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January 15, 2015

Irene Stith-Coleman, Ph.D.  
Office for Human Research Protections  
1101 Wootton Parkway, Suite 200  
Rockville, MD 20852

Sent via email to: <http://www.regulations.gov>

Re: Draft Guidance on Disclosing Reasonably Foreseeable Risks in Research Evaluating Standards of Care; Docket ID number HHS–OPHS–2014–0005

Dear Dr. Stith-Coleman:

The American Nurses Association (ANA) welcomes the opportunity to provide comments on this proposed draft *Guidance on Disclosing Reasonably Foreseeable Risks in Research Evaluating Standards of Care*. As the only full-service professional organization representing the interests of the nation's 3.1 million registered nurses (RNs), ANA is privileged to speak on behalf of its state and constituent member associations, organizational affiliates, and individual members. RNs serve in multiple direct care, care coordination, and administrative leadership roles, across the full spectrum of healthcare settings. ANA members also include advanced practice registered nurses such as nurse practitioners, certified registered nurse anesthetists, clinical nurse specialists, and certified nurse-midwives.

We appreciate the efforts of the Office for Human Research Protections (OHRP) to develop guidance to clarify OHRP's interpretation of the risks related to "standard of care" research. However, we urge OHRP to consider using more inclusive language when referencing and describing the term "standards of care." As currently written, the Guidance refers to "*medically recognized* standards of care" throughout the document. Further, in describing what is meant by the term "standards of care," the document refers to treatments or procedures that have been accepted by *medical* experts, and states that "*medical recognition* of standards of care is typically represented by publication in a peer-reviewed journal or some other form of recognition by a professional *medical society*" (emphasis added).

Use of the phrase "medically recognized standards of care," along with references to *medical* experts and professional *medical* societies, fails to recognize that all health care providers, including nurses, physician assistants, psychologists, social workers, physical therapists, and others, have discipline-specific standards of care, and all may be involved in research concerning their unique, discipline-specific standards of care. We urge OHRP to revise the draft guidance to reflect the diversity of health care disciplines that engage in standard of care research. This could be accomplished by eliminating the word "medically" and simply referring to recognized standards of care. In the alternative, the guidance could utilize provider-neutral language (such as "discipline-specific standards of care") rather than the phrase "medically recognized standards of care." Similarly, we urge OHRP to refer to clinical experts (or a similar, provider-neutral term) rather than medical experts and to professional societies or associations rather than professional *medical* societies.

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We appreciate the opportunity to share our views on this matter. If you have questions, please contact Jane Clare Joyner, Senior Policy Fellow for Health Systems and Regulatory Policy ([janeclare.joyner@ana.org](mailto:janeclare.joyner@ana.org) or 301-628-5083).

Sincerely,

A handwritten signature in cursive script that reads "Debbie D. Hatmaker".

Debbie D. Hatmaker, PhD, RN, FAAN  
Executive Director

cc: Pamela Cipriano, PhD, RN, NEA-BC, FAAN, ANA President  
Marla Weston, PhD, RN, FAAN, ANA Chief Executive Officer