KENNESAW STATE UNIVERSITY
OFFICE OF RESEARCH
Research Compliance

INSTITUTIONAL REVIEW BOARD APPLICATION

Review the IRB website for information about what type of IRB review applies to your study (https://research.kennesaw.edu/irb/review-classifications.php)

Review type:

___Check here for a Request for Exemption

__X_Check here for an Expedited Review [IRB Reviewers may recommend a Full Board Review]

Status of Primary Investigator:

_X__Faculty ___Staff ___Student

Students as the Primary Investigator (PI) and their Faculty Advisors

Students (graduate and undergraduate) must have a faculty advisor complete the last page of this form and submit all documents from the faculty advisor's KSU email address. Students must also use their KSU email address in all IRB correspondence.

By submitting this form, you agree that you have read KSU's Federal-wide Assurance of Compliance and agree to provide for the protection of the rights and welfare of your research participants as outlined in the Assurance. You also agree to submit any significant changes in the procedures of your project to the IRB for prior approval and agree to report to the IRB any unanticipated problems or adverse events involving risks to subjects or others.

Title of Research

The Phoenix Sign: Is it due to vasodilation? Blinded prospective comparing the effects of papaverine to lidocaine without epinephrine

Start Date is date of IRB approval *Proposed start date*: ____3/1/2020_____

***The official start date for research is the date the IRB approval letter is issued. Research activities may not begin prior to final IRB approval. Studies should be submitted well in advance of the proposed start date to allow for processing, review, and approval. If you have not received a letter from the IRB in 10 business days of submission, please call or email requesting status update.**

Is your research being funded in any way? ___Yes* __X_ No

*Where is the funding coming from? [Name of Federal Agency/Foundation/Department]

If you have obtained funding, please submit your award documentation along with this application.

Primary Investigator

All IRB correspondence goes only to the primary investigator (PI) and advisors are copied on student projects.

Name:

Stephen L. Barrett, D.P.M., FACFAS FAENS

Department:

Molecular and Cellular Biology

Telephone: Email: sbarre52@kennesaw.edu

832-524-7254

FOR RESEARCH CONDUCTED BY STUDENTS AS THE PRIMARY INVESTIGATOR, GO TO THE LAST PAGE OF THE APPLICATION FORM TO ENTER REQUIRED FACULTY ADVISOR INFORMATION.

Co-Investigator(s) who are faculty, staff, or students at KSU

Name: Kerry McCardel Email: kmccard1@students.kennesaw.edu	____Faculty ____Staff __X__Student
Name: Destiny Page Email: dpaige2@students.kennesaw.edu	____Faculty ____Staff __X__Student
Name: Cynney Walters Email: cwalte43@students.kennesaw.edu	____Faculty ____Staff __X__Student
Additional Names (include status and email): Adam Kahn Student akhan42@students.kennesaw.edu	

Co-Investigator(s) who are NOT employees or students at KSU: Please submit your human participants training certificate with application materials.

Name: Sequioa DuCasse, D.P.M., MS Email: sducasse.dpm@gmail.com Home Institution: US Neuropathy Centers, LLC
Name: Porscha Bailey, D.P.M. Email: porschaba@gmail.com Home Institution: US Neuropathy Centers, LLC
Additional Names (include email and home institution): Nia Mitchell US Neuropathy Centers LLC nia.m.mitchell@gmail.com

ALL researchers listed on this application MUST have completed CITI training BEFORE an IRB Approval will be provided.

Visit http://research.kennesaw.edu/irb/citi-training.php for additional information about CITI training, how to choose the right course, and how to create a profile. ALL KSU faculty/staff/students MUST use their KSU provided email address on all correspondence.

NOTE: It is each researcher's responsibility to ensure that the CITI Certificate does not expire during the course of the approved study. Failure to maintain a current certificate will invalidate your approval. Please use your KSU email address on your CITI profile and make sure your profile name matches the one provided above.

Does your research involve minors? ___Yes __X_No
See item number 5 below for parental consent and minor assent information. See http://research.kennesaw.edu/irb/consent-templates.php for forms and information.

Will this research involve COLLABORATION with ANOTHER INSTITUTION?

___Yes __X_No, go to question 1

If yes, provide the name of the Institution _____

Has the other Institution conducted an IRB review of the study?

___No ___Yes – Send that review with this approval form to the KSU IRB.

1. Prior Research

Have you submitted research on this topic to the KSU IRB previously? _X__Yes* ___ No

*If yes, list the date, title, name of investigator, and study number:

Study 20-143: Sonographically Guided Infiltration of Low dose infiltration of 1% lidocaine as a Predictor for the Efficacy of Surgical Peripheral Nerve Decompression 11/6/2019 PI: Stephen L. Barrett, D.P.M.

See http://research.kennesaw.edu/irb/application-tips.php for detailed explanations of questions 2-8. Provide complete sentences with sufficient information for an IRB review.

2. Description of Research

a. Purpose of and anticipated findings for this study:

A neurological phenomenon has been observed clinically that when after a small amount of 1% lidocaine (usually less than .5cc's) has been infiltrated adjacent to the Common Fibular (Peroneal) nerve under sonographic guidance, in patients with drop foot, or significantly weakened motor potentials of the lower extremity dorsiflexors (Extensor Hallucis Longus (EHL), Tibialis Anterior (TA), and Extensor Digitorum Longus (EDL)), the patient will regain partial or full dorsiflexion temporarily during the effect of this nerve block. This has been named the Phoenix Sign, in reference to

ancient Greek folklore, as the non-functioning nerve (like the bird) becomes functional due to the effect of lidocaine, similar in a way that the mythical bird rose from the ashes. This sign has significant benefit to the diagnosis and assessment of Common Fibular (Peroneal) nerve palsy as clinically when a nerve does not manifest a Tinel's or Provocation sign it is believed that the nerve damage is so severe that peripheral nerve decompression will not likely benefit the patient. However, when a patient manifests a "positive Phoenix sign" the prognosis has been greater than 90%--that the patient will gain improvement in motor function of the dorsiflexors of the lower extremity after surgical decompression. Thus, many patients with this crippling condition are not receiving definitive treatment because of the inability of standard clinical work-up and diagnosis. A "positive Phoenix sign" also differentiates a focal nerve compression peripherally versus a central CNS manifestation. It is hypothesized that this observation of improved nerve function is due to the vasodilatory nature of the local anesthetic. By comparing the block given with lidocaine versus papaverine (a known vasodilator), the vasodilation hypothesis can be tested. The purpose of this study is to help determine if this is a valid explanation for the phenomenon.

b. Nature of data to be collected (interview (includes focus groups), online or hardcopy survey, observations, experimental procedures, etc.):

This study is doubly blinded so that the clinician and the patient do not know what infiltrate is being used. They will be consented to have either an infiltration of lidocaine, or papaverine. All of these compounds are FDA approved for human use, and all are commonly used in clinical practice. If the "Phoenix Sign" is observed in the both the lidocaine and papaverine arms it would provide compelling evidence that this phenomenon is due to the vasodilation effect of the local anesthetic. A comparison could lend credence to solely using papaverine clinically.

Data that will be collected:

1. Pre-infiltration EHL, TA and EHL strength assessment as measured clinically on a 1-5/5 scale and with a dynamometer.
2. Pre-infiltration pain assessment as measured on a 1-10 VAS pain scale
3. Post-infiltration at 4 minutes after injection EHL, TA and EHL strength assessment as measured clinically on a 1-5/5 scale and with a dynamometer
4. Post-infiltration pain assessment as measured on a 1-10 VAS pain scale
5. Length of duration of the effect-if any

c. Data collection procedures: (include information on how consent will be obtained, how links will be provided, where interviews will be conducted, audio or video taping, etc.). Note: student email addresses are FERPA protected. Student email addresses, grades, or work cannot be collected without student consent and IRB approval.

Informed Consent will be obtained in the clinical setting from patients

d. Survey instruments to be used (pre-/post-tests, interview and focus group questionnaires, online surveys, standardized assessments etc.). Attach all survey instruments with your application document):

e. Method of selection/recruitment of participants:
Refer to the KSU Mass Email policy on the use emails to faculty/staff. For student recruitment via email, please also follow these mandatory instructions. ALL recruitment materials (flyers, emails, posters, etc.) MUST include your IRB Approval Study # and a statement that your study has been reviewed and approved by KSU's IRB.

Subjects will be recruited from our existing clinical practice.

f. Participant age range: __18-85__ Number: _20___

Sex: __Males __ Females or 20__Both

g. Incentives, follow-ups, compensation to be used: (e.g., Gift cards, course credit, etc.). Please visit HERE on our website for guidelines on participant incentive payments.

No incentives will be given to the subjects

3. Risks

Describe in detail any psychological, social, legal, economic, or physical risk that might occur to participants. *Note that all research may entail some level of risk, though perhaps minimal.* According to the federal regulations at **§46.102(i)**, *minimal risk* means that the probability **and** magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

_X_ There is minimal risk (if selected, must be reflected within consent documents)

__ There is more than minimal risk (requires full explanation below and in consent documents)

Anticipated risks include (if selected, specific potential risks must be incorporated into the consent documents):

If more than minimal risk is anticipated, describe your method for handling risk.

4. Benefits

Federal Guidelines and University policy require that risks from participation be outweighed by potential benefits to participants and/or humankind in general.

a. Identify potential benefits to participants resulting from this research (It is possible that there are no direct benefits or *possible* specific benefits, either must be reflected in the consent documents):

As a positive "phoenix sign" is highly predictive of a positive result after surgical peripheral nerve decompression surgery the subject will have the benefit of an additional level of diagnosis and assessment of their particular level of nerve status or function.

b. Identify benefits to humankind in general resulting from this research. While there may be no potential benefits to participants there must be some benefit to humankind in order to receive IRB approval. Please include these benefits in the consent documents:

There are many patients who suffer from drop foot due to an entrapment of the Common Fibular (Peroneal) nerve who are told that there is nothing that can be done for them to restore their function, and that only bracing with an ankle foot orthosis can be done. Drop foot is a crippling condition, that in many cases can be completely reversed, that subjects the patient to not only a decreased quality of life, but increased falls—which have a very high level of mortality in the aging population. Validation of the hypothesis could lead to wider clinical implementation affording patients additional diagnostic data.

5. Informed Consent

All studies of human participants must include informed consent (see IRB approved templates). Consent may require a signature or may simply require that participants be informed. Minor participants must receive an assent form in conjunction with parental consent (see IRB approved templates). If deception is necessary, please justify and describe, and submit debriefing procedures.

What is the consent process to be followed in this study? Submit your consent form(s) with the application as a separate document(s).

See attached consents

6. Online Surveys (For all electronic surveys, you must submit a link to the final version of the survey.)

Will you use an online survey to obtain data from human participants in this study?
Check all that apply.

_X_ No. If no, skip to Question 7 below.

__Yes, I will use an online survey to obtain data in this study. If yes:

a. How will **online data** be collected and handled? Select one and add the chosen statement to your consent document.

__ Data collected online will be handled in an anonymous manner and Internet Protocol addresses **WILL NOT** be collected by the survey program.

__ Data collected online will be handled in a confidential manner (identifiers will be used), but Internet Protocol addresses **WILL NOT** be collected by the survey program.

__ Data collected online will be handled in a confidential manner and Internet Protocol addresses **WILL** be collected by the survey program.

b. Include an "I agree to participate" **and** an "I do not agree to participate" answer at the bottom of your consent document. Program the "I do not agree to participate" statement to exclude the participant from answering the remainder of the survey questions (this is accomplished through "question logic" in Survey Monkey or "skip logic" in Qualtrics).

Ensure that the online consent document is the first page the participant sees after clicking on the link to your online survey.

Although you may construct your own consent document, see the IRB approved Online Survey Cover Letter template (http://research.kennesaw.edu/irb/consent-templates.php), which contains all of the required **elements of informed consent** that must be addressed within any online consent document.

7. Vulnerable Participants

Will minors or other vulnerable participants (e.g., prisoners, pregnant women, those with intellectual disabilities) be included in this research?

__Yes. Outline procedures to be used in obtaining the agreement (parental consent, assent or guardian consent) for vulnerable participants. Describe plans for obtaining consent of the parent, guardian, or authorized representative of these participants. For research conducted within the researcher's own classroom, describe plans for having someone other than the researcher obtain consent/assent so as to reduce the perception of coercion.

_X_ No. All studies excluding minors as participants should include language within the consent document stating that only participants aged 18 and over may participate in the study.

8. Future Risks

How are participants protected from the potentially harmful future use of the data collected in this research?

a. Describe measures planned to ensure anonymity or confidentiality. Studies can only be considered completely anonymous if no identifying information is collected; therefore, a cover letter must be used in place of a signed consent form.

At the time a person becomes a patient in our practice, they are offered the opportunity to be part of clinical research. They also have the option to not participate. The form is attached that they are given at the time of them becoming a new patient. If they give this general consent, they allow us to report data without anonymity, but will have additional informed consent for this study. That consent is attached with this application

b. Describe methods for storing data while study is underway. Personal laptops are not considered secure.

Data will be kept in our encrypted electronic medical record keeping system, and patient data will only be referenced to by non-identifying initials, age, and sex in any reporting of the data.

c. List dates and plans for storing and/or destroying data and media once study is completed. Please note that all final records relating to conducted research, including signed consent documents, must be retained for at least three years following completion of the research and must be accessible for inspection by authorized representatives as needed.

Data will be stored for a minimum of 7 years or as directed by any authoritative body participating in the research.

d. If digital audio, video, or other electronic data are to be used, when will they be destroyed?

See above

9. Illegal Activities

Will collected data relate to any illegal activities? __Yes* _X_No
This includes asking about illegal activities from participants or surveys containing any reference to illegal activities (e.g., questions requesting information about witnessing illegal behaviors that others have engaged in, minors drinking or using drugs, or any illegal drug use or violence of any nature that would result in legal action).

*If yes, please explain.

Is My Study Ready for Review?

Every research protocol, consent document, and survey instrument approved by the IRB is designated as an official institutional document; therefore, study documents must be as complete as possible. Research proposals containing spelling or grammatical errors, missing required elements of informed consent (within consent or assent documents), not addressing all questions within this form, or missing required documents will be classified as incomplete.

All studies classified as incomplete may be administratively rejected and returned to the researcher and/or faculty advisor without further processing.

If you are a non-KSU researcher wishing to recruit participants from the KSU campus, please follow these instructions: https://research.kennesaw.edu/irb/international-research.php

Student researchers make sure that your faculty advisor completes the following page and sends all study related material from their KSU email address to irb@kennesaw.edu. Failure to follow this procedure will result in a significant delay in the approval process.

RESEARCH CONDUCTED BY UNDERGRADUATE AND GRADUATE STUDENTS AS PRIMARY INVESTIGATORS

All undergraduate and graduate students who will be acting as the Primary Investigator must be under the direct supervision of a faculty advisor. The faculty advisor must review the IRB application materials and agrees to supervise the student's proposed human subject research project by completion and submission of this routing sheet.

All application materials must be submitted by the faculty advisor from their KSU email address to irb@kennesaw.edu. Students may not submit their materials to the IRB for the first review; however, subsequent revisions can be sent directly to irb@kennesaw.edu with a cc to your advisor and MUST come from your KSU provided email account.

FOR RESEARCH CONDUCTED BY STUDENTS OR NON-FACULTY STAFF. This study, if approved, will be under the direct supervision of the following faculty advisor who is a member of the KSU faculty:

Faculty Advisor

Name:

Department:	
Email:	Phone:

By checking the items below and submitting all materials from your KSU email, the faculty advisor for this project attests the following:

___I have personally reviewed each of my student's IRB application documents (approval request, exemption request, informed consent documents, child assent documents, survey instruments, etc.) for completeness, and all documents pertaining to the conduct of this study are enclosed (consents, assents, questionnaires, surveys, assessments, etc.)

___ I have completed the Social/Behavioral Research course (Biomedical version only for medical/biological human studies) CITI training course in the ethics of human subject research within the past three years as have all researchers named within this application.

___I approve this research and agree to supervise the student(s) as the study is conducted.

Date: _____