CONSENT FORM TO PARTICIPATE IN A RESEARCH STUDY

Study title: Integrative Approaches in Palliative Care: Provider-Driven Online Continuing Education -- Phase I
Agency responsible for the project: Collinge and Associates, Inc., Eugene, Oregon
Principal Investigator: William Collinge, PhD, MPH
Study sponsor: National Cancer Institute

You are being asked to participate in a research study to develop an online continuing education course for multidisciplinary health care practitioners working in the field of palliative care. The purpose is to develop an online course that effectively delivers evidence-based education on the use of complementary therapies in palliative care.

In order to decide whether you want to be part of this project, you should understand enough about the activities and responsibilities involved, and any risks and benefits of participation, so that you can make an informed choice. This is known as "informed consent." Please take your time to make your decision.

Why is this project being conducted?
Palliative care represents one of the most rapidly expanding sectors of health care. Some complementary therapies have been shown to offer comfort, reduce suffering and improve quality of life in palliative care patients. As the empirical evidence about the efficacy of these complementary therapies in palliative care is growing and an increasing number of palliative care patients seek such therapies, there is a need for greater educational opportunities for multidisciplinary palliative care personnel to become familiar with these options.

This project seeks to address an unmet need for educational content for palliative care personnel in the evidence-based application of complementary therapies in the palliative care setting. The goal is to help multidisciplinary personnel integrate such therapies successfully in care planning and service delivery, advise patients and family members effectively, and communicate effectively with colleagues.

How many people will take part in the study, and who is being recruited?
This is Phase I of a two phase study. In this phase, 108 health care providers who are currently working in palliative care settings will participate. We will seek roughly equal representation of physicians, nursing professionals, social workers, chaplains, pharmacists, and others from other allied health disciplines.

Who is eligible to participate?
The following personnel are eligible to participate: physicians, physician assistants, nurse practitioners, nurses, social workers, psychologists, counselors, pharmacists, chaplains, administrators, and other palliative care professionals. Participating professionals must be currently active within palliative care settings.

What is involved in being in the study?
48 subjects will be assigned to participate one time in an online videoconference focus group (6

subjects per group).

If selected for this activity you will:

1. Access the project web page to read this Consent Form.
2. Complete the online Application Form. The Application Form includes giving consent to be a research participant.
3. Applicants will be selected based on the needs of the study for gender and ethnic diversity and representation of the range of disciplines being sought.
4. If your application is selected you will be contacted for a telephone interview to go over this Consent Form.
5. After the interview, if you affirm consent verbally, you will be entered into the list of candidates for final selection to be in the Focus Group portion OR the Instrument Development portion of the study. We will then determine whether you will be invited to participate in one or the other of these activities based on the project's needs for diversity and representation.
6. If invited to participate in Focus Group you will receive a two page orientation sheet to read before the meeting and then spend 60 minutes participating in an online videoconference focus group led by two expert project consultants in the field of palliative care education. The Focus Group will discuss questions pertaining to what kinds of educational content are appropriate and needed for an online CME course on use of integrative therapies in palliative care. This would complete your participation in the project.

60 subjects who applied and were NOT selected for the Focus Group activity will be assigned to participate in development of a new Assessment Instrument by completing it one time.

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6. If invited to participate in the Instrument Development activity you will be assigned to complete an online survey instrument taking about 15 minutes. This will conclude your participation.

What information is collected?

Subject information collected on the application form:

1. Contact information (phone, address, email)
2. Demographic information (age, gender, race/ethnicity)
3. Occupational status (current job, position)
4. Years of experience in health care and palliative care

5. License or credential(s)
6. Education history
7. Self-ratings of your level of confidence in recommending evidence-based use of integrative therapies for patients receiving palliative care.

Procedures that are considered experimental and are being tested in this study:
No experimental procedures will be used in this Phase I study. The Focus Group activity consists of group discussion only, to be recorded and analyzed for content analysis. The Instrument Development activity will provide metrics on survey item construction to be used in survey development, to determine what survey items are useful in this topic area.

How long will you be in the study?
Focus Group participants: 60 minutes.
Instrument Development participants: around 15 minutes.

What are the risks of the study?
There is slight risk of loss of confidentiality if the security of the server holding project data is breached.

What are the benefits of your participation?
You may or may not benefit from participating in this study. Benefits for Focus Group participants may be in the form of hearing peers' opinions and thoughts about the field of integrative therapies in palliative care. Benefits for Instrument Development participants may be from self-observation in responding to questions related to palliative care posed in the survey.

Compensation:
Focus Group participants: You will be paid an honorarium of $200 for completion of the Focus Group activity. We will mail you a check within one week upon completion of your participation. If you do not complete participation in the focus group we will pay you a pro-rated amount based on the proportion completed.

Instrument Development participants: $40.

What other options are there?
The alternative to participating in this study is not participating.

New Findings
Not applicable.

Withdrawal/Removal:
Your participation in this study is voluntary. Your refusal to participate or your withdrawal from the study will involve no penalty or loss of benefits to which you are entitled. You may stop your participation at any time, and be paid a pro-rated amount based on the proportion of the activities completed.

The investigator (Dr. Collinge) may end your participation in this study for any of the following reasons:

1. If you begin the project but are unable to finish the project activities within their scheduled timeframe.
2. If the study is cancelled by the National Cancer Institute, the New England Independent Review Board, DHHS or by the FDA;
3. For administrative reasons.

Who will see the personal information provided?

1. The information on your application form will be seen by the Investigators (Dr. William Collinge and Dr. Leila Kozak) and a Research Assistant (to be named).
2. For participants in the Focus Groups, your participation will be viewed via internet video conference by the other participants and the Investigators. Personal information will be limited to your first name, city and discipline. Your voice will be audio recorded for transcribing and qualitative analysis of focus group transcripts. For participants in the Instrument Development activity, your responses to the survey instrument will be seen only by the PI's and the statistician conducting analysis of subject responses.
3. No information about your identity will be included in any publications about the project.
4. No information about your participation or your responses to questions will be released to your employer or anyone else.
5. In order to assure that your rights and safety are protected, members of the New England Independent Review Board; or personnel of the National Cancer Institute, or the federal Office of Human Research Protections, may also see parts of the information you provide for this study and, therefore, may see your name and other personally identifiable information about you. The information collected is the property of Collinge and Associates, Inc., and you will not be able to get it back.

What about confidentiality?

Your records will be kept safely in the offices of Collinge and Associates, Inc. and InterVision Media, Inc., the website development and hosting company that will be producing the project website and collecting course data. Efforts will be made to keep your personal information confidential. We cannot guarantee absolute confidentiality, as your personal information may be disclosed if required by law. Also see "Who will see this information?" section above. Any publication of findings will not include any way of identifying you.

What are the costs?

There is no cost to you for participating in this study.

What are your rights as a participant?

Taking part in this study is your choice. You may choose not to take part or may leave the study at any time. Leaving will not result in any penalty or loss of benefits to which you are entitled. However, if you leave the project early you will not be paid for any activity not completed.

Who do you call if you have questions or problems?

For questions about the study contact Dr. Collinge at (541) 632-3502 or Dr. Kozak at (425)765-1096.

For questions about your rights as a research participant, contact the New England Independent Review Board (which is a group of people who review the research to protect your rights) at (800) 232-9570.

[SEE NEXT PAGE]

VOLUNTEER'S STATEMENT

I have been given a chance to ask questions about this research study. These questions have been answered to my satisfaction. I may contact Dr. William Collinge or Dr. Leila Kozak if I have any more questions about taking part in this study. Collinge and Associates, Inc. is being paid by the National Institutes of Health for my participation in this study.

I understand that my participation in this research project is voluntary. I know that I may withdraw from the study at any time without losing any benefits to which I might be entitled. I also understand that the investigator in charge of this study may decide at any time that I should no longer participate in this study.

If I have any questions about my rights as a research subject in this study I may contact:

New England Independent Review Board
Telephone: 1-800-232-9570

By marking the Consent box on the Application Form, I have not waived any of my legal rights.

By marking the Consent box on the Application Form, I attest that I have read and understand the above information. I agree to participate in this study if selected. I understand that I should download and save a copy of this Consent Form for my own records.