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March 1, 2010

Mr. David Horowitz  
Assistant Commissioner for Policy  
Food and Drug Administration  
Division of Dockets Management (HFA-305)  
5630 Fishers Lane, Room 1061  
Rockville, MD 20852

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

Re: **U.S. Food and Drug Administration Proposed Rule:  
Informed Consent Elements. Docket No. FDA-2009-N-0592/  
RIN No. 0910-AG32; 74 Fed. Reg. 68736232 (December 29, 2009)**

Dear Assistant Commissioner Horowitz:

The American Nurses Association (ANA) is the only full-service professional organization representing the interests of the nation's 2.9 million registered nurses through its constituent member nurses associations, its organizational affiliates, and its workforce advocacy affiliate, the Center for American Nurses. The ANA advances the nursing profession by fostering high standards of nursing practice, promoting the rights of nurses in the workplace, projecting a positive and realistic view of nursing, and by lobbying the Congress and regulatory agencies on health care issues affecting nurses and the public.

Many registered nurses and APRNs care for patients who participate in interdisciplinary clinical trials and other types of research. A burgeoning number of nurse researchers and academicians conduct or participate in nursing or other health care research. Given the increasing opportunities for patients to participate in research, and the reliance on patients' willingness to take part, RNs take very seriously our duty to educate our patients, advocate for their interests, and protect the confidentiality of their information. We believe it is in patients' interests for federal rules and policies to be as comprehensive and understandable as possible, and that this will promote public trust in the research system and enhance patients' ability to make informed decisions.

The ANA supports the concept of amending the informed consent regulations to require that information regarding submission of clinical trial information to the clinical trial registry data bank is included as part of the Required Elements of Informed Consent.

Although we support this mechanism to notify participants about data bank submissions, we do not support the proposal to include the following language regarding elements of informed consent, at 21 CFR § 50.25(a)(9):

Information, that does not include personally identifiable information, concerning this clinical trial has been or will be submitted, at the appropriate and required time, to the government-operated clinical trial registry data bank, which contains registration, results, and other information about registered clinical trials. This data bank can be accessed by you, and the general public at *www.ClinicalTrials.gov*. Federal Law requires clinical trial information for certain clinical trials to be submitted to the data bank.

To provide greater clarity and transparency, and increase the ability of research participants to understand its provisions, we urge the FDA to consider the following comments and revisions in its final rule on Informed Consent Elements:

- The information must be treated as re-identifiable, and research participants should be told that it is probable that the information will be re-identified.
- In general, the proposed language is written at a level beyond the reading skills of many research participants. All provisions which apply to research participants should be written in clear and concise language that most participants can readily comprehend.
- Descriptions of the clinical trial registry and data bank should be expanded.
- The final rule should define which personally identifiable information will not be included. For example, are HIPAA identifiers included?
- We suggest adding a lay-person description of participant-related data and information that is required to be submitted in an unidentifiable format in accordance with the Basic Results Data Element Definitions. For example, Participant Flow, Reason Not Completed, Baseline Characteristics, Baseline Measures, Outcome Measures, and Adverse Events.
- It would be helpful to describe instances where data may contain patient identifiers and demographics, such as SAE (Summary of Adverse Events) or AE (Adverse Events) tables.
- Finally, to provide greater transparency, the FDA should provide information in the final rule about how the data may be used, and how the information could specifically be of use to the individual participants and the general public.

According to Ohm (2009), it is easy to re-identify data and this re-identification changes our understanding of privacy.<sup>1</sup> Instead of attempting to make a system that removes personally identifiable information work we should discuss the costs and benefits of sharing information openly with those who will use it responsibly.

### **Conclusion**

The American Nurses Association appreciates this opportunity to comment on this important FDA rule. We believe that informing all participants about required data submission in a comprehensive and understandable manner will promote trust in the research system and enhance informed decision-making. If we can be of further assistance, or if you have any questions or comments, please feel free to contact Eileen Carlson, RN, JD, Associate Director, ANA Government Affairs, at [Eileen.carlson@ana.org](mailto:Eileen.carlson@ana.org) or 301-628-5093.

Sincerely,

A handwritten signature in cursive script that reads "Rebecca M. Patton".

Rebecca M. Patton, MSN, RN, CNOR  
President  
American Nurses Association

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<sup>1</sup> Ohm, P, (2009) Broken Promises of Privacy: Responding to the Surprising Failure of Anonymization. University of Colorado Law Legal Studies Research Paper No. 09-12. Available at SSRN: <http://ssrn.com/abstract=1450006>.