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December 28, 2015

Jerry Menikoff, M.D., J.D.
Office of Human Research Protection
U.S. Department of Health and Human Services
1101 Wootton Parkway, Suite 200
Rockville, MD 20852.

RE: Docket ID number HHS–OPHS–2015–0008, Federal Policy for the Protection of Human Subjects, proposed rule

Dear Dr. Menikoff:

The Association for Professionals in Infection Control and Epidemiology (APIC) appreciates the opportunity to provide comments on revisions to the Federal Policy for the Protection of Human Subjects, generally known as the Common Rule. APIC is a nonprofit, multidisciplinary organization representing over 15,000 infection preventionists whose mission is to create a safer world through prevention of infection. In their roles, our members work in settings across the continuum of healthcare as well as in public health settings. We collect, analyze and report data. These activities can lead to a Quality Improvement (QI) project or may be the result of such a project. Additionally, the data our members collect are used to identify changes or trends in infectious diseases as well as inform public health interventions to prevent the spread of infectious diseases and microorganisms.

Research and implementation science are also key aspects of infection prevention. APIC sponsors and collaborates with academic investigators, governmental agencies such as the Centers for Disease Control and Prevention (CDC), and private sector organizations on research projects. These projects assist infection preventionists to make clinically relevant and meaningful improvements to patient safety.

We recognize the importance of balancing the protection of human subjects and facilitation of valuable research with the equally important reduction in the burden to or ambiguity for the researchers. At the same time we acknowledge the consequences of delaying research in the process. We are in agreement with the Infectious Diseases Society of America, that the need for research and oversight are not competing priorities.[1]

We believe the following proposed changes outlined as most significant in the notice of proposed rulemaking (NPRM) are within the scope of our work, and we support:

- improving the informed consent process through transparency and improved communication to assure participants are appropriately informed,
- excluding certain categories such as those determined not to be research or to be very low risk,
- adding categories of exempt research that would allow a level of review relative to the level of risk and would not require administrative or Institutional Review Board (IRB) review,
- creating multisite IRBs for institutions involved in cooperative research,
- eliminating continuing review for studies approved under expedited review and those that have completed interventions and are in the data analysis or observational follow up phase, and
- extending the scope to all clinical trials regardless of funding source.

We would like to provide more detailed comment on the fourth and fifth categories of excluded activities. Regarding the fourth category, our members have concerns related to activities that would meet the QI exclusions. We believe that it is equally and in some cases more important to study the effectiveness (outcome measure) of a practice as it is to increase use of the practice (process measure). It is possible that increasing the use of a process may not provide benefit to a patient population or improve the outcome. For instance as currently written, evaluation of staff training to improve the use of gloves to prevent transmission of microorganisms would be excluded from the IRB process, but evaluating the impact of the use of gloves on decreasing transmission of microorganisms would require IRB approval despite the fact that the use of gloves is a well-established best practice. Both are important to providing safe care. In order for the intervention to be successful, investigators must know not only how to best educate providers on the process, but also be able to evaluate the outcome of the intervention, in this case the reduction in transmission.

Many of our members participate in state or regional QI collaboratives that measure the outcome of individual or bundled interventions. These QI collaboratives often have a rapid start up and implementation phase, frequently with timelines mandated by the Centers for Medicare and Medicaid Services. Requiring such projects to be subject to IRB approval could act as a disincentive for participation in many organizations due to the added paperwork and burden. The Health Resources and Services Administration describes QI as consisting of "systematic and continuous actions that lead to measurable improvement in health care services and the health status of targeted patient groups."[2] To support the work we perform on a daily basis, our members recommend that both QI processes and outcomes are included in the Common Rule excluded activities.

Regarding the fifth category of excluded activities, we are concerned there may be unintended consequences when these regulations are put into place. The NPRM notes that public health activities that would not fall under the exemption act include exploratory studies to better understand risk factors. Public health practice can be defined as "the collection and analysis of identifiable health data by a public health authority for the purpose of protecting the health of a particular community where the benefits and risk are primarily designed to accrue to the participating community."[3] As an example, hospitals and other health settings are required by regulation to report healthcare-associated infections and certain process measures such as healthcare personnel influenza immunization to the CDC. The data

is examined in efforts to better stratify surgical risks, and identify opportunities for improving the health of the population in the future. Furthermore, with new and/or rapidly emerging infectious diseases, the risks may be unknown. To require IRB approval before the public health authority can collect data on risk factors will unnecessarily delay detection of those risks. Not exempting these activities could have a profound unintentional impact not only on public health's ability to perform its duties, but also its ability to halt ongoing transmission of an infectious agent.

As pointed put in the NPRM, the line between public health surveillance and epidemiologic research is difficult to establish. We recommend further defining the difference between the two activities, specifically under what purpose or context the activities would be excluded from the Common Rule. Our members are passionate about contributing to improving the quality of care provided in healthcare settings across the continuum and assuring the safety of the public. We trust our comments have been informative. Thank you for the opportunity to review the proposed changes to the Common Rule and provide input on behalf of our members.

Sincerely,

Mary Lou Manning, PhD, CRNP, CIC, FAAN, FNAP
2015 APIC President

[1] Infectious Disease Society of America. Grinding to a halt: The effects of the increasing regulatory burden on research and quality improvement efforts. *Clinical Infectious Diseases* 2009 Aug 1;49(3):328–335.

[2] Health Resources and Services Administration. Quality Improvement. Available at: http://www.hrsa.gov/quality/toolbox/methodology/qualityimprovement/index.html Accessed December 1, 2015.

[3] Gostin L. *Public health law and ethics: a reader*. Vol. 4. Univ of California Press, 2010.