

Appendix E-2 Informed Consent (COVID Data Collection)

Consent to Participate in a Research Study

Clergy Health Initiative: Selah (Protocol #2019-0238)

INTRODUCTION

You are being asked to take part in this research study because you are a clergy member of the North Carolina or Western North Carolina Conference of the United Methodist Church. This study is being sponsored by a grant from the Rural Church Program Area of The Duke Endowment. Portions of the salaries of the principal investigators, Rae Jean Proeschold-Bell and Carl Weisner, and the research team members, are being paid by this grant.

KEY INFORMATION

WHY IS THIS STUDY BEING DONE?

This intervention research study is being done to see whether clergy will participate in several stress symptom reduction interventions and whether participation results in decreased stress symptoms.

WHAT IS INVOLVED IN THE STUDY?

If you agree to enroll in the intervention study, you will indicate your preference for three different programs. You will be assigned to a program based on your preference. However, if a program has fewer than 50 people interested, this program may be dropped and you will be assigned to your second choice. If you indicate you have no preference between the programs, you will be randomly assigned to one of the programs. Some participants of each program will also be randomly assigned to a later start date. These interventions are not guaranteed to reduce stress.

The three program options are:

- Stress Proofing, a program focused on physiology that includes exercises that work directly on the body to help release stress held in the body; it bypasses the mind, because it can be very hard to think your way out of stress. This system is based on Stress Inoculation Training, which uses scenarios and recovery skills to prepare people in advance for stressful episodes. The techniques taught in this program include a variety of breathing and blood flow control techniques, as well as ways to conduct deep tissue massage on oneself to release muscle tension. Stress Proofing will be taught during a 2 day workshop that includes two overnight stays; the study will cover food and lodging. In addition, you will receive a workbook with 30 days of specific practice activities of 10-25 minutes each to do on your own schedule for the month following the workshop.
- The Daily Examen, is a technique of prayerful reflection on the events of the day in order to detect God's presence and help discern how God is calling you in small and large ways. St. Ignatius of Loyola created the Daily Examen to be a very short prayer that can be done at any time. The Daily Examen will be taught during a 1 day workshop that

includes an overnight stay; the study will cover food and lodging. In addition, you will receive a book on of the Daily Examen for home use.

- Mindfulness Based Stress Reduction, offered by Duke Integrative Medicine, teaches several different kinds of meditation, including mindfulness and walking meditation, and other stress reduction techniques such as bringing awareness to the present moment. The program will kickoff with a 1 day workshop that includes an overnight stay; the study will cover food and lodging. The remainder of the program (6 weeks) 8 week program will be conducted through a web platform like Zoom or by phone (your choice) with approximately 20 clergy participants. The weekly sessions last 90 minutes each. In addition, there is an optional, in-person day of meditation held in Cary or Durham to which the 20 participants in your clergy group and other people (non-clergy) practicing the skills will be invited.

Workshops will be offered at several locations in North Carolina. You will be directed to a website listing locations and dates and then, taking into account timing, and geographic preferences, you will sign up for a program. Programs will fill up on a first come, first serve basis. The following table compares the three programs based on workshop format, length, amount of practice involved, and type of follow-up booster:

	Daily Examen	Mindfulness Based Stress Reduction	Stress Proofing
Workshop format	In person	In person and online or by phone	In person
Workshop length	One day (one overnight stay)	One day (one overnight stay) followed by A 90-minute, weekly class for 6 weeks + an optional in-person Day of Mindfulness in Cary, NC	2 days' of content that may be delivered across more than 2 days (includes 2 overnight stays; food and lodging will be paid for by the study)
Option for significant others	No	No	No
How much practice per week?	15 minutes per day for 3 months	45-60 minutes per day for 3 months	10-25 minutes per day for 3 months
Is there a follow-up session?	Yes, two 60-90 minute small group session with a spiritual director that you can attend online or by phone about 2 and 6 weeks after the workshop	The program itself is a workshop and 6 8 sessions; there are not any follow-up sessions.	Yes, one- two 60-90 minute webinars that you can attend online or by phone about 2 and 6 weeks after the workshop

We will collect two-four kinds of data from you at repeated intervals during your time in the study. Survey and text message data will be collected from all participants and a substantial percentage of participants will be asked to participate in heart rate data collection. Between 30 and 48 in-depth interviews or heart rate data collection. The data collection involves:

- Survey. You will be asked to complete a survey lasting about 45 minutes. The survey will ask questions about your emotional health, stress and burnout, physical health behaviors, and spiritual vitality. All participants will be asked to take this survey at baseline (prior to attending the workshop), 12 weeks, and 26 weeks.
- Text messages. You will receive two text messages at the same time each day for 26 weeks. One message will ask you the amount of time that you engaged in program activities that day, and the other message will ask what the activities were. You will be encouraged to respond to the two questions.
- Heart rate. You will be asked to wear an electronic device, which you will receive through the mail and need to mail back to the study team. You will be taught how to attach two to three sensors (electrodes) and be asked to wear the device for approximately 48 hours on two separate occasions. Heart rate data will be collected at 0 weeks and 12 weeks.
- Approximately 30-48 participants will be invited to participate in in-depth interviews lasting approximately 30 minutes each and conducted at 5 and 12 weeks after workshop participation. The interviews will be conducted in person or by phone or web platform. The interview questions will ask about your experiences trying to incorporate what you learned in the workshop into your weekly routines and whether you perceive a reduction in your stress symptoms. If invited, you may choose or decline to participate in the in-depth interviews. Interviews will be audio-recorded.

HOW MANY PEOPLE WILL TAKE PART IN THIS STUDY?

Between 350 and 600 United Methodist Church clergy, from across the NC and Western NC Conferences, will be invited to participate in the study.

HOW LONG WILL I BE IN THIS STUDY?

Your participation in this study is for a period of 6 months. Participants assigned to the later start date will be in the study for approximately a year. A change in conference appointment will not affect your standing with the study.

WILL MY INFORMATION BE KEPT PRIVATE?

Study records that identify you will be kept confidential. You will not be identified in public or to your conference by name, address, conference appointment, or any other direct personal identifier with any of your health data or survey responses. Your research record will be assigned a unique code number. The key to the code will be held by Duke and will always be kept separate from the research database. We will keep the key in order to be able to link individual responses at one point in time to the same individual's responses at other points in time. Any hard copies of your health data or survey responses will be marked only with your code number and kept separate from the key in a locked cabinet in a locked room at Duke University.

Digital files will not have any personal identifiers (e.g., we will not record your name or any other identifying information on the audio tape) and will be stored on a protected network drive. The Duke Clergy Health Initiative Research Team will be the only party with access to this information.

We will need to collect your phone number in order for you to receive surveys via SMS (short message service, or text messaging). SMS is not a secure form of communication, and there is a risk of loss of privacy with any text message exchange. Text surveys will be sent out by a company called Twilio, which is a third party system. Twilio, or their business partners, may use or sell data collected by the system, which is not covered by this consent form or Duke's Privacy Policies.

Your health and survey data will be kept on a secure, protected network and will continue to be used for research purposes, including studies not yet planned. We plan to link data gathered in this survey with data gathered in the Duke Clergy Health Initiative's statewide longitudinal survey and Spirited Life, and to demographic data provided by the conferences. We will destroy all study records containing identifying data seven years after the last publication yielded by the study. Data files with identifying information stripped out may be retained indefinitely by the Duke Clergy Health Initiative.

Data without names will be analyzed by Duke Clergy Health Initiative research staff. While the findings resulting from this study may be presented to denominational officials, presented at scientific meetings, or published in scientific journals, data will be presented in ways that prevent individual participants from being identified.

WHAT ARE THE RISKS OF THE STUDY?

It is possible that survey or interview questions, for example, questions about stressful situations, will make you feel uncomfortable. You may decline to answer any question at any time. As long as you answer at least half the survey questions at any timepoint, declining to answer questions will not affect your compensation.

Additionally, the process of measuring your heart rate may cause some discomfort. In order to collect this measurement, you will be asked to stick 2-3 electrodes onto your body and wear them for a period of time. While we do not anticipate this causing problems, it may be uncomfortable. You may, at any time, choose to decline to provide heart rate data.

ARE THERE BENEFITS TO TAKING PART IN THE STUDY?

The knowledge gained from the study will be incorporated into the research and services of the Duke Clergy Health Initiative, and shared with United Methodist Church leaders, and may benefit you and your ministry peers in the future.

WHAT ABOUT COMPENSATION?

You will receive compensation for any survey you complete at least half at the end of the study (26 weeks after the in-person workshop or the first Mindfulness Based Stress Reduction session), provided you at minimum attend the workshop/first class (even if held virtually);

complete half of the first survey; and complete half of the survey given at 26 weeks. However, it is most helpful if you complete the full survey at 0, 12 and 26 weeks and provide text message data. Participants will be asked to complete 3 surveys at 0, 12 and 26 weeks and will be paid \$20 and \$25 for completion, totaling \$65 for surveys.

In addition, you may be invited to provide more data and receive compensation for doing so. If you are invited to provide heart rate data at the time of your workshop/first class and at 12 weeks and choose to do so, you will receive \$25 after your first measurement and \$25 after your final assessment for a total of \$50.

Some participants may be asked to participate in a 30-60 minute interview about their experience and will be paid \$25 for that time.

Before we are able to compensate you, we will ask you to provide us with your date of birth and social security number in order to process the payment. If you decide not to provide us with this information, you are still able to participate in the study but we will not be able to pay you.

WHAT ABOUT MY RIGHTS TO DECLINE PARTICIPATION OR WITHDRAW FROM THE STUDY?

Your participation is voluntary. You may choose not to participate in any or all parts of the study. We will not tell any UMC conference leaders who is and is not participating in the study, and they will not know any of your health data or survey responses. However, we anticipate that 15-25 NC UMC clergy will participate in each workshop, so you may know someone in the group and it is possible that they will tell another UMC clergy person or conference leader that you are participating. Also, you may decline to answer any question at any time.

You may withdraw your authorization for us to use your data that have already been collected (other than data needed to keep track of your withdrawal), but you must do this in writing by contacting the Duke Clergy Health Initiative, 310 Trent Drive, 319 Trent Hall, Durham, NC 27705, e-mail clergyhealth@div.duke.edu.

WHOM DO I CALL IF I HAVE QUESTIONS OR PROBLEMS?

For questions now or at any time about the study, contact:

Jessica Choi
Project Coordinator
919-668-4052 or Jessica.choi@duke.edu

For questions about your rights as a research participant, contact the Chair of the Human Subjects Committee at Duke University at 684-3030.

STATEMENT OF CONSENT

"The purpose of this study, procedures to be followed, risks and benefits have been explained to me. I have been allowed to ask questions, and my questions have been answered to my satisfaction. I have been told whom to contact if I have additional questions. I have read this consent form and agree to be in this study, with the understanding that I may withdraw at any time."

Signature of Participant

Date

Phone Number

Email Address

Town of Residency

/

/

Date of Birth