DEPARTMENT OF HEALTH & HUMAN SERVICES

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National Cancer Institute
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To: Office of Management and Budget (OMB)

Through: Mikia Currie, NIH Program Analyst, OPERA
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From: Nina Goodman, MPH, Program Officer
Office of Communications and Education (OCE)
National Cancer Institute/NIH

Subject: In-Depth Interviews (IDI) and Online Focus Group on Clinical Research and Clinical Trials in Undergraduate Nursing Education (OMB No. 0925-0046-03, Expiration Date 2/28/13)

The National Cancer Institute (NCI) proposes conducting formative research to explore the thoughts and opinions of practicing nurses and individuals about needs regarding educating nurses in the area of clinical research and clinical trials at the undergraduate level. The formative research would involve in-depth interviews (IDIs) as well as an online focus group discussion (using a methodology called "Advance Strategy Online (ASO) session," described below). The goal of this formative research is to help inform NCI's efforts to collaborate with key stakeholders (both internal and external) to develop clinical research and clinical trials core competencies and curricula guidelines for entry-level professional nursing practice.

Background on the Project

The need for nurses to have an understanding of the principles of clinical research and clinical trials, regardless of their practice setting or area of specialty, is becoming increasingly clear. However, current nursing educational programs at the baccalaureate are not addressing the need to prepare nursing students for the increasing and changing roles of nursing staff in the implementation of clinical research. Both the published literature and key-decision makers have highlighted the existing deficiencies in nursing education related to clinical research and clinical trials.

Currently, there is no organization addressing the existing deficiencies in clinical research and clinical trials content in baccalaureate nursing education programs. Based on past experience leading similar efforts—and as the primary Federal agencies for funding medical research and for cancer research and training—the National Institutes of Health (NIH) and the National Cancer Institute (NCI) are well-suited to address this issue at a national level. In 2005, NCI, in

conjunction with the National Human Genome Research Institute and the National Institute of Nursing Research, led efforts that resulted in the development of essential genetic and genomic competencies for all registered nurses. NCI, in collaboration with our research partners – the NIH Clinical Center, The Johns Hopkins University and Georgetown University Hospital, is interested in once again leading a similar national effort, in this case to potentially develop core competencies and curricula for undergraduate professional nurses in the area of clinical research and clinical trials.

Through this current study, NCI is interested in conducting formative research to help gain a better understanding of the current environment regarding clinical research and clinical trials nursing education from the perspective of key decision-makers in the field of nursing education.

Methodology
For this study, 27 in-depth interviews and one online focus group will be conducted. Each of these two methodologies is described in more detail below.

In-depth interviews (IDIs)
Individual, in-depth interviews (IDIs) will be conducted with a sample of 9 key informants from each of 3 distinct audiences. The audiences are (1) nurses who are directors of their institutions' nurse staff development efforts, (2) nurse executives, and (3) practicing nurses. A total of 27 interviews will be conducted.

In-depth interviews are being used because they are useful when the goal of the data collection is to obtain extremely detailed information about a person's thoughts and behaviors or when the goal is to explore new issues in depth – both of which are true in this instance. In-depth interviews are also being used because this research is seeking to gather the opinions of individuals without the influence of a group, as might occur in a focus group.

Each IDI will last approximately 60 minutes and will be conducted by telephone using an experienced interviewer. Customized interview guides will be used to facilitate the interviews with each of the three different research audiences. The interviews will be conducted by AED, an NCI contractor that specializes in communications as well research of this nature.

Participation will be strictly voluntary and based on informed consent **(Attachment A1)**. The interviews will be audio-recorded for the purposes of report writing only and all audio-recordings will be destroyed afterward. To maintain participant security, names and any other personal identifying information will not appear on notes, recordings, or in the summary report.

Online focus group
A methodology called "Advanced Strategy Online (ASO)" session—for conducting online focus groups—will be used for the other portion of this study. The ASO session is a qualitative research process that uses an online interactive discussion. Typically, about 20 participants participate in each ASO session. One ASO session will be conducted with approximately 20 individuals who are high-level staff (deans or leaders) in their nursing schools. Participation will be strictly voluntary and based on informed consent **(Attachment A2)**. The session will be facilitated by Stratacomm, an NCI contractor that specializes in communications and research of

this nature.

For an ASO session, each participant needs two modes of communication: a computer with an internet connection, and a telephone to call into a toll-free conference line. Sessions are designed in accordance with project objectives and moderated by one or more research professionals with extensive experience in both the software technology and opinion research techniques.

In ASO sessions, participants are connected to each other in a 90-minute online session. They receive instructions and are asked questions from the moderator over the phone on the conference call. Participants then type their answers into their designated dialogue box (which hides their identity from the other participants, such that each participant can see all the responses, but will not know who wrote which entry). As part of this process, the facilitator guides the group through online brainstorming, assessment exercises to prioritize key issues, and open discussion as appropriate. All responses are anonymous to others in the session to maintain security and free thinking within a guided format.

The ASO's methodology is designed to provide a range of online activities among the participants, including:

- Electronic Brainstorming
- Idea Categorization
- Idea Prioritization
- Voting
- Survey Questions
- Topic Commentary

The ASO's software automatically formats and tabulates data as the session proceeds. This means immediate turnaround: summaries of survey results are available seconds after respondents complete a question, and full verbatim reports are available within hours after a session.

Research Instruments

Discussion guides **(Attachments A3-A6)** have been developed to focus the IDIs and the ASO around particular topic areas. More specifically, the guides for the 3 sets of IDIs and the ASO session have been developed to explore the following:

- Knowledge and attitudes toward clinical research and clinical trials in nursing education and practice.
- Process/sources of information by which nurses learn about clinical research/clinical trials concepts.
- Nurses' learning needs about clinical research/clinical trials concepts.
- Barriers to incorporating clinical research/clinical trials content into nursing education (undergraduate) and training (job orientation).
- Current and potential opportunities for nurses with clinical trial training/experience in a variety of practice settings.

- Educational resources nurses use to learn about clinical research/clinical trials and to teach patients about clinical research/clinical trials.
- Information and resources used to design curricula to teach nurses about clinical research/clinical trials.
- Information and topic areas that are considered important for inclusion in a clinical research/clinical trials curriculum.
- Perceptions about the relative importance/priority of clinical research/clinical trials education in nursing education programs and practice.

Participants

In-Depth Interviews

IDI participants will include individuals from organizations that are currently participating in clinical research/clinical trials. Participants in the IDIs will not be limited to those working in oncology. To ensure a mix of experiences and perspectives, participants from larger academic/medical centers as well as smaller community-based settings will be included, and efforts will also be made to include individuals from a mix of urban and rural locations. For each of the three audience groups, the individuals who will be recruited to participate will include the following:

- **Nursing Educators:** Participants will be from nurse-employing organizations and will include individuals who are responsible for the oversight and organization of new graduate nurse orientation. In particular, it will include 9 individuals with at least 3 years of experience in this role, although the experience need not be at their current institution. The discussion guide is **Attachment A3.**
- **Nurse Executives:** Participants will consist of 9 individuals who have held the chief nursing position within their inpatient (i.e., hospital) or outpatient (e.g., hospital or private practice ambulatory care setting, , VA outpatient clinic) setting for at least 3 years. The discussion guide is **Attachment A4.**
- **Practicing Nurses:** Participants will consist of 9 individuals who are currently employed as care providers in clinical settings. To obtain information from a range of perspectives, approximately half of the participants will have been practicing nurses for less than three years while the other half will have been nurses for three or more years. The discussion guide is **Attachment A5.**

Participants for the IDIs will be recruited by AED staff. The NCI project staff, as well as several individuals from the Johns Hopkins University, Georgetown University, and the NIH Clinical Center will provide AED a list for potential participants and contact information for the purposes of recruiting nine participants from each of the three audience groups.

To recruit the participants for the study, AED will follow up by e-mail and phone **(Attachment A6)** with potential participants from the list provided by the NCI project team and those who may be referred to AED by other contacts provided by the NCI project team. A screener **(Attachment A7)** has been developed to assist in assuring eligibility. AED will screen participants over the phone and eligible participants will be invited to participate in the interview

at a time that is convenient for them. We expect a total of 27 participants for the IDIs.

The average total participation time for the interviews will be 80 minutes (1 hour 20 minutes) per participant; this time includes the 60 minutes for the discussion, as well as an additional 20 minutes for the time involved in other related activities including the recruitment process and completing and returning the consent form (See Table 1).

Online Focus Group
ASO participants will include approximately 20 individuals who are high-level faculty (deans or leaders) in their nursing schools. They will be recruited from nursing schools across the United States that offer undergraduate (baccalaureate) nursing degrees.

Participants for the ASO session will be recruited by Stratacomm staff. The NCI project staff will provide Stratacomm a list of names, institutions, and work email addresses of the potential participants for the ASO group discussion session, which Stratacomm will use as its recruiting pool. Participants will be invited to participate by email **(Attachment A8)**. We expect a total of approximately 20 participants for the ASO group, assuming a list of 80-100 qualified possible recruits. Participants will receive an honorarium of $100 for their time. Research on participation in focus groups indicates that, without providing minimal levels of monetary compensation, insufficient numbers of participants will attend and results will not be useful. The session will last 90 minutes. The focus group guide is **Attachment A9**.

The average total participation time will be 120 minutes (2 hours) per participant; this time includes the 90 minutes for the group discussion, as well as an additional 30 minutes for the time involved in other related activities including the recruitment process; completing and returning the consent form; reviewing the ASO instructions; and getting online and accessing the discussion group via computer and telephone conference line.

The total burden requested for this substudy is 36 hours for the IDIs and 40 hours for the ASO session, plus 8 hours for screening, totaling 84 hours (see Table 1). The full generic study, approved on February 10, 2010, requested a total of 7,050 burden hours. This effort will account for 84 hours, or approximately 3.8 percent of the total annual burden hours granted in our approval package. Approval of this submission, along with the two previous approvals amounts to 1096 hours, leaves 5,964 total hours available for future sub-studies.

Table 1: Estimates of Hour Burden for IDIs and ASO session

Types of Respondents	Number of Respondents	Frequency of Response	Average Response Time	Annual Hour Burden

			(Minutes/Hour)	
Screener for Nurses, nurse educators, and nurse executives (Attachment A7)	50	1	10/60 (0.1667)	8
In-Depth Interviews with Nurses, nurse educators, and nurse executives (Attachments A3, A4, and A5)	27	1	80/60 (1.333)	36
Focus Group with Deans or leaders in nursing schools (Attachment A9)	20	1	120/60 (2)	40
Totals				84

Thank you for your consideration of this proposed sub-study 0925-0046-03. Please feel free to contact me at 301-435-7789 if you have any questions.

Attachments

Attachments (attached below)

- Attachment A1: Informed Consent for In-Depth Interviews
- Attachment A2: Informed Consent for Group Discussions
- Attachment A6: IDIs Invitation Email
- Attachment A8: Nursing ASO Invitation Letter

Attachments (attached in a separate document)

- Attachment A3: Discussion Guide for Nurse Educators
- Attachment A4: Discussion Guide for Nurse Executives
- Attachment A5: Discussion Guide for Practicing Nurses
- Attachment A7: Script and Screener for In-Depth Interviews
- Attachment A9: Focus Group Guide

Attachment A1: Informed Consent Form for Interviews

Identification of Project	**Clinical Research/Clinical Trials Nursing Education Interviews**
Statement of Age of Subject	I state that I am at least 18 years of age, in good physical health, and wish to participate in a program of research being conducted by the Office of Market Research and Evaluation of the National Cancer Institute (NCI), Bethesda, MD 20742.
Purpose	The purpose of this research is to explore the perspective of practicing nurses and the individuals who educate and employ them— particularly nurse staff development professionals and nurse executives—regarding current practices and potential core competencies for training nurses in the area of clinical research and clinical trials at the undergraduate level.
Procedures	Participants will be asked to take part in an individual interview about their experiences, thoughts and opinions related to the current practices for training nurses about clinical research/ clinical trials, as well as potential core competencies for nurse education in topics related to clinical research/clinical trials. The total time involved in the interview, including instructions, will be no more than 60 minutes.
Confidentiality	All information collected in this study will be kept secure to the extent permitted by law. I understand that the data I provide will be grouped with data others provide for the purpose of reporting and presentation and that my name and affiliation will not be used. I understand that the interview will be audio-recorded. My voice recording will not be played to others besides the research team without my written permission. The recordings will be kept in a secured location and will be destroyed by December 31, 2014.
Risks	I understand that the risks of my participation are expected to be minimal in nature.
Benefits, Freedom to Withdraw, & Ability to Ask Questions	I understand that this study is not designed to help me personally. Rather, investigators hope to gain a better understanding of the current environment around clinical research and clinical trials nursing education at the undergraduate level from the perspective of the practicing nurse, educator and the employer. I am free to ask questions or withdraw from participation at any time and without penalty.
Contact Information of Investigators	Program Officer, Office of Market Research and Evaluation, National Cancer Institute Telephone: 301-435-5646 Email: gradym@mail.nih.gov

Printed Name of Research Participant _____
Signature of Research Participant _____
Date_____

Attachment A2: Informed Consent Form for Group Discussions

Identification of Project	**Clinical Research/Clinical Trials Nursing Education Formative Research**
Statement of Age of Subject	I state that I am at least 18 years of age, in good physical health, and wish to participate in a program of research being conducted the Office of Market Research and Evaluation of the National Cancer Institute, Bethesda, MD 20742.
Purpose	The purpose of this research is to explore the perspective of individuals in leadership positions within nursing schools regarding issues related to integrating clinical research and clinical trials topics in undergraduate nursing programs as well as the value of such an inclusion to nurses and the organizations in which they will work.
Procedures	Participants will be asked to take part in a group discussion session regarding their thoughts and opinions related to training nurses at the undergraduate level on topics related to clinical research and clinical trials. The discussion session will be conducted primarily online—in real time— with participants sharing their comments in written format using their computer. During the session, there may be times when participants will be asked to discuss their thoughts and opinions over a conference phone line; all feedback collected online and verbally will be completely anonymous. The total time involved in the discussion, including instructions, will be no more than 90 minutes.
Confidentiality	All information collected in this study will be kept secure to the extent permitted by law. I understand that the data I provide will be grouped with data others provide for the purpose of reporting and presentation and that my name and affiliation will not be used. I understand that the written comments I make during the discussion session will be electronically captured and that my verbal comments will be audio-recorded; neither my name nor institution will be associated with either source of information. The recordings will not be shared beyond the research team without my written permission. The recordings will be kept in a secured location and will be destroyed by December 31, 2014.
Risks	I understand that the risks of my participation are expected to be minimal in nature.
Benefits, Freedom to Withdraw, & Ability to Ask Questions	I understand that this study is not designed to help me personally. Rather, investigators hope to gain a better understanding of issues related to clinical research and clinical trials nursing education at the undergraduate level from the perspective of key decision-makers within nursing schools. I am free to ask questions or withdraw from participation at any time and without penalty.
Contact Information of Investigators	Program Officer, Office of Market Research and Evaluation, National Cancer Institute Telephone: 301-435-5646 Email: gradym@mail.nih.gov

Printed Name of Research Participant _____
Signature of Research Participant _____
Date_____

Attachment A6: IDIs INVITATION EMAIL

Recruitment E-mail
Subject line: [REVISE AS IS APPROPRIATE] The National Cancer Institute requests your assistance with a nursing education research project

Dear [INSERT NAME]:

You have been recommended as someone who can provide valuable input on a project that the National Cancer Institute (NCI) is undertaking to gain a better understanding of current nursing education practices in the area of clinical research and clinical trials. As nursing shifts from a traditional practice to an evidence-based one, the role of and opportunities for nurses in clinical research and clinical trials settings has and will continue to increase.

I am a member of a group led by the NCI's Office of Communications and Education that includes representatives from Johns Hopkins University and Georgetown University. We are interested in speaking with faculty at schools of nursing, nurse staff development professionals, nurse executives, and practicing nurses.

I am hoping that you will agree to participate in this study and that you may be able to recommend other potential study participants and how best to reach them. Participation is voluntary and involves a 1-hour telephone interview with the Academy for Educational Development (AED), a social science research company that NCI has contracted with to do the interviews. More information is contained in the attachment to this e-mail.

If you are interested in participating and/or know of other potential participants, please reply to this email or call me at [INSERT PHONE NUMBER] and I will have an AED representative follow up with you.

If you have any questions about this research, please feel free to contact me or Meredith Grady in NCI's Office of Market Research and Evaluation at (301) 435-5646 or OCEresearch@mail.nih.gov

Cordially,

[Insert Name]
[Signature line information]

Attachment A8: NURSING ASO INVITATION LETTER

Dear [insert Dr./Mr./Ms. insert name]:

I am writing to request your help with an important initiative we are pursuing at the National Institutes of Health in collaboration with the National Cancer Institute, The NIH Clinical Center, The Johns Hopkins University and Georgetown University Hospital.

As you know, the expansion of clinical research as a national priority and the emergence of research nursing as a clinical specialty have been underway for some time. Some nursing schools offer graduate programs in clinical research management and clinical trials, less attention has been given to incorporating this content into baccalaureate programs.

Over the past several months, we have gathered a great deal of feedback from the academic and health care communities to assess the need for and value of incorporating concepts related to clinical research practice and clinical trials content in undergraduate nursing programs. Additionally, we believe it is critically important to hear from academic leaders, like yourself, regarding your thoughts and opinions on this subject, as well as your level of support for a potential initiative to enhance research nursing practice and clinical trials content for undergraduate nursing students.

We are hoping that you are willing to join an online discussion group with approximately 20 deans and senior faculty at baccalaureate schools of nursing across the United States. The session will last approximately 90 minutes and be conducted as an interactive discussion. It will be facilitated by Stratacomm, an NCI contractor that specializes in communications and research. You and other participants will be guided through online brainstorming, discussion, and assessment exercises designed for state-of-the-art qualitative data collection. All online responses are anonymous to maintain your security and free thinking within a guided format. In appreciation for your time and input, we are offering an incentive of $100 for your participation.

The research session will take place from [insert time] on [insert date], and you may participate from the privacy of your home or office. All you will need are two lines of communication for the session: a computer with internet connection, and a telephone to call into a toll-free conference line that will be provided.

If you are interested, please reply to this email or send an email to our contact at Stratacomm, [insert name], who will work directly with you to arrange your participation. [His/her] email is **[insert name]@advancedstrategycenter.com**. If you are unable to attend, I encourage you to designate an appropriate alternate representative.
I sincerely thank you for your interest and willingness to inform this important initiative and look forward to hearing from you in the session.
Best regards,

Clare Hastings, RN, PhD, FAAN
Chief Nurse Officer
National Institutes of Health Clinical Center