



January 9, 2019

Dockets Management Staff (HFA-305)  
Food and Drug Administration  
5630 Fishers Lane, Rm. 1061  
Rockville, MD 20852

Submitted electronically to <https://www.regulations.gov>

Re: FDA-2018-N-2727 for “Institutional Review Board Waiver or Alteration of Informed Consent for Minimal Risk Clinical Investigations.”

Dear Commissioner Gottlieb,

The American Nurses Association (ANA) is pleased to provide written comment to the Centers for Disease Control and Prevention (CDC), regarding Docket No. FDA-2018-N-2727 for “Institutional Review Board Waiver or Alteration of Informed Consent for Minimal Risk Clinical Investigations”. ANA is the premier organization representing the interests of the nation’s 4 million registered nurses (RNs) through its constituent and state nurses associations, organizational affiliates, and individual members. RNs serve in multiple direct care, care coordination, and administrative leadership roles, across the full spectrum of health care settings. RNs provide and coordinate patient care, educate patients and the public about various health conditions, and provide advice and emotional support to patients and their family members. ANA members also include those practicing in the four advanced practice registered nurse (APRN) roles: nurse practitioners, clinical nurse specialists, certified nurse-midwives and certified registered nurse anesthetists.<sup>1</sup> ANA is dedicated to partnering with health care consumers to improve practices, policies, delivery models, outcomes, and access across the health care continuum.

The intent of a provision of the the 21<sup>st</sup> Century Cures Act was harmonization of regulations which allows for the waiving of informed consent for some FDA research. Science and research are fundamental to continued quality of care to all patients. ANA is concerned with the vagueness of the proposed rule as written and requests more clarification around the type of research that the proposed rule is intended to allow. We are also concerned about the potential for variability of decision making of Institutional Review Boards (IRB) and the subjective nature of determining the definition of minimal harm in approving a waiver for informed consent.

ANA stands firm in its belief that protection of privacy and confidentiality is essential to maintaining the trusting relationship between health care providers and patients and integral to professional practice. ANA’s original position in 1991 was developed in short to address the increased need for informed

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<sup>1</sup>The Consensus Model for APRN Regulation defines four APRN roles: certified nurse practitioner, clinical nurse specialist, certified nurse-midwife and certified registered nurse anesthetist. In addition to defining the four roles, the Consensus Model describes the APRN regulatory model, identifies the titles to be used, defines specialty, describes the emergence of new roles and population foci, and presents strategies for implementation.

consent for research participants. This is accomplished through ensuring that human rights are fulfilled through the process of ongoing informed consent, continual assessment of risk benefit for research participants, and the prevention of harm.<sup>2</sup> The Code of Ethics for Nurses with Interpretative Statements (the Code) lays out factors needed in order to gain informed consent, these include “the nature of participation, potential risks and benefits; available alternatives to taking part in the study; disclosure of incidental findings; return of research results; and an explanation of how the data will be used, managed, and protected.”<sup>3</sup>

The Code also specifically states that “all research proposals must be approved by a formally constituted and qualified IRB to ensure participant protection and the ethical integrity of the research.”<sup>4</sup> While the proposed rule states that an IRB would determine whether to grant a waiver, there is no mention of continued review to assess minimal harm, the situations in which undue burden to get consent arises, or processes to remove the risks of varied results in when and how informed consent waivers are performed. ANA supports a strong health research agenda that keeps participants and researchers safe and informed. However, as written, ANA would appreciate clarification of the process and rule to ensure safety, privacy, and when necessary informed consent should be obtained prior to authorization.

We look forward to the opportunity to further engage with FDA with respect to the changes above. If you have any questions, please contact Ingrida Lusic, Vice President, ANA Policy and Government Affairs, at 301.628.5081 or [Ingrid.Lusic@ana.org](mailto:Ingrid.Lusic@ana.org).

Sincerely,



Debbie Hatmaker, PhD, RN, FAAN  
Chief Nursing Officer/EVP

cc: Ernest Grant, PhD, RN, FAAN, ANA President  
Loressa Cole, DNP, MBA, RN, NEA-BC, FACHE, ANA Chief Executive Officer

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<sup>2</sup> American Nurses Association (2016) *The Nurse’s Role in Ethics and Human Rights: Protecting and Promoting Individual Worth, Dignity, and Human Rights in Practice Setting* [Position Statement]. Retrieved from: <https://www.nursingworld.org/~4af078/globalassets/docs/ana/ethics/ethics-and-human-rights-protecting-and-promoting-final-formatted-20161130.pdf>

<sup>3</sup> American Nurses Association (2015, Jan.). Code of Ethics for Nurses with Interpretive Statements. Provision 3.2. Retrieved from <https://www.nursingworld.org/coe-view-only>

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