The Ohio State University Consent to Participate in Research

Study Title:  *From Cancer to Health* biobehavioral intervention training for mental health care professionals (Trainees)

Researcher:  Andersen, Barbara L., PhD, & Brothers, Brittany M., PhD

Sponsor:  National Cancer Institute (R25E CA163197)

This is a consent form for research participation. It contains important information about this study and what to expect if you decide to participate.

Your participation is voluntary.

Please consider the information carefully. Feel free to ask questions before making your decision whether or not to participate. If you decide to participate, you will be asked to note your agreement for participation and will receive a copy of the form.

Purpose:

The purpose of the study is to evaluate an educational and training program for professionals currently providing supportive mental health services to cancer patients and survivors.

Procedures/Tasks:

You will participate in a three-day training institute (referred to as “Institute” from here on), which will be held on the campus of The Ohio State University in Columbus, Ohio, with up to 40 trainees in total participating. The Institute will be scheduled from 8 a.m. to 5 p.m. on three consecutive days (specific dates will be provided by the research staff). You are responsible for making your own travel arrangements to the Institute. Directions to the training site and nearby parking garage locations will be available from the research staff.

The Institute curriculum will be based on the empirically supported *From Cancer to Health* (C2H) biobehavioral intervention, developed and tested by the research study’s Principal Investigator, Barbara L. Andersen, PhD. The curriculum will consist of lecture-type presentations and small group clinical competence exercises. The curriculum will be delivered in six half-day sessions mapped onto the key components of the C2H. All sessions will be audio/video-recorded and your image may appear on those recordings. Recordings will be used in the future for research and training purposes.

After the Institute concludes, you will be asked to participate in six monthly conference calls and/or online webinars or chat sessions, each lasting one hour. Meetings will be topical and will focus on intervention implementation or content. Training staff will moderate the calls. The calls will be recorded and/or transcribed and used in the future for research purposes.
You will also have the opportunity to participate in an email listserv and view and post content on a website with exclusive access only to trainees who have attended the Institute and their supervisors. The purpose of the email listserv and Institute website is to provide opportunities to connect with other mental health care professionals who are using the C2H intervention and have access to resources regarding the C2H intervention that may provide additional training. Any postings to the website may be used for research purposes.

Participation also involves assessments. Prior to attending the Institute, you will complete a pre-Institute assessment, consisting of written questions. During the Institute, you will periodically complete interview and written questions and up to six video/audio-taped assessments of clinical competence. These analogue assessments are individual role-play exercises with a member of the research staff demonstrating clinical skills that have been taught in the Institute. The analogue assessments are completed in a private room but may be viewed by the training staff in the viewing room to provide feedback on the demonstrated clinical skills to you. You will identify yourself only using your assigned subject number during the analogue assessments. Recordings will be stored, viewed and analyzed by research staff for research purposes.

After the Institute concludes, you will complete an adaptation plan at 1-month post-Institute. The adaptation plan is a written document where you assess how the C2H intervention might need to be adapted for unique characteristics of the patient population that you treat. Individual feedback from training staff on the adaptation plans will be offered to you and provided within two weeks of submission of the adaptation plans. Brief self-report written questionnaires will be assessed at 2-, 4-, 6-, and 12-months post-Institute. You will also be asked to regularly report your actual usage of the C2H intervention in clinical practice, submitted through a usage log on a weekly basis. All information collected, including the adaptation plan, will be used for research purposes.

Assessments completed either before or after the Institute can be completed via electronic format through a secure website. You will be provided with a unique identifier to access the secure website. You may also complete assessments via paper and mail them to the research staff if you prefer not to use the electronic submission website. Assessments completed during the Institute may be in paper or electronic format, such as completing questions on a laptop or tablet computer. The adaptation plan may either be uploaded via the secure website or sent via email or regular mail.

**Duration:**

The total participation duration is approximately 13 months. Participation starts approximately one month prior to the Institute and continues for 12 months after the conclusion of the Institute.

Total time for participating in the study is estimated to be 38 hours, including travel time to/from the Institute. Total time to participate in the Institute is estimated to be 33.5 hours (24 hours of training and 9.5 hours for travelling to/from the Institute); this includes curriculum
and all assessments completed during the Institute. Estimated time to complete the pre-
Institute assessment, adaptation plan, usage logs, and the 2-, 4-, 6-, and 12-month assessments
is 4.5 hours. Participation in the conference calls is voluntary and is estimated at an
additional 6 hours.

You may leave the study at any time. If you decide to stop participating in the study, there
will be no penalty to you, and you will not lose any benefits to which you are otherwise
entitled. Your decision will not affect your future relationship with The Ohio State
University.

Risks and Benefits:

You may feel uncomfortable responding to measures related to your job as well as your
attitudes, such as self-efficacy, competence, and the like. You may feel uncomfortable being
video-recorded. All personnel are trained to remain sensitive to a participant’s needs,
confidentiality procedures, and privacy information. You may omit any items/questions that
make you feel uncomfortable without consequence, you may discontinue the study at any
time, and you may be in contact with the research staff as needed with any
questions/concerns.

Potential benefits include learning supportive care skills that enhance your professional
capabilities, thereby helping your patients cope with stress and cancer diagnosis and
treatment more effectively. You may also be eligible for no-cost continuing education
credits. You will be contributing to the promulgation of an empirically supported treatment
for cancer survivors. In this way you are contributing to increased knowledge of what
psychological treatments are best for cancer patients. Contributions to society could also
include a better understanding of the possible impact of psychological efforts on physical
and mental health.

Confidentiality:

All electronic data will be uploaded to a secure Access database on a password-protected
terminal and server. All paper data will be scanned into a secure Access database. Paper
copies of the data will be stored in the PI’s secure (locked) laboratory, in a locked office, in a
locked filing cabinet. Only key research personnel will have: 1) keys to the locked offices and
2) keys to the cabinets with data. All data will be coded by an assigned subject number only,
and only the PI and senior research staff will have access to the name/number code during
data collection. There will be one master list, in electronic form, kept in the PI’s laboratory.
Electronic data used for analyses will be stored in a separate Microsoft Access software
database with no connection to the electronic list of trainees. The server that will house the
data will also be firewall- and password-protected. After completion of data collection, the PI
will retain the master list. You are only identified by your subject number in data
analyses/publications. For recordings of the analogue assessments, you will identify yourself
using your subject number. All research data will remain separate from the master list and
identifiers. All research data in hard copy form (paper questionnaires and DVDs of video
recordings) will be kept in locked cabinets in a locked office in the Department of Psychology. During non-business hours the Psychology Building is only accessible to affiliated faculty and staff via key card access. All data will be de-identified.

The recordings of the Institute lecture-type presentations and small group clinical competence exercises may be used to train other mental health professionals. If you do not wish to have your image appear in these types of recordings, an “off-camera” area will be identified where you can participate in both didactic and experiential sessions without appearing on video.

Efforts will be made to keep your study-related information confidential. However, there may be circumstances where this information must be released. For example, personal information regarding your participation in this study may be disclosed if required by state law. Also, your records may be reviewed by the following groups (as applicable to the research):

- Office for Human Research Protections or other federal, state, or international regulatory agencies;
- The Ohio State University Institutional Review Board or Office of Responsible Research Practices;
- The sponsor, if any, or agency (including the Food and Drug Administration for FDA-regulated research) supporting the study.

**Incentives:**

During the Institute, complimentary lunch, snacks and beverages during breaks will be provided every day. Parking passes will be provided every day to those travelling by car to the Institute. Individuals who attend the Institute will be provided with an intervention therapist manual on day one of the Institute and three intervention manuals for patients on day three.

If you live more than 75 miles from The Ohio State University campus, you will be eligible for $250 in a travel stipend to attend the Institute. You will be compensated (in the form of a gift card to a national retailer) $15 for completing the adaptation plan, $10 for the 2-month assessment, $15 for the 4-month assessment, $15 for the 6-month assessment, and $25 for the 12-month assessment. Alternately, you may elect to receive patient manuals for assessment completion (i.e., one manual/assessment).

**Participant Rights:**

You may refuse to participate in this study without penalty or loss of benefits to which you are otherwise entitled. If you are a student or employee at Ohio State, your decision will not affect your grades or employment status.

If you choose to participate in the study, you may discontinue participation at any time without penalty or loss of benefits. By signing this form, you do not give up any personal legal rights you may have as a participant in this study.
An Institutional Review Board responsible for human subjects research at The Ohio State University reviewed this research project and found it to be acceptable, according to applicable state and federal regulations and University policies designed to protect the rights and welfare of participants in research.

**Contacts and Questions:**
For questions, concerns, or complaints about the study you may contact Barbara L. Andersen, PhD, at 614-292-8429.

For questions about your rights as a participant in this study or to discuss other study-related concerns or complaints with someone who is not part of the research team, you may contact Ms. Sandra Meadows in the Office of Responsible Research Practices at 1-800-678-6251.

If you are harmed as a result of participating in this study or for questions about a study-related harm, you may contact Kyle Patterson at 614-292-3541 or cancertohealth@osu.edu.

I have read this form and I am aware that I am being asked to participate in a research study. I voluntarily agree to participate in this study.

**AGREEMENT:** Please click one of the following statements to indicate whether you agree to participate in the study described above.

(Informed consent is completed during the online application process).