FORT HAYS STATE UNIVERSITY
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INSTITUTIONAL REVIEW BOARD FOR HUMAN SUBJECTS RESEARCH

NEW IRB SUBMISSION

I. Project Title and Research Team Members

Project Title:

The Effects of Meditation on Anxiety, Self-Compassion, and Perceived Stress

Principal Investigator Name:

Albert Herring

Faculty Research Supervisor (If student is the PI):

Dr. Benjamin Britten

Additional Team Members:

This form must be used to submit an application through the IRBNet system.
No other methods of submission will be accepted.

Access the system here: www.irbnet.org
Student and Adjunct Faculty researchers: Please note that Faculty Research Supervisor approval is required prior to submission to IRB. The Faculty Research Supervisor signature in IRBNet indicates approval and agreement with section XII.
For faster processing, ensure all research team members have completed all required CITI training through https://www.citiprogram.org/ prior to submitting this application.

II. Type of investigator and nature of the activity: (Check all appropriate categories.)

A. Faculty/Staff at FHSU:
- ☐ Submitted for extramural funding to:
- ☐ Submitted for intramural funding to:
- ☑ Project unfunded
- ☐ Quality improvement/program evaluation
- ☐ Quality assurance
- ☐ Other (Please explain)

B. Student at FHSU: ☐ Graduate ☑ Undergraduate ☑ Independent Study
☐ Thesis ☐ Specialist Field Study ☐ Graduate Research Paper

C. Class Project (Course Number and Course Title), explain activity:

N/A

D. Other than faculty, staff, or student at FHSU (Unaffiliated with FHSU)
Please explain:

N/A

III. Human Subjects Research Ethics Training: The IRB will not review submissions without verification of appropriate CITI training. The Principal Investigator and all members of the research team must complete the appropriate CITI training modules. Faculty Research Advisors, when listed above, must also complete CITI training. If the PI is not affiliated with FHSU, documentation of CITI or other comparable training must be provided.
Date completed CITI training:

Albert Herring: February 2017; Dr. Benjamin Britten: July 2016

IV. Project Information

A. Expected study period from: 8/21/2017 To: 8/20/2018

B. Describe the purpose of the research. Explain what is intended to be discovered, including goals, aims, and objectives and/or state the hypothesis to be tested. Background: provide a brief scientific or scholarly rationale for the research activities, and address gaps in current knowledge.

The purpose of this research project is to gain understanding on the effects of meditation on anxiety, perceived stress, and self-compassion. Previous research has focused mainly on physiological or neurological effects, thus creating a need for further examination of psychological effects. Differentiation between the practice of meditation and the effects also need to be further studied (Dooley, 2009).

As it is a commonly suggested practice for patients receiving psychological help, this study will be useful to assist in more fully comprehending its value as a clinical tool. Additionally, it will help to assess the influence of cognitive bias for/against, in this case, meditation.

Researchers expect to find positive effects on participants in the treatment group, particularly decreases in anxiety and perceived stress, as well as increases in self-compassion.

☐ Investigators NOT currently affiliated with FHSU will collaborate on this project.

C. (If checked above) Identify any cooperating institutions by name.

D. This study is being/has been reviewed by another IRB. Yes ◯ No ◉
If yes, please attach relevant documentation.

V. Subject Information

A. Number of subjects:

20-30 FHSU students with no exclusions except participants must be 18 or over and 65 or under.

B. Subject Age (Check all that apply):

- ☐ 1-7
- ☐ 8-17
- ☑ 18-65
- ☐ 65+

C. Special Populations (Check all that apply):

- ☐ Minors
- ☐ Non-English speaking
- ☐ Prisoners
- ☐ Individuals with impaired decision-making capacity
- ☐ Individuals who are economically or educationally disadvantaged
- ☐ Individuals with Legally Authorized Representatives
- ☐ Individuals who are vulnerable to coercion or undue influence

D. Describe target demographic of proposed subjects; explain how you will ensure that selection is equitable and that all relevant ethnic groups, genders, and populations have access to the study.

Approximately 20-30 FHSU undergraduate students will be recruited with no exclusions related to gender or ethnicity. However, only participants 18 years of age or over and 65 years of age or under will be allowed to participate. This is done to avoid sampling from a protected population.

E. Describe any specific populations targeted for inclusion or exclusion: Justify criteria based on age, gender, race, ethnicity, sexual orientation, or origin.

Age exclusion is utilized to avoid testing vulnerable participants.

VI. Recruitment

A. Describe the recruitment process for the study. Explain in detail how you will gain access to and recruit participants for participation in this project. Upload scripts, emails, letters, advertising, and all marketing materials with your application. Provide a step-by-step description of how potential participants will be recruited.

Researchers will enter the classroom of a teacher who has given permission to recruit in his/her class. Upon arrival, students will be read a recruiting script/information statement (see attachment) and invited to participate. Individuals who are interested in participating will sign two copies of an informed consent form, one to keep, as well as one to return to the researchers. After collecting the signed consent forms, researchers will proceed to the next step of the study.

B. Identify all applicable recruitment methods. (Please provide copies of materials).

- ☐ Flyers
- ☐ Purchased Sample List
- ☐ Email
- ☐ Telephone
- ☐ Newspaper
- ☐ Poster
- ☑ Class Announcement
- ☑ Departmental Communication
- ☐ Third Party (Professional or Charitable Organization)
- ☐ Internet
- ☐ Letter
- ☐ Personal or Professional Contacts
- ☐ Amazon MTurk
- ☐ Social Media
- ☐ SONA
- ☐ Snowball method (if used, must describe process in detail)
- ☐ Other (describe)

C. Are you recruiting students from a class you teach or for which you have responsibility? ◯ Yes ◉ No

D. Are you recruiting employees who directly or indirectly report to you?

◯ Yes ◉ No

E. If yes to either VI C or D, please explain why this population is necessary and describe what precautions have been taken to minimize potential undue influence or coercion.

N/A

VII. Compensation

- ☐ Participants will not receive compensation
- ☑ Students will receive extra credit or course credit
- ☐ Participants will receive monetary compensation
- ☐ Participants' names will be entered into a drawing for a prize

Describe the compensation or credit, including amount, scheduling and method. Explain what will happen if participants withdraw from the study.

Psychology instructors often provide research opportunities as one of many ways to earn extra credit in their classes. The amount of extra credit earned is determined by individual instructors. Students are not required to do research as there are other ways to earn extra points in courses. Choosing not to participate in research for extra credit will not negatively impact students' standing in the course or in their academic department.

VIII. Risks and Benefits

A. Describe the anticipated benefits of the research for individual subjects.

Though meditation is a very ancient practice, it has had few non-physiological examinations, particularly for first-time meditators. As with any study addressing relatively unexamined phenomena, this study will add to the psychological knowledge base. Student researchers expect, too, that participants assigned to the treatment group will benefit from the practice of meditation, particularly by experiencing decreased anxiety and stress, as well as increased self-compassion.

B. Describe the anticipated benefits of the research for society or the discipline. Explain how the benefits outweigh the risks.

The findings of this study, if hypotheses are supported, may influence clinical practitioners to encourage their patients to use meditation as a form of symptom management.

C. Does this study involve any of the following? (Check all that apply.)

- ☐ Deception
- ☐ Omission
- ☐ Misleading Information/false feedback
- ☐ Physical or mental stress
- ☐ Collection of fluids or tissue
- ☐ Substances taken internally or applied externally
- ☐ Information pertaining to illegal activity
- ☐ Information relating to sexual attitudes, orientation or practice
- ☐ Private identifiable information
- ☐ Personal or sensitive information
- ☐ Private records (academic or medical)
- ☐ Social or economic burden to participants
- ☐ Mechanical or electrical device applied to subjects
- ☐ Information pertaining to substance use
- ☐ DXA Scan, X-RAY, MRI
- ☐ Information that, if released, could damage an individual's financial standing, reputation, employability, or cause social stigmatization, discrimination, or embarrassment
- ☐ Other
- ☑ **None of these**

D. Describe the nature and degree of the risk or harm checked above. If using deception, include a justification for the deception.

N/A

E. What steps will be taken to minimize risks or harm and to protect the subject's welfare (when risk is greater than minimal)?

Some of the items in the scales used (i.e., anxiety and perceived stress; see attached) may present more than minimal risk. As such, participants will be given a debriefing form that has contact information for the Kelly Center, the Psychology Department Ethics Chair, and the course instructor. Participants will be instructed to contact these parties if they become distressed. Also, researchers will reiterate to participants that their participation is voluntary and that they may skip any questions that might cause discomfort.

IX. Emergencies

How will emergencies or unanticipated events related to the research be handled if they arise? (Please note that this refers to an emergency situation associated with the research activity not an emergency such as a fire alarm.)

Building safety procedures will be followed. Kelly Center staff will be utilized if the participant is emotionally upset. If emergencies occur, the IRB will be contacted immediately.

X. Data Collection and Security

A. Procedures: Describe the setting and tasks subjects will be asked to perform. Describe the frequency and duration of procedures, tests, and experiments. Include a timeline or a step-by-step description.

After recruiting procedures have been completed, the student researchers will divide willing participants into two random groups. One group will be the control group and will remain in the classroom to complete the study. They will not be informed of what the treatment group will be doing until the debriefing script is read. Instead, they will complete three counterbalanced measures, which assess anxiety, perceived stress, and self-compassion. When finished with the measures, the control group will be debriefed, thanked, and excused.

The treatment group, on the other hand, will be led to another room where the meditation will take place. They will not be informed about the activities of the control group. Researchers will request that participants keep an open mind about the experience and will be asked to participate to the best of their abilities. Next, the lights will be dimmed, participants will be asked to make themselves comfortable, and the Cleveland Clinic's “Loving Kindness Meditation” will be played. After the track has finished playing, participants will be given a few moments to become more alert. Next, they will be asked to complete the same three counterbalanced measures, and lastly, a self-created survey. The self-created survey will contain questions regarding the participant’s demographics as well as their personal history and experiences with meditation. After these have been completed, researchers will collect the surveys.

Next, a debriefing script (see attachment) will be given to them. They will be invited to ask any questions, as well as reminded to contact any of the mentioned parties immediately should an issue arise. Participants will have the opportunity to receive results of the study once it is finished. Finally, students will be thanked and excused. The total time for the study will be about 30 minutes.

B. Describe the steps that will be taken to secure the data during storage, use, and transmission. How and where will the data be stored, for how long will it be kept, when will it be destroyed, what safeguards are in place for data with identifying information? Include a description of physical and electronic security.

Informed consents will be gathered separately from surveys, because the informed consent is signed. Surveys will have anonymous participant numbers, names will not be on the surveys. Surveys will be turned in when the participant places his/her survey in a manila envelope in the location of his/her choice. Surveys will be kept under lock and key in the faculty advisor's office. Data will be entered in a computer program (SPSS) and be kept on the faculty advisor's password-protected laptop.

If presented at a conference and/or published, records will be retained for 5 years.

C. Identify any direct identifiers like name, unique identifier, address, email, etc. that will be kept with the records. Explain why it is necessary to record the identifiers and describe the coding system to be used.

N/A

D. If retaining a link between study code numbers and direct identifiers after data collection is complete, please explain why this is necessary, how long the link will be kept, how it will be stored, and when it will be destroyed.

N/A

E. Data collection methods (check all that apply)

- ☐ Observation
- ☐ Interviews
- ☐ Focus groups
- ☑ Surveys/Questionnaires
- ☐ Psychological tests
- ☐ Educational tests
- ☐ Blood draw, saliva swab, or other biological sampling
- ☐ Audio recording (see section X. F)
- ☐ Video Recording (see section X. F)
- ☐ Previously collected data (no individual identifiers)
- ☐ Previously collected data (with individual identifiers)
- ☐ Internet-based methods
- ☐ Other (describe)

F. If using audio or video recording, describe how the recordings will be used, how confidentiality will be maintained, who will have access, and how and when the recordings will be destroyed or completely deidentified.

N/A

G. Protected data to be collected (check all that apply)
☐ Protected health Information (see Section X, Part H)
☐ Unique ID number (e.g. employee ID, driver's license number, student ID number, etc.)
☐ Academic records
☐ Social security number
☐ Other personally identifiable information

H. If the research involves protected health information, it must comply with the HIPAA Privacy Rule.
Select one:
☑ The research does not involve protected health information
Do you plan to use or disclose identifiable health information outside FHSU?
○ Yes ◉ No
If yes, the consent form must include a release of protected health information.

The IRB may make a waiver of authorization for disclosure if criteria are met under the HIPAA Privacy Rule. *If a waiver of authorization is being requested, the researcher must contact the IRB administrator prior to submitting this application.*

Will the protected health information to be used or disclosed be deidentified, or will a limited data set be used or disclosed? *Please describe*:

N/A

I. Sharing results with subjects (Indicate if results, like tests or incidental findings, will be shared with the subject or others, and if so, indicate how it will be shared.)

Should the study be presented at a conference or published, the results will be aggregated and no identifiable information will be shared.

J. Withdrawal of subjects (Describe the procedures to be followed when subjects withdraw from research or under what circumstances subjects may be withdrawn without their consent.)

Participation in the study is voluntary; participants may choose to withdraw at any point and their materials will not be used in the study if they withdraw. Participants will not receive any penalty and academic standing will not be affected if they choose to withdraw from the study.

XI. Informed Consent

A. Specify the type of informed consent you will use with this research project.

☑**Signed Consent**

Consent forms included with this submission:

☑Adult ☐Assent Script/Procedures ☐Parent/Guardian
☐Foreign Language Version ☐Agency Consent

☐**Oral Consent** (Waiver of documentation of consent, include script with application)

☐Signed consent form would be the only record linking the subject to the research, and the principal risk of signing a consent form would be the potential harm resulting from a breach of confidentiality.

☐The research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside the research context.

☑**Information Statement** (include with application)

☑**Debriefing Statement** (include with application)

B. Describe any potential concerns with obtaining informed consent (Foreign language, minimizing possibility of coercion, etc.)

We do not foresee any concerns with obtaining informed consent. Students will be given an opportunity to ask questions before signing. In order to minimize possibility of perceived coercion, the researcher will reiterate that the study is voluntary and participants may withdraw at any time without penalty.

C. Describe the process you will follow to obtain consent and/or assent. Include names of individuals on the research team who will obtain consent, where and when the process will take place, and how you will ensure the subject's understanding.

Participants will be read the recruiting script, and if they are interested in possibly participating, they will be given the informed consent to read. They will be given a chance to ask any questions and sign the consent if they wish to participate. The primary researcher (Albert Herring) and faculty advisor will be present when consent is obtained in the classroom and available to answer questions.

All materials related to this study must be uploaded into your IRBNet study workspace. Instructions for using IRBNet are located at the FHSU IRB website. Required materials may include, but are not limited to:

- Completed application
- Copies of all recruiting materials, including scripts, emails, letters, posters, advertising, etc.
- Copies of all measurements, instruments, surveys, interview questions being used, etc.
- All consent forms and assent forms or scripts (for children).
- Debriefing materials, if used.

Please note that all materials and scripts to be used for this study need to be reviewed and approved by the IRB.

XII Certifications:

I am familiar with the policies and procedures of Fort Hays State University regarding human subjects in research. I subscribe to the university standards and applicable state and federal standards and will adhere to the policies and procedures of the Institutional Review Board for the Protection of Human Subjects. I will comply with all instructions from the IRB at the beginning and during the project or will stop the project.

AND

I am familiar with the published guidelines for the ethical treatment of human subjects associated with my particular field of study.

Statement of Agreement:

By electronically signing and submitting this application package, I certify that I am willing to conduct and /or supervise these activities in accordance with the guidelines for human subjects in research. Further, I certify that any changes in procedures from those outlined above or in the attached proposal will be cleared through the IRB.

If the Principal Investigator is a student, the electronic signature of the Faculty Advisor certifies:
1) Agreement to supervise the student research; and, 2) This application is ready for IRB review. The Student is the "Principal Investigator". The Faculty Research Advisor is the "Advisor". Designees may not sign the package. It is the student's responsibility to contact their Faculty Research Advisor when the study is ready for the Advisor's signature.

I certify the information provided in this application is complete and correct.
I understand that I have ultimate responsibility for the conduct of the study, the ethical performance of the project, the protection of the rights and welfare of human subjects and strict adherence to any stipulations imposed by the IRB.
I agree to comply with all FHSU policies, as well as all federal, state and local laws on the protection of human subjects in research, including:

- Ensuring all study personnel satisfactorily complete human subjects research training.
- Performing the study according to the approved protocol.
- Implementing no changes in the approved study without IRB approval.
- Obtaining informed consent from subjects using only the currently approved process and form.
- Protecting identifiable health information in accordance with HIPAA Privacy rule.
- Promptly reporting significant or untoward adverse effects or unanticipated problems to the IRB.

Example of Adult Informed Consent Statement

Name of the Study: The Effects of Meditation on Anxiety, Self-Compassion, and Perceived Stress

INTRODUCTION

The Department of Psychology at Fort Hays State University supports the practice of protection for human subjects participating in research. **You are being asked to participate in a research study. It is your choice whether or not to participate.** The following information is provided for you to decide whether you wish to participate in the present study. You may refuse to sign this form and not participate in this study. You should be aware that even if you agree to participate, you are free to withdraw at any time. If you do withdraw from this study, it will not affect your relationship with this unit, the services it may provide to you, or Fort Hays State University.

PURPOSE OF THE STUDY

The purpose of this research project is to gain a better understanding of how a brief practice of meditation might reduce anxiety and perceived stress as well as promote self-compassion.

PROCEDURES

As part of this study, you will be asked to complete three short questionnaires about your current mood, attention and awareness, as well as depression, anxiety, and stress. Next, you might practice a form of meditation. If you are assigned to the meditation group, you will be asked to keep an open mind about the experience and to participate to the best of your abilities. After engaging in the meditation, you will complete the same questionnaires.

If you decide to participate in this research study, you will be asked to sign this consent form after you have had all of your questions answered and understand what will happen to you. The length of time of your participation in this study is about 30 minutes. Approximately 20 to 30 participants will be in this study.

RISKS

It is unlikely that this project will result in harm to you as a participant. However, if you do experience abnormal stress you will be able to stop participation at any time with no penalty. A researcher will be in the room at all times to answer your questions and to help you if you feel uncomfortable or distressed.

BENEFITS

You may benefit from the knowledge gained of the scientific process through participation and exposure to research. You may also find the strategy to be applicable after the study is completed and continue to engage in the strategy they are introduced to for continued benefits. Essentially, this research can also be a teaching moment, especially for general psychology students who may not be aware of the scientific nature of psychology. FHSU (and you as a participant) may benefit from any tangible knowledge gained during this study. Also, you may benefit by receiving course credit or

extra credit for participating. In these instances, professors will offer equitable alternative options in order to give students other opportunities to receive the same amount of credit, even if they do not want to participate in this project.

PAYMENT TO PARTICIPANTS
You will not receive any compensation for participation in this experiment. However, you may receive extra credit or research credit, but this is at your instructor's discretion.

PARTICIPANT CONFIDENTIALITY (HOW WILL PRIVACY BE PROTECTED)
Efforts will be made to protect the identities of the participants and the confidentiality of the research data used in this study. Potentially identifiable information about you will consist of your answers to the surveys, the given task, and your demographics (i.e., age, sex, ethnicity). Data is collected only for research purposes. Your data will be identified by ID number, not name, so there will be no way to link your name back to your responses in the data. All personal identifying information, such as your signature on this Informed Consent, will be kept in locked files and these files will be shredded approximately 5 years after publication of this data. Data files which do not contain your identifying information will be kept in an electronic file for five years. However, access to all data will be limited to the principal researcher.

The information collected for this study will be used only for the purposes of conducting this study. What we find from this study may be presented at meetings or published in papers but your name will never be used in these presentations or papers.

OTHER IMPORTANT ITEMS YOU SHOULD KNOW

- **Withdrawal from the study:** You may choose to stop your participation in this study at any time. Your decision to stop your participation will have no effect on your academic standing at Fort Hays State University.
- **Funding:** There is no outside funding for this research project.
- **Alternative options:** If your instructor is providing extra credit or research credit for your participation, he/she should also provide you with alternative ways to earn this credit that do not include participating in this research study if you do not want to. Please speak directly with your instructor about alternative options.

REFUSAL TO SIGN CONSENT AND AUTHORIZATION
You are not required to sign this Consent and Authorization form and you may refuse to do so without affecting your right to any services you are receiving or may receive from Fort Hays State University or to participate in any programs or events of Fort Hays State University. However, if you refuse to sign, you cannot participate in this study.

CANCELLING THIS CONSENT AND AUTHORIZATION
You may withdraw your consent to participate in this study at any time. You also have the right to cancel your permission to use and disclose further information collected about you, in writing, at any time, by sending your written request to: Albert Herring, Department of Psychology, 600 Park St. Hays, KS 67601.

If you cancel permission to use your information, the researchers will stop collecting additional information about you. However, the research team may use and disclose information that was gathered before they received your cancellation, as described above.

QUESTIONS ABOUT PARTICIPATION
Questions about procedures should be directed to the researcher(s) listed at the end of this consent form.

PARTICIPANT CERTIFICATION:
I have read this Consent and Authorization form. I have had the opportunity to ask, and I have received answers to, any questions I had regarding the study. I understand that if I have any additional questions about my rights as a research participant, I may call (785) 628-4349, write the Office of Scholarship and Sponsored Projects (OSSP), Fort Hays State University, 600 Park St., Hays, Kansas 67601, or email irb@fhsu.edu.

I agree to take part in this study as a research participant. By my signature I affirm that I am at least 18 years old and that I have received a copy of this Consent and Authorization form.

_____ _____
Type/Print Participant's Name Date

_____
Participant's Signature

RESEARCHER CONTACT INFORMATION:

Albert Herring
Principal Investigator
Department of Psychology
600 Park St.
Fort Hays State University
Hays, KS 67601
(785) 628-5555

Benjamin Britten, Ph.D.
Faculty Supervisor
Department of Psychology
600 Park St.
Fort Hays State University
Hays, KS 67601
(785) 628-5555

Recruitment Message: "The Effects of Meditation on Anxiety, Self-Compassion, and Perceived Stress"

Greetings! My name is Albert Herring, and I am an undergraduate student in the Psychology department at FHSU. I would like to invite you to participate in a psychology experiment. The purpose of my experiment is to gain further understanding on the effects of meditation on anxiety, perceived stress, and self-compassion. If you choose to participate, you will be given a survey to fill out asking questions about your thoughts and opinions related to daily stressors you experience as well as your general outlook on life. Participating might help you learn something new about yourself (e.g., what stressors you are currently experiencing).

Your professor may be offering research or extra credit for participating. I would appreciate your help with this research project. If you would like to participate you will be asked to fill out a consent form related to the study after your questions are answered and then asked to complete a survey. Next you will possibly practice a meditation exercise and then a follow-up survey. If you choose to participate, the study will take approximately 30 minutes. If you have any questions about this study, please do not hesitate to contact me and/or my faculty adviser, Dr. Ben Britten.

Thank you!

Albert Herring
aherring2@mail.fhsu.edu

Dr. Benjamin Britten
bbritten@fhsu.edu
(Faculty Supervisor)

Debriefing Form: "The Effects of Meditation on Anxiety, Self-Compassion, and Perceived Stress"

You have just completed a study titled "The Effects of Meditation on Anxiety, Self-Compassion, and Perceived Stress." The purpose of this study was to examine how practicing a form of meditation impacts a person's anxiety, perceived stress, and self-compassion. You were asked to fill out a survey asking questions about your thoughts and opinions related to different topics, practice a meditation strategy, and fill out a final questionnaire. The information provided will help researchers understand how impactful engaging in meditation may be for different psychological factors. It is hoped that the research will help us better understand ways that can help individuals improve their mental health.

The research team greatly appreciates your help with this project! If you feel distressed after your participation in this project, you can contact the Kelly Center (free to students) at 785-628-4401 to schedule an appointment to talk with someone about how the project impacted you, or the Office of Scholarship and Sponsored Projects at 785-625-4349 if you have questions about the process of this research project. For more information about the research project, you can contact the principal researcher, Albert Herring. You may also contact the faculty adviser, Dr. Ben Britten.

Sincerely,

Albert Herring
aherring2@mail.fhsu.edu

Dr. Benjamin Britten
bbritten@fhsu.edu
(Faculty Supervisor)