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Jerry Menikoff, MD, JD
Director, Office for Human Research Protections
Department of Health and Human Services
1101 Wootton Parkway, Suite 200
Rockville, MD 20852

Submitted via www.regulations.gov

Re: Federal Policy for the Protection of Human Subjects: Docket ID number HHS–OPHS–2015–0008

Dear Dr. Menikoff:

On behalf of the American Nurses Association (ANA), we are pleased to comment on the proposed rule referenced above. As the only full-service professional organization representing the interests of the nation's 3.4 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 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 the four advanced practice registered nurse (APRN) roles: nurse practitioners, clinical nurse specialists, certified nurse-midwives and certified registered nurse anesthetists.[1]

ANA appreciates the intent of this notice of proposed rulemaking (NPRM), which "seeks comment on proposals to better protect human subjects involved in research, while facilitating valuable research and reducing burden, delay, and ambiguity for investigators." Further, ANA supports the broad goal to modernize, simplify, and enhance the current system of oversight. However, we are concerned that this NPRM, with various alternative proposals and eighty-eight questions, results in a proposed rule that is not fully developed. The NPRM lacks clarity and precise definitions and concepts on a number of important topics, including the consent template, the list of minimal risk research, the decision tool and various proposed safeguards. Including these undeveloped topics in the proposed rule may result in a final rule that has not been subject to full public review and comment. We urge OHRP to reconsider this approach and refrain from including in the final rule the various topics that are undeveloped in this NPRM.

We want to reiterate and express support for a number of important points made in the letter submitted by ***Genetic Alliance***, a nonprofit health advocacy organization. Initially, we note that ANA recommends that OHRP carefully consider and evaluate the recommendation to change the terminology of the rule by replacing the terms 'subject' and 'patient' with the term 'participant' when referring to individuals in research. Use of the term 'participant' acknowledges the agency and autonomy of these individuals. In contrast, the phrase "human subjects" fails to adequately reflect participants' involvement as essential

[1]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.

partners in biomedical research, while the term 'patients' suggests a passive role and does not reflect the dignity and respect the NPRM aims to instill in this updated regulation.

Informed consent should be simple and offer more meaningful, culturally appropriate engagement

- ANA agrees with the NPRM's recommendation to shorten and simplify consent forms, as well as the emphasis on meaningful choices and decisions informed by information that a reasonable person would want to know. Further, ANA supports the assertion that the Common Rule should recognize consent as a process and not a translational form. The Common Rule should also enable culturally and clinically appropriate consent processes that are contextually appropriate; rely on the Fair Information Practice Principles; and employ other relational methods of engaging individuals in research.

- ANA supports the recommendation to include the proposed notifications of potential commercial profit; return of clinically relevant results; and possibilities for re-contact as standard procedure in consent forms unless researchers can justify their omission through documented approval from an appointed oversight professional or participating IRB. Further, we agree with the recommendation that results be returned in accordance with the preferences of the participant.

- With regard to allowable waivers of signatures, ANA agrees with the recommendation that in order to preserve justice, beneficence, and proper respect for participants' autonomy, such waivers of signature should only be permitted after documented consultation with a recognized cultural expert and/or the community under consideration.

Comments on a broad informed consent for primary and secondary research conducted on biospecimens and for the storage of biospecimens and identifiable private information

- ANA agrees that biospecimens should be afforded the same protections as other information from human research participants with consent required for inclusion in research. ANA also shares concerns expressed by ***Genetic Alliance*** about the use of broad consent for biospecimens-related research, and notes that the NPRM fails to provide clear definitions of broad consent or adequate explanation for how and when such consent should be used.

- ANA agrees that broad consent may exclude participants who might hesitate to include their specimens in secondary research for which they had insufficient knowledge, and may also prevent participants from choosing to broadly share their biospecimens. Further, numerous studies suggest that participants prefer to be offered relevant information, granular choices, the opportunity to withdraw, and research results. A broad consent may not achieve these goals.

- A number of commenters on this proposed rule have expressed concerns and resistance to even broad consent for biospecimens, citing cost and coordination issues. When evaluating these cost and coordination concerns, ANA urges OHRP to consider some of the new technologies referenced in the ***Genetic Alliance*** letter, as they may offer novel methods of engagement without significant increases in costs and time.

NPRM exclusions and exemptions

- ANA notes that the systematic changes described in the NPRM could have the inadvertent effect of encouraging researchers to design studies eligible for exemption or exclusion, and discourage researchers from planning more rigorous and involved human research. We urge OHRP to carefully consider and evaluate this issue going forward. Further, with regard to Common Rule exclusions, we agree that studies excluded from oversight under the Common Rule should still be subject to a regular review process by someone other than the principal investigator.

- As noted at the outset of this letter, we urge OHRP to refrain from including in the final rule references to web-based tools that are not yet developed. All referenced tools should be developed before becoming part of the rule. ANA also notes that the exemption for the secondary use of identifiable private information is confusing and lacks specificity, and that the term 'identifiable private information' is not well defined.

Guidelines around obtaining a waiver of consent require further clarity

- The current requirements stipulate that waivers will only be considered for work that is scientifically compelling and that cannot secure consented biospecimens. ANA urges OHRP to develop clear guidelines identifying when a waiver is appropriate. With regard to using a single IRB for multi-site collaborations, ANA agrees that such use should be context dependent as experts do not agree on whether such utilization would relieve or impose greater burden on researchers.

We appreciate the opportunity to share our views on this matter. If you have questions please contact Cheryl Peterson, Senior Director (301.628.5089; cheryl.peterson@ana.org).

Sincerely,

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

cc: Pamela Cipriano, PhD, RN, NEA-BC, FAAN, ANA President
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