

**THIS FORM IS FOR PREVIEWING PURPOSES ONLY.  
THOSE INVITED TO ENROLL WILL SUBMIT AN ELECTRONIC VERSION VIA A SECURE WEBSITE.**

## **Consent to Participate In a Research Study**

### **Clergy Health Initiative: “Spirited Life” Multiple Baseline Intervention (Protocol # A0208)**

#### **INTRODUCTION**

You are being asked to take part in this research study because you are a minister under appointment, serving a local church or on the conference staff, in 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. Duke Divinity School has contracted with Westat to collect some of the data for this study. Westat is being paid for their services with funds from the grant. Portions of the salaries of the principal investigator, David Toole, and the research team members, are being paid by this grant.

#### **Why is this study being done?**

This intervention research study is being done to attempt to develop a holistic health intervention for clergy that promotes physical, mental, and spiritual health.

#### **What is involved in the study?**

If you agree to enroll in the intervention study, you will receive an initial screening in November 2011, and will begin to receive intervention services in January 2012. The services will extend over a period of 23 months.

The intervention services are:

- A three-day workshop combining spiritual reflection with life skills and stress reduction training (Winter 2012).
- Access to a skill-based program focused on healthy eating habits and customized using your own health data (Spring 2012).
- A one-day holistic workshop that combines spiritual reflection with stress reduction and healthy eating components (Fall 2012).
- Assignment to a Wellness Advocate (employed by Duke University) available to you by phone and sometimes in person, to help you maintain healthy behaviors learned through the stress-reduction and healthy-eating curricula, and the spiritual workshops, and to refer you to health resources. Wellness Advocates will also ask you to complete optional spiritual and mental health assessment screeners so you can discuss your needs and examine changes over the 12 months of services. Wellness Advocate conversations will occur approximately monthly.

- Access to funds up to \$500 for a health promotion activity that you and your Wellness Advocate agree upon, from a menu of possible activities. Options include physical trainers, health club memberships, subsidies toward mental and physical health co-pays, retreats, and life coaching.

Workshops will be offered at several locations in North Carolina to reduce travel time and expense.

In conjunction with the health promotion services of the program, Duke/Westat will collect a panel of physical health data and survey data at repeated intervals during your time in the Spirited Life program. Data collection will be done at a location convenient to your region of North Carolina. As part of each data collection:

- A technician will stick your finger to obtain a few drops of blood for testing. Your blood glucose and cholesterol will be measured. The technician will measure your height, weight, blood pressure, and waist circumference. This physical data will be recorded in your research record by Duke/Westat and will be reported to you, usually on the same day you give blood. If any of your test results are dangerously high, you will be told the same day. Your physical data will also be seen by the Wellness Advocates.
- You will 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. Your survey answers will not be seen by the Wellness Advocates.

This panel of health and survey data will be collected:

- In November 2011. (No cash compensation.)
- At the 9-, 15- and 23-month milestones of your active participation in the intervention. (No cash compensation.)
- You may be asked to submit a survey and provide health data during the 18-month period after completing the intervention. There would not be more than three (3) data collections. At each point in time, you would receive \$75 for your time and travel to a screening event in your region of North Carolina.

If you are unable to attend a scheduled screening event as outlined above, Duke may send a technician to collect health data from you at your home or office. Your attendance at screening events and workshops is important, but please do not travel if weather conditions are threatening or if you are feeling poorly on the day of an event.

In addition, three months after your initial Winter 2012 workshop, you will complete an evaluation survey (no blood stick or physical measurements).

If you agree to be in the study, you give Duke consent to access the following information from your health insurance provider:

- Medication claims
- Outpatient visits with diagnosis and procedure codes
- Inpatient hospitalizations with diagnosis and procedure codes
- Emergency room visits with diagnosis and procedure codes.

Duke will receive these claims data for a period from July 1, 2007 through December 31, 2019.

NOTE: Duke will contact you at intervals of 24 months from the date of your agreement to this consent

form, to remind you of the ongoing collection of insurance claims data, and to remind you of your right to opt out of this phase of the study. Please note that this is an opt-out mechanism. We will continue to collect claims data unless we hear from you that you wish to withdraw from the study population.

If you participated in the Duke/Westat Clergy Health survey conducted in 2008 and 2010, we will link your responses to the Duke/Westat survey. Referring to your survey data is necessary to create well-balanced groups, and as a baseline of health measures before you took part in the Spirited Life program.

### **How many people will take part in this study?**

This study has enrolled 1,120 pastors from both the North Carolina and Western North Carolina Conferences thus far. Around 110 new pastors will be invited to participate at this time.

### **How long will I be in this study?**

Your participation in this study is for 3 ½ years, plus permission to collect your health insurance data through 2019, an activity that does not require your active participation. A change in conference appointment will not affect your standing with Spirited Life.

### **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 by the social science research firm Westat, and will be always 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 the offices of the Clergy Health Initiative at Duke University.

If you participate in the mindful eating program Naturally Slim, Duke will share your health data with Naturally Slim to set up your custom profile. Naturally Slim typically collects the same health data as we do in this study, so sharing your health data with Naturally Slim helps you avoid additional data collection while allowing the health coaches at Naturally Slim to access it to provide you customized services. We will share your data with Naturally Slim for any time points prior to your participation in Naturally Slim and throughout the 12 months of the program. These data will be encrypted.

If you enroll in the Spirited Life program, your name, group number, and contact information will be furnished to LTG Associates, the research firm working under contract with The Duke Endowment to do external evaluation on the Clergy Health Initiative. LTG may contact you to request data (surveys or interviews) on your experience with the Spirited Life program. You are free to accept or decline these offers. The data you provide LTG are confidential and will not be reported even to Clergy Health Initiative staff except in aggregate or in a way that protects your identity. LTG will not have access to your research data, and like Duke Divinity School staff, they are bound not to reveal your status with the Spirited Life to your conference, congregation, or elsewhere.

Your Wellness Advocate will have access to your physical health data (blood test values, etc.) and to your health insurance claims data. Your Wellness Advocate will also keep a log of his or her session dates with you, the duration of each session, and general information about the content areas covered

in your conversations (e.g. stress management, nutrition, etc.). The research staff of the Clergy Health Initiative will have access to this log data.

Your de-identified health and survey data will be kept in a secure password-protected database 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 other phases of the project or initiative and to demographic data provided by the conferences. Duke 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 Duke.

Data without names will be analyzed by Clergy Health Initiative research staff, as well as faculty and research staff of the Duke Center for Health Policy and Inequalities Research and the Duke Children's Environmental Health Initiative. While the findings resulting from this study may be reported to the Conferences or other church bodies, presented at scientific meetings, or published in a scientific journal, no individual participant will be identified.

### **What are the risks of the study?**

It is possible that during this study, you may receive information about your health status that is upsetting. We pledge to inform you promptly of your health test results, and to help you develop skills in healthful decision making. If we believe that you might want to consider other health interventions, we will let you know about their availability. What course of action you take in response to new information is up to you, and should be taken with the advice of a physician or other appropriate professional. Data collection is similar to a routine physical and psychological examination. You may experience pain or discomfort when your finger is stuck in order to draw blood. You will undertake wellness-promotion activities, possibly including diet or exercise programs, which carry some risk and should be reviewed and approved by a physician and/or other appropriately qualified professional.

### **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 Clergy Health Initiative, which may benefit you and your ministry peers in the future. The stress reduction and mindful eating programs included in the Spirited Life program have been evaluated for their efficacy in improving health outcomes. We fully hope that you will experience personal health benefits from the health intervention, although we cannot guarantee that.

### **What about compensation?**

You will receive compensation in the form of the services of the Wellness Advocates, life skills coaches, and mindful eating coaches. If you participate in surveys and health screening data collection after the end of your 23 months of intervention services, you will receive \$75 each time you complete both a survey and the health screening.

### **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. The Conferences will have no way of knowing whether you have agreed to participate in the program and they will not know any of your health data or survey responses. Also, you may decline to answer any questions on the surveys.

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 Clergy Health Initiative, 312 Blackwell St. Suite 101, Durham, NC 27701, e-mail [clergyhealth@div.duke.edu](mailto:clergyhealth@div.duke.edu). Once you have confirmed your desire to withdraw from the study, data already collected from you will not be used and will be erased.

**Whom do I call if I have questions or problems?**

For questions now or at any time about the study, contact the Clergy Health Research Coordinator at 919-613-5350.

For questions about your rights as a research participant, contact the Chair of the Human Subjects Committee at Duke University at 919-684-3030.

**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

Duke University IRB Protocol Number: **A0208**

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