be listed here. If the Department Chair is the PI, a proxy may be listed.

Name of Department Chair	Degree	Title
Brown, Jeffrey	MD	Professor
Email	Phone	Fax
jjbrown@slu.edu	(314) 268-5780	
Department Name		
Radiology		

Is this individual also a member of the research team? N

Human Subjects Training Completed?  
WARNING: Proof of training must show below or the application will be returned. If your training information isn't showing, upload a copy in the Attachments section.

Research Experience **\*?HELP?\***

**Research Team Member Duties Picklist**

- |   |   |
|---|---|
| 1. Recruitment  | 2. Obtains consent  |
| 3. Determine Subject Eligibility for Accrual  | 4a. Subject Physical Examinations   |
| 4b. Follow-up Visits including physical assessments                                 | 5. Perform study procedures or Specimen Collection                              |
| 6a. Administer and/or Dispense Study Drugs, Biologics or Devices (must be licensed) | 6b. Receive, Store, Manipulate or Account for Study Drugs, Biologics or Devices |

- |  |  |
|--|--|
| 7. Subject Randomization or Registry         | 8. Collection of Subject Data          |
| 9. Report Data (CRFs, e-CRFs, Spreadsheets)  | 10. Data Analysis                      |
| 11a. Review Adverse Events                   | 11b. Treat and Classify Adverse Events |
| 12. Other (Please insert explanation below.) |  |

UserID	CourseCompletionDate	Course
jjbrown	01-31-2013	CITI Biomedical Research Basic Training
jjbrown	01-29-2013	Good Clinical Practice (GCP)

Research Team Roles

Name(s), Degree	Department	Experience	Duties
Pereira, Keith, MD	Radiology	Dr. Pereira is a board certified Interventional Radiologist. As an Interventional Radiologist on tenure track, I have expertise in minimally invasive procedures (MIIPs) for PAD as a clinician focused in prevention and developing new PAD treatment options,	Recruitment, Obtains consent, Determine Subject Eligibility for Accrual, Subject Physical Examinations, Follow-up Visits including physical assessments, Perform study procedures or Specimen Collection, Subject Randomization or Registry, Collection of Subject Data, Report Data (CRFs, e-CRFs, Spreadsheets), Data Analysis, Review Adverse Events, Treat and Classify Adverse Events
Hardy, Anna, RN, MPH	Radiology	Anna is a clinical nurse with additional training on research	Recruitment, Obtains consent, Collection of Subject Data, Data Analysis
Manard, William, MD	Family and Community Medicine	Dr. William Manard provides full-spectrum primary health care for people and families of all ages. He specializes in preventive/wellness care, chronic disease management and mental health, using the latest information technology to aid him in ensuring quality care for his patients.  Dr. Manard's research interests include process and health system improvement, use of decision support mechanisms to provide	Obtains consent, Determine Subject Eligibility for Accrual, Subject Physical Examinations, Perform study procedures or Specimen Collection, Collection of Subject Data, Report Data (CRFs, e-CRFs, Spreadsheets), Data Analysis

		<p>quality care, and use of interactive medical records to improve patient clinical outcomes.</p> <p>He is medical director and associate professor for the Department of Family Medicine at Saint Louis University School of Medicine and is faculty advisor for the Family Medicine Interest Group.</p>	
Gupta, Deepashree, MD	IM-Endocrinology	<p>Dr. Deepashree Gupta treats patients who have diabetes, thyroid disorders, thyroid cancer, and bone disorders. In her practice, she manages treatment through the use of insulin pumps, continuous glucose monitoring, thyroid ultrasound and biopsies. She also provides medical weight loss options, using the latest medications available.</p> <p>Dr. Gupta is interested in research that investigates changes in blood glucose levels after weight loss surgery.</p> <p>She is an assistant professor in the Department of Internal Medicine, Division of Endocrinology, Diabetes and Metabolism, at Saint Louis University School of Medicine. She serves as chair of the Inpatient Diabetes Advisory Committee.</p> <p>Dr. Gupta is a member of the Endocrine Society.</p>	<p>Recruitment, Obtains consent, Subject Physical Examinations , Perform study procedures or Specimen Collection, Collection of Subject Data, Report Data (CRFs, e-CRFs, Spreadsheets), Data Analysis</p>
Hellebusch, Dana, FNP	IM-Endocrinology	<p>Dana Hellebusch is a certified diabetes educator who provides diabetes management and counseling for her patients. She utilizes the latest technology in developing treatment plans, including the use of the insulin pump</p>	<p>Recruitment, Obtains consent, Subject Physical Examinations , Perform study procedures or Specimen Collection, Collection of Subject Data, Report Data (CRFs, e-CRFs, Spreadsheets), Data Analysis</p>

		<p>and continuous glucose monitoring.</p> <p>Hellebusch is a clinical staff instructor in the Department of Internal Medicine, Division of Endocrinology, Diabetes and Metabolism, at Saint Louis University School of Medicine.</p> <p>She is a member of the American Association of Diabetes Educators, the American Diabetes Association, and the American Association of Nurse Practitioners.</p>	
Morley, John, MD	IM-Geriatrics	<p>board certified by American Board of Internal Medicine (Endocrinology Diabetes &amp; Metabolism)</p> <p>American Board of Internal Medicine (Geriatrics)</p> <p>American Board of Internal Medicine (Internal Medicine)</p>	<p>Recruitment, Obtains consent, Subject Physical Examinations , Perform study procedures or Specimen Collection, Collection of Subject Data, Report Data (CRFs, e-CRFs, Spreadsheets), Data Analysis</p>
Gammack, Julie, MD	IM-Geriatrics	<p>Dr. Julie Gammack specializes in geriatric medicine, long-term care, and post-acute care. She provides primary care services in her practice, and also offers geriatric assessment and dementia evaluation. Her areas of interest include coronary artery disease, end-of-life care, eating disorders, osteoporosis, and nutrition counseling, among other concerns specific to elderly patients.</p> <p>Dr. Gammack is a professor in the Department of Internal Medicine, Division of Geriatric Medicine, at Saint Louis University School of Medicine.</p> <p>She is an active member of the Society for Post-Acute and Long-Term Care Medicine (AMDA).</p>	<p>Recruitment, Obtains consent, Determine Subject Eligibility for Accrual, Subject Physical Examinations , Administer and/or Dispense Study Drugs, Biologics or Devices (must be licensed)</p>

		Dr. Gammack is a leader in the field of geriatrics, named a Best Doctor by St. Louis Magazine several years running.	
Gorukanti, Srecharan, MD Candidate	Radiology	Sre Gorukanti is a first year medical student at Saint Louis University School of Medicine. He has previously done research with the Music Therapy program at the SLU Cancer Center ascertaining the effects of music therapy for patients with otolaryngological related cancers. He is currently seeking IRB approval to participate in a study involving digital ABIs on Peripheral Vascular Disease to expand on anatomical and hematological knowledge gained in medical school. He will be mentored by experienced research staff.	Recruitment, Obtains consent, Determine Subject Eligibility for Accrual, Subject Physical Examinations , Follow-up Visits including physical assessments, Perform study procedures or Specimen Collection, Subject Randomization or Registry, Collection of Subject Data, Report Data (CRFs, e-CRFs, Spreadsheets), Data Analysis
Salamo, Russell, MD candidate	Radiology	Russell Salamo is a 4th year medical student at Saint Louis University with intention of pursuing research in interventional radiology. He has previously been on two IRB protocols at Saint Louis University, Protocol ID: 27458 and 26665. Russell will be mentored in this study by the PI	Recruitment, Obtains consent, Subject Physical Examinations , Follow-up Visits including physical assessments, Perform study procedures or Specimen Collection, Subject Randomization or Registry, Report Data (CRFs, e-CRFs, Spreadsheets), Data Analysis, Treat and Classify Adverse Events
McLaughlin, Lauren, NP	Radiology	Lauren has more than 10 years of clinical trial experience from her positions at Washington University	Recruitment, Obtains consent, Determine Subject Eligibility for Accrual, Perform study procedures or Specimen Collection, Collection of Subject Data, Report Data (CRFs, e-CRFs, Spreadsheets)
Wilson-Flewelling, Scott, MD candidate	Radiology	Scott has been involved in several prospective studies, consenting subjects, data management, and analysis.	Recruitment, Obtains consent, Determine Subject Eligibility for Accrual, Collection of Subject Data, Report Data (CRFs, e-CRFs,

			Spreadsheets), Data Analysis
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\* \* \* Subject Population \* \* \*

Subject Population(s) Checklist

Select All That Apply :

- X Adults
- Cognitively Impaired Subjects
- Employees (specifically targeted)
- Fetuses
- Minors (under 18)
- Neonates
- Non English Speaking Subjects
- Pregnant Women
- Prisoners
- Students (specifically targeted)
- Terminally Ill Subjects
- Wards of the State
- Other (any population that is not specified above)

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\* \* \* Study Location \* \* \*

Study Location(s) Checklist

Indicate where the study will be conducted. Select all that apply:

- X Saint Louis University, Medical Center Campus
  - Saint Louis University, Frost Campus
  - Saint Louis University, Madrid Campus
  - X Saint Louis University, SLUCare Practice Locations
  - SSM STL (DePaul Hospital, St. Mary's Health Center, St. Joseph (St. Charles, Wentzville, Lake Saint Louis), St. Clare)
  - Cardinal Glennon Children's Medical Center
  - X Saint Louis University Hospital (SSM Health- SLU Hospital)
  - SLU-SSM Cancer Center Research Alliance Sites
- Other (In the box below, list any off-campus institutions or locations and describe the activities being conducted there. Please provide letters of cooperation and/or IRB approvals from each location to document support/approval of the study. You may provide such documentation as it becomes available, but you may not begin work at those sites until documentation of support is provided to the IRB.) Please refer to the Guidance for involving non-SLU institutions in human subject research.

\*\*\* General Checklist \*\*\*

General Checklist

- Select All That Apply :
- Collection of Specimens
- Data collection via e-mail or the Internet
- Deception/Incomplete Disclosure
- Dietary Supplements, Vitamins, and Other Food Agents
- X FDA Approved Device
- FDA approved drugs, reagents, other chemicals administered to subjects (even if they are not being studied), or biologic products
- Genetic Testing
- HIV Testing
- Human blood, cells, tissues, or body fluids
- International Research or Research on International Populations
- Investigational drugs, reagents, chemicals, or biologic products
- Investigational Device
- X Investigator Initiated Study   \*?HELP?\*
- X Medical Records
- Photography, Video, or Voice-Recording Subjects
- Questionnaires and/or tests
- Radioisotopes/radiation-producing machines, even if standard of care
- rDNA/Gene Transfer Therapy
- Registry(ies)
- Specimens to be stored for future research projects (must be in consent form)
- Study of existing data or specimens
- X University Indemnified Study (SLU is responsible for liability coverage)   \*?HELP?\*
- X Other (clarify in text box to the right)

Single Use. Provide a brief summary and justification for the Single Use Therapy. Note: This application will refer to research. For Single Use applications it is understood that 'research' will mean 'therapy'.

\*\*\* Funding \*\*\*

Funding Checklist

NONE



Funding - Saint Louis University

What type of Saint Louis University funding?	SLU eRS #
SPARK Microgrant	n/a

NOTE: Applicable grant application, contract or subcontract, investigator's brochure, and sponsor's protocol (for all industry sponsored clinical trials) must be attached. You will be prompted for these in section #16 (Attachments).

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\* \* \* Expedited Paragraphs \* \* \*

To request an Expedited Review, check the appropriate category(ies) below. Provide justification for your request for Expedited Review.

To qualify for expedited review, research activities must (1) present no more than minimal risk to human subjects, and (2) involve only procedures listed in one or more of the categories below.

- X 1. Clinical studies of drugs and medical devices only when condition (a) or (b) is met.
  - a) Research on drugs for which an investigational new drug application (21 CFR Part 31, 32) is not required. (Note: Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review.)
  - b) Research on medical devices for which
    - (i) An investigational device exemption application (21 CFR Part 812) is not required; or
    - (ii) The medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.
 

The medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.
- 2. Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:

- a) From healthy, nonpregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8-week period and collection may not occur more frequently than 2 times per week; or

From other adults and children, considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8-week period and collection may not occur more frequently than 2 times per week.

Children are "persons who have not attained the legal age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted."

3. Prospective collection of biological specimens for research purposes by non-invasive means.

EXAMPLES: (a) hair and nail clippings in a nondisfiguring manner; (b) deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction; (c) permanent teeth if routine patient care indicates a need for extraction; (d) excreta and external secretions (including sweat); (e) uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gumbase or wax or by applying a dilute citric solution to the tongue; (f) placenta removed at delivery; (g) amniotic fluid obtained at the time of rupture of the membrane prior to or during labor; (h) supra- and subgingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques; (i) mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings; (j) sputum collected after saline mist nebulization.

- X 4. Collection of data through non-invasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving X-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications.)

EXAMPLES: (a) physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subjects' privacy; (b) weighing or testing sensory acuity; (c) magnetic resonance imaging; (d) electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiology; (e) moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight and health of the individual.

Ankle Brachial Index for Peripheral Arterial Disease

- X 5. Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for nonresearch purposes (such as medical treatment or diagnosis). (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. 45CFR 46.101(b)(4). This listing refers only to research that is not exempt.)

Will be accessing medical records to collect data that has been collected, or will be collected solely for nonresearch purposes.

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6. Collection of data from voice, video, digital, or image recordings made for research purposes.
7. Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies. (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. 45 CFR 46.101(b)(2) and (b)(3). This listing refers only to research that is not exempt.)
8. [FOR IRB use only]. Continuing review of research previously approved by a convened IRB only when condition (a), (b), or (c) is met.
  - a) Previously approved research where
    - (i) The research is permanently closed to the enrollment of new subjects;
    - (ii) All subjects have completed all research-related interventions; and
    - (iii) The research remains active only for the long term follow-up of subjects.
  - b) Previously approved research where no subjects have been enrolled and no additional risks have been identified.
  - c) Previously approved research where the remaining research activities are limited to data analysis.
9. [FOR IRB use only]. Continuing review or research not conducted under an investigational new drug application or investigational drug exemption where expedited categories two (2) through eight (8) do not apply but the IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified.

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**\* \* \* Background, Purpose, Study Procedures \* \* \***

Title

Sensitivity and specificity of digital ankle brachial index (ABI) as a screening tool in detecting peripheral arterial disease: A single center, prospective clinical trial
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Complete Sections 1 - 16. In sections that allow reference to sponsor protocol or grant, clearly state section and page numbers. Any information that is different or specific to the local site should be in the SLU application. Specify N/A as appropriate.

1. Background

Page numbers from a sponsor's protocol/grant may be referenced in 1a and 1b.

- a) Provide an introduction and background information. Describe past experimental and/or clinical findings leading to the formulation of the study, if applicable. Investigator Initiated studies must cite references in the response provided or attach a bibliography. \*?HELP?\*

Protocol Title: Sensitivity and specificity of digital ankle brachial index (ABI) as a screening tool in detecting peripheral arterial disease: A single center, prospective clinical trial

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cite references in the response provided or attach a bibliography. \*?HELP?\*

Peripheral artery disease (PAD) affects 8–18 million in the US and is an economic burden, currently estimated to be greater than cancer and heart disease. Older age (> 65 years), smoking, diabetes and kidney diseases are some risk factors associated with PAD and are known to have increased morbidity and mortality[1, 2]. PAD progression directly results in claudication, impaired walking, and amputation. Amputation is not benign - impacts are physical and emotional. Recovery from amputation involves long-term rehabilitation. The American Heart Association (AHA) in 2016 guidelines suggests an algorithm for diagnosis and management of PAD. They recommend a collaborative multidisciplinary team approach between the primary care physician and specialists including; a diabetologists/ endocrinologist, smoking cessation expert, hypertension and lipid specialist, interventional radiologist, vascular surgeon, orthopedist, neurologist, wound healing expert, and/or others for 'the greatest chance of providing optimal care for the patient with PAD'[3].

Early detection is critical for mitigating PAD progression. Ankle-brachial index (ABI) testing is recommended by the US Preventative Services Task Force as an affordable and effective screening tool for evaluating PAD risk[3]. ABI testing is especially useful in primary care settings allowing for earlier diagnosis and treatment. Several ABI methods are used; classically this test uses a device for measuring blood pressure with an inflatable cuff, and blood pressure measurements are taken at the upper arm and the ankle; healthcare providers have used a doppler probe to detect audible systolic pressure signals within the arteries - Doppler ABI. Barriers to implementation include; time required to conduct tests, training and required technical skills. Hence, Doppler-based ABI in primary care has been limited. Recently designed oscillometric (manual or digital with automatic electronic calculation of blood pressure) and photoplethysmographic devices are now available. However current guidelines do not endorse the use of these newer devices but recommend the hand-held doppler technique[4].

Digital ABI is noninvasive, automated ABI using pulsatile blood volume changes - plethysmography, irrespective of vessel compressibility. The QuantaFlo™ (Semler Scientific, Inc.) is an innovative, 510K FDA approved device that provides bilateral, non-invasive physiologic studies of upper and lower extremity arteries using volume plethysmography of the posterior tibial and anterior tibial/dorsalis pedis arterial distributions. QuantaFlo™ uses an optical sensor attached onto a digit in the hand and feet to assess extremity blood volume. It then displays a signal, directly related to blood volume, on a Volume Plethysmography Chart used to calculate PAD probability. This test is easy to use and portable, delivering fast, accurate results in ~5 minutes; an attractive option in primary care settings. While maintaining accuracy, results comparing digital methods to Doppler show concordance above 90%. The American Medical Association (AMA) concluded, "Evaluation of the digits in both legs with volume plethysmography is appropriate for this code provided that an ankle/brachial index (ABI) be performed." QuantaFlo™ meets both of these standards.

ABI  $\leq$  0.9 has been used as the criterion for diagnosing PAD based on ACC/AHA guidelines for the management of patients with PAD [3]; the cutoff value of ABPI  $\leq$ 0.9 it has been reported that the sensitivity of diagnosing PAD was 83% to 85% and a specificity of 95% to 100% [5]. ABI has been validated against lower extremity contrast angiography obtaining high sensitivity (85%–95%) and specificity (90%–100%), for diagnosing PAD [6, 7]. Many studies have reported more than 95% of sensitivity and specificity of colour duplex ultrasound scan in detecting a significant stenosis of the arteries [8, 9].

Please save frequently

- b) Describe any animal experimentation and findings leading to the formulation of the study, if there is no supporting human data.

Protocol Title: Sensitivity and specificity of digital ankle brachial index (ABI) as a screening tool in detecting peripheral arterial disease: A single center, prospective clinical trial

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N/A

## 2. Purpose of the study

- a) Provide a brief lay summary of the project in <200 words. The lay summary should be readily understandable to the general public.

QuantaFlo™ (Semler Scientific, Inc.) is a novel, noninvasive, 510K FDA approved digital device that is used as a screening tool to measure ABI of patients at risk of PAD. This single center prospective clinical trial will evaluate the sensitivity and specificity of digital ABI in detecting PAD using color Doppler ultrasound and 'gold standard' angiography as reference. Specifically in participant undergoing dialysis and who cannot undergo ABI using pressure cuffs dialysis grafts/ fistulae in the arms, we will evaluate the value of digital ABI in detecting PAD.

Page numbers from a sponsor's protocol/grant may be referenced in 2b and 2c.

- b) List your research objectives (specific aims & hypotheses of the study).

Primary aim:  
 To evaluate the sensitivity and specificity of digital ABI in diagnosing PAD using color Doppler ultrasound and 'gold standard' angiography as reference.  
  
 Secondary aim:  
 •To correlate the digital ABI index with symptoms of PAD.  
 •To evaluate the value of digital ABI in detecting PAD in patients on dialysis in whom the presence of dialysis grafts/ fistulae in the arms would have prohibited the use of ABI using pressure cuffs.

Please save frequently

- c) Describe the study design (e.g., single/double blind, parallel, crossover, control, experimental, observational, etc.). If the study is investigator-initiated, a timeline for individual subject recruitment, follow-up, and analysis for the study is required. Also, indicate if the subjects will be randomized.

This is a pilot, Single Center, Prospective study. A total of 100 participants will be enrolled

- d) If subjects will be given placebo, please justify placebo use. \*?HELP?\*

N/A

## 3. Study Procedures

- a) N Is this project a multicenter study (i.e., same project is conducted elsewhere by a different investigator) OR does this study involve conduct of research at multiple sites? Is SLU acting as a coordinating center for other sites OR is the SLU PI a direct recipient of a federal grant for this research? If yes, complete and attach the Supplemental Application for Coordinating Center Activities.

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Will the SLU site be participating in all parts/procedures/arms of the study?  
If No, explain what SLU will NOT participate in:

Please save frequently

Page numbers from a sponsor's protocol/grant may be referenced in 3b, 3c, and 3d.

- b) Describe all the procedures, from screening through end-of-study, that the human subject must undergo in the research project, including study visits, drug treatments, randomization and the procedures that are part of standard of care. Specify which procedures are for research and which are standard of care. Please note: The box below is for text only. If you would like to add tables, charts, etc., attach those files in the Attachment section (#16).

1. Screening sites: The digital ABI screening test will be offered at various outpatient clinics in departments belonging to family medicine, endocrinology, geriatric medicine.

2. Participant information: Participant will get information about Peripheral arterial disease based on a poster which will be placed in the waiting areas as well as flyers that will be presented to them during their routine clinic visit to the respective specialists.

3. Screening questionnaire: On registration at these respective clinics, all patients in the clinic will be given the screening questionnaire by the front desk. Patient will fill out the questionnaire, saying YES or NO. If ANY of the questions is a YES - this is an indication for doing a screening digital ABI.  
The screening questionnaire is considered part of clinical care, and would occur regardless of this research study.

4. If ANY of the questions is a YES - this is an indication for doing a screening digital ABI. This patient will then be approached by the Research Coordinator and asked if they want to participate. The Research Coordinator will then consent the patient for the study.

5. After consent, an EPIC order will be placed for the ABI. The medical assistant / nurse/ front desk will speak to the study coordinator to put an order for a digital ABI in EPIC. Along with the order, the answers from the screening questionnaire will be entered into EPIC via a flowsheet that has been created. The screening questionnaire will be uploaded in EPIC regardless of this research study.

6. Perform Digital ABI:

Performing ABI is within the normal duties of any nurse/ medical assistant

- Will be performed by the nurse/medical assistant/ research coordinator with training to perform this test
- The participant will be placed in the supine position, with the arms and legs at the same level as the heart, for a minimum of 5 minutes before measurement. Foot warmers will be placed during this time on the patients feet with foot liners. The foot warmers are like a heating pad for feet.
- The optical sensor (similar to a pulse oximeter) will be placed sequentially in the fingers of the hands and feet: Right and left hand fingers and then right and left feet toes.
- Usually each digit takes about 15 seconds to obtain a waveform
- At the end of 60 seconds, an automated digital ABI will be generated.

IF the data produced seem unreliable, sometimes indicated by the device we will ask the

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participant to do exercise 25-40 heel lifts (until they can feel it in their calf muscle). and then the test with the pulse Oximeter will be repeated.

6. Interpreting ABI: Interventional Radiology physician will pick up these studies from EPIC at the end of the day and put in a formal report in EPIC.

7. Clinical course: If based on Screening questionnaire and digital ABI,  
I. Participant is diagnosed with PAD- the referring physician and participant will receive a phone call about the same. He/ she will then be advised any further testing/ referral to IR clinic.  
II. There is no evidence of PAD- no further action will be taken. The participant will be informed of the same.

8. The data of all patients who have answered the questionnaire will be accessed. This includes those patients who are screened but do not meet the criteria to undergo digital ABI. Those who were screened, do meet the criteria to undergo the digital ABI but choose not to will be asked if their data can still be used for this research study (and will be asked to sign a separate consent document).

- c) If the proposed study is a clinical trial where a drug, vaccine, device or other treatment is compared to a placebo group or comparison treatment group, what are the guidelines or endpoints by which early decisions regarding efficacy or lack of efficacy can be made? For example, it may be reasonable to stop enrollment on a study when efficacy has already been clearly demonstrated, to avoid unnecessary enrollments of additional subjects. Alternatively, it may be reasonable to stop enrollment when it is clear that efficacy will never be demonstrated, given the statistical power of the study as designed. Describe the guidelines that are in place to assist in making these determinations, if relevant to the proposed study.

N/A

- d) Describe how data analysis will be performed (statistical tests, methods of evaluating data) and indicate the smallest group/unit for which separate reporting will occur. For studies involving a questionnaire, if data and reliability information are available, please describe or provide references. For full board, unfunded studies describe sample size determination and power analysis. If none, please justify.

Statistical analysis will be performed using R version 3.3.2 or newer (R Core Team, Vienna, Austria). Binary variables will be created for each sign, symptom, or risk factor based on the corresponding questionnaire response. Standard summary statistics will be calculated for study variables of interest. For continuous variables, statistics included the number of observations (N), mean, standard deviation, and 95% confidence interval. Categorical variables will be summarized in frequency distributions. The results of ABI will be categorized based on the ABI index obtained as normal (>0.9), calcified arteries (>1.4), Mild to moderate disease (0.4-0.9), Severed disease- <0.4 and compared to symptoms (e.g. asymptomatic, claudication, critical limb ischemia). A 'Positive ABI' will then be compared to gold standard 'angiography'; if angiography shows evidence of PAD, this will be termed 'angiographic positive'. Sensitivity will be defined as the proportion of 'ABI positive results' out of the number of samples which were actually 'angiographically positive'. When there are no positive results, sensitivity will not be defined and a value of NA is returned. Similarly, when there are no negative results, specificity will not be defined and a value of NA is returned. Similar statements will be true for predictive values. The positive predictive value will be defined as the percent of predicted positives that are actually positive while the negative predictive value will be defined as the percent of negative positives that are actually negative.

Please save frequently

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- e) State if deception (including incomplete disclosure of study purpose/procedures) will be used. If so, describe the nature of the deception and provide a rationale for its use. Also, describe debriefing procedures or justify a waiver of the requirement to debrief. NOTE: for studies using deception, an alteration of consent must be justified in the Informed Consent section of the protocol (#13) and the debriefing script/statement must be uploaded in the Attachments section (#16). See IRB Deception Guidelines.

- f) Is there an accepted standard of care and/or standard practice at SLU for the condition/disease/situation being studied? This information will assist in comparing the risk/benefit ratio of study procedures relevant to usual care that would be received outside of the research context. \*?HELP?\* Y

If yes, please describe the standard of care and standard practice at SLU for the condition/disease/situation being studied.

Several ABI methods are used, with Doppler ABI being most common.

Currently at Saint Louis University hospital, patients who have signs and symptoms of PAD undergo traditional ABI or Doppler ultrasound. Traditional ABI involves a slightly different process involving the use of blood pressure cuffs and manual measurement of flow using Doppler. Some patient may also receive angiography, which involves an injection of a dye into the artery of the leg to evaluate for blocks in arteries.

- g) Does this study involve any diagnostic imaging, labwork or genetic testing that could result in clinical discovery (diagnoses, genetic mutations, etc.)? Note that this could include discovery that is expected (related to the research) or incidental (not related to research aims, but possible, like a mass/shadow found in imaging despite not looking for it). Y

If yes, please describe and include whether there are plans to share findings with study participants.

Yes we may discover the participant has an undiagnosed PAD. This information will be shared with the subjects.

- h) Is this study subject to the NIH Genomic Data Sharing Policy? N

The NIH GDS policy applies to all NIH-funded research that generates large-scale human genomic data as well as the use of these data for subsequent research and includes: genome-wide association studies (GWAS), single nucleotide polymorphisms (SNP) arrays, and genome sequence, transcriptomic, metagenomics, epigenomic and gene expression data, irrespective of NIH funding mechanism. Click here for more specific examples.

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\* \* \* Radioisotopes or Radiation Machines \* \* \*

You have not selected the Radioisotopes option in the General Checklist. If you would like to add Radioisotopes information, please select the option to enable this section.



4. Radioisotopes or Radiation Machines

In this section, investigators must enter all radiation usage associated with the protocol.

Important: Protocols that involve non-standard of care radioactive materials (which includes the terms "radioisotopes", "radionuclides", "radiopharmaceuticals", and "nuclear medicine studies", e.g., "PET", "MUGA", "Zevalin", and/or specific radionuclides such as "F-18", "Tc-99m", "Th-201", "I-131", "Ra-233", "Y-90", etc.) will receive review by the Radiation Safety Officer (RSO) and/or Radiation Safety Committee (RSC). In these cases, submission to the RSO/RSC should occur first, even before submission to IRB. For more information on how to submit for radiation safety review, see RSC instructions or contact the Radiation Safety Officer at 977-6895.

(1) It is the responsibility of the PI to assure the accuracy and completeness of the data submitted in this section, consistent with guidelines provided below. (2) For projects requiring radiation procedures, please refer to this guidance.

- a) If applicable, list and quantify the radiographic diagnostic and therapeutic procedures associated with this protocol by clicking "Add" and adding to Table 1 below. (Includes X-ray, fluoroscopy, CT, radioactive materials, nuclear medicine, PET-CT, radiation oncology, accelerator, Cyber Knife procedures, etc.)

- b) Total estimated research radiation dose \* :

\* Calculate from the table above by adding the Effective Dose Subtotals for all procedures.

NOTE: Informed Consent Radiation Exposure Risk Statement- The applicant must insert the appropriate Informed Consent Radiation Exposure Risk Statement template language into the SLU IRB Informed Consent, inclusive of applying the total estimated research radiation dose specified in item b) from the table above, as instructed in the SLU IRB Informed Consent Template. Contact the IRB Office at 977-7744 or irb@slu.edu with any questions.

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\* \* \* Devices \* \* \*

5. Devices

- a) Please list in the space below all investigational devices to be used on subjects during this study.

b) Please list in the space below all FDA approved devices to be used on subjects during this study.

FDA Approved Devices

Device Name	Manufacturer	Provide IDE #. Documentation of IDE # required unless imprinted on sponsor protocol (attach in section #16).
Quantaflo	Semler Scientific, Inc	

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\* \* \* Drugs, Reagents, Chemicals, or Biologic Products \* \* \*

6. Drugs, Reagents, Chemicals, Biologic Products, or Dietary Supplements, Vitamins, and Other Food Agents

Pilot	Phase I	Phase II
Phase III	Phase IV	Not Phased

List placebo if it is considered a drug (contains more than inactive ingredients). For example, normal saline is considered a drug that should be listed, whereas placebo tablets are usually inert ingredients that do not need to be listed.

- b) Please list in the space below all investigational drugs, reagents or chemicals to be administered to subjects during this study. Attach all applicable Investigator Brochures in section #16 (Attachments).
- c) Please list in the space below all FDA approved drugs, reagents, chemicals to be administered to subjects during this study. Attach all applicable package inserts in section #16 (Attachments).
- d) Please list in the space below all dietary supplements, vitamins, minerals, or foods to be administered to subjects during this study.

Please read the IND Statements.

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\* \* \* Other Levels Of Review \* \* \*

7. Other Levels Of Review

1. University Radiation Safety

Protocols that involve non-standard of care radioactive materials (which includes the terms "radioisotopes", "radionuclides", "radiopharmaceuticals", and "nuclear medicine studies", e.g., "PET", "MUGA", "Zevalin", and/or specific radionuclides such as "F-18", "Tc-99m", "Th-201", "I-131", "Ra-223", "Y-90", etc.) will receive review by the Radiation Safety Officer (RSO) and/or Radiation Safety Committee (RSC). For information on how to submit for radiation safety review, see RSC instructions or contact the Radiation Safety Officer at 977-6895.

Not Applicable

Yes, study involves radioactive materials (per instructions, submit to RSC before IRB)

## 2. Institutional Biosafety

Experiments involving the deliberate transfer of Recombinant or Synthetic Nucleic Acid Molecules (e.g., Gene Transfer), or DNA or RNA derived from Recombinant or Synthetic Nucleic Acid Molecules, or Microorganisms containing Recombinant or Synthetic Nucleic Acid Molecules and/or infectious agents (including select agents and toxins as defined by CDC and/or Animal and Plant Health Inspection Service (APHIS)) into one or more human research participants must be reviewed by the SLU Biological Safety Officer. Most of these protocols also require review and approval by the SLU Institutional Biosafety Committee (IBC). Please contact the SLU Biological Safety Officer at 977-6888 for more information.

Not Applicable

Yes, study requires Institutional Biosafety review

## 3. Pharmacy, Therapeutics, Nutrition, and Transfusion (PTNT) Committee

Saint Louis University Hospital requires that all research involving the administration of medications within the hospital (including outpatient areas such as the Emergency Department, Outpatient Center, Saint Louis University Hospital-South Campus, etc.) be reviewed and approved by the Pharmacy, Therapeutics, Nutrition, and Transfusion (PTNT) Committee and that study drugs are received, stored, prepared, and dispensed by the Hospital's Department of Pharmacy Services. Please contact the Investigational Drug Services Clinical Pharmacist at 268-7156 or SLUH-IDS@ssmsluh.com for more information.

Not Applicable

Yes, study requires PTNT review

## 4. Saint Louis University Hospital

All research involving Saint Louis University Hospital, including the Emergency Department, inpatient or outpatient services (including outpatient surgery at ABI and the infusion center at DOB) and medical record access, requires approval from the Saint Louis University Hospital Research Review Committee prior to study initiation. This process is designed to facilitate compliance with state and federal regulations as they pertain to research in hospitals and clinical research billing. Documents should be submitted as soon as possible, or at the latest, concurrently with IRB submission. Please contact the Research Compliance Office at 577-8113 or sluh-research@ssmhealth.com of the SLU Clinical Trials Office (CTO) at 977-6335 or clinical-trials-office@health.slu.edu for more information.

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Not Applicable

X Yes, study requires Saint Louis University Hospital review

5. SSMSL

All research involving SSMSL locations (including Cardinal Glennon), including inpatient or outpatient services and medical record access, requires approval from the SSM STL or SSM Cardinal Glennon Research Business Review (RBR) prior to study initiation. This process is designed to facilitate compliance with state and federal regulations as they pertain to research in hospitals and clinical research billing. While researchers can begin to complete the SSM RBR form at any time, the form should not be submitted until the IRB and the CTO have approved the study. Please contact the SSMSL Office at 989-2058 or Marcy.Young@ssmhealth.com for more information.

Not Applicable

X Yes, study requires RBR review

6. Does this project require registration on ClinicalTrials.gov, and/or is this project subject to the NIH GCP Training Requirement? (Select "Yes" if either apply) Y

Registration may be required if any of the following apply: 1) The project meets the FDAAA definition of an "Applicable Clinical Trial", which requires registration on ClinicalTrials.gov. 2) As of January 1, 2017, a new NIH policy mandated biomedical and behavioral "Clinical Trials" to be registered on ClinicalTrials.gov. In addition, NIH policies require personnel on NIH "Clinical Trials" to take GCP training every three years. 3) Registering may be required for Journal Publication (ICMJE). Please review relevant definitions here. Contact the CTO at clinical-trials-office@slu.edu with questions about registering on ClinicalTrials.gov and refer to the training page of the IRB website for information on NIH GCP Training requirements.

\*\*\* Subject Population \*\*\*

8. Subject Population - In the space below, please detail the participants that you are requesting to recruit (include description of each group requested)

a) Expected age range of subjects. (For example ≥ 18 yrs to 90 yrs).

18 years to 90 years old

b) Number of evaluable subjects to be accrued at SLU or SLU site (this includes all sites under the direction of the SLU PI). 750

Exceeding the number listed here is a protocol violation. Prior IRB approval is required if additional participants are to be accrued. If applicable, this number should be consistent with your power analysis described in 3d.

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c) Number of evaluable subjects to be accrued study wide. \*?HELP?\*

d) If including vulnerable populations (<a href=https://www.slu.edu/Documents/research/IRB/Minors\_in\_Research.doc target=\_blank>minors, <a href=https://www.slu.edu/Documents/research/IRB/Pregnant\_Women\_Fetuses.docx target=\_blank>pregnant women and fetuses, <a href=https://www.slu.edu/Documents/research/IRB/Neonates.docx target=\_blank>neonates, <a href=https://www.slu.edu/Documents/research/IRB/Non-English\_Speaking\_Subjects.doc target=\_blank>non-English speaking, economically or educationally disadvantaged, <a href=https://www.slu.edu/Documents/research/IRB/Prisoner\_Research.doc target=\_blank>prisoners, <a href=https://www.slu.edu/Documents/research/IRB/Adults\_Unable\_to\_Provide\_Consent.docx target=\_blank>adults temporarily or permanently unable to consent for themselves): 1) provide the rationale for the importance of including this population in the research, and 2) specify the measures being taken to minimize risks to potentially vulnerable subjects. Click on hyperlinks to access <a href=https://www.slu.edu/division-of-research-administration-home/institutional-review-board-(irb)/general-guidelines target=\_blank>SLU Guidelines containing additional considerations and strategies for mitigating risks.

n/a

e) If women, minorities, or minors are not included, a clear compelling rationale must be provided unless not applicable. Examples for not including minors: disease does not occur in children; drug or device would interfere with normal growth and development; etc. If federally funded reference appropriate section of the sponsors protocol/grant. \*?HELP?\*

Minors will not be included in this study as they do not present to the study locations nor are they at risk of PAD.

f) If any specifically targeted subjects are students, employees, or laboratory personnel, specify the measures being taken to minimize the risks and the chance of harm to these potentially vulnerable subjects. See <a href=https://www.slu.edu/division-of-research-administration-home/institutional-review-board-(irb)/general-guidelines target=\_blank>SLU Guidelines for additional considerations and strategies for mitigating risks.

g) Describe how potential subjects will be identified for recruitment (e.g., chart review, referral from individual's treating physician, those individuals answering an ad). How will potential participants learn about the research, and how will they be recruited (e.g., flyer, e-mail, web posting, telephone, etc.)? Upload recruitment materials in the Attachment Section (#16). Important to remember: potential subjects cannot be contacted before IRB approval. NOTE: The use of SLU owned websites in an approved SLU format (e.g., Cancer Center website, etc.) are always approved methods of recruitment.

This portable system will be placed in primary care and geriatric offices, endocrinology/diabetic clinics. Patients will complete the screening questionnaire (SOC) and if they are indicated for the ABI will be approached and consented for participation in the protocol.  
A recruitment poster will be displayed in the clinic outpatient patient areas to educate patients about risks of PAD and need for ABI.

A description of this study and study results will be available on <http://www.ClinicalTrials.gov>, as required by U.S. Law. This website will not include information that can identify you. You can search this website at any time.

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\* \* \* Subject Population \* \* \*

8. Subject Population (continued)

Page numbers from a sponsor's protocol/grant may be referenced in 8h.

h) Inclusion and Exclusion Criteria.

Identify inclusion criteria.

Answering yes to any of the following questions on the clinical screening questionnaire:

- Are you 65 years or older?
- Have you ever smoked?
- Do you have diabetes?
- Do you have high blood pressure or take medication for high blood pressure?
- Do you have high cholesterol, or take medication for high cholesterol?
- Have you previously had a stroke?
- Do you have heart disease?
- Do you experience any pain at rest in your lower legs or feet?
- Do you have discomfort (aching, fatigue, tingling, cramping or pain) when you walk, which is relieved by rest? Does the pain go away within 10 minutes after stopping?
- Are your toes or feet pale, discolored, or bluish?
- Do you have an infection, skin wound, or ulcer on your feet or toes?

Identify exclusion criteria.

- Not meeting the above criteria.
- Previously screened with ABI in past 12 months

i) Compensation. Explain the amount and schedule of compensation, if any, that will be paid for participation in the study. Include provisions for prorating payment.

None

j) Describe who will cover study related costs. Explain any costs that will be charged to the subject.

SPARK Microgrant will cover cost of the digital ABI machine.

Insurance carriers ordinarily would cover the costs of the ABI machine as it is being used in accordance to its approved use. Participants should check with their insurance companies to verify that they cover standard of care procedures.

k) Estimate the probable duration of the entire study including data analysis and publication. This estimate should include the total time each subject is to be involved and the duration the data about the subject is to be collected. If the study is Investigator-initiated, a timeline for individual subject recruitment, follow-up, total time for subject accrual, and data analysis for the study is required.

April 10 2017- start of the project of performing ABI  
July 10, 2017- end of project of administering digital ABI  
Dec 10, 2017 - collection of data, analysis  
Feb 10, 2018- writing manuscript/ abstract

Patients will be in the study until their results are obtained. If they qualify for further testing, they will

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Patients will be in the study until their results are obtained. If they qualify for further testing, they will receive standard of care treatment, but their records will be reviewed and information from their records will still be obtained.  
The digital ABI test can be complete and results available in around 5 minutes.

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\*\*\* Risks \*\*\*

9. Risks

There is no research that can be considered totally risk free (e.g., a potential risk of breach of confidentiality). Therefore, when describing the risk, the lowest level of risk is "no more than minimal risk".

Page numbers from a sponsor's protocol/grant may be referenced in 9.1, 9.2, 9.3, and 9.4.

1. Use of investigational devices. Please include the clinical adverse events (AEs) associated with each of the devices with an indication of frequency, severity and reversibility. This information can often be found in the Investigator(s) brochure. NOTE: Include any likely adverse effects associated with procedures that subjects may experience while in the study.
2. Use of investigational drugs. Please include the clinical AEs associated with each of the drugs with an indication of frequency, severity and reversibility. This information can often be found in the Investigator(s) brochure. NOTE: Include any likely adverse effects associated with placebos or washout periods that subjects may experience while in the study.
3. Use of FDA approved drugs, reagents, chemicals, or biologic products. Please include the clinical AEs associated with each of the drugs with an indication of frequency, severity and reversibility. This information can often be found in the package insert provided by the manufacturer. NOTE: Include any likely adverse effects associated with placebos or washout periods that subjects may experience while in the study.
4. Use of FDA approved devices. Please include the clinical adverse events (AEs) associated with each of the devices with an indication of frequency, severity and reversibility. This information can often be found in the Investigator(s) brochure. NOTE: Include any likely adverse effects associated with procedures that subjects may experience while in the study.

Minimal discomfort from placement of the monitors on fingers

5. Describe any risks related to performing study procedures. Please include all investigational, non-investigational, and non-invasive procedures (e.g., surgery, blood draws, treadmill tests).

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There may be a small amount of pressure on your finger and toe where the monitor is placed this minor and should not be a problem.

6. Describe any risks related to the use of radioisotopes/radiation-producing machines (e.g., X-rays, CT scans, fluoroscopy).

7. Describe why this investigational compound/drug/device/procedure's risks/benefits are potentially better than standard of care or other common alternatives. Any standard treatment that is being withheld must be disclosed and the information must be included in the consent form. \*?HELP?\*

The early detection of PAD is minimal compared to the problems PAD going undiagnosed could cause.

8. Describe any psychological, social, or legal risks the subject may experience. \*?HELP?\*

Loss of confidentiality

Page numbers from a sponsor's protocol/grant may be referenced in 9.9 and 9.10.

9. Special Precautions. Describe the planned procedures for protecting against or minimizing potential risks. If appropriate, include the standards for termination of the participation of the individual subject. Discuss plans for ensuring necessary medical or professional intervention in the event of adverse effects to the subjects.

All patient data will be kept in a secure locked location or on a SLU password protected database.

10. Reproductive Risks.

a. Please list the pregnancy category of any drugs or N/A.

N/A

b. Please describe any reproductive risk associated with any part of the research study. Include any data from other studies (animal or human).

none



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11. Data Safety Monitoring

Federal regulations require that when appropriate, the research protocol makes adequate provisions for monitoring the data to ensure the safety of participants. Monitoring should be commensurate with risks and with the size and complexity of the research, and could range from no plan needed to an independent data safety monitoring board. Please refer to SLU Guidelines for Data and Safety Monitoring as you complete the questions below.

a. Is there a Data Monitoring Committee (DMC) or Board (DSMB)? N/A

If yes, please provide the following information (labeled a-g): a) the composition of the board (degrees/qualifications of members), b) whether the board is independent from the sponsor and research team or not, c) frequency of meetings and issuance of reports to sites, d) assurance that the board is reviewing aggregate safety data and making recommendations regarding study continuance, e) provisions for ad hoc meetings if needed, f) who is reviewing SAEs in real time (MD or DO), and g) stopping/halting rules (if any exist).

A DSM charter can be referenced for all items except for "f) who is reviewing SAEs in real time."

If no, please justify why not.

b. Is there a Data Safety Monitoring Plan (DSMP)? N/A

Note, if all relevant plan information is included in DSMB question above, select 'Yes' and state "see above" in the answer box.

If yes, provide details (labeled a-e) including: a) what types of data or events are captured and how are they documented, b) who is monitoring data, their independence/affiliation with the research and their degrees/qualifications, c) frequency of aggregate data review, d) who is reviewing SAEs in real time (MD or DO), and e) stopping/halting rules (if any exist).

If no, please justify why not.

12. In case of international research (research outside of the U.S. or research on international populations (non-U.S.)), describe qualifications/preparations that enable you to evaluate cultural appropriateness and estimate/minimize risks to subjects. Include whether research is sensitive given cultural norms.

- a. State any local laws/regulations governing Human Subjects Research in the country(ies) you will conduct the research and attach any relevant approvals. If none, state N/A.
- b. Will there be language barriers and if so, how will they be addressed?

Note: If materials are to be distributed to subjects in their native language, please follow SLU's Guidance For Studies Involving Non-English Speaking Subjects.

NOTE: Export control laws include the transfer of technical information and data, as well as information and technology to foreign nationals. If this study has international components, contact the SLU Export Control Officer for direction on whether export control policies apply.

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\* \* \* Benefits/Alternatives, Procedures to Maintain Confidentiality and Privacy \* \* \*

#### 10. Benefits/Alternatives

- a) Benefits. Describe the potential benefit(s) to be gained by the subjects and how the results of the study may benefit future subjects and/or society in general. Indicate if there is no direct benefit to the participants.

Early detection is critical for mitigating PAD progression. Ankle-brachial index (ABI) testing is recommended by the US Preventative Services Task Force as an affordable and effective screening tool for evaluating PAD risk. ABI testing is especially useful in primary care settings allowing for earlier diagnosis and treatment. Several ABI methods are used, with Doppler ABI being most common. Barriers to implementation include; time required to conduct tests, training and required technical skills. Hence, Doppler-based ABI in primary care has been limited. Participants may benefit if PAD is detected and is able to be treated early.

Participants may also not receive any direct benefits.

- b) Alternatives. Describe any alternative treatments and procedures available to the subjects should they choose not to participate in the study. If no such alternatives exist, please state that the alternative is nonparticipation. For some studies, such as record reviews, a description of alternatives would not be applicable.

Participants can choose the current standard PAD evaluation methods. This includes in hospital ABI using blood pressure cuffs.

#### 11. Procedures to Maintain Confidentiality and Privacy

Federal regulations require that research materials be kept for a minimum of three (3) years and HIPAA documents be kept for a minimum of six (6) years after the closure of the study. For FDA-regulated or sponsored projects, the PI may be required to keep the data and documents for a longer time period.

Confidentiality

To determine whether adequate provisions for confidentiality of data are in place, the IRB must ensure that research materials are stored in appropriate locations throughout the study (during collection, transport/transmission, analysis and long term storage). Research information must be protected using appropriate safeguards based on identifiability of the data and risk associated with the study (See SLU IRB Confidentiality Guidelines).

For the questions below, please use the following definitions:

**Anonymous/De-identified:** data contain no identifiers, including code numbers that investigators can link to individual identities;

**Coded:** data in which (1) identifying information, such as name or social security number, has been replaced with a number, letter, symbol, or combination thereof (i.e., the code), and (2) a key to decipher the code exists

**enabling linkage of data to identifying information (e.g., a master list), and (3) the key (master list) is kept separately from coded data; AND/OR**

**Identifiable:** data that includes personal identifiers (e.g., name, social security number), such that information could be readily connected to respective individuals.

a) Electronic (Computer) Data

Click "Add" to enter data security information for each type of electronic data that will be created in the study: anonymous/de-identified, coded, and/or identifiable (see definitions above).

To properly address this question, there should only be one listing of each type of data in the table. Depending on your project, you could have up to three types of data. See the SLU ITS Sensitive Data Guide for acceptable data security methods.

Not Applicable, No Electronic (Computer) Data

Study IRB-approved Prior to New Question (Question N/A- Grandfathered)

Electronic Data

Type of Data	Storage Location	Data Transmission Outside of SLU	Supplemental information related to above items can be entered here or leave blank:
Identifiable	SLU ITS managed device (computer, tablet, etc.) with encryption; SLU ITS network storage (T: drive (shared drive), U: drive (personal drive))	Not Applicable, I will not be sending/sharing electronic data outside of SLU	

b) Hardcopy (Paper) Data

Click "Add" to enter information for each type of hardcopy (paper) data that will be created in the study: anonymous/de-identified, coded, and/or identifiable (see definitions above).

To properly address this question, there should only be one listing of each type of data in the table. Depending on your project, you could have up to three types of data.

Not Applicable, No Hardcopy (Paper) Data

Study IRB-approved Prior to New Question (Question N/A- Grandfathered)

Hardcopy Data

Type of Data	Storage Location	Transported Data Security	Supplemental information related to above items can be entered here or leave blank:
Identifiable	SLU Locked Cabinet; SLU Locked Room/Office	Personnel Supervision	

c) If a master list is used in this study (linking study codes to subject identifiers), explain: a) how and where you will secure the master list, b) how long it will be kept/when it will be destroyed, and c) provide a sample of the code.

Participants hard copy forms will have Participant initials and Age and physician or nurse signature and date of procedure this information will be entered into EPIC in the Participants chart.

d) If data or specimens are being shared outside of the research team, indicate who will receive the material, specifically what they will receive (data or specimens), and if an agreement has been signed to cover the transfer. Note: unless covered under a Clinical Trial or other agreement, the transfer of data or specimens to an external entity will require an agreement. For the transfer of materials (specimens), a Materials Transfer Agreement (MTA) is used; for the transfer of data, a Data Use or Data Transfer Agreement is used. Please contact the Research Innovation Group at 314-925-3027 for assistance.

n/a

e) If samples or data will be provided to SLU from an outside source, indicate whether you will have access to identifiers, and if so, how identifiable information is protected. Note: unless covered under another agreement (e.g., Clinical Trial Agreement or subcontract), the transfer of data or specimens from an external entity to SLU may require an agreement. For the transfer of materials (specimens), a Materials Transfer Agreement (MTA) may be required; for the transfer of data, a Data Use or Data Transfer Agreement may be required. Please contact the Research Innovation Group at 314-925-3027 for assistance.

assistance.

n/a

- f) If data will be collected via e-mail or the Internet, how will anonymity or confidentiality be affected? Describe how data will be recorded (i.e., will internet protocol (IP) addresses and/or e-mail addresses be removed from data?).
- g) If you will be audio/video recording or photographing subjects, provide a rationale as voiceprints and images of faces/unique body markings are considered identifiers. Describe confidentiality procedures, including any restricted access to images and/or the final disposition of the recordings/photos (destruction, archiving, etc.).
- h) Describe any study-specific (non standard of care) information or documentation that will be put in the participants' medical records for this research (e.g., study visit notes, lab results, etc.). If none, state "not applicable". NOTE: documentation of research in Epic should be done in accordance with the <a href=https://www.slu.edu/Documents/research/IRB/Epic\_Research\_Charting\_Policy.pdf target=\_blank>SLUCare Epic Research Charting Policy and <a href=https://www.slu.edu/Documents/research/IRB/Reasearch\_Documentation\_Epic.pdf target=\_blank>Clinical Workflow: Documenting Research Encounters in Epic.

Yes, ABI data will be included in the medical record.

- i) Are there any information security requirements identified in the project's RFP/Award Notice/Contract? This could include data security, technical safeguards, security controls, NIST, FISMA, CFR, etc. N  
  
If yes, SLU ITS approval is required. Contact InfoSecurityTeam@slu.edu to start the approval process.

Privacy

Privacy refers to persons having control over the sharing of oneself with others.

- j) Please indicate how participant privacy will be protected in this study (select all that apply):
  - X Discussion of health related and/or personal information in a private room/area
  - X Research interactions/interventions are conducted in a private room/area
  - Use of drapes or other privacy measures
  - X Collection of sensitive/identifiable information is limited to the minimum necessary to achieve the aims of the research

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- X Access to study information is limited to the minimum amount of persons necessary to achieve the aims of the research (e.g., access restricted to research team members only)

Consideration of parental inclusion/absence for studies involving minors

Other (please explain):

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**\*\*\* Potential Conflict of Interest \*\*\***

**12. Potential Conflict of Interest**

Indicate whether you, your spouse or dependent children, have, or anticipate having, any income from or financial interest in a sponsor, device or drug manufacturer of this protocol, or a company that owns/licenses the technology being studied. Please remember that you are responding for you and any other investigator participating in the study. Financial Interest includes but is not limited to: consulting; speaking or other fees; honoraria; gifts; licensing revenues; equity interests (including stock, stock options, warrants, partnership and other equitable ownership interests). For questions regarding Conflict of Interest consult the Conflict of Interest in Research Policy.

Check one of the following (please remember that you are responding for yourself, your spouse, dependent children and any investigator, investigator's spouse and dependent children participating in the study):

- 1) X No equity interest and/or Financial Interest less than or equal to \$5K
- 2) Any equity interest and/or Financial Interest exceeding \$5K but not exceeding \$25K in the past year or expected in the current year
- 3) Financial Interest exceeding \$25K in the past year or expected in the current year

Check all those that apply:

Consulting

Speaking Fees or Honoraria

Gifts

Licensing agreement or royalty income

Equity interests, (including stock, stock options, warrants, partnership or equitable ownership interests), or serving on a scientific advisory board or board of directors

Other fees/compensation

If you have marked #2 or #3, please contact [coi@slu.edu](mailto:coi@slu.edu) to initiate review of this study and provide the following information:

1. A Conflict of Interest Management Plan.  
has been approved for all investigators for this study  
is pending  
has not been initiated
2. Describe who has, and briefly explain, the conflict of interest and indicate specific amounts for each subcategory checked:

#### Note to Investigator(s) Reporting a Potential Conflict of Interest

Investigator(s) must have:

1. Current, up-to-date Conflict of Interest Disclosure Form on file with the SLU Conflict of Interest in Research Committee (COIRC) that describes any financial relationship indicated above.  
  
This information must be disclosed on the SLU confidential Conflict of Interest Disclosure Form and reviewed by the COIRC before accruing research subjects in this study. If your current Disclosure Form does not contain this information, you are required to submit an updated Disclosure Form to the COIRC.
2. You may not begin your study until your disclosure form has been reviewed and any required management plan has been approved by the COIRC for this study. To initiate COIRC review of your study, please contact [coi@slu.edu](mailto:coi@slu.edu).

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#### \*\*\* Informed Consent \*\*\*

### 13. Informed Consent

Federal regulations require that informed consent be obtained from individuals prior to their participation in research unless the IRB grants a waiver of consent. Answer the questions, below, then click Add to provide the necessary consent documents and information regarding subject consent. Multiple consents/waivers may be added, but they must be uploaded one at a time.

NOTE: You may refer to the SLU IRB Guidance for Obtaining Informed Consent for considerations regarding the consent/assent process.

State N/A if not applicable.

- 1) How is consent being obtained? When and where will the discussion take place? If the study involves a Non-English Speaking participant/population, please include details about plans for translated consent materials and interpreters to be used (see [https://www.slu.edu/Documents/research/IRB/Non-English\\_Speaking\\_Subjects.doc](https://www.slu.edu/Documents/research/IRB/Non-English_Speaking_Subjects.doc) target=\_blank>SLU Guidelines for Involving Non-English Speaking Subjects for more details).

An informed consent will be obtained by an approved member of the research staff.

The digital ABI we are offering can be performed right at the time of the patients visit to the physician (for the unrelated condition, e.g. Ms Mary jane visiting Dr John Doe for diabetes, but filling the questionnaire and needing an ABI for detecting APD). It does not involve making a new appointment for the test, and could save the participant time and travel in coming another visit. The participant will be given ample time to review the consent form, but if he / she needs additional time, the participant can take it home, review it and secure an appointment for this test at another day.

- 2) If the study involves adults unable to consent for themselves (whether diminished capacity to consent is temporary, permanent, progressive or fluctuating), please address the following: a) how is capacity to provide consent being assessed (initially and throughout study, if applicable); b) if unable to provide consent, how is LAR being determined (See <a href=https://www.slu.edu/Documents/research/IRB/LAR\_Guidelines.docx target=\_blank>SLU LAR Guidelines); c) if unable to provide consent, will assent be obtained and if not, why not?; d) if unable to provide assent, will dissent be honored and if not, why not? Note: participants initially unable to provide consent for themselves are expected to be given an opportunity to provide consent once capacity is gained. See <a href=https://www.slu.edu/Documents/research/IRB/Adults\_Unable\_to\_Provide\_Consent.docx target=\_blank>SLU Guidelines for Adults Unable to Provide Consent for additional detail.

n/a

Note: Any assent documents which will be used per the Adults Unable to Provide Consent guidance, should be appropriately named and uploaded using the Add button and the Consent drop down menu selection.

Informed Consent

Title	Consent Type	Attached Date
Screening Waiver of consent	Waiver of Consent	
Approved_ no QuantFlo tracked 04-02-2018	Consent	04/26/2018
Approved_ABI + QuantaFlo tracked 04-02-2018	Consent	04/26/2018

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\* \* \* Assent \* \* \*

14. Assent

Complete this section if your study includes minors. The Assent Form Template provides guidelines for writing assent documents.

- Will minors be asked to give assent, then consent once they reach adulthood? If not, please justify. If not capable to provide assent initially, please address whether assent will be obtained as the minor gains capacity. Note: children who reach the age of adulthood during participation should be given the opportunity to provide consent as parent/guardian consent no longer applies. If obtaining consent would be impracticable (e.g., this is a registry with data/specimen obtained long ago), a waiver of



consent should be added for IRB review. See <a href=https://www.slu.edu/Documents/research/IRB/Minors\_in\_Research.doc target=\_blank>SLU Guidelines for Research Involving Minors for additional detail.

2. If minors are asked to assent and do not wish to participate, will they still be accrued in the study? If yes, justify.
  
3. How will the minor's ability to give assent be assessed? (Consider the age and maturity of the minors as well as their physical or mental condition). If capacity is fluctuating, please explain how capacity will be assessed throughout the study.

Note: For studies that require a discussion about reproductive risks, note that the conversation with the minor should take place separately from the parents. Also, if a minor will reach adulthood (18 in Missouri) during the course of the study, they will need to be asked to consent as an adult at that time to continue in the study.

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\* \* \* HIPAA \* \* \*

#### 15. HIPAA

Studies that access, receive or collect protected health information (PHI) are subject to HIPAA regulations. PHI is health information with one or more personal identifiers. For more information visit the IRB HIPAA page or refer to the SLU IRB HIPAA Guidance.

1. Will health information be accessed, received or collected?

No health information. HIPAA does not apply.

- Yes (continue to question 2).

2. Which personal identifiers will be received or collected/recorded?

No identifiers. I certify that no identifiers from the list below will be received or collected and linked to health information. (Skip remainder of page).

Limited identifiers will be received or collected/recorded (study will likely require a data use agreement). Select Data Use Agreement- INTERNAL or Data Use Agreement- EXTERNAL as appropriate, below.

City/State/Zip codes

Person-specific dates (e.g., date of birth, dates of service, admission/discharge dates, etc.)

Age (if subjects are 90+ years)

- At least one direct identifier will be received or collected/recorded.

Names

Social Security numbers

Telephone numbers

Linkable code or any other unique identifying number (note this does not mean the unique code assigned by the Investigator(s) to code the research data)

All geographic subdivisions smaller than a State, including street address, city, county, precinct, zip code, and their equivalent geocodes, except for the initial three digits of a zip code, if, according to the current publicly available data from the Bureau of the Census:

(1) The geographic unit formed by combining all zip codes with the same three initial digits contains more than 20,000 people; and (2) The initial three digits of a zip code for all such geographic units containing 20,000 or fewer people is changed to 000

- X All elements of dates (except year) for dates directly related to an individual, including birth date, admission date, discharge date, date of death; and all ages over 89 and all elements of dates (including year) indicative of such age, except that such ages and elements may be aggregated into a single category of age 90 or older

Fax numbers

Electronic mail addresses

- X Medical record numbers

- X Health plan beneficiary numbers

- X Account numbers

Certificate/license numbers

Vehicle identifiers and serial numbers, including license plate numbers

Device identifiers and serial numbers

Web Universal Resource Locations (URLs)

Internet Protocol (IP) address numbers

Biometric identifiers, including finger and voice prints

Full face photographic images and any comparable images

If you are receiving or collecting/recording health information and at least one personal identifier, please continue to complete the sections, below.

3. Sources of Protected Health Information:

- X Hospital/medical records for in or out patients

- X Physician/clinic records

- X Laboratory, pathology and/or radiology results

Biological samples

Interviews or questionnaires/health histories

Mental health records

Data previously collected for research purposes

Billing records

Other

Please describe:

4. If data will be shared outside the research team and the study involves PHI indicate how the research team will share the information.

X Not applicable (continue to question 5).

Only linkable code that can link data to the identity of the subject. A code access agreement or business associate agreement may be needed when data are shared with other non-SLU entities. If necessary, the agreement can be added and uploaded in item #5, below.

Limited identifiers: Zip codes, dates of birth, or other dates only. The study qualifies as a Limited Data Set. A data use agreement may be needed when data are shared with other non-SLU entities. If necessary, the agreement can be added and uploaded in item #5, below, using DUA-external option.

With unlimited identifiers. The consent document and HIPAA Authorization form must describe how the information will be disclosed.

5. HIPAA Documentation is required for this study. Use the table below to add HIPAA Documents for your study.

HIPAA Documents

HIPAA Documents	Title	Attached Date
Waiver of Authorization	Waiver of Authorization	
HIPAA Authorization	Approved_28225 marked HIPAA Version 2	04/26/2017

\*\*\* Attachments \*\*\*

16. Attachments

In this section, please upload additional documents associated with your protocol. Failure to attach files associated with the protocol may result in the protocol being returned to you.

Possible documents for this protocol could include:

- Bibliography
- Cooperating Institution's IRB Approval
- Data Collection Sheet
- Debriefing Script
- Device Information/Documentation
- Grant Proposal/Sub-Contract
- Human Subjects Training Certificate/Proof of Training
- Information Sheet/Brochure
- Interview/Focus Group Questions
- Investigator's Brochure

- Letter of Agreement/Cooperation
- IND Application Letter
- Package Insert
- Patient Diary Form
- Questionnaire/Survey
- Recruitment Material (e.g., flyers, ads, e-mail text)
- Safety Information (DSM Information)
- Scientific/PPC Review or Department Chair Review
- Sponsor's Protocol
- Sponsor's Protocol Amendment
- Study Design Chart/Table
- Other files associated with the protocol (most standard formats accepted: pdf, jpg, tiff, mp3, wmv, etc.)

To update or revise any attachments, please delete the existing attachment and upload the revised document to replace it.

Document Type	Document Name	Attached Date	Submitted Date
Other	Spark Microgrant_Pereira	03/21/2017	03/29/2017
Bibliography	References	03/22/2017	03/29/2017
Package Insert	35-0076.A-QuantaFlo-User-Manual1	03/24/2017	03/29/2017
Device Information/Documentation	Quantaflow 510k approval	03/24/2017	03/29/2017
Device Information/Documentation	Quantaflow 510k	03/24/2017	03/29/2017
Grant Proposal/Sub-Contract	Spark Microgrant approval letter from ORS	03/24/2017	03/29/2017
Data Collection Sheet	Approved_Data sheet	04/26/2017	04/26/2017
Recruitment Material (e.g., flyers, ads, e-mail text)	Approved_ABI poster Version 3	05/02/2017	05/02/2017

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\*\*\* PI Obligations \*\*\*

PI Obligations

By clicking the box below you indicate that you accept responsibility for and will follow the ethical guidelines set forth by the Belmont Report, Declaration of Helsinki, the Nuremberg Code, and the Ethical Principles of the American Psychological Association (if applicable) for the research described. It also indicates that you have the

American Psychological Association (if applicable) for the research described. It also indicates that you have the requisite funding, credentials, training, and any necessary hospital privileges, if needed, to carry out all procedures and treatments involved in the protocol.

Clicking the box also affirms that the activities involving human subjects will not begin without prior review and approval by the Institutional Review Board, and that all activities will be performed in accordance with state and federal regulations and Saint Louis University's assurance with the Department of Health and Human Services. The PI assures that if members of the SLU research team access protected health information (PHI) from a covered entity in order to seek consent/authorization for research or to conduct research, such access is necessary for the research, is solely for that purpose, and the information will not be removed from the covered entity without IRB authorization or approved waiver. PI further assures that the SLU research team will comply with the terms of a Data Use Agreement to PHI (if any).

- 1) Have you completed the annual Conflict of Interest in Research Disclosure Form? Y

You can only select N/A if you are not currently listed on any externally funded research projects nor listed on any proposals for externally funded research support.

NOTE: An annual disclosure must be completed by all faculty, staff and students involved in the design, conduct or reporting of externally funded research applications and awards.

- 2) Have your financial interests changed significantly since you completed the annual disclosure form? N

The PRINCIPAL INVESTIGATOR certifies that he/she has read the University's Conflict of Interest Research Policy and has checked the appropriate box in the 'Potential Conflict of Interest' section of the application. In addition, the PRINCIPAL INVESTIGATOR certifies that, to the best of his/her knowledge, no person working on this project at SLU has a conflict of interest or if a conflict of interest does exist, that an appropriate management plan is in place.

According to the Saint Louis University Conflict of Interest in Research Policy, as PI, it is your responsibility to inform co-investigators, staff, or students involved in the design, conduct, or reporting of externally sponsored research of their requirement to complete a Conflict of Interest in Research Disclosure Form.

I accept this responsibility.

The Principal Investigator has read and agrees to the above certifications and will abide by the above obligations.

Protocol Title: Sensitivity and specificity of digital ankle brachial index (ABI) as a screening tool in detecting peripheral arterial disease: A single center, prospective clinical trial

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\*\*\* Event History \*\*\*

Event History

Date	Status	View Attachments	Letters
05/07/2018	REPORT 2 FORM APPROVED	Y	Y
04/26/2018	CONTINUING REVIEW 1 FORM APPROVED	Y	Y
04/26/2018	PROTOCOL EXPIRED		
04/20/2018	REPORT 2 FORM REVIEWER(S) ASSIGNED		
04/19/2018	REPORT 2 FORM PANEL MANAGER REVIEW		
04/19/2018	CONTINUING REVIEW 1 FORM REVIEWER(S) ASSIGNED		
04/19/2018	REPORT 2 FORM PANEL REASSIGNED		
04/17/2018	REPORT 2 FORM SUBMITTED (CYCLE 1)	Y	
04/09/2018	REPORT 2 FORM REVIEWER(S) ASSIGNED		
04/04/2018	CONTINUING REVIEW 1 FORM SUBMITTED	Y	
04/02/2018	REPORT 2 FORM SUBMITTED	Y	
04/02/2018	REPORT 2 FORM CREATED		
03/27/2018	CONTINUING REVIEW 1 FORM CREATED		
11/06/2017	AMENDMENT 5 FORM APPROVED	Y	Y
11/04/2017	AMENDMENT 5 FORM REVIEWER(S) ASSIGNED		
10/27/2017	AMENDMENT 5 FORM SUBMITTED	Y	
09/18/2017	AMENDMENT 5 FORM CREATED		
06/08/2017	AMENDMENT 4 FORM APPROVED	Y	Y
06/07/2017	AMENDMENT 4 FORM REVIEWER(S) ASSIGNED		
06/06/2017	AMENDMENT 4 FORM SUBMITTED	Y	
06/06/2017	AMENDMENT 4 FORM CREATED		

Protocol Title: Sensitivity and specificity of digital ankle brachial index (ABI) as a screening tool in detecting peripheral arterial disease: A single center, prospective clinical trial

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05/30/2017	AMENDMENT 3 FORM APPROVED	Y	Y
05/30/2017	AMENDMENT 3 FORM REVIEWER(S) ASSIGNED		
05/27/2017	AMENDMENT 3 FORM SUBMITTED	Y	
05/27/2017	AMENDMENT 3 FORM CREATED		
05/17/2017	AMENDMENT 2 FORM APPROVED	Y	Y
05/16/2017	AMENDMENT 2 FORM REVIEWER(S) ASSIGNED		
05/16/2017	AMENDMENT 2 FORM SUBMITTED	Y	
05/16/2017	AMENDMENT 2 FORM CREATED		
05/16/2017	REPORT 1 FORM CREATED		
05/02/2017	AMENDMENT 1 FORM APPROVED	Y	Y
05/02/2017	AMENDMENT 1 FORM REVIEWER(S) ASSIGNED		
04/28/2017	AMENDMENT 1 FORM SUBMITTED	Y	
04/28/2017	AMENDMENT 1 FORM CREATED		
04/26/2017	NEW FORM APPROVED	Y	Y
04/26/2017	NEW FORM REVIEWER(S) ASSIGNED		
04/13/2017	NEW FORM REVIEWER(S) ASSIGNED		
03/30/2017	NEW FORM PANEL ASSIGNED		
03/29/2017	NEW FORM SUBMITTED	Y	
03/29/2017	NEW FORM PREREVIEWED		
03/29/2017	NEW FORM PREAPPROVAL		
03/21/2017	NEW FORM CREATED		