



**DEPARTMENT OF HEALTH & HUMAN SERVICES**

Public Health Service

National Institutes of Health  
National Cancer Institute  
Bethesda, Maryland 20892

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To: Office of Management and Budget (OMB)

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Subject: Assessing Baccalaureate Nursing Students' Feedback on Clinical Research Class and Intentions to Pursue Further Education or Training (OMB No. 0925-0046-01, Expiration Date x/xx/2016)

The National Cancer Institute (NCI) proposes collaborating with baccalaureate faculty to conduct a 3-hour pilot clinical research class for baccalaureate students at schools of nursing in Maryland. The goal of this pilot course is to provide an overview of clinical research and clinical trials, the trends in health care that are affecting clinical research and the nurse's role, and career opportunities in the clinical research enterprise. Following the class, students will be given the option of completing a brief survey to provide feedback on the course and their intentions to pursue additional education or training in clinical research.

**Background on the Project**

The changing health care environment requires training nurses to be knowledgeable about clinical research, to competently care for clinical research participants, and to be able to incorporate research finding into practice. Specifically there is an increase in the number and types of clinical research studies, an expansion in the diversity of settings in which they are taking place, and a potential growth in the number of participants due to clinical trial coverage by the Affordable Care Act beginning in 2014. These trends, combined with a call by the Institute of Medicine to bring the clinical trials enterprise and

healthcare delivery system together<sup>1</sup>, make it increasingly important for nurses, regardless of their practice setting or specialty, to understand the principles of clinical research.

This raises several questions:

- Are nurses prepared to practice safely in care settings where clinical research is being conducted?
- Are they prepared to provide patient and family education related to clinical research?
- Can they evaluate the evidence from clinical research to provide evidence-based care?

These questions led our project team to undertake a formative research project in 2010 (OMB# 0925-0046-03, approved 10/19/2010) that began with an environmental scan of the course catalogues of select baccalaureate nursing programs. The purpose was to broadly assess the presence and extent of clinical research content in the curricula. Findings indicated that the baccalaureate nursing programs focused primarily on research as a fundamental component of the scholarly process, and on understanding the research process as it relates to the science and practice of nursing.

In-depth interviews were conducted with practicing nurses, educators, and employers to understand the current environment around clinical research from their perspectives. Based on the results of those interviews, an interactive online discussion was held with deans of baccalaureate nursing programs. One of the key findings from baccalaureate faculty interviews and the online discussion with deans was that while they thought clinical research education was important, they lacked time and resources to provide this content in their programs.

The study highlights were presented to six school representatives at the biannual Maryland Dean and Directors Meeting held in June, 2012. Their feedback was both positive and enthusiastic; follow-up interest from the deans and their designated representatives has remained strong. In response, we propose implementing a pilot 3-hour class on clinical research for baccalaureate nursing students. The goal of this class will be to provide an overview of the trends in health care that are affecting clinical research and the nurse's role and career opportunities in the clinical research enterprise.

## **Methodology**

The project team plans to pilot the 3-hour, in-person class with interested baccalaureate programs in Maryland. The class would be delivered as a guest lecture as part of an existing course in nursing research, evidence-based practice, or professional roles. The NIH project team members would be responsible for planning, delivering, and evaluating the class in collaboration with school of nursing course faculty. The project team would provide a class description, objectives, detailed slides, list of suggested readings, and scenarios for group discussion. The team proposes conducting a brief survey with

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<sup>1</sup> IOM (Institute of Medicine). 2010. *Transforming Clinical Research in the United States: Challenges and Opportunities: Workshop Summary*. Washington, DC: The National Academies Press.

student participants to (1) assess students' interest in further education or training in clinical research and (2) gather their feedback on the course implementation. Students will be offered an opportunity to complete a paper and pencil survey at the conclusion of the class. They will be informed that participation is voluntary, no personal identifying information will be collected, and they may skip any questions they choose not to answer. Data will be input and analyzed using MS Excel and reported in aggregate. The results of the pilot class would inform the team's next steps, which may potentially include wider dissemination of class materials or development of an online class.

**Research Instruments**

A brief survey (see attachment #1) has been developed to obtain students' feedback on their intentions to pursue additional clinical research education or training and their reactions to the pilot class.

**Participation**

Four schools<sup>2</sup> have indicated interest in having the project team present the class to their baccalaureate nursing students. In some cases, courses may be offered at multiple times and therefore, the project team will deliver the class material to approximately 6 individual classes at these schools. Classes are expected to average 70 students per class for a total of 420 students. The average participation time for the survey is 5 minutes per participant. The total respondent burden for this effort is 35 hours.

<b>Estimates of Hour Burden for Student Survey</b>				
<b>Types of Respondents</b>	<b>Number of Respondents</b>	<b>Responses Per Respondent</b>	<b>Average Response Time (in hours)</b>	<b>Total Hour Burden</b>
<i>Nurses, nurse educators, and nurse executives</i>	420	1	5/60	35

This will be the first approved sub-study under this recently approved generic.

Thank you for your consideration of this proposed sub-study 0925-0046-01.

Attachment 1: Student Survey

Attachment 2: Office of Human Subjects Research Protection Review

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<sup>2</sup> The following four schools have expressed interest in having NCI staff conduct a guest lecture on clinical research as part of their nursing research or professional roles course: Georgetown University, Stevenson University, Johns Hopkins University, and Towson University.