Northwell Health

# RESEARCH PROTOCOL

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| Protocol Title: | Examining the Use of Three Dimensional Ultrasound in the Assessment of Vascular Pathologies |
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| Date Revised: | 26 February 2021 |
| IRB Number: | 20-1292 |

Guidelines for Preparing a Research Protocol

Instructions:

- You do not need to complete this document if you are submitting an *Application for Exemption* or *Application for a Chart Review*.
- Do not use this template if:
  - Your study involves an FDA regulated product. In this case, use the *Clinical Trial Protocol Template.*
  - Your study has a protocol from a sponsor or cooperative group. In this case, use the *Protocol Plus*.
  - Your study is a registry or repository for data and/or samples, In this case, use *Protocol Template – Registry Studies.* .
- If a section of this protocol is not applicable, please indicate such.
- Do not delete any of the text contained within this document.
- Please make sure to keep an electronic copy of this document. You will need to use it, if you make modifications in the future.
- Start by entering study information into the table above, according to these rules:
  - Protocol Title: Include the full protocol title as listed on the application.
  - Investigator: include the principal investigator's name as listed on the application form
  - Date Revised: Indicate the date at which the protocol was last revised
  - IRB Number: Indicate the assigned IRB number, when known. At initial submission, this row will be left blank.
- Once the table information in entered, proceed to page 2 and complete the rest of the form.

↓ Continue to next page to begin entering information about this study ↓

## 1. PREVIOUS STUDY HISTORY

Has this study ever been reviewed and rejected/disapproved by another IRB prior to submission to this IRB?

☒ No ☐ Yes – if yes, please explain:

## 2. BRIEF SUMMARY OF RESEARCH

- *The summary should be written in **language intelligible to a moderately educated, non-scientific layperson**.*
- *It should contain a clear statement of the rationale and hypothesis of your study, a concise description of the methodology, with an emphasis on what will happen to the subjects, and a discussion of the results.*
- *This section should be ½ page*

Peripheral arterial disease (PAD) affects approximately 10% of the American population, with 30% to 40% of these patients presenting with claudication symptoms. The prevalence of PAD increases with age and the number of vascular risk factors. More importantly, it is a marker of atherosclerotic disease burden, and is associated with increased mortality from cardiovascular and cerebrovascular causes. There have been recent advances in noninvasive imaging, endovascular approaches for revascularization, and aggressive risk factor management for prevention of cardiac and cerebrovascular complications in PAD.

Ultrasound scanning imaging systems are currently the primary choice for vascular diagnostics. After a standard vascular study, the ultrasound technologist produces a handwritten sketch that highlights various parameters (vessel size and blood flow) throughout the vasculature in question. This sketch is then interpreted by the physician who then assesses and, if need be, performs interventions. This sketch is shown to the patient to better illustrate the vascular insufficiency issues that are affecting the patient. A digital copy of the sketch is also uploaded to the patient portal.

Due to a limited field of action and poor quantification accuracy, patients are often referred for secondary scanning procedures such as computed tomography angiography, magnetic resonance angiography and catheter angiography for more detailed imaging. Referrals delay treatment, expose the patient to potential health risks and pose higher costs to healthcare providers. This can lead to poor patient compliance and avoidable hospital readmissions. This presents a need to improve the rapidity and safety of the diagnosis of vascular conditions in patients to enable rapid treatment of conditions such as peripheral artery disease. There is also a need for cost effective preventative screening and surveillance to enable early intervention, for example, people at high risk of limb amputation.

The ability to have a visual aid to depict areas of vascular disease that are affecting the patient's health can help in patient comprehension of the problem. This comprehension can lead to better understanding of the issue and increase patient compliance to treatment. The hand drawn sketch produced by the ultrasound technologist provides an inadequate visualization of the vascular insufficiency that is causing the patient's symptoms.

PIUR imaging has developed PIUR Infinity tUS, a 3D freehand tomographic ultrasound system capable of rapid, safe and accurate reconstructive 3D quantifiable vascular imaging. This system will provide a low cost and reproducible imaging solution that will be an effective educational tool for people with vascular disease.

## 3. INTRODUCTION/BACKGROUND MATERIAL/PRELIMINARY STUDIES AND SIGNIFICANCE

- *Describe and provide the results of previous work by yourself or others, including animal studies, laboratory studies, pilot studies, pre-clinical and/or clinical studies involving the compound or device to be studied.*
- *Include information as to why you are conducting the study and how the study differs from what has been previously researched, including what the knowledge gaps are.*
- *Describe the importance of the knowledge expected to result*

The PIUR tUS Imaging System has been approved for use in the European Union for over 1 year. Studies performed in Europe have highlighted the system's ability to accurately depict various pathologies in a 3D form. Currently, there is no market equivalent of this technology approved by the FDA for use in the United States. We are conducting this study to determine whether the 3D images created by the device shown to patients can be used as an educational tool to increase patient comprehension of the disease process, compared with the standard of care 2D images. This will be measured in terms of compliance with follow-up appointments and 30-day readmission rates.

## 4. OBJECTIVE(S)/SPECIFIC AIMS AND HYPOTHESES

- *A concise statement of the goal(s) of the current study.*
- *The rationale for and specific objectives of the study.*
- *The goals and the hypothesis to be tested should be stated.*

The objective of this study is to compare readmission rates and compliance with follow-up appointments among patients who are shown the 3D rendering of their ultrasound compared with a historical cohort of patients who viewed 2D based sketches of their vasculature. We hypothesize that patients receiving the 3D ultrasound would have higher compliance with follow-up appointments and lower

readmission rates compared with patients who did not have a 3D rendering of their study created because patients in the 3D subset would be better able to visualize their affected blood vessels and understand disease severity.

## 5. RESOURCES AVAILABLE TO CONDUCT THE HUMAN RESEARCH

- *Explain the feasibility of meeting recruitment goals of this project and demonstrate a potential for recruiting the required number of suitable subjects within the agreed recruitment period*
    - *How many potential subjects do you have access to?*
- *Describe your process to ensure that all persons assisting with the trial are adequately informed about the protocol and their trial related duties and functions*

The wound center has a vascular suite in which 10-15 vascular ultrasound tests are performed on a daily basis. The vascular suite has its own ultrasound machine. Potential subjects will be recruited from the pool of patients who have been scheduled to undergo ultrasound testing of their vasculature.
The ultrasound technologists will be instructed in how to use the device. The method and technique of performing the test will not be altered in any way. The tech will perform the standard vascular testing as designated by the clinician who ordered the test.

## 6. RECRUITMENT METHODS

- *Describe the source of potential subjects*
- *Describe the methods that will be used to identify potential subjects*
- *Describe any materials that will be used to recruit subjects. A copy of any advertisements (flyers, radio scripts, etc.) should be submitted along with the protocol.*
- *If monetary compensation is to be offered, this should be indicated in the protocol*

Participants will be recruited from the wound center's patient population. The wound center's vascular suite performs 10-15 ultrasound studies on a daily basis. These patients are experiencing symptoms of vascular insufficiency. There are various anatomical locations that are studied with ultrasound and therefore subjects will be grouped for analysis. These patients will be approached to enroll in the study. No materials will be used to recruit subjects. Subjects will not be offered compensation to participate.

## 7. ELIGIBILITY CRITERIA

- *Describe the characteristics of the subject population, including their anticipated number, age, ranges, sex, ethnic background, and health status. Identify the criteria for inclusion or exclusion of any subpopulation.*
- *Explain the rationale for the involvement of special classes of subjects, such as fetuses, pregnant women, children, prisoners or other institutionalized individuals, or*

*others who are likely to be vulnerable. You cannot include these populations in your research, unless you indicate such in the protocol*

- *Similarly, detail exclusionary criteria: age limits, special populations (minors, pregnant women, decisionally impaired), use of concomitant medications, subjects with other diseases, severity of illness, etc.*

INTERVENTIONAL COHORT:
Inclusion:

- Age 18 years of age or older
- Suspected vascular insufficiency that requires ultrasound evaluation
- Subject is able to sign a consent form
- Scheduled ultrasound testing at the wound center to evaluate vasculature

Exclusion:

- Younger than 18 years old
- Subject is not scheduled to have ultrasound testing at the wound center
- Subject is unable to or refuses to consent to participate

RETROPECTIVE COHORT:
Inclusion:

- Age 18 years of age or older
- Subjects who have undergone vascular ultrasound testing at the wound center
- Ultrasound tests performed from 1/1/2019-12/31/2019
- Subjects who were followed by the wound center team after undergoing ultrasound testing for vascular insufficiency

Exclusion:

- Younger than 18 years old
- Subjects who underwent testing outside the above mentioned timeframe
- Subjects who were not followed by the wound center team after undergoing ultrasound testing for vascular insufficiency

## 8. NUMBER OF SUBJECTS

- *Indicate the total number of subjects to be accrued locally. If applicable, distinguish between the number of subjects who are expected to be pre-screened, enrolled (consent obtained), randomized and complete the research procedures.*
- *If your study includes different cohorts, include the total number of subjects in each cohort.*
- *If this is multisite study, include total number of subjects across all sites.*

The total number of subjects we plan to enroll is 270. We plan to enroll 135 subjects into the 3D imaging cohort of this study. Another 135 patients will be identified retrospectively for the historical cohort.

The sample size calculation was based on the primary outcome of 30-day readmission. We assumed a readmission rate of 10% in the 2D group and a readmission rate of 2% in the 3D group. We would need 135 patients in each group to have 80% and a confidence level of 95% to detect this difference.

## 9. STUDY TIMELINES

- *Describe the duration of an individuals participation in the study*
- *Describe the duration anticipated to enroll all study subjects*
- *The estimated date of study completion*

The duration of an individual's participation will last as long as it takes to perform their scheduled ultrasound testing. Ultrasound testing usually takes no more than 30 minutes. Enrolled subject's EMR will be reviewed for 6 months after they undergo the ultrasound testing. We anticipate it will take 6-8 months to enroll all study subjects.

## 10. ENDPOINTS

- *Describe the primary and secondary study endpoints*
- *Describe any primary or secondary safety endpoints*

The primary endpoint of the study will be the treatment outcomes for the patients. We will review readmission rates (30 days from the day of the ultrasound) as well as compliance to first follow-up appointment after the ultrasound of interventional cohort. These endpoints will be compared to those of a historical cohort of persons who were treated for similar pathologies in the past.

## 11. RESEARCH PROCEDURES

- *Include a detailed description of all procedures to be performed on the research subject and the schedule for each procedure.*
- *Include any screening procedures for eligibility and/or baseline diagnostic tests*
- *Include procedures being performed to monitor subjects for safety or minimize risks*
- *Include information about drug washout periods*
- *If drugs or biologics are being administered provide information on dosing and route of administration*
- *Clearly indicate which procedures are only being conducted for research purposes.*
- *If any specimens will be used for this research, explain whether they are being collected specifically for research purposes.*
- *Describe any source records that will be used to collect data about subjects*
- *Indicate the data to be collected, including long term follow-up*

The imaging device acts as an attachment to a standard ultrasound machine. The device has 2 parts. The first is a sensor which clips onto the side of the ultrasound probe. The sensor does not come into contact with the subject. This sensor then wirelessly transmits positional data to a TV box that is connected to the ultrasound's CPU. After completion of the test, this box analyzes data from the sensor and images from the ultrasound and renders a 3 dimensional model of the vasculature that was studied in the test.

The ultrasound technologist performs a standard vascular testing examination. No additional or alternative procedure and/or actions are required for the device to develop its image.

Additional data (demographics, past medical history, etc) will be garnered from the subject's EMR and stored in a password protected REDCap database. The images developed by the device will be saved on a laptop that is used exclusively for this research study.

## 12. STATISTICAL ANALYSIS

- *Describe how your data will be used to test the hypotheses.*
- *State clearly what variables will be tested and what statistical tests will be used.*
- *Include sample size calculations.*
- *If this is a pilot study, state which variables will be examined for hypothesis generation in later studies.*

Patients who consent to have 3D imaging of their study rendered will be shown the computer animation in addition to the handwritten sketch traditionally used by vascular surgeons. We will then compare outcomes such as 30-day re-admission rates and compliance to follow-up appointments. Ultrasound types will be grouped for analysis (lower extremity to lower extremity, upper extremity to upper extremity, etc).

The primary analysis will compare the proportion of patients readmitted within 30 days of their ultrasound among those who received the 3D ultrasound vs. those who received the 2D ultrasound using a chi-square test. We will also compare the proportion of patients who showed up for their follow-up appointment among those who received the 3D ultrasound vs. those who received the 2D ultrasound using a chi-square test. We will assess for differences in baseline characteristics and factors known to be associated with readmission and compliance with follow-up among the two groups. If warranted, we will adjust for these differences using multivariable regression models.

## 13. SPECIMEN BANKING

- *If specimens will be banked for future research, describe where the specimens will be stored, how long they will be stored, how they will be accessed and who will have access to the specimens*
- *List the information that will be stored with each specimen, including how specimens are labeled/coded*
- *Describe the procedures to release the specimens, including: the process to request release, approvals required for release, who can obtain the specimens, and the information to be provided with the specimens.*

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| N/A |

## 14. DATA MANAGEMENT AND CONFIDENTIALITY

- *Describe the data and specimens to be sent out or received. As applicable, describe:*
  - *What information will be included in that data or associated with the specimens?*
  - *Where and how data and specimens will be stored?*
  - *How long the data will be stored?*
  - *Who will have access to the data?*
  - *Who is responsible for receipt or transmission of data and specimens?*
- *Describe the steps that will be taken to secure the data during storage, use and transmission.*

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| Imaging data will be stored on a secure laptop sourced specifically for use in this study. This laptop will require an advanced graphics card and CPU to accommodate for the vast amount of data processed by the device. Software for processing and visualizing the 3D model will be pre-loaded into the laptop. Only study personnel will have access to this laptop. Additional data may be obtained from the subject's EMR. This will include but not limited to: demographics, past medical history, past radiologic findings, etc. Data will be stored on a password protected REDCap database accessible only to research personnel. Data will be stored for 7 years. |

## 15. DATA AND SAFETY MONITORING PLAN

*A specific data and safety monitoring plan is only required for greater than minimal risk research. For guidance on creating this plan, please see the* Guidance Document *on the HRPP website.*

*Part I – this part should be completed for all studies that require a DSMP.*
*Part II – This part should be completed when your study needs a Data and Safety Monitoring Board or Committee (DSMB/C) as part of your Data and Safety Monitoring Plan.*

Part I: Elements of the Data and Safety Monitoring Plan

- *Indicate who will perform the data and safety monitoring for this study.*
- *Justify your choice of monitor, in terms of assessed risk to the research subject's health and well being. In studies where the monitor is independent of the study staff, indicate the individual's credentials, relationship to the PI, and rationale for selection*
- *List the specific items that will be monitored for safety (e.g. adverse events, protocol compliance, etc)*
- *Indicate the frequency at which accumulated safety and data information (items listed in # above) will be reviewed by the monitor (s) or the DSMB/C.*
- *Where applicable, describe rules which will guide interruption or alteration of the study design.*
- *Where applicable, indicate dose selection procedures that will be used to minimize toxicity.*
- *Should a temporary or permanent suspension of your study occur, in addition to the IRB, indicate to whom will you report the occurrence.*

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| N/A |

Part II: Data and Safety Monitoring Board or Committee

- *When appropriate, attach a description of the DSMB.*
- *Provide the number of members and area of professional expertise.*
- *Provide confirmation that the members of the board are all independent of the study.*

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| N/A |

## 16. WITHDRAWAL OF SUBJECTS

- *Describe anticipated circumstances under which subjects will be withdrawn from the research without their consent*
- *Describe procedures for orderly termination*
- *Describe procedures that will be followed when subjects withdraw from the research, including partial withdrawal from procedures with continued data collection.*

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| We do not anticipate any circumstances in which a subject will be withdrawn from the research without their consent. Once the ultrasound testing is complete, in-person participation is done. We will continue to collect data from the subject's medical record for the next 6 months. If subjects choose not to participate with the study, they will undergo their prescribed ultrasound testing but no 3D data will be recorded. |

## 17. RISKS TO SUBJECTS

- *Describe any potential risks and discomforts to the subject (physical, psychological, social, legal, or other) and assess their likelihood and seriousness and whether side effects are reversible. Where appropriate, describe alternative treatments and procedures that might be advantageous to the subjects.*
- *Include risks to others , like sexual partners (if appropriate)*

- *Discuss why the risks to subjects are reasonable in relation to the anticipated benefits and in relation to the importance of the knowledge that may reasonably be expected to results*
- *Describe the procedures for protecting against or minimizing any potential risks, including risks to confidentiality, and assess their likely effectiveness.*

There are no additional physical risks to subjects participating in this study. The device in question attaches to the ultrasound probe. The participant will undergo a standard ultrasound exam to evaluate their vasculature. The ultrasound technologist will not perform any specific or unique testing maneuvers for the sake of the device. The ultrasound technologist will be performing the standard of care ultrasound exam, and the device will create 3D images of the vasculature based on the ultrasound exam. The patient and ultrasound technologist do not have to do anything differently. The only risk in this study is breach of confidentiality. All precautions and procedures will be undertaken to prevent such an occurrence. Only study personnel will have access to the data which will be under password protection. This minimal risk is appropriate for the potential knowledge gained by obtaining a 3D image of the subject's diseased vasculature

## 18. RESEARCH RELATED HARM/INJURY

- *Describe the availability of medical or psychological resources that subjects might need as a result of anticipated problems that may be known to be associated with the research.*
- *If the research is greater than minimal risk, explain any medical treatments that are available if research-related injury occurs, who will provide it, what will be provided, and who will pay for it.*

This is a minimal risk study. The participant will face no greater risk than those posed by undergoing ultrasound testing for vascular diseases.

## 19. POTENTIAL BENEFIT TO SUBJECTS

- *Explain what benefits might be derived from participation in the study, noting in particular the benefit over standard treatment (e.g. a once-a-day administration instead of four times a day, an oral formulation over an IV administration).*
- *Also state if there are no known benefits to subjects, but detail the value of knowledge to be gained*

The subject has the potential to have immediate impact from participation. They will be able to view the 3D rendering of their vasculature and their clinician will be able to highlight areas of vascular disease if any. The ability to view the disease process in a 3D model of their own vessels might increase compliance with

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| treatment (i.e. demonstrating stenosis of a vessel). This is a more detailed and informative picture than what is provided by standard ultrasound studies. |

## 20. PROVISIONS TO PROTECT PRIVACY INTERESTS OF SUBJECTS

- *Describe the methods used to identify potential research subjects, obtain consent and gather information about subjects to ensure that their privacy is not invaded.*
- *In addition consider privacy protections that may be needed due to communications with subjects (such as phone messages or mail).*

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| Potential research subjects will be identified from the patient pool scheduled to undergo ultrasound testing at the wound center. Participant data will not be collected until the subject is consented. Study personnel will not have to communicate with subjects once their imaging study is complete. |

## 21. COSTS TO SUBJECTS

- *Describe any foreseeable costs that subjects may incur through participation in the research*
- *Indicate whether research procedures will be billed to insurance or paid for by the research study.*

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| Participants will not incur any costs for enrolling in the study. |

## 22. PAYMENT TO SUBJECTS

- *Describe the amount of payment to subjects, in what form payment will be received and the timing of the payments.*

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| Participants will not be compensated for enrolling in the study. |

## 23. CONSENT PROCESS

*If obtaining consent for this study, describe:*

- *Who will be obtaining consent*
- *Where consent will be obtained*
- *Any waiting period available between informing the prospective participant and obtaining consent*
- *Steps that will be taken to assure the participants' understanding*
- *Any tools that will be utilized during the consent process*

- *Information about how the consent will be documented in writing. If using a standard consent form, indicate such.*
- *Procedures for maintaining informed consent.*

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| Consent will occur prior to the participant undergoing their ultrasound testing. The consenting will be performed by the PI or study coordinators when the patient is in the vascular suite. This is a private area where the patient will be able to ask questions and/or raise any concerns. The standard Northwell Health minimal risk consent form template will be utilized. |

*In the state of NY, any participants under the age of 18 are considered children. If your study involves children, additional information should be provided to describe:*

- *How parental permission will be obtained*
- *From how many parents will parental permission be obtained*
- *Whether permission will be obtained from individuals other than parents, and if so, who will be allowed to provide permission. The process used to determine these individual's authority to consent for the child should be provided*
- *Whether or not assent will be obtained from the child*
- *How will assent be documented*
- *Whether child subjects may be expected to attain legal age to consent to the procedures for research prior to the completion of their participation in the research. If so, describe the process that will be used to obtain their legal consent to continue participation in the study. Indicate what will occur if consent is not obtained from the now-adult subjects.*

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| N/A |

*If the study involves cognitively impaired adults, additional information should be provided to describe:*

- *The process to determine whether an individual is capable of consent*
- *Indicate who will make this assessment*
- *The plan should indicate that documentation of the determination and assessment will be placed in the medical record, when applicable, in addition to the research record.*
- *If permission of a legally authorized representative will be obtained,*
  - *list the individuals from who permission will be obtained in order of priority*
  - *Describe the process for assent of subjects; indicate whether assent will be required of all, some or none of the subjects. If some, which subjects will be required to assent and which will not.*
  - *If assent will not be obtained from some or all subjects, provide an explanation as to why not*
  - *Describe whether assent will be documented and the process to document assent*

- *Indicate if the subject could regain capacity and at what point you would obtain their consent for continued participation in the study*

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| N/A |

*If the study will enroll non-English speaking subjects:*

- *Indicate what language(s) other than English are understood by prospective subjects or representatives*
- *Indicate whether or not consent forms will be translated into a language other than English*
- *Describe the process to ensure that the oral and written information provided to those subjects will be in that language*
- *If non-English speaking subjects will be excluded, provide a justification for doing so*

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| Spanish consents will be made available for potential subjects who are Spanish-speaking. |

## 24. WAIVER OR ALTERATION OF THE CONSENT PROCESS ☐ N/A

***Complete this section if you are seeking an alteration or complete waiver of the consent process.***

- *Describe the possible risks of harm to the subjects involved in this study and explain why the study involves no more than minimal risk to the subject:*
- *Explain why the waiver/ alteration will not adversely affect the rights and welfare of subjects*
- *Explain why it is impracticable to conduct this research if informed consent is required*
- *Explain why it is not possible to conduct this research without using the information or biospecimens in an identifiable form*
- *If appropriate, explain how the subjects will be provided with additional pertinent information after participation. If not appropriate to do so, explain why.*

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| In regards to the RETROSPECTIVE COHORT:<br><br>This study poses minimal risk of harm to subjects within this cohort as the intervention to be studied has already occurred. The subject consented to undergoing the vascular study at that time. Our research team will access these subject charts to collect information regarding the results and outcomes of these subjects after their vascular studies were performed.<br><br>The waiver of consent will not adversely affect subject's rights and welfare because there is no clinical intervention and/or assessment being made on these subjects. The intervention in question has already been performed on the |

subject to which they consented to at the time of the procedure. Inclusion in the study will not affect their care in any form.

Requiring informed consent for this cohort would be impracticable because many subjects who qualify for this cohort are no longer under the care of the researchers. In addition, tracking down and locating these subjects in order to have a consent form delivered and signed would create a significant logistical challenge. Finally, the creation of a consent form would then create the only traceable paper trail linking the subjects to the study. All other records of these subjects are digitized and will be accessed via EMR.

Identifiable information is required to perform the data collection. To ensure accuracy and quality of the data, subject records may be accessed more than once. Once the data collection phase is complete, all identifiers will be permanently erased from the database. The final dataset to be analyzed will not contain any PHI.

Subjects in this cohort will not be provided with any information after participation because no findings will directly affect their care. They have already undergone ultrasound testing. Any findings from our study will have no direct benefit to subjects within this cohort.

***Complete this section if you are obtaining informed consent but you are requesting a waiver of the documentation of consent (i.e., verbal consent will be obtained).*** *To proceed with a waiver based on these criteria, each subject must be asked whether they wish to have documentation linking them to this study.* ***Only complete subsection 1 OR subsection 2.***

**SUBSECTION 1**

- *Explain how the only record linking the subject to the research would be the consent document.*
- *Explain how the principal risk of this study would be the potential harm resulting from a breach in the confidentiality*
- *Indicate whether or not subjects will be provided with a written statement regarding the research.*

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| N/A |

**SUBSECTION 2**

- *Describe the possible risks of harm to the subjects involved in this study and explain why the study involves no more than minimal risk.*
- *Confirm that the research only involves procedure for which consent is not normally required outside the research context.*
- *Indicate whether or not subjects will be provided with a written statement regarding the research.*

N/A

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## 25. WAIVER OF HIPAA AUTHORIZATION ☐ N/A

***Complete this section if you seek to obtain a full waiver of HIPAA authorization to use and/or disclose protected health information.***

- *Describe the risks to privacy involved in this study and explain why the study involves no more than minimal risk to privacy:*
- *Describe your plan to protect identifiers from improper use or disclosure and to destroy them at the earliest time.*
- *Indicate why it is not possible to seek subjects' authorization for use or disclosure of PHI.*
- *Indicate why it is not possible to conduct this research without use or disclosure of the PHI.*
- *Indicate if PHI will be disclosed outside NSLIJ Health System, and if so, to whom. Note: PHI disclosed outside NSLIJ Health System, without HIPAA authorization needs to be tracked. Please see guidance at www.nslij.com/irb for information about tracking disclosures.*

In regards to the RETROSPECTIVE COHORT:

This study involves the use of data from clinical records. Patient identifiers are only needed for accurate data acquisition and tracking of outcomes. Once the data is completely abstracted, it will be de-identified. Patient privacy is protected by the anonymity of the data.

All data will be handled by only the study staff responsible for abstraction. After that it will be de-identified. Data will be stored on password protected databases housed on institutional servers. Only research personnel will have access to the database. Once accuracy of the data is verified, subjects will be assigned study IDs, and identifiers will be deleted.

Identifiers are used only during the abstraction period to access the medical records to conduct the study.

Consent to use PHI is not possible as this study only requires PHI to track and obtain additional data from Northwell EMR. Once data collection is complete, all PHI will be destroyed from the database. No PHI will be disclosed to third parties.

PHI is required to locate additional information from subject EMR.
No PHI will be disclosed to outside 3rd parties.

***Complete this section if you seek to obtain a partial waiver of the patient's authorization for screening/recruitment purposes*** *(i.e., the researcher does not have access to patient records as s/he is not part of the covered entity)*

*Note: Information collected through a partial waiver for recruitment cannot be shared or disclosed to any other person or entity.*

- *Describe how data will be collected and used:*
- *Indicate why you need the PHI (e.g.PHI is required to determine eligibility, identifiers are necessary to contact the individual to discuss participation, other)*
- *Indicate why the research cannot practicably be conducted without the partial waiver (e.g. no access to medical records or contact information of the targeted population, no treating clinician to assist in recruitment of the study population, other)*

## 26. VULNERABLE POPULATIONS:

Indicate whether you will include any of these vulnerable populations. If indicated, submit the appropriate appendix to the IRB for review:

- ☐ *Children or viable neonate*
- ☐ *Cognitively impaired*
- ☐ *Pregnant Women, Fetuses or neonates of uncertain viability or nonviable*
- ☐ *Prisoners*
- ☐ *NSLIJ Employees, residents, fellows, etc*
- ☐ *poor/uninsured*
- ☐ *Students*
- ☐ *Minorities*
- ☐ *Elderly*
- ☐ *Healthy Controls*

*If any of these populations are included in the study, describe additional safeguards that will be used to protect their rights and welfare.*

N/A

## 27. MULTI-SITE HUMAN RESEARCH (COORDINATING CENTER)

*If this is a multi-site study where you are the lead investigator, describe the management of information (e.g. results, new information, unanticipated problems involving risks to subjects or others, or protocol modifications) among sites to protect subjects.*

This is not a multi-site study.

## 28. REFERENCES/BIBIOGRAPHY

*Provide a reasonable list of references directly related to the study. Any diagrams for new medical devices or brief reprints from journals might also prove useful.*

Rogers S, Carreira J, Phair A, Olech C, Ghosh J, McCollum C. Comparison Between Below Knee Contrast Enhanced Tomographic 3D Ultrasound and CT, MR or Catheter Angiography for Peripheral Artery Imaging. Eur J Vasc Endovasc Surg. 2020 Nov 20:S1078-5884(20)30913-8. doi: 10.1016/j.ejvs.2020.10.007. Epub ahead of print. PMID: 33229220.