

**Screener and Guides for In-Depth Interviews (IDI) and Online Focus Group
on Clinical Research and Clinical Trials in Undergraduate
Nursing Education (OMB No. 0925-0046-03)**

Revised October 5, 2010

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Attachment A3: Discussion Guide for Nurse Educators

OMB No. 0925-0046-03
EXPIRATION DATE: 02/28/2013

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Interviewer Identification
Name of interviewer
Date of interview
Interview start time Interview end time
Interviewee Identification
Name of interviewee

I. Introduction (2 minutes)

Hello, my name is and I work for AED, a nonprofit organization working to improve health, education, civil society and economic development. Also on the phone with me is from AED. She will be taking notes today, so we can accurately capture your feedback.

We are currently working on a research project for the National Cancer Institute (or NCI). We are talking to nurses – including faculty at nursing schools, nursing staff development professionals, nurse executives, and practicing nurses – about current practices and potential core competencies for educating nurses about clinical research and clinical trials. This interview will take no more than 60 minutes. Your feedback will be kept secure to the extent provided by law. The findings will be reported to the NIH in summary form and no names or other identifying information will be used.

With your permission, we would like to audiotape today's interview. The recording will be used by AED to aid in writing a report of findings and will be destroyed after the report has been completed. As mentioned on the consent form you signed prior to our interview, your participation is voluntary and you can skip any questions you would prefer not to answer or stop the interview at any time during our discussion.

Please let me know if I have your permission to record this call. If so, I will turn on the recorder now. [If participant agrees – and has signed a consent form – proceed with taping the interview. If participant is uncomfortable or unsure, proceed without taping.]

Do you have any questions for me before we get started?

II. Warm-up / Intro (5 minutes)

1. Before I start asking you questions, let's briefly go over the NIH definitions of clinical research and clinical trials to be sure that we are on the same page. [*Read out loud*]
 - a. Clinical trials are defined as a prospective research study used to determine whether new biomedical or behavioral interventions, such as drugs, treatments, devices, and new ways of using them, are safe, efficacious, and effective.
 - b. Clinical research is typically research conducted with human subjects to understand the mechanisms of human disease or assess a new therapeutic intervention or technology; it also includes epidemiologic and behavioral studies, outcomes research, and health services research.

Clinical research then is broader than nursing research as I believe it is commonly taught in nursing research courses. My understanding is that most nursing research courses teach the methods used to conduct studies to provide an evidence or research-base for nursing practices.

2. Now, if you could tell me a little about your current position as a nursing staff development professional. Let's start by having you tell me about your position, how long you've had this role, and what it entails.
 - a. Probe: Were you a full-time nurse providing care to patients/families at one time?
 - b. Probe: While you were providing care to patients/families were you in any way engaged in clinical research and/or clinical trials? If yes, how so?

III. Current practices and perceptions of clinical research and clinical trials (20 minutes)

Now we'd like to spend some time discussing clinical research and clinical trials in the context of nursing staff development. We are specifically interested in the current practices at your institution and how content about clinical research and clinical trials may be integrated into the new employee orientation and the continuing education opportunities for nurses.

1. What are the positions or roles in clinical research and clinical trials available to nurses in your institution?
 - a. Probe: Have these changed in the past few years? Do you find a need for more nurses with clinical research/clinical trials experience?
 - b. Probe: When recruiting nurses to work at your institution, how important is it for them to have knowledge and/or skills related to clinical research/clinical trials?
2. How prepared are nurses to play a role in clinical research and/or clinical trials at your institution?
 - a. Probe: How prepared are new graduate nurses? What about more experienced nurses?
 - b. Probe: How do you evaluate their level of performance?
3. If nurses were differently prepared/taught more about clinical research/clinical trials in nursing school what difference would that make on roles they could take on in clinical research in your institution?
4. Are nurses newly employed by your institution aware of clinical research and clinical trials professional opportunities?
 - a. Probe: What do newly employed nurses know about roles nurses play/can play in clinical research/what level of awareness do they have? Do you perceive a gap in nurses' knowledge about clinical research and clinical trials?
 - b. Probe: How interested are newly employed nurses in being a part of clinical research/clinical trials?
 - c. Probe: What skills necessary for working in clinical research do newly employed nurses have? Are there skill sets that are lacking?
5. How much of a priority is educating nurses about clinical research and clinical trials at your institution?

6. How is clinical research and clinical trials content incorporated into your staff development curriculum including orientation and/or continuing education?
 - a. Probe: Is it required or is it an opportunity that nurses can elect to pursue?
 - b. Probe: Who provides training to nurses around these topics?
 - c. Probe: If this curriculum exists, is it based on certain competencies?

7. What content is taught about clinical research and clinical trials in new employee orientation? As part of a new graduate nurse orientation program if different from new employee orientation? As part of your continuing education program for nurses?
 - a. Probe: How in-depth is the training that they receive?
 - b. Probe: What does this training prepare them to do?
 - c. Probe: Do you evaluate knowledge gain if offered as continuing education? How is this done?

IV. Future Directions in Clinical Research/Clinical Trial Curriculum Content (20 minutes)

NCI and key stakeholders are discussing future directions that might be considered related to clinical research and clinical trials for professional nursing education. As they consider these issues, they wanted to hear from nursing staff development professionals like you to gather your insights and input.

1. What are your thoughts on baccalaureate programs developing or incorporating clinical research/clinical trials content into their academic curricula for nursing students?
 - a. Probe: What do you think about clinical research and clinical trial curriculum guidelines for schools of nursing?
 - b. Probe: How receptive are you towards related content being incorporated into the NCLEX (National Council Licensure Examination) and certification requirements?
 - c. Probe: How important is teaching nursing students about clinical research and clinical trials to familiarize them on these topics before they seek employment? Why do you feel that way?

2. What are your thoughts on refining/expanding clinical research/clinical trials content into a staff development curriculum?
 - a. Probe: What do you think is the best way to integrate clinical research/clinical trials into staff training?
 - b. Probe: Into the orientation for new staff?
 - c. Probe: And into continuing education options for current staff?
 - d. Probe: What is the process for incorporating new professional nursing competencies into the staff training programs at your institution?
 - e. Probe: How receptive are you towards incorporating clinical research/clinical trial competencies into your staff development program?

3. What challenges do you foresee with incorporating clinical research and clinical trials content into:
 - a. Probe: The curriculum of nursing schools?
 - b. Probe: Into new employee orientation?
 - c. Probe: Into new graduate orientation?
 - d. Probe: Into staff development programs?
 - e. Probe: Would you anticipate competing priorities or staff resistance, etc.?
 - f. Probe: How might these challenges be able to be overcome?

4. If you were asked to incorporate clinical research/clinical trials training into your staff development curriculum what kinds of resources or supports would you require?
 - a. Probe: What support do you need from within your institution? How easy or difficult will this be to obtain? What would be helpful?
 - b. Probe: What support do you need from professional organizations (both nursing and research) and why will this be helpful?
 - c. Probe: What assistance could governmental agencies like the National Cancer Institute and the Agency for Healthcare Research and Quality be in providing information related to clinical research/clinical trials?

5. What do you think would make it easier to teach about clinical research/clinical trials at your institution? (e.g., materials, information, examples, sample course modules, observation forms, other resources, etc.)
 - a. Probe: What additional related topics should these materials address?
 - b. Probe: How should information be “packaged” so that it can most easily be used?

V. Access to related materials for nursing staff development and training professionals (5-10 minutes)

1. To what extent have you looked for and used clinical research/clinical trials related information and materials for educating nurses on these topics?
 - a. Probe: What resources and information do you look for?
 - b. Probe: What sources do you access them from?

2. What materials are available for nursing educators to help them teach new and current staff nurses about clinical research and clinical trials?
 - a. Probe: How adequate are the resources that are currently available?

3. What educational materials and information about clinical research and clinical trials, if any, do you feel you still need or should have access to?
 - a. Probe: What additional related topics should these materials address?

4. Are there other ways for NCI, etc. to enhance or motivate the teaching of clinical research and clinical trials to practicing nurses that is not related to the development of curriculum content and competencies? Are there other things that should be done at the same time, in addition to focusing on curriculum content and competencies, would help?
 - a. Probe: What are these things – and who could/should be undertaking them?

IV. Closing (3 minutes)

1. Do you have any other comments about incorporating clinical research and clinical trials into academic and/or staff development curriculum that you would like to share with us today?

Thank you for your time today. The information you provided will be very helpful to NCI in deciding what next steps to take regarding clinical research and clinical trials education and competencies.

Attachment A4: Discussion Guide for Nurse Executives

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Interviewer Identification	
Name of interviewer _____	
Date of interview _____	
Interview start time _____	Interview end time _____
Interviewee Identification	
Name of interviewee _____	

Introduction (2 minutes)

Hello, my name is _____ and I work for AED, a nonprofit organization working to improve health, education, civil society and economic development. Also on the phone with me is _____ from AED. She will be taking notes today, so we can accurately capture your feedback.

We are currently working on a research project for the National Cancer Institute (or NCI). We are talking to nurses – including faculty at nursing schools, nursing staff development professionals, nurse executives, and practicing nurses – about current practices and potential core competencies for educating nurses about clinical research and clinical trials. This interview will take no more than 60 minutes. Your feedback will be kept **secure to the extent provided by law**. The findings will be reported to the NIH in summary form and no names or other identifying information will be used.

With your permission, we would like to audiotape today's interview. The recording will be used by AED to aid in writing a report of findings and will be destroyed after the report has been completed. As mentioned on the consent form you signed prior to our interview, your participation is voluntary and you can skip any questions you would prefer not to answer or stop the interview at any time during our discussion.

Please let me know if I have your permission to record this call. If so, I will turn on the recorder now. [If participant agrees – and has signed a consent form – proceed with taping the interview. If participant is uncomfortable or unsure, proceed without taping.]

Do you have any questions for me before we get started?

I. Warm-up / Intro (5 minutes)

1. Before I start asking you questions, let's briefly go over the NIH definitions of clinical research and clinical trials to be sure that we are on the same page. [*Read out loud*]
 - c. Clinical trials are defined as a prospective research study used to determine whether new biomedical or behavioral interventions, such as drugs, treatments, devices, and new ways of using them, are safe, efficacious, and effective.
 - d. Clinical research is typically research conducted with human subjects to understand the mechanisms of human disease or assess a new therapeutic intervention or technology; it also includes epidemiologic and behavioral studies, outcomes research, and health services research.

Clinical research then is broader than nursing research as I believe it is commonly taught in nursing research courses. My understanding is that most nursing research courses teach the methods used to conduct studies to provide an evidence or research-base for nursing practices.

2. Now, if you could tell me a bit about your current position as a nurse executive at this institution. Specifically, would you share with me something about your background, current position, and core responsibilities?
 - a. Probe: Were you a full time nurse providing care to patients/families at one time?
 - b. Probe: While you were caring for patients/families, were you in any way engaged in clinical research and/or clinical trials? If yes, how so?
 - c. Probe: How did you make the decision to go into management? When in your career did this occur?
 - d. Probe: How long have you been in your current position?
 - e. Probe: What are your main roles and responsibilities in this position?
 - f. Probe: Do any of your roles and responsibilities intersect with clinical research and clinical trials being conducted in your facility? If so, how?

II. Current practices and perceptions of clinical research and clinical trials practice and training for nurses (20 minutes)

Now we'd like to spend some time discussing clinical research and clinical trials in the context of professional nursing education and practice. We are specifically interested in the current practices at your institution and how content on clinical research and clinical trials may be integrated into the new employee orientation, staff development programs and continuing education opportunities for nurses.

PRACTICE

1. What clinical research and clinical trials work does your institution engage in?
 - a. Probe: How important is this work for your institution?
 - b. Probe: Have you noticed any trends with respect to clinical trials/clinical research in your institution? For example, has your institution's involvement in clinical trials/clinical research increased over time? Have the settings in which they are taking place changed over time? If so, how?
 - c. Probe: Is this an area that your institution plans on growing in the future?
2. What are the positions or roles in clinical research and clinical trials available to nurses in your institution?
 - a. Probe: Have these changed in the past few years? Do you find a need for more nurses with clinical research/clinical trials experience?
 - b. Probe: When recruiting nurses to work at your institution, how important is it for them to have knowledge and/or skills related to clinical research/clinical trials?
3. How prepared are nurses to play a role in clinical research and/or clinical trials at your institution?
 - a. Probe: How prepared are new graduate nurses? What about more experienced nurses?
 - b. Probe: How do you evaluate their level of performance in the area of clinical research/clinical trials?

TRAINING/STAFF DEVELOPMENT

4. What do you see as the role of nursing management in providing opportunities for new and current nurses to learn about clinical research and clinical trials?
5. How much of a priority is educating nurses about clinical research and clinical trials at your institution?

6. How is clinical research and clinical trials content incorporated into your staff development curriculum including orientation and/or continuing education?
 - a. Probe: Who decides what content will be included in their training?
 - b. Probe: How in-depth is the clinical research and clinical trial training that nurses receive? Does the training vary by their role or level of involvement in research?
 - c. Probe: Are there barriers that make it challenging to incorporate clinical research/clinical trials into nurse orientation, training, and continuing education programs? What are they?

7. What content is taught about clinical research and clinical trials in new employee orientation? As part of a new graduate nurse orientation program if different from new employee orientation? As part of your continuing education program for nurses?
 - a. Probe: How in-depth is the training that they receive?
 - b. Probe: What does this training prepare them to do?
 - c. Probe: Do you evaluate knowledge gain if offered as continuing education? How is this done?

8. If nurses were differently prepared/taught more about clinical research/clinical trials in nursing school what difference would that make on roles they could take on in clinical research in your institution?

III. Future Directions in Clinical Research and Clinical Trials Roles for Nurses (25 minutes)

NCI and key stakeholders are discussing future directions that might be considered related to clinical research and clinical trials for professional nursing education. As they consider these issues, they wanted to hear from leading executives at nursing-employing institutions about your future needs in these areas and things to bear in mind.

1. What future opportunities do you think will exist at your institution for nurses with interest, training, and experience in clinical research and clinical trials?
 - a. Probe: Are the opportunities increasing or decreasing?
 - b. Probe: How are these potential opportunities and roles being developed now?
 - c. Probe: How might they be expanded in the future?
 - d. Probe: How can nursing executives like you help facilitate these opportunities?
 - e. Probe: How can nursing executives like you help facilitate the education about the opportunities on the horizon to existing nurses? Nursing students?

2. What would facilitate the expansion of opportunities for nurses to work in clinical research and clinical trial?
 - a. Probe: Who can help make this happen?
 - b. Probe: What needs to be in place? What steps need to be taken?
3. What barriers exist that may make it challenging to increase nurses' roles in clinical research/clinical trials at your institution?
 - a. Probe: How are nurses working in these practice areas supported/not supported by your institution?
 - b. Probe: How might these challenges be overcome?

I would also appreciate it if you would share your insights about what nursing students could be taught in 4 year baccalaureate nursing programs that would better prepare them to undertake roles in clinical research and clinical trials.

4. What are your thoughts on baccalaureate programs developing or incorporating clinical research/clinical trials content into their academic curricula for nursing students?
 - a. Probe: What do you think about clinical research and clinical trial curriculum guidelines for schools of nursing?
 - b. Probe: How receptive are you towards related content being incorporated into the NCLEX (National Council Licensure Examination) and certification requirements?
 - c. Probe: How important is teaching nursing students about clinical research and clinical trials to familiarize them on these topics before they seek employment? Why do you feel that way?
5. What are your thoughts on refining/expanding clinical research/clinical trials content into a staff development curriculum?
 - a. Probe: What do you think is the best way to integrate clinical research/clinical trials into staff training?
 - b. Probe: Into the orientation for new staff?
 - c. Probe: And into continuing education options for current staff?
 - d. Probe: What is the process for incorporating new professional nursing competencies into the staff training programs at your institution?
 - e. Probe: How receptive are you towards incorporating clinical research/clinical trial competencies into your staff development program?

6. What challenges do you foresee with incorporating clinical research and clinical trials content into:...
 - a. Probe: The curriculum of nursing schools?
 - b. Probe: Into new employee orientation?
 - c. Probe: Into new graduate orientation?
 - d. Probe: Into staff development programs?
 - e. Probe: Would you anticipate competing priorities or staff resistance, etc.?
 - f. Probe: How might these challenges be able to be overcome?

7. If you were asked to incorporate clinical research/clinical trials training into your staff development curriculum what kinds of resources or supports would you require?
 - a. Probe: What support do you need from within your institution? How easy or difficult will this be to obtain? What would be helpful?
 - b. Probe: What support do you need from professional organizations (both nursing and research) and why will this be helpful?
 - c. Probe: What assistance could governmental agencies like the National Cancer Institute and the Agency for Healthcare Research and Quality be in providing information related to clinical research/clinical trials?

8. Are there other ways for NCI, etc. to enhance the teaching of clinical research and clinical trials to nurses who are already practicing that is not related to the development of curriculum content and competencies? Are there other things that should be done at the same time, in addition to focusing on curriculum content and competencies, would help?
 - a. Probe: What are these things – and who could/should be undertaking them?

Closing (5 minutes)

1. Do you have any other comments regarding incorporating clinical research and clinical trials into professional nursing training and practice that you would like to share with us today?

Thank you for your time today. The information you provided will be very helpful to NCI in deciding what next steps to take regarding clinical research and clinical trials education and competencies.

Attachment A5: Discussion Guide for Practicing Nurses

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CENTER FOR SOCIAL MARKETING
AND BEHAVIOR CHANGE

Interviewer Identification

Name of interviewer _____

Date of interview _____

Interview start time _____ Interview end time _____

Interviewee Identification

Name of interviewee _____

Introduction (3 minutes)

Hello, my name is _____ and I work for AED, a nonprofit organization working to improve health, education, civil society and economic development. Also on the phone with me is _____ from AED. She will be taking notes today, so we can accurately capture your feedback.

We are currently working on a research project for the National Cancer Institute (or NCI). We are talking to nurses – including nursing staff development professionals, nurse executives, and practicing nurses – about current practices and potential core competencies for educating nurses about clinical research and clinical trials. This interview will take no more than 60 minutes. Your feedback will be kept **secure to the extent provided by law**. The findings will be reported to the NCI in summary form and no names or other identifying information will be used.

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Please let me know if I have your permission to record this call. If so, I will turn on the recorder now. [If participant agrees – and has signed a consent form – proceed with taping the interview. If participant is uncomfortable or unsure, proceed without taping.]

Do you have any questions for me before we get started?

I. Warm-up / Intro (5 minutes)

1. Before I start asking you questions, let's briefly go over the NIH definitions of clinical research and clinical trials to be sure that we are on the same page. [*Read out loud*]
 - e. Clinical trials are defined as a prospective research study used to determine whether new biomedical or behavioral interventions, such as drugs, treatments, devices, and new ways of using them, are safe, efficacious, and effective.
 - f. Clinical research is typically research conducted with human subjects to understand the mechanisms of human disease or assess a new therapeutic intervention or technology; it also includes epidemiologic and behavioral studies, outcomes research, and health services research.

Clinical research then is broader than nursing research as I believe it is commonly taught in nursing research courses in nursing schools. My understanding is that most nursing research courses teach the methods used to conduct studies to provide an evidence or research-base for nursing practices.

2. Now, I would appreciate it if you would tell me a bit about your academic background in nursing. Please tell me briefly about the undergraduate nursing program you attended.
 - a. Probe: What school(s) did you get your undergraduate nursing degree from?
 - b. Probe: When did you graduate? Is a BS in nursing the highest nursing degree you have completed? If not, what is the highest nursing degree you have completed?
3. Now, I would appreciate it if you would tell me a bit about your experience as a practicing nurse. Could you briefly tell me how long you have been working as a nurse, your current place of employment, and about your position and responsibilities?
 - a. Probe: What particular department or division do you work for within this organization? What type of patients do you care for?
 - b. Probe: Have you held any other nursing positions since you graduated from your undergraduate program? If so, what other positions and responsibilities have you had?

II. Experience and Perceptions Related to Clinical Research and Clinical Trials (10 minutes)

1. We would appreciate learning a bit about your experience and perceptions from working in clinical research and clinical trials, including caring for patients on a clinical trial or participating in clinical research. Let me start by asking, in your current and/or past nursing positions to what extent, if any, have you worked in clinical research or clinical trials?

If past/current experience:

- a. Probe: In what capacity have you worked on clinical research/clinical trials? What responsibilities have you had in clinical research and clinical trials?
- b. Probe: Overall, how much of your work has been clinical research /clinical trials – related? (About half, less than half, more than half, all). Why has this been?
- c. Probe: Do you anticipate continuing to work on clinical trials and clinical research in the future? Why or why not? In what capacity?

If no experience:

- a. Probe: Thinking about work in clinical research and clinical trials, is there a particular reason why you have not done this type of work? (look for awareness of roles, lack of opportunity, lack of interest, intensity of requirement....)
2. What do you see is/are the role(s) of nurses in clinical research and clinical trials?
 - a. Probe: What roles in clinical research/clinical trials work are available for nurses in your institution – or the other institutions where you have worked or friends of yours work?
 - b. Probe: Thinking generally about nursing, how should nurses be involved in clinical research/clinical trials? What roles should they fill?
 - c. Probe: Do you see the roles as being different for clinical (staff) nurses and research nurses? What specific responsibilities in clinical research/clinical trials should each undertake?
 3. How interested are you in working on/continuing to work on clinical research and clinical trials in an investigator and non-investigator capacity?
 - a. Probe: What about working in clinical research/clinical trials interests you?
 - b. Probe: What do you see as some of the aspects of this work that are of less interest or get in the way of your working in clinical research/on clinical trials?
 - c. Probe: What would make it easier for you to work more comfortably or with increasing responsibility in clinical research/clinical trials?

III. Undergraduate Nursing Education in Clinical Research and Clinical Trials (15 minutes)

1. We would appreciate learning a bit about the research courses that were offered to you as a nursing student. To what extent, if at all, was clinical research and clinical trials covered in the nursing curriculum at your school?
 - a. Probe: What content was taught about clinical research and clinical trials?
 - b. Probe: Was there a specific course in clinical research/clinical trials? If yes, what was the content of this course? Was it part of other classes? If it was part of other classes, which one(s)?
 - c. Probe: Was clinical research/clinical trials integrated into the curriculum by using clinical research/clinical trials examples? If so, how? When?
2. Did you care for clinical trial patients during your clinical practice rotations?
 - a. Probe: Were you required or encouraged to do so, either by your advisor or others in your nursing program?
 - b. Probe: Were you involved in clinical research and clinical trials in any other capacity (other than patient care)?
3. To the best of your recollection, did any of the required textbooks or educational materials (e.g., journal articles) in your undergraduate program cover clinical research and clinical trials? If so, to what extent?
4. How much interest in clinical research and clinical trial subjects did you personally have as a nursing student?
 - a. Probe: What do you feel accounts for your level of interest at that time (exposure level, mentor and their interest, career path, etc.)
5. How aware were you during your undergraduate education of clinical research and clinical trials nursing roles, other than that of the nurse scientist or nurse researcher?
 - a. Probe: In what context did you learn about clinical research/clinical trials as a career option?
 - b. Probe: What was your level of interest in this career path? How interested in this as a career path were other nursing students?

6. Do you think the extent to which topics related to clinical research and clinical trials were covered in your undergraduate nursing program(s) was sufficient? Why or why not?
 - a. Probe: What topics, if any, were particularly well covered in this area?
 - b. Probe: What, if any, were some gaps in terms of content related to clinical research and clinical trials that you now feel should be addressed as part of an undergraduate nursing education program?

IV. Other Training/Education in Clinical Research and Clinical Trials (5 minutes)

Let's now shift our focus from your undergraduate nursing education to briefly discuss the training and education related to clinical trials and clinical research you may have received from other sources.

1. While you have been a practicing nurse, have you received training or education related to clinical research and clinical trials from your current or past employer(s)?
 - a. Probe: What type of training have you received? What has been the content covered in these trainings?
2. Have you gotten any other training in clinical research/clinical trials— that is, not from your undergraduate education or the places where you have worked? If so, what other trainings or education have you received?
 - a. Probe: What type of training have you received? (e.g., in-person continuing education course; attendance at a professional society meeting or conference; completion of an online or web-based course; participation in a webinar) What has been the content of these trainings or education?
 - b. Probe: From what sources did you receive these training and education from? Who provided the training? (e.g., name of professional organization)

V. Knowledge and Information Gaps in Clinical Research and Clinical Trials (10 minutes)

1. Overall, how informed do you feel you are about clinical research and clinical trial-related topics and opportunities in the area for nurses?
2. How comfortable do you feel caring for a patient on a clinical trial? [If not particularly comfortable] Why do you feel this way?

3. How much of your current knowledge and preparation related to clinical research and clinical trials did you acquire from each of the following sources:
 - a. Probe: Your undergraduate nursing program?
 - b. Probe: Training received through your employer(s)?
 - c. Probe: On-the-job experience?
 - d. Probe: Other trainings/education? (e.g., continuing education through professional organizations, professional conferences, etc.)

4. What personal gaps in knowledge or unfulfilled needs do you have with regard to clinical research/clinical trials information or exposure?
 - a. Probe: What topics, if any, do you feel you have limited or no knowledge about?
 - b. Probe: How did you identify these gaps in your knowledge? (e.g., are these things you were required to do at work and felt ill-prepared to do?)
 - c. Probe: Thinking about particular topics that may help better prepare you to undertake future roles/responsibilities in clinical research/clinical trials, which in particular are you interested learning more about?

5. What do you see as the benefits of learning more about clinical research and clinical trials?
 - a. Probe: Job satisfaction, money, security, versatility, patient education/answer patient's questions, other,

6. What preferences, if any, do you have in how you receive education and training related to clinical research and clinical trials?
 - a. Probe: What are your preferred sources or methods for receiving information related to clinical research and clinical trials?
 - b. Probe: In-service trainings from employer? Other trainings from employer? If so, what type of trainings (look for delivery methods – classroom vs. independent study, on-line courses, webinars, etc.)?
 - c. Probe: Continuing education trainings offered by professional organizations or other entities? If so, what type of continuing education offerings? (e.g., online short-course, workshop at a professional conference?)
 - d. Probe: Seeking information yourself via the Internet, library, books, on-line courses, independent study, etc.? If so, what specific sources do you prefer to get information from?
 - e. Probe: Other sources or methods?

VI. Future Directions in Clinical Research/Clinical Trial Curriculum Content and Development of Competencies (7 minutes)

NCI and key stakeholders are discussing future directions that they might take related to clinical research and clinical trials for professional nursing education. As they consider these issues, they are interested in hearing from practicing nurses like you about future needs in these areas and things to bear in mind when thinking about institution-level curriculum change.

1. How much priority do you think undergraduate nursing programs should give to teaching undergraduate nursing students about clinical research and clinical trials?
 - a. Probe: Do you think your undergraduate program(s) gave enough priority to teaching about clinical trials/clinical research? Should it have been given a higher priority? Lower priority? Please explain.

2. In what specific ways, if any, do you think your undergraduate nursing school could or should expand what it teaches nursing students about clinical research and clinical trials? Please explain.
 - a. Probe: Establish an elective course? A required course?
 - b. Probe: Integrate clinical research topics into existing course(s)? If so, in what course(s) do you think it would be relevant and/or motivating?
 - c. Probe: Should nursing students be required or encouraged to care for clinical trial participants as part of their clinical practice rotations?
 - d. Probe: Are there other ways in which you think it could be expanded? If so, in what ways?

3. What are your thoughts on the development of clinical research/clinical trials core competencies for nurses?
 - a. Probe: How important is this? Why is it important/not important? What, if anything, do you think might be important to include?

VII. Closing (5 minutes)

1. How receptive are you personally to clinical research and clinical trials related content being incorporated into nurses' examination and certification requirements? Please explain.
2. Do you have any other comments regarding incorporating clinical research and clinical trials into professional nursing education that you would like to share with us today?

Thank you for your time today. The information you provided will be very helpful in deciding what next steps to take regarding clinical research and clinical trials education and competencies for nursing students.

As we move forward, might you be willing to participate in conference calls or work groups related to these efforts?

YES

NO

Attachment A7: Script and Screeners for In-Depth Interviews

OMB No. 0925-0046-03

EXPIRATION DATE: 02/28/2013

Public reporting burden for this collection of information is estimated to average 10 minutes total, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to: NIH, Project Clearance Branch, 6705 Rockledge Drive, MSC 7974, Bethesda, MD 20892-7974, ATTN; PRA (0925-0046-03). Do not return the completed form to this address.



CENTER FOR SOCIAL MARKETING
AND BEHAVIOR CHANGE

Hello, I'm _____ from AED. I'm calling today on behalf of the National Cancer Institute, or NCI. I believe that _____ from the NCI/JHU/GU recently shared information with you, either by e-mail and/or phone, about a study NCI is conducting. The purpose of the study is to explore the perspective of practicing nurses and individuals who educate and employ nurses about needs regarding educating nurses in the area of clinical research and clinical trials at the undergraduate level. Of particular interest are nurse staff development professionals and nurse executives. Participation in the study would involve taking part in a 1 hour telephone interview to share your thoughts, opinions, and experiences about this subject. I am calling you today to ask if you would be interested in participating in the study.

[If interested say: Thank you for your interest. Before we schedule a time for the interview, I would like to ask you a few questions about your organization and your current role. This will only take a couple of minutes.]

[If not interested say: Thank you very much for your time today. Would you know of someone else within your institution or at another institution who may be interested in participating? If so, I would appreciate your sharing the information regarding this study with them. Would you feel comfortable giving me their name(s) and contact information – I would like to be able to reach out to them. (Note: To the extent possible, get names and contact information during the call)]

Screening Questions

For Nursing Educators

1) I have that the name of your institution is _____.
Is this correct?

2) What specific division/department do you work in within your institution?

3) Is your institution currently involved in clinical research or clinical trials?

___ Yes
[Terminate] ___ No

4) What is your official title at your institution? _____

5) How long have you been in that position at your institution? _____

6) As part of your role, are you responsible for the oversight and organization of new graduate nurse orientation?

___ Yes
___ No

7) Did you serve in this capacity in a past position?

___ Yes
___ No

[If No to Questions 6 AND 7 Terminate]

8) How many years have you overseen and organized new graduate nurse orientation— here or at other institutions? [Record: _____]

___ 3 or more years
[Terminate] ___ Less than 3 years

For Nursing Executives

1) I have that the name of your institution is _____.
Is this correct?

2) What specific division/department do you currently work in within your institution?

3) Is your institution currently involved in clinical research or clinical trials?

[Terminate] Yes
 No

4) What is your official title at your institution? _____

5) Is this the lead/chief nursing position within your institution?

[Terminate] Yes
 No

6) How long have you been in that position at your institution? [Record: _____]

[Terminate] 3 or more years
 Less than 3 years

For Practicing Nurses

1) Are you currently working as a nurse?

Yes
[Terminate] No

2) Overall, how long have you been a practicing nurse? [Record: _____]

Less than 3 years
 3 or more years

3) What is the highest nursing degree you have completed?

Bachelor's Degree
Graduate Degree
[Terminate] Associate Degree
[Terminate] No degree (e.g., nursing diploma)

4) Where did you complete this nursing degree? _____.

5) I have that the name of the institution where you currently work is:
_____. Is this correct?

6) What specific division/department do you currently work in within your institution?

7) What is your official title at your institution? _____

8) How long have you been in that position at your institution? _____

****TERMINATE LANGUAGE:**

Thank you very much for your time. For this study, we are particularly interested in interviewing *[mention the eligibility criteria for which they were terminated]* so we won't be able to include you in our study. But we thank you for your time and interest. Is there anyone within your institution who you think would be eligible and interested in participating? If so, could you share their name and contact information with us? *[If "no", say: Could we send you information about the study and our contact information by e-mail so you can share it with them?]*

INVITE TO INTERVIEW:

MOVE FROM QUESTIONS ABOVE TO... As I mentioned before, the interview will last no more than 60 minutes and will be over the phone. What day between *[MM/DD/YY]* and *[MM/DD/YY]* would work for us to conduct an interview with you? What time that day will work best for you?

SCHEDULED IDI DATE AND TIME: _____

We will need to send you a consent form that you will need to fax back prior to the interview. Let me make sure that I have all of the necessary contact information.

NAME: _____

EMAIL *** _____

PHONE: (TO CALL FOR INTERVIEW) _____

(FAX) _____

(CELL) _____

MAILING ADDRESS: _____

Do you have a preference for receiving the consent form by e-mail or fax? Once you receive it, please read it and sign it, and return it to AED. You can scan the signed form and return it by e-mail, or you can fax to us the signed form.

Thank you for your time today and for agreeing to participate in this study.

Attachment A9: FOCUS GROUP DISCUSSION GUIDE

**OMB No. 0925-0046-03
EXPIRATION DATE: 02/28/2013**

**Online Focus Group Seeking Input from
Senior Faculty and Deans at Schools of Nursing Regarding
Clinical Research and Clinical Trials Education at the
Undergraduate Level**

Advanced Strategy Online (ASO)

**Research to be Conducted for:
Office of Communications and Education
National Cancer Institute**

Date: August 2010

Public reporting burden for this collection of information is estimated to average 120 minutes total, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to: NIH, Project Clearance Branch, 6705 Rockledge Drive, MSC 7974, Bethesda, MD 20892-7974, ATTN; PRA (0925-0046-03). Do not return the completed form to this address.

INTRODUCTION & BACKGROUND ON PARTICIPANTS (10 MIN)

1. Please indicate your title:

2. Please indicate the approximate length of your career in nursing education:

Times Selected	Items
0 (0%)	1. Less than 5 years
0 (0%)	2. Between 5 and 10 years
0 (0%)	3. Between 10 and 20 years
0 (0%)	4. More than 20 years

3. How long have you served in your current position?

Times Selected	Items
0 (0%)	1. Less than 1 year
0 (0%)	2. Between 1 and 5 years
0 (0%)	3. Between 5 and 10 years
0 (0%)	4. Between 10 and 20 years
0 (0%)	5. More than 20 years

4. Please indicate approximately how many students graduate from your undergraduate nursing program each year:

1. NURSING SCHOOL CURRICULUM CONTENT PRIORITIES (5 MIN)

Instructions:

Based on a series of interviews conducted recently with school of nursing faculty, the following is a list of topics that were mentioned in discussions about content priorities for changes/additions to undergraduate nursing school curricula (not the honors program). In your opinion, is anything missing from this list that you would consider a key priority for a content change or addition to your institution's undergraduate nursing school curricula?

Programmer note: list will be provided following conclusion of in-depth interviews but will include the following among others:

- *Clinical research and clinical trials*

(1A) Prioritization of Curriculum Content Priorities

Instructions:

Now, in reviewing this list, how would you prioritize each of these topics in terms of their importance for your institution in considering curriculum changes? Use a scale of 1-10 where a '1' means not important at all and a '10' means a great deal of importance:

2. SURVEY: RECENT CURRICULUM EXPANSIONS (7 MIN)

Questions:

1. In recent years, there have been efforts to expand curricula to include end-of-life care, geriatric content, and genetic and genome content. Have you made any changes to your undergraduate nursing curricula in these areas? To what extent? Please explain.
2. Why (or why not) have you made these changes? What drivers or conditions were present (or missing) to foster (or inhibit) such changes?
3. If changes were made: What was the process for implementing these changes?

3. FACTORS THAT INFLUENCE CHANGES OR ADDITIONS TO UNDERGRADUATE NURSING SCHOOL CURRICULUM CONTENT (20 MIN)

Instructions:

What factors are most most influential in making decisions about what topics or content are included in your institution's curriculum and practicum opportunities for undergraduate nursing students?

(3A) Categorization of Influencing Factors

Instructions:

The following is a summary of our responses. In a moment, we'll prioritize the list...

Programmer note: If not mentioned, seed the following items in the list for prioritization:

- Evidence-based practice
- Needs of hospitals and other prospective employers
- Faculty interest (presume will come up organically)
- Undergraduate student interest (presume will come up organically)

(3B) Prioritization of Influencing Factors

Instructions:

Now, please assess how influential each of the following factors is in making decisions about what content to include in your undergraduate nursing curriculum. Use a scale of 1-10 where a '1' means not at all influential and a '10' means extremely influential:

(3C) Most Important Influencing Factor *(ignore "Accreditation" if ranked #1 and say, "other than Accreditation," XX ranked highest...)*

Instructions:

As a group, you selected [MOST IMPORTANT FACTOR] as the most

important factor. Why is this factor so important, so influential?

(3D) Exploring Additional Influencing Factors (see *“Use of Evidence-Based Practice,”* assuming it is not discussed in 3C; if it is discussed in 3C, skip this)

Instructions: We’d also like to explore the use of evidence-based practice as an influencing factor. How has the expansion of evidence-based practice affected your approach to educating undergraduate nursing students?

(3E) Exploring Additional Influencing Factors (see *“Needs of Hospitals and Other Prospective Employers,”* assuming it is not discussed in 3C; if it is discussed in 3C, skip this)

Instructions: And finally, we’d like to explore to what extent your content is influenced by the needs of prospective employers such as hospitals. How do you learn about the current and projected needs of hospitals? Do you adjust your approach to educating undergraduate nursing students in response to these needs? If so, how?

4. ESTABLISHING DEFINITIONS (2 MIN)

For the rest of this session we will be talking about clinical trials and clinical research content in the context of your undergraduate nursing curriculum (not the honors program). Please review the following definitions below to ensure we are on the same page:

- Clinical trials are defined as a prospective research study used to determine whether new biomedical or behavioral interventions, such as drugs, treatments, devices, and new ways of using them, are safe and effective.
- Clinical research is typically research conducted with human subjects to understand the mechanisms of human disease or assess a new therapeutic intervention or technology; it also includes epidemiologic and behavioral studies, outcomes research, and health services research.

(4A) Survey

Does your institution offer courses to undergraduate nursing students specifically on clinical research or clinical trials that is separate and distinct from a nursing research course?

Times Selected	Items
0 (0%)	1. Yes, clinical research courses
0 (0%)	2. Yes, clinical trial courses
0 (0%)	3. Yes, both
0 (0%)	4. No, but clinical research/clinical trials content is required to be incorporated into other courses
0 (0%)	5. No

5. PRIORITY OF CLINICAL TRIALS/CLINICAL RESEARCH CONTENT (5 MIN)

Instructions: According to your earlier responses (*see 1A*), clinical trials/clinical research ranked X.X on a scale of 1 to 10 when evaluating its importance for inclusion in undergraduate nursing programs, with 10 being a priority with a great deal of importance. What are some reasons for why you think it was ranked this way? Is this higher or lower than how you responded for your institution?

6. IDENTIFICATION OF BARRIERS (15 MIN)

Instructions: What are the barriers or challenges you would face to incorporating more clinical research/clinical trial content into the undergraduate nursing curriculum at your institution? (multiple responses)

(6A) Categorization of Barriers

Instructions: The following is a summary of our responses. In a moment, we'll prioritize the list...

(6B) Prioritization of Barriers

Instructions: Now, please assess each of the following in terms of how significant you feel each would be as a challenge to incorporating more clinical research/clinical trial into the undergraduate nursing curriculum at your institution. Use a scale of 1-10 where a '1' means not at all significant/challenging and a '10' means extremely significant/challenging:

(6C) Addressing Curriculum Change Barrier #1

Instructions: What could be done to help you most effectively address BARRIER #1? What information and/or support would you need to move forward in this

area? (multiple responses)

(6D) Addressing Curriculum Change Barrier #2

Instructions: What could be done to help you most effectively address BARRIER #2?
What information and/or support would you need to move forward in this area? (multiple responses)

7. IDENTIFICATION OF BEST APPROACHES FOR INCORPORATING CLINICAL TRIALS/CLINICAL RESEARCH CONTENT (15 MIN)

Instructions: What would be the best approaches at an institution such as yours for incorporating more clinical research/clinical trial content into the undergraduate curriculum for nurses? (multiple responses)

(7A) Categorization of Best Approaches

Instructions: The following is a summary of our responses. In a moment, we'll prioritize the list...

(7B) Prioritization of Best Approaches

Now, please assess each of the following aspects in terms of how significant you feel each would be as an approach for enhancing clinical trial and clinical research content within the undergraduate nursing curriculum. Use a scale of 1-10 where a '1' means not at all viable and a '10' means extremely viable:

Instructions: *Programmer Note: If not mentioned, seed the following items in the list for prioritization:*

- *Elective course*
- *Required course*
- *Ask faculty to integrate content into existing courses*
- *Provide faculty training on how to integrate content into specific courses(e.g., pharmacology, nursing research)*

(7C) Addressing Approach #1

Instructions: Why would this approach be most suitable? How would you envision this happening in an ideal scenario? (multiple responses)

(7D) Addressing Approach #2

Instructions: Why would this approach be most suitable? How would you envision this happening in an ideal scenario? (multiple responses)

SESSION FEEDBACK SURVEY (5 MIN)

Instructions: Please respond to the following survey questions. There will be an instruction at the end of the survey on how to submit your responses.

Session Identification and Feedback

1. Overall, how would you rate your willingness to advocate for clinical research or clinical trial changes to the current undergraduate nursing curriculum at your institution? Please choose one category and feel free to elaborate below:

Times Selected	Items
0 (0%)	Absolutely willing
0 (0%)	Very willing
0 (0%)	Somewhat willing
0 (0%)	Not particularly willing
0 (0%)	Not at all willing

Feel free to elaborate further on why or why not you may be willing to advocate for for clinical research or clinical trial changes to the current curriculum at your institution:

2. Do you have any additional comments or observations about today's session or any additional advice/input for the NIH and others as they explore the need for and options to enhance understanding of clinical research and clinical trials concepts among undergraduate nursing students?

3. What did you enjoy most about the session today? What did you find to be most positive?

[End]