Informed Consent Document

IRB Approved 3/28/19

PROTOCOL TITLE: Investigating the short-term effects of *Passiflora incarnata* and mobile audio-guided meditation on blood pressure and heart rate in naturopathic medical students

PROTOCOL DATE: 3/28/19

Primary Investigator: Kimberly M. Sanders, ND

Co-Investigator: Mark Mattie, PhD, MD

UNIVERSITY OF BRIDGEPORT
CONSENT TO BE PART OF A RESEARCH STUDY

1. KEY INFORMATION ABOUT THE RESEARCHERS AND THIS STUDY

Study Title: Investigating the short-term effects of Passiflora incarnata and mobile audio-guided meditation on blood pressure and heart rate in naturopathic medical students
Study Sponsor: There is no sponsor for this study
Principal Investigators: *Kimberly M. Sanders, ND, School of Naturopathic Medicine, University of Bridgeport and Mark Mattie, MD, PhD, School of Naturopathic Medicine, University of Bridgeport*

1.1 Invitation to be Part of a Research Study

You are invited to take part in this research study. You are invited to be in this study because you are a naturopathic medical student who will be taking a classroom exam on the day of the research, and because you are A) not taking hypertensive, anti-anxiety, MAOI medication, or blood-thinning medication B) not pregnant or likely to be pregnant C) not scheduled to have surgery 2 weeks before or 2 weeks after the study date D) Able to access the Headspace app on a smartphone device connected to WiFi. Taking part in this research study is voluntary.

1.2 Important Information about the Research Study[1]

Things you should know:

- The purpose of the research study is to determine the effects of Passiflora incarnata and meditation on blood pressure and heart rate. Our research aims to discover if one-time dosing of Passionflower incarnata and a 10-minute audio-guided mobile meditation application can lower blood pressure and heart rate in students after a classroom examination
- If you choose to participate, we will take your blood pressure three times and your heart rate right after your classroom examination and again 15 minutes after that. You may receive an herbal extract to consume and a meditation to follow, as well.
- This will take approximately 45 minutes total.

[1] See Duke University's example of summary statements at https://irb.duhs.duke.edu/forms/duhs-sample-consent

- Risks or discomforts from this research include

    a. Physical Risks

        i. You may feel a slight discomfort when the blood pressure cuff is tightened around your arm. This is a temporary sensation that will last no more than 1 minute on each occasion.

        ii. There are no known serious adverse effects related to meditation, but an unforeseeable adverse effect is possible though unlikely.

        iii. You may dislike the taste of the *Passiflora incarnata* extract or the placebo.

        iv. Studies on *Passiflora incarnata* have generally found mild-moderate adverse effects when taken for weeks-months including:

            1. Drowsiness (very common, up to 50% reported this adverse effect in studies)

                a. We advise you to exercise caution and avoid operating a vehicle or heavy machinery for one hour after taking the dose

            2. Muscle relaxation (common, up to 20% reported this in studies)

                a. We advise you to exercise caution and avoid operating a vehicle or heavy machinery for one hour after taking the dose

            3. Dizziness (common, up to 5% reported this in studies)

                a. We advise you to exercise caution and avoid operating a vehicle or heavy machinery for one hour after taking the dose

            4. Headache

            5. Abdominal Pain

            6. Flatulence

            7. Vasculitis (rare)

            8. Asthma

            9. Rhinitis

            10. Urticaria/Allergic Reaction

            11. Cardiovascular effects, including Ventricular Tachycardia (one case study, rare)

            12. Uterine contractions

            13. Nosebleed, blood-thinning

            14. Impairment of Job Performance

            15. Confusion

            16. Ataxia

    b. Privacy Risks

        i. Since naturopathic medical students will be studied in groups, it is important to understand that your classmates will know that you are participating in the study. To minimize any privacy risks, all medical information will be collected in private before the day of the study.

On the day of the study, we will not read your blood pressure and heart rate readings out loud. We also will ask you to write down what medications or drinks that you took on the day of the study so that you do not have to say this information out loud in order to protect your privacy.

c. Economic Risks

i. You may use data or wifi on your smartphone by downloading and utilizing the Headspace application. Taking part in this research study may lead to added costs to you if your mobile plan charges for wifi or data usage.

ii. You may have to purchase headphones to listen to the Headspace meditation on your smartphone if you do not already own them.

d. Inconveniences

i. You may be inconvenienced by sparing no more than 45 minutes after your classroom examination

ii. You may not eat any food, caffeine, or alcoholic beverages for 2 hours before the study period, which may be an inconvenience for you

iii. You may not consume tyramine containing foods (blue cheese, gorgonzola cheese, red wine, cured meat, cured fish, sauerkraut, sourdough bread, soy sauce, teriyaki sauce, miso tempeh, or overripe fruits) for 2 hours before the study.

iv. You may not take cold medicine, decongestant medication, antihistamine medication, or cough suppressant for 2 hours before the study period.

v. You may feel distracted during your examination in anticipation of the upcoming research. This is unlikely since the research is intended to have a relaxing benefit.

vi. You may be late to your next class by participating in the research. The research will last about 45 minutes.

vii. You may be inconvenienced by having to download the Headspace application onto your smartphone. Instructions will be provided ahead of time to minimize this inconvenience.

- The study will have the possible benefits:

a. *Passiflora incarnata* has been found to have anxiolytic properties. You may note an increased sense of relaxation and well-being after participating in the research

b. Meditation has been found to improve well-being in medical students. You may note a sense of relaxation and an improved sense of well-being after participating in the research

c. These relaxation effects are likely and should last for the rest of the research day

- Taking part in this research study is voluntary. You don't have to participate and you can stop at any time. Whatever you decide will not be held against you.
- There is no extra credit given to those who participate
- There will be no implications for you in your classes if you choose not to participate

Please take the time to read this entire form and ask questions before deciding whether to take part in this research study.

2. PURPOSE OF THIS STUDY

2.1 ***What is the research study about and why are we doing the research study?*** We are aiming to discover if one-time dosing of *Passionflower incarnata* and a 10-minute audio-guided mobile meditation application can lower blood pressure and heart rate in medical students after taking a classroom examination, when their sympathetic tone would be higher.

2.2 How long will the research last?

We expect that you will be in this research study for no more than 45 minutes.

2.3 How many people will be studied?

We expect about 70 people here will be in this research study in 4 groups of 15-25. We expect that you will be in this research study for no more than 45 minutes.

3 WHO MAY PARTICIPATE IN THE STUDY

3.1 What happens if I say yes, I want to be in this research?

If you agree to take part in this study, the following will occur:

a. First, we will gather some initial information about you including your age, sex, past medical history including previous medical diagnoses, and current medication usage.

b. Next, we will provide you with instructions on how to download and use the Headspace application. You will be required to bring your smartphone and headphones to the study area.

c. Next, we will tell you the day and time to report to the study area. Make sure you arrive at the study area within 15 minutes of the end of taking your exam. **Do not consume caffeine or eat food during this time.**

d. When you arrive at the study area, your blood pressure will be taken three times and your heart rate will be taken once after resting quietly for at least 5 minutes.

e. Next you will either,

i. Sit quietly in the study area – you may surf the internet, read a book but you may not talk, eat food, listen to meditation, or consume caffeine.

ii. Listen to a 10 minute meditation on the Headspace app and take a placebo syrup. You may not talk, eat food, or consume caffeine.

iii. Listen to a 10 minute meditation on the Headspace app and take a *Passiflora incarnata* extract. You may not talk, eat food, or consume caffeine.

f. 15 minutes after the first blood pressure and heart rate was taken, another round of three blood pressure readings and one heart rate reading will be taken.

g. You will be given a survey on which you can report any side effects from the research back to the research team

h. During the research, you will interact with Dr. Sanders, Dr. Mattie, and/or the student research assistants.

i. The research will take place in the Health Sciences Building on the 8th floor in either a clinic room or the 8th floor classroom.

j. The treatment you get will be chosen by chance, like flipping a coin. Neither you nor the study doctor will choose what treatment you get. You will have a one in three chance of receiving both the meditation and *Passiflora incarnata* extract. You will have a one in three chance of receiving the meditation and the placebo. You will have a one in three chance of receiving neither intervention. Neither you nor the study doctor will know which treatment you are getting

3.2 What happens if I say no, I do not want to be in this research?

You may decide not to take part in the research and it will not be held against you.

3.3 What happens if I say yes, but I change my mind later?

You agree to take part in the research now. You may stop at any time and it will not be held against you. If you decide to leave the research in the middle of the study period, your data will be discarded.

4 INFORMATION ABOUT STUDY RISKS AND BENEFITS

4.1 Is there any way being in this study could be bad for me?

k. Physical Risks

i. You may feel a slight discomfort when the blood pressure cuff is tightened around your arm. This is a temporary sensation that will last no more than 1 minute on each occasion.

ii. There are no known serious adverse effects related to meditation, but an unforeseeable adverse effect is possible though unlikely.

iii. You may dislike the taste of the *Passiflora incarnata* extract or the placebo.

iv. Studies on *Passiflora incarnata* have generally found mild-moderate adverse effects when taken for weeks-months including:

1. Drowsiness (very common, up to 50% reported this adverse effect in studies) - We advise you to exercise caution and avoid operating a vehicle or heavy machinery for one hour after taking the dose

2. Muscle relaxation (common, up to 20% reported this in studies) - We advise you to exercise caution and avoid operating a vehicle or heavy machinery for one hour after taking the dose

3. Dizziness (common, up to 5% reported this in studies) - We advise you to exercise caution and avoid operating a vehicle or heavy machinery for one hour after taking the dose

4. Headache

5. Abdominal Pain

6. Flatulence

7. Vasculitis, which is an inflammation of the blood vessels (rare)

8. Asthma

9. Rhinitis, which is an inflammation of the nasal passages

10. Urticaria (hives)/Allergic Reaction

11. Cardiovascular effects, including Ventricular Tachycardia, which is a very serious increased heart rate (one case study, rare)

12. Uterine contractions
13. Nosebleed, blood-thinning
14. Impairment of Job Performance
15. Confusion
16. Ataxia

l. Privacy Risks

i. Since naturopathic medical students will be studied in groups, it is important to understand that your classmates will know that you are participating in the study. To minimize any privacy risks, all medical information will be collected in private before the day of the study. On the day of the study, we will not read your blood pressure and heart rate readings out loud. We also will ask you to write down what medications or drinks that you took on the day of the study so that you do not have to say this information out loud in order to protect your privacy.

m. Economic Risks

i. You may use data or wifi on your smartphone by downloading and utilizing the Headspace application. Taking part in this research study

may lead to added costs to you if your mobile plan charges for wifi or data usage.

ii. You may have to purchase headphones to listen to the Headspace meditation on your smartphone if you do not already own them.

n. Inconveniences

i. You may be inconvenienced by sparing no more than 45 minutes after your classroom examination

ii. You may be inconvenienced by not being allowed to eat food, drink caffeine, or consume alcoholic beverages for 2 hours before the study period

iii. You may not consume tyramine containing foods (blue cheese, gorgonzola cheese, red wine, cured meat, cured fish, sauerkraut, sourdough bread, soy sauce, teriyaki sauce, miso tempeh, or overripe fruits) for 2 hours before the study.

iv. You may not take cold medicine, decongestant medication, antihistamine medication, or cough suppressant for 2 hours before the study period.

v. You may feel distracted during your examination in anticipation of the upcoming research. This is unlikely since the research is intended to have a relaxing benefit.

vi. You may not be able to drive a vehicle or operate heavy machinery for one hour after the study.

vii. You may be late to your next class by participating in the research. The research will last no more than 45 minutes.

viii. You may be inconvenienced by having to download the Headspace application onto your smartphone. Instructions will be provided ahead of time to minimize this inconvenience.

4.2 Will being in this study help me any way?

We cannot promise any benefits to you or others from your taking part in this research. However, possible benefits include:

- *Passiflora incarnata* has been found to have anxiolytic properties. You may note a sense of relaxation and increased sense of well-being after participating in the research
- Meditation has been found to improve well-being in medical students. You may note a sense of relaxation and improved sense of well-being after participating in the research
- These relaxation effects are likely and should last for the rest of the research day

5 CONFIDENTIALITY OF SUBJECT RECORDS

5.1 What happens to the information you collect?

Efforts will be made to limit your personal information, including research study and medical records, to people who have a need to review this information. We cannot promise complete secrecy. Organizations that may inspect and copy your information include the IRB and other representatives of this organization. We may publish the results of this research. However, we will keep your name and other identifying information confidential. In an effort to protect your privacy, you will be given a unique code that is a series of numbers/letters. The only link back to your name and information will exist on a password-protected document on the University laptop belonging to Dr. Sanders and/or Dr. Mattie only. Hard copies of the inclusion/exclusion criteria checklist, initial data questionnaire, your blood pressure and heart rate readings, and the adverse event survey will contain only your unique code. These hard copies will be stored in a locked file cabinet in the locked office of Dr. Sanders and will be shredded after three years.

Student research assistants will not have access to your data or medical/medication history, and will only be involved in collecting your blood pressure and heart rate readings.

HIPAA protections: Federal law provides additional protections of your personal information. These are described in an attached document. Your identifiable information (name, address, etc.) or identifiable biospecimens collected for this research study will ***not*** be used or distributed to other investigators for future research studies, even if your identifiers are removed.

5.2 Can I be removed from the research without my OK?

The person in charge of the research study or the sponsor can remove you from the research study without your approval. Possible reasons for removal include:

- Your smartphone or Headspace application is not functioning within 30 minutes after the end of your classroom examination
- You did not take the classroom examination that day
- You eat food/tyramine containing food, stimulant medication, decongestant medication, cold medicine, antihistamine medication, cough suppressant medication, alcoholic beverages, stimulant energy drinks, or consume caffeine within 2 hours before the study period or during the study period.

5.3 What else do I need to know?

5.3.1 The research study involves no more than minimal risk

5.3.2 Participants will <u>not</u> get paid to participate in the research study

6 CONTACT INFORMATION

6.1 Who can I talk to?

If you have questions about this research (e.g. concerns, or complaints, or think the research has hurt you), you may contact

Kimberly M. Sanders, ND

HSC 633

203-806-5138

kimbersa@bridgeport.edu

This research has been reviewed and approved by an Institutional Review Board. If you have questions about your rights as a research participant, or wish to obtain information, ask questions, or discuss any concerns about this study with someone other than the researcher(s), you may talk to UB's IRB Administrator at (203) 576-4974 or irb@bridgeport.edu.

7 RECORD OF INFORMATION PROVIDED

7.1 What documents will be given to me?

Your signature in the next section means that you have received copies of all of the following documents:

- This "Consent to be Part of a Research Study" document.
- HIPAA Authorization form

HIPAA Authorization Form

Privacy Protection for Research Volunteers

Participant	**IRB Number: 2019-02-01**

Principal Investigator	Kimberly M. Sanders, ND	PI's Phone Number	203-806-5138

Title of Project: Investigating the short-term effects of Passiflora incarnata and mobile audio-guided meditation on blood pressure and heart rate in naturopathic medical students

State and Federal privacy laws protect the use and release of your health information. The University of Bridgeport requires that private information about you be protected. This is especially true for your personal health information. Protected Health Information (PHI) is any health information that can identify you. To take part in this research study, you must give the research team permission to access your health information and to use and share your PHI. The research team will only use and/or share your information as described below and in the research consent form.

What Health Information about me may be used or shared for this research study?

The PHI in this study will include:

xx	Name		Social Security Number	xx	Telephone Number
	Address	xx	Date of Birth		Fax Number
xx	Email Address		Medical Record Number		Health Plan Beneficiary (Insurance) Number
	Account Number		Certificate or License Number:		Vehicle identifiers and serial numbers
	Patient-Specific Dates (e.g., treatment dates)		Biometric Identifiers (finger or voice prints)		Device Identifiers and serial numbers
	Web universe resource locators (URLs) or Internet Protocol (IP) addresses		Photographic images, including:	xx	Other: Global health survey answers; chief medical concerns

Permission to Take Part in a Human Research Study

The PHI will be collected from the following sources:

	Hospital Medical Records	xx	Physician or clinic records	xx	Laboratory, pathology and/or radiology results
	Biological samples	xx	Interviews or questionnaires/health histories		Data previously collected for research purposes obtained from:
	Other:				

Do I have to give my permission for certain information to be released? Yes. The following information will only be released if you give your specific permission by putting your initials on the line(s). This is your specific permission for release of this information. Federal rules do not allow any use of the information to criminally investigate or prosecute any alcohol or drug abuse.

____I agree to the release of information pertaining to drug and alcohol abuse, diagnosis or treatment.

____I agree to the release of HIV/AIDS testing information.

____I agree to the release of information pertaining to sexually transmitted diseases.

____I agree to the release of information pertaining to mental health diagnosis or treatment.

Who will my information be shared with? Your PHI will be maintained by researchers at the University of Bridgeport and they will only share the information as described below.

The researchers may use or share your health information with:

- The University of Bridgeport IRB and other University personnel in order to provide research oversight
- Federal or state government representatives, when required by law
- Physicians who have access to your medical record when required for your medical care

The researchers at the University of Bridgeport agree to protect your health information by using and/or disclosing it only as you authorize. However, if your PHI is shared with someone outside of the University of Bridgeport research team and/or if you choose to share this information with others outside of this study, your health information may no longer be protected by HIPAA.

Am I required to sign this document? Your decision to sign or not sign this form will not affect your standard medical treatment, payment or enrollment in any health plans or affect your eligibility for benefits. However, if you choose not to sign this form, you may not take part in this research study.

Does my permission expire? This permission to release your PHI expires when the research study is over and all required study monitoring has ended.

If you choose to sign this form:

- You can change your mind and not allow the researcher to use and/or share your PHI (revoke your authorization).
- If you revoke your authorization, you must send a written letter to: Kimberly Sanders, ND 60 Lafayette Street Bridgeport, CT 06604 to inform him/her of your decision.
- If you revoke your authorization, researchers may only use and/or share your PHI **already** collected for this research study.
- If you revoke your authorization, your PHI may still be used and/or shared should you have an adverse event (a bad effect).
- If you withdraw your authorization, you may not be allowed to continue in the study.

Signature Block for Capable Adult: Long Form

Your signature below documents your permission to take part in this research and to the use and disclosure of your protected health information

DO NOT SIGN THIS FORM AFTER THIS DATE → March 28, 2020

Signature of subject	Date
Printed name of subject	
Signature of person obtaining consent	Date
	March 28, 2019
Printed name of person obtaining consent	Form Date