University of Miami
CONSENT TO PARTICIPATE IN A RESEARCH STUDY

Consent (Permission) to Participate in a Clinical Research Study
Title of Study: Compassion Cultivation Training for Nurses
Principal Investigator: William Pirl, MD, MPH
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READ THE FOLLOWING CAREFULLY

You are being asked to give permission to participate in a research study. Before you give your consent (permission) to be part of this study, please read the following and ask as many questions as necessary to be sure that you understand what participation will involve.

PURPOSE OF STUDY:
The purpose of this study is to understand the potential benefit of a training program to help nurses promote caring behavior for oneself and others, improve connection with patients and co-workers, and give rise to altruistic behavior and generous actions. Stress and compassion fatigue is a prevalent symptom in oncology nurses and the present research study is an on-site educational program designed to support oncology nurses. More specifically, this educational program may help nurses build resilience, reduce burnout and stress, and compassion fatigue. We are asking you to take part in this research study because you are a nurse who works in oncology at the University of Miami Sylvester Comprehensive Cancer Center.

NUMBER OF STUDY PARTICIPANTS:
We hope to enroll 25 participants.

PROCEDURES:
If you choose to participate, the program involves several steps. The first step is to complete a series of questionnaires administered on-line. Completing the questionnaires will take approximately 20-30 minutes. The on-line questionnaires will include items about your

background, work experiences (including medical errors and level of stress), and recent thoughts and feelings. Your responses will be kept confidential, and only study staff (i.e. the principal investigator and a research assistant) will have access to the identifiable responses. You may skip over any questions that you choose not to answer. After this assessment, if you decide not to participate in the study, or if we believe that the educational program is not right for you, we will assist you in finding resources that are more suitable to your needs.

If we believe the educational program is right for you, and you decide you would like to participate, a member of our study staff will work with you and the other participants to explain the time and location that the educational sessions will take place. You will then participate in the educational sessions with the other oncology nurses as participants.

The Compassion Cultivation Training (CCT) is a secular course that was developed by the Center for Compassion & Altruism Research and Education (CCARE) at Stanford University, School of Medicine (Jinpa, 2013). The course was developed by Thupten Jinpa, PhD, in collaboration with contemplative scholars, psychologists, and scientist at Stanford. The goal of CCT is to provide a structured and systematic way of cultivating daily-life skills needed to strengthen qualities of compassion, empathy, and kindness for oneself and others.
The training is composed of 8 sessions, which can be delivered in 7-10 weeks. The content, order, and duration of each component may vary depending on the group dynamic and needs. The sessions consist of didactic instruction, meditation, exercises and home practices. Each session may be video-recorded for purposes of missed-session make up, training quality assurance, and practice materials. The recordings will be uploaded to Dr. Amishi Jha's private Youtube account and only participants will be sent links to those recordings. These links are not searchable online.

Around the 7-10 week of participation, you will be sent an email with instructions to complete another set of questionnaires. Two months later, you will receive an email to complete one last questionnaire.

RISKS AND/OR DISCOMFORTS:
You may find some of the questions asked in the assessments emotionally upsetting. You may decline to answer questions which upset you and you are free to leave the session at any time. Also, there is a risk that the confidentiality of what you say during the group educational sessions could be broken. However, our research study staff members are trained to create a supportive and safe environment for talking about sensitive issues. We follow strict procedures for protecting confidentiality. We will ask all study participants to keep private the information discussed in the group.

BENEFITS:
There may not be direct benefit to you in this study. However, it is hoped that you will learn new skills that may reduce work-related stress and compassion fatigue.

We hope to learn more about this intervention in the hope that the development of an efficient, low-cost psychosocial training program for oncology nurses has the potential to reduce both patient and provider frustrations, to increase provider retention, and to enhance care provision.

ALTERNATIVES:
You have the alternative **not** to participate in this study. If you take part in this research study, and want to drop out, you should tell us.

It is possible that we will have to ask you to drop out before you finish the study. If this happens, we will tell you why. We will also help arrange other care for you, if needed. The Institutional Review Board (IRB), regulatory authorities, or the sponsor may also discontinue your participation in the study.

Taking part in this research study is up to you. You can decide not to take part. If you decide to take part now, you can change your mind and drop out later. We will tell you if we learn new information that could make you change your mind about taking part in this research study. You do not waive any legal rights by signing this consent form.

CONFIDENTIALITY:
Your participation in this research will be completely confidential. All participants will be assigned a unique study ID number. Identifying information will be stored separately from other study data in a password-protected, encrypted Excel file. All data will be stored locally on a secure server. Data will be stored for at least 3 years, or until the study is completed. Only study personnel within Dr. Pirl's team will have access to these data.

Records and results for you will not be identified as pertaining to them in any publication without your expressed permission. The Investigator and his/her collaborators, staff will consider both records confidential to the extent permitted by law. The Department of Health and Human Services (DHHS) and your family's health care providers, including authorized University or Hospital staff not involved in the study may review these research records. Your records may also be reviewed for audit purposes by authorized University of Miami employees or other agents who will be bound by the same provisions of confidentiality.

COMPENSATION:
Food and refreshments will be provided during the educational sessions. You will also receive nursing continuing education credits for each hour you attend the educational sessions. You will also receive a $15 gift card upon completion of the study.

CONTACT INFORMATION:
You can call us with your questions or concerns. Our telephone numbers are listed below. Ask questions as often as you want.

William Pirl, MD, is the person in charge of this research study. You can call him at (305)243-4198 from 9:00AM to 5:00PM, Monday through Friday. For questions about the research study assessments, the consent process, you can call William Hurwitz at (305)243-5385 from 9:00AM to 5:00PM, Monday through Friday. If you have questions about the educational sessions, call Maria Paula Jimenez at (305)284-8148.

If you have any questions relating to you rights as a research subject, please contact **the University of Miami's HUMAN SUBJECTS RESEARCH OFFICE (HSRO)**, at **305-243-3195**.

AGREEMENT OF DECISION TO PARTICIPATE:
You will receive a copy of this signed informed consent form.

I have read this consent, which is printed in English (a language which I read and understand). This study has been explained to my satisfaction and all of my questions relating to the study, the study procedures, risks and discomforts, and side effects have been answered. If I have any further questions regarding this study, or in the event of a study-related injury, I should contact the appropriate person named above. Based on this information, I voluntarily agree to give permission (consent) to take part in this study.

_____ _____
Signature of Participant Date

_____
Printed Name of Participant

_____ _____
Signature of Person Obtaining Consent Date

_____
Printed Name of Person Obtaining Consent